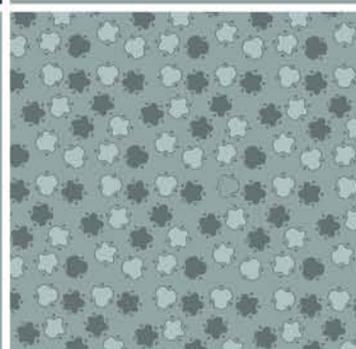




# 2007 Biotechnology & Biomedical Skill Standards

Research & Development  
Regulatory Affairs & Clinical Trials · Manufacturing  
Shoreline Community College



2007  
BIOTECHNOLOGY/  
BIOMEDICAL  
SKILL  
STANDARDS

- Research, Development
- Regulatory Affairs and Clinical Trials
- Manufacturing



**FOR MORE INFORMATION**

Berta Lloyd, Dean, Workforce Education  
Shoreline Community College  
16101 Greenwood Ave. North  
Seattle, WA 98133

Phone: 206-546-4595  
blloyd@shoreline.edu

**COPYRIGHT © 2007**

State of Washington through the State Board for Community and Technical Colleges

Unless otherwise provided, data which originates from this agreement shall be “works for hire” as defined by the U.S. Copyright Act of 1976, and shall be owned by the State of Washington. Data shall include, but not be limited to, reports, documents, pamphlets, advertisements, books, magazines, surveys, studies, computer programs, films, tapes, and/or sound reproductions. Ownership includes the right to copyright, patent, register, and the ability to transfer these rights.

**PROJECT FUNDING**

This project was made possible through the Washington State Community & Technical College’s 2006-07 Workforce Development/Rural Grant.

**PERMISSION TO  
PHOTOCOPY AND QUOTE**

General permission is granted for educators to photocopy limited material from *Biotechnology/Biomedical Skill Standards* for noncommercial instructional or scholarly use. Permission must be sought from the Washington State Board for Community and Technical Colleges in order to charge for photocopies, to quote material in advertising, or to reprint substantial portions of the document in other publications. Credit should always be given to the source of the photocopies or quotes by citing a complete reference.

**DOCUMENT CREDITS**

Document and lead technical writing by:  
Berta Lloyd, Shoreline Community College and  
Terryll Bailey, The Allison Group at 206-525-7175 or tbailey@theallisongroup.com.

Document design and layout by the Public Information Office at Shoreline Community College.

Printing by Printing Services, Shoreline Community College  
at 206-546-4674 or aconrad@shoreline.edu

## Dedication



Dedicated to the Washington Biotechnology & Biomedical Association (WBBA)

This project would not have been possible without the industry experts within the Biotechnology/Biomedical field. Their knowledge and insight have been phenomenal. Collaboration has been the key to this very successful project.

Many thanks for their time and energy.

Berta Lloyd, Project Manager  
Dean, Workforce Education  
Shoreline Community College

## Acknowledgments

### Biotechnology & Biomedical Skill Standards 2007 Project Update

#### Subject Matter Experts

The subject matter experts groups consisted of front-line workers, first line supervisors and professionals in the Biotechnology and Biomedical field in the Puget Sound Region. They reviewed and revised the critical work functions and key activities performed by biotechnology and biomedical professionals. They then identified and revised the performance indicators, technical knowledge, skills and abilities, and employability skills for new key activities and existing key activities to ensure that the skill standards are current in describing the knowledge and skills required to succeed in this field. Their insights were an invaluable contribution to this work.

Jenny Mulligan, Ph.D, MDS Phama

Dirk Windgassenm Dendreon Corp

Bart Steiner, Ph.D, ICOS-Corp

Wendy Blay, Ph.D, Seattle Biomedical Research Institute

Mindy Miner, Graduate Student/Freitag Lab, Seattle Biomedical Research  
Institute, Program in Pathobiology University of Washington

Brandon Seaton, Seattle Cancer Care Alliance

Peter J. Myler, Ph.D, SBRI

Jesus Lopez-Guisa, Children's Hospital

Darren Kamikura Ph.D, Xactagen

Legresse Adhanom, Baylor (Berlex)

Steve Plichta, Baylor, (Berlex)

Janis Wignall, Biotechnology Education Consultant

Ron Manger, Fred Hutchinson Cancer Research Center

Estrella Randle, Bio-Rad

#### Special Thanks

Dr. Guy Hamilton, Ph.D., Director Biotechnology Lab Specialist Program,  
Shoreline Community College, for his knowledge and mentorship.

Dr. Ron Manger, Ph.D., Fred Hutchinson Cancer Research Center, for his expertise  
and critique of the Clinical Trials and Regulatory Affairs Skill Standards Section.

## 2007 Biotechnology/ Biomedical Skill Standards Project

### 2007 Update Outcomes

- Review the state of the industry through primary and secondary research and determine the correct clusters to meet the current situation in Puget Sound.
- Revise and update the 2000 skill standards to develop skill standards needed for Biotechnology/Biomedical careers consistent with the current and future needs of the public and business.
- A report for biotechnology/biomedical employers and educators showing the standards and the data that supported those standards.

### Original Project Outcomes, 2000

The following are the outcomes of *Biotechnology/Biomedical Skill Standards*, as determined by the partnership:

- Skill standards needed for Biotechnology/Biomedical careers consistent with the current and future needs of the public and business.
- Validation of worker input by written survey.
- A report for biotechnology/biomedical employers and educators showing.

### 2000 Curriculum and Assessments

Once the skill standards were developed, a second phase of work was completed. The following is excerpted from the Phase 2 report of outcomes. The complete report may be found at [www.wa-skills.com](http://www.wa-skills.com).

The primary goal of Phase II was to leverage the industry skill standards information to review and strengthen existing Biotechnology programs, and to support skill articulation between high schools, 2-year colleges, and 4-year universities.

The primary goals were to:

- Review existing Biotechnology programs at two-year and four year institutions to better align with the industry Biotechnology and Biomedical Skill Standards information.
- Leverage the industry Biotechnology and Biomedical Skill Standards information to support articulation between high schools, two-year and four-year colleges.

### Curriculum and Assessment

The purpose was to evaluate existing curriculum for two-year degree Biotechnology Programs at partner Community and Technical Colleges and 4-year colleges against the industry Biotechnology and Biomedical Skill Standards information, in order to recommend strategies for closer alignment between program graduate skills and industry-required entry-level skills.

Three college partners participated in the curriculum/assessment component of the project.

- Shoreline Community College completed a full program evaluation against the Biotechnology and Biomedical Skill Standards as part of this project. As a result of this process, specific recommendations and scenarios were formulated to improve the alignment of the existing curriculum with industry expectations.

- Seattle Central Community College Biotechnology Program is undergoing significant revisions and restructuring at this time. Even though Seattle Central CC could not participate fully in the curriculum/assessment evaluation process in the time frame of this project, the faculty are using information generated by Shoreline CC to guide the program revision.
- Seattle Pacific University used the Skill Standards to review SPU Biology, Chemistry and Biochemistry BS degree program. As a result of this process, SPU developed a proposal for a new Biotechnology degree that effectively leverages existing courses at SPU and Shoreline CC, by requiring students to take specific laboratory classes at the community college.

Faculty involved reported that the process of reviewing existing curriculum against industry expectations in such a formal process was very valuable. The process enabled them to conduct an in-depth review of students learning outcomes and assessment, class projects and activities, and course content and sequence. The industry perspective, as presented through the skill standards information, enabled faculty to look at the overall program from a more integrated and holistic viewpoint. Therefore it was easier to identify gaps in knowledge and skills, and misalignment between program outcomes and specific projects and assessments.

## **Articulation**

The purpose was to use the industry Biotechnology and Biomedical Skill Standards information to identify what should be taught at the high school level in order to ensure success for an entering student in a biotechnology course of study at either a community or four-year college. A committee consisting of two high schools, Juanita High School from the Lake Washington School District, Shorewood High School in the Shoreline School District, two community colleges, Shoreline Community College, Seattle Central Community College, and one 4-year university, Seattle Pacific University, was formed to discuss articulation issues and develop articulation guidelines.

The committee designed Biotechnology Articulation Guidelines to document student-learning outcomes at the end of high school. These outcomes are in skill areas identified as critical by the Biotechnology/Biomedical industry. Each guideline includes a description of the workplace application, skills that students should master, and a description of how skill mastery could be demonstrated in the classroom.

The committee's final report includes the ten articulation guidelines and additional material such as project examples, and recommendations for next steps. Committee members reported several benefits from participating in this process. In particular, community college and college members gained a better understanding of curriculum at their feeder institutions, and high school faculty gained an understanding of college level expectations for entering students. High school, community college, and four year college faculty all reported that this process will be useful in their ongoing curriculum development endeavors. The recommendations include developing a biotechnology information packet for high school counselors, proposing that the Washington Biotechnical and Biomedical Association (WBBA) develop a web page for high school teachers on its existing site, and developing assessment tools for teachers to use in conjunction with the articulation guidelines.



### **The Next Steps**

The completion of the skill standards represents phase one of this endeavor. The next step is to provide oversight to the development of assessments and curriculum based on the skill standards. This is a cooperative and collaborative project with the Biotechnology/Biomedical industry, labor unions, high schools, and colleges throughout the state.



# Table of Contents

## OVERVIEW

Introduction and Perspectives .....	1
The State of the Industry .....	2

## NATIONAL CONTEXT

A National Context for Skill Standards .....	5
Skill Standards to Curriculum: A Continuous Development Process .....	9

## 2007 BIOTECHNOLOGY/BIOMEDICAL SKILL STANDARDS PROJECT

Biotechnology/Biomedical Skill Standards Project Goals, Guidelines, and Methodologies .....	11
Definition of Terms .....	13

## RESEARCH OUTCOMES: SKILL STANDARDS FOR RESEARCH, DEVELOPMENT

Research Findings .....	15
Typical Job Description and Sample Job Title .....	16
Scenarios: Routine, Crisis, and Long Term .....	17 – 19
Summary of Critical Work Functions and Key Activities .....	20
Skill Standards .....	21 – 32

## RESEARCH OUTCOMES: SKILL STANDARDS FOR REGULATORY AFFAIRS AND CLINICAL TRIALS

Research Findings .....	33
Typical Job Description and Sample Job Title .....	35
Scenarios: Routine, Crisis and Long Term .....	36 – 38
Summary of Critical Work Functions and Key Activities .....	39
Skill Standards .....	40 – 54

## RESEARCH OUTCOMES: MANUFACTURING

Cluster Structure .....	55
Biotechnology and Biomedical Manufacturing .....	57

## INTEGRATION

Assessment and Certification: A Vital Connection .....	59
Assessment Strategies .....	61
Assessment Design .....	63

## APPENDICES

References .....	66
------------------	----

Shoreline Community College does not discriminate on the basis of race, color, national origin, sex, disability, sexual orientation, or age in its programs and activities.



# OVERVIEW

Introduction

The State of the Industry

## Introduction



**S**kill Standards are an outcome of concerns expressed by key industries that they will not be able to remain competitive in global markets if the U.S. cannot provide sufficient quantities of qualified, skilled workers. These key industries, in conjunction with federal and state governments, are providing funding to develop voluntary skill standards for those industries with a critical need for trained workers. The standards identify what people must know and be able to do to qualify for beginning and middle level jobs. This information, generated through strong collaboration between industry and educators, provides a sound starting point for the development of training programs that will prepare people for employment and career advancement and meet the country's need for knowledgeable, highly-skilled workers. Industry-based skill standards can help ensure that more people, particularly those who have been underserved by our education system, are prepared for high-wage jobs requiring highly skilled workers. This project proposes the development of regional industry-based skill standards within the Biotechnology/Biomedical industry. These standards will be implemented in an integrated articulation model among the partners of this consortium of schools and colleges.

## The State of the Industry



Washington State is one of the premier biotechnology centers in the world and one of the fastest growing research centers in the United States due to its world-class research institutions, access to capital, highly educated workforce, and exceptional quality of life.

The technology foundation of the biotechnology and medical device industry in Washington State is the cutting edge research conducted at the University of Washington, Washington State University, Eastern Washington University, Fred Hutchinson Cancer Research Center, Institute for Systems Biology, Battelle/Pacific Northwest National Laboratory, Benaroya Research Institute at Virginia Mason, and Pacific Northwest Research Institute.

The biotechnology and medical device industry in the state of Washington is comprised of more than 220 privately or publicly owned companies, and twenty-two non-profit research organizations. Note that universities, including the University of Washington, Washington State University, Eastern Washington University, and other colleges, along with organization such as Children's Hospital and Regional Medical Center, Pacific Northwest National Laboratory, Swedish Medical Center and Veterans Administration Hospital are excluded from the following given the difficulty in separating biotechnology and device specific employment from organization/institution total employment.

*(<http://www.wabio.com/about/WBBA-2008>)*

At the close of 2005, total aggregated biotechnology and medical device industry employment in Washington exceeded 18,500 people, an increase of 5.5 percent from 2004. In 2005, the biotechnology sector had more than 10,800 employees -- a 5.7% increase from the prior year. And the state's medical device employment exceeded 7,600 -- a 5.0% increase from a year earlier. This is an industry that is founded on and thrives due to the state's world-class research institutions and pervasive entrepreneurial spirit. Combined with the region's rapidly growing financial wealth, and unsurpassed quality of life, the Pacific Northwest is one of the most desirable places to work, live, and play.

*(<http://www.wabio.com/about/WBBA-2008>)*

Biotechnology development requires well educated and trained people, and as the state's biotechnology and device industry matures it requires a more diverse employee base. It requires people who understand biology, including microbiology, molecular biology, virology, genetics, pathology, biochemical engineering, fermentation, informatics and more. It needs people with Ph.D.s, Masters, Bachelors and Associate degrees. Importantly, over the last decade, Washington's biotechnology and medical device companies, and non-profit research organizations hired almost 1,000 new employees per year and with improving financial markets, including the support of the Bill & Melinda Gates Foundation in the non-profit sector, this trend will continue.

*(<http://www.wabio.com/about/WBBA-2008>)*

The following is average entry level salary data and percentage of science related hiring by degree level derived from the Washington Workforce Training Survey conducted by Info.Resource in collaboration with the Washington Biotechnology & Biomedical Association (WBBA) and the Workforce Development Council of Seattle-King County. (*Washington State Workforce Training Report, April 2006 497kb pdf*)

### **Average Entry-Level Salary**

- Salary AA Degree (n=9): \$29,380
- Salary BS Degree (n=15): \$43,200
- Science Related Hiring by Degree (n=17)
  - AA Degree: 3%
  - BA/BS Degree: 41%
  - MS Degree: 14%
  - PhD/MD Degree: 42%

Additional information regarding salaries was provided by Applied HR Strategies. A research associate with a BS degree and eight years of experience annual salary is \$65,000. A quality control specialist with an AA degree makes an average salary of \$36,000 and with five years experience makes close to \$60,000. An entry level manufacturing associate with an AA degree is paid an average \$35,000. A manufacturing manager with a BS degree has an annual salary of nearly \$59,000.

Using the common advanced technology multiplier (3:1) it is estimated that these sectors combined indirectly employ more than 55,500 people in the state of Washington.





# **NATIONAL CONTEXT**

**A National Context for Skill Standards**

**Skill Standards to Curriculum:**

**A Continuous Development Process**

## A National Context for Skill Standards



### What Are Skill Standards?

The National Skill Standards Board was established by Congress in 1994 to encourage the creation and adoption of a national system of voluntary skill standards that would enhance the ability of the U.S. to compete effectively in a global economy. Several voluntary skill standards projects have been developed by various industries in full partnership with education, labor and community-based organizations. The intent is to have voluntary skill standards that are flexible, portable, and continuously updated and improved.

Skill standards are performance specifications that identify the knowledge, skills and abilities an individual needs to succeed in the workplace. They are critical to improving workforce skills, raising living standards, and improving the competitiveness of the U.S. economy. To be effective, skill standards must reflect the consensus of biotechnology/biomedical professionals.

Skill standards provide measurable benchmarks of skill and performance achievement. They answer two critical questions: What do workers need to know and be able to do to succeed in today's workplace? And, How do we know when workers are performing well? Without this fundamental information, employers do not know whom to hire or where to focus their limited training dollars; employees and new entrants to the workforce do not know what they need to do to improve their performance; educators do not know how to prepare students for the challenge of the workplace.

#### **Voluntary, industry-based skill standards should be:**

- Responsive to changing work organizations, technologies and market structure.
- Benchmarked to world-class levels of industry performance and free from gender, racial, or other forms of bias.
- Tied to measurable, competency-based outcomes that can be readily assessed.
- Inclusive of basic reading, writing, and critical thinking skills.
- Useful for qualifying new hires and continuously upgrading employees' skills.
- Applicable to a wide variety of education and training providers, both work and school-based.
- Based on a relatively simple structure to make the system user-friendly.
- A cooperative effort among all stakeholders.
- Developed independently of any single training/education provider or type of education/training provider.

*–National Alliance of Business*

## Why Are Skill Standards Important?



In today's workplaces, the only constant is change. Jobs that once were relatively simple now require high performance work processes and enhanced skills. Because skill standards reflect changing workplace realities, they are a tool that can be used by applicants and employees to access greater career opportunities.

National recognition of skill standards in career fields provides a common basis for certifying achievement against those standards, thereby allowing for the portability of skills across geographic areas, companies and careers.

Updating skills and knowledge is now a lifelong endeavor, causing many employers and employees to spend more effort, time, and money on education and training. Skill standards provide benchmarks for making education and training decisions, shaping curricula, and directing funds toward highest value education and training investments.

## The Benefits and Uses of Skill Standards

Skill standards benefit all the stakeholders—business, labor, educators, government, and the community. The success of a skill standards development project and its usefulness to the community is dependent on the full participation and commitment of all stakeholders. These benefits can be used as a benchmark for evaluating the effectiveness of collaborative efforts.

### How Skill Standards Benefit Employers

**EMPLOYERS** can use skill standards to establish personnel qualification requirements. Interviews, performance reviews, and productivity can be evaluated and assessed to a higher degree of accuracy and efficacy. Employers are also able to identify core competencies and workers' abilities to demonstrate competencies. By matching competencies to critical work functions and key activities, employers can significantly improve efficiencies and productivity. Performance-based skill standards also provide a vehicle for varying degrees of job certainty and the structure for establishing competency-based pay scales. In addition, employers use skill standards to:

- Align personnel qualification requirements with nationally adopted certificates of competence.
- Modify employee training.
- Simplify measurement of employee training effectiveness.
- Assess employee skill levels based on industry standards.
- Match employee skills to the work needed.
- More easily document employee skills, training needs, and performance criteria.
- Improve consumer satisfaction and confidence through better developed evaluation skills for customer contact personnel.
- Improve employee satisfaction and morale by clarifying expectations.
- Improve quality, productivity, time-to-market and competitiveness.
- Achieve business goals.
- Partner with education and labor in developing school-to-work initiatives.

### How Skill Standards Benefit Educators

**EDUCATORS** can identify core competencies and assessments based on the skill standards and implement them in their curricula. Students can then be required to demonstrate competency throughout their coursework. Academia and industry can build a cohesive relationship through a like-minded expectation of student competencies and work readiness. This enhances an instructor's ability to teach information consistent with industry's entry level expectations and needs. In addition, educators use skill standards to:

- Partner with business and labor in developing school-to-work initiatives.
- Provide effective, targeted instruction.
- Develop benchmarks for certificates of competence earned by students.
- Communicate what companies expect of employees.
- Develop new and evaluate existing curriculum and programs based on industry needs.
- Develop assessments to evaluate skills, knowledge, and abilities in classrooms and internships.
- Develop a common language on workforce preparation with business and labor.
- Improve relationships with local businesses, labor unions, other educators and agencies.
- Provide students with relevant career education and counseling.

### How Skill Standards Benefit Labor Unions

**LABOR UNIONS** can use skill standards to gain support for company-sponsored worker training programs and to identify career paths for workers within companies and industries. Unions can provide this information to union members and develop strategies to improve career mobility and stability. Skill standards help unions to:

- Improve member value to the company.
- Provide a greater worker voice in the company.
- Link skill standards to increased training and upward career mobility for union members.
- Assist employers to match employee skills to the work needed.
- Develop skills-based training and certification initiatives that complement union apprenticeship programs.
- Communicate effectively with employers about worker training and retraining needs.
- Cooperate with education and industry in developing school-to-work initiatives.

### **How Skill Standards Benefit Students and Workers**

**SKILL STANDARDS** assist students in making career choices by providing industry expectations for success in the workplace. In addition, standards-based curriculum and assessments provide students with credentials that certify work-readiness. Work-ready students can anticipate being hired at higher rates of pay and can experience faster advancement in their chosen fields. Workers can accurately assess their skills against those required for career advancement and plan effectively for their career pathways. They can determine the skills and abilities needed for advancement or transfer within industries, and determine the continuous learning and training they need to upgrade their skills. In addition, students and workers can use skill standards to:

- Achieve clarity regarding what they are expected to learn and how to prepare for work.
- Enter and reenter the workforce with better control of their choices of high paying jobs requiring high skills.
- Accurately assess business expectations of the skills needed for positions and careers of their choice.
- Improve mobility and portability of their credentials.
- Obtain certification of competence in the skills they gain through experience, school, training, or self-study.
- Enhance their performance and achievement by self-evaluation against known standards.
- Be active contributors to the activities that make their organizations successful.

### **How Skill Standards Benefit Government**

**GOVERNMENT** can provide information that will ensure a better skill match between workers and employers and initiate education reform to better educate future members of the workforce. Skill standards better enable agencies to provide options for career and job mobility and link learning to the needs of the workplace. In addition, government can use skill standards to:

- Assist in the development of a highly skilled, high-quality, and competitive workforce and industry base.
- Evaluate the effectiveness of publicly-funded education and training.
- Increase opportunities for under-represented populations by making public the information that defines the skills required for success, and by facilitating the national adoption of those definitions and their use.
- Support the creation of high performance organizations to improve living standards for all members of the population.
- Facilitate collaboration between educators and industry.
- Communicate the need and basis for education reform to business, education, labor, and the community-at-large on both local and national levels.

## Skill Standards to Curriculum:

# A Continuous Development Process

The skill standards generated in this project are designed to be used by participating education partners to develop or modify curriculum at the high school and community college level. By providing the necessary input from industry, this skill standards document is a first step in curriculum development to serve the Biotechnology/Biomedical industry in particular, and to demonstrate what can be done across industries.

In order to keep current with a rapidly changing workplace, standards need to be reevaluated and updated on a regular basis, with full partner participation at each step. New technological developments impact the ways that workers organize and apply their skills, including time management and interpersonal relationships. Increased technological complexity may simplify some of the job tasks but make others more intricate. Today's successful biotechnology/biomedical workers are challenged to acquire a broader range of decision making and customer service skills as well as keep current with emerging technologies. Ongoing changes like these must be reflected in curriculum in order to meet the needs of industry, where expectations for workers are evolving.

**A model of continuous improvement for economic development:**

## Using Skill Standards

### Step 1: Skill Standards Identification

- Compile and research existing standards in related jobs and careers.
- Conduct focus groups to identify critical work functions and key activities, define key activity performance indicators, and identify technical knowledge, foundation skills, and personal qualities.
- Conduct a survey of current workers to determine the level of SCANS skills required for each job.
- Develop work-related scenarios to place the skill standards in the context of the work environment.
- Validate the data gathered from focus groups.
- Disseminate skill standards information to involved parties from industry, education, and labor for their review and editing.



### Step 2: Assessment

- Develop assessments through the collaboration of industry and education to reflect competent performance as defined by the skill standards.
- Collect evidence of a person's ability to perform at the levels determined by the skill standards.
- Determine present skill level through direct and indirect evidence by assessing a student, trainee, apprentice, prospective worker, or worker seeking additional training.
- Use products and items produced by the person being assessed as direct evidence.
- Gather supporting information to use as indirect evidence.
- Assess results using the criteria of validity, currency, authenticity, and sufficiency.
- Demonstrate validity using a tangible item or record of action.
- Demonstrate authenticity by having the individual being assessed produce the item or specific piece of a team-effort.
- Demonstrate sufficiency by providing enough evidence to match key tasks and performance criteria as defined in the skill standards.

### Step 3: Curriculum Development

- Identify necessary competencies based on the skill standards information and assessments.
- Develop program outcomes for specific academic and training programs, including Tech Prep, 2-year, and apprenticeship programs.
- Perform gap analysis to determine changes or additions to be made to curriculum.
- Revise existing curriculum to better meet the current and future needs of the industry.
- Develop new curriculum and establish new programs based on these competencies.

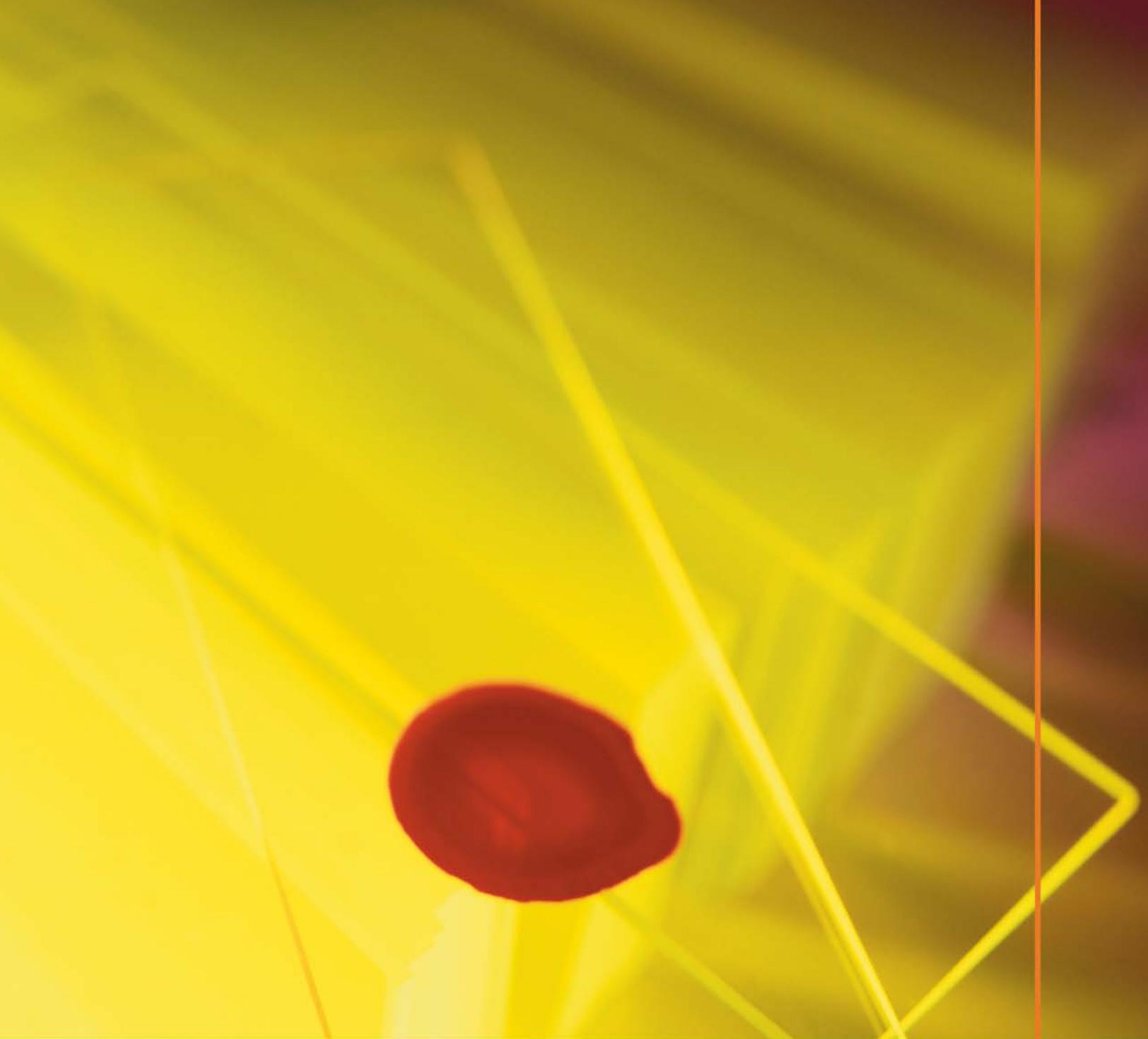
### Step 4: Articulation

- Develop models to support the articulation of program outcomes and competencies between academic and training systems.
- Establish articulation agreements between existing programs to ensure portability of skills.
- Connect competencies and Certificates of Competence with benchmark documentation to build national portability systems.

## A Continuous Updating Process

A continuous exercise is necessary: all partners must revise and verify skill standards on a regular basis. For national economic development success, curriculum and current training methods must be updated to meet workplace standards.

Individual workers must have access to clearly stated competency goals and direct access to skill development assistance. With cooperative effort on local and national levels, we can begin to resolve the workforce shortages in the Biotechnology/Biomedical industry that face us today.

A microscope slide with a red circular stain is centered in the upper half of the image. The background is a bright yellow with a grid of thin, glowing lines. A horizontal orange line separates the image from the text below.

# **2007 BIOTECHNOLOGY/BIOMEDICAL SKILL STANDARDS PROJECT**

**Project Goals, Guidelines, and Methodologies  
Definition of Terms**

# Biotechnology/ Biomedical Skill Standards

## Project Goals, Guiding Principles, and Methodologies



### Goals for 2007 Project

- Revise and update the voluntary skill standards developed for the Biotechnology/Biomedical industry in 2000. These standards will serve as benchmarks for entry into biotechnology/biomedical careers at the technical level.
- Disseminate the results and support the use of skill standards by educators, businesses, unions, students, workers, and government agencies.

### Guiding Principles

- Experienced workers are the experts in their career field and are best able to identify the work performed as well as the skills, knowledge, and abilities required to be successful.
- Business, labor, and education must work as partners to ensure the creation of a link between the work expectations and the curriculum.
- The standards must be consistent with existing civil rights laws and practices.
- Standards must be flexible, portable, and should be updated continuously.
- Skill standards describe the major functions and key activities, as well as the performance indicators, technical knowledge and skills, employability skills, and personal attributes needed to succeed in the workplace.
- Integrated skill standards define work duties and the skills required to perform them in the context of work settings.

The experience of the partners involved in this project holds that the success of any skill standards project is critically linked to the full participation and commitment of all partners.

### Update of Skill Standards: Research Methodology

#### 2000 Methodology

The original voluntary skill standards were developed using specific research-based processes. This project followed the process required by the Washington State Board for Community and Technical Colleges (SBCTC) as prescribed in Skill Standards Guidebook I, Rose Ann Stevenson, Washington State Board for Community and Technical Colleges, 1996, and through policies and procedures provided by the SBCTC.

To download the 2000 skill standards study and outcomes, go to [www.wa-skills.com](http://www.wa-skills.com).

The update of the skill standards followed a structured research process, aligned with the skill standards development process of the National Skill Standards Board and the State Board for Community and Technical Colleges.

**Step One:  
Current State of the Industry**

Shoreline Community College interviewed its Industry Advisory Committee to obtain an update on the current state of the industry. Secondly, Berta Lloyd was a member of the Life Sciences Skill Panel, which conducted a study of the biotechnology & biomedical industry in Washington State. In addition, Terryll Bailey conducted extensive internet research on the state of the industry. The outcomes of this research are found in the Research Outcomes section of this document.

**Step Two:  
Review and Revise Clusters**

The cluster structure of the 2000 skill standards was reviewed. That structure contained two clusters:

- Research, Development and Manufacturing
- Regulatory Affairs and Clinical Trials

Based on the research in step one, the cluster structure was revised to split out Research and Development and Manufacturing, to create three clusters as follows:

- Research, Development
- Regulatory Affairs and Clinical Trials
- Manufacturing

**Step Three:  
Research and Development  
Focus Group**

On April 11, 2007 a focus group was conducted to obtain industry input in order to update the skill standards. A multi-employer focus group consisting of front-line workers and leaders in the Biotechnology/Biomedical industry met for a half-day focus group process. The 20 participants were selected from several areas of the state and approved by the Steering Committee. The participants represented all aspects of Research and Development in the Biotechnology/Biomedical industry in the Puget Sound Region. In addition, there was diversity in terms of the size and area of specialty of the companies. Participants were asked to define competent work for a front-line worker in the first six months to one year on the job.

Focus group participants were provided an orientation to skill standards, including the history, uses, guidelines and components of skill standards. Participants were then asked to review the critical work functions and key activities from the 2000 skill standards. They were asked to take into account a number of considerations:

- Changes that have taken place in the biotechnology & biomedical in the Puget Sound Region over the past six years.
- Changes in technology and emerging technologies.
- Future trends in research and development in the biotechnology & biomedical industry.

The second step for the focus group was to identify new knowledge and skills required for entry level work in research and development. Participants were asked to connect these knowledge and skills with specific key activities. In addition, the focus group identified new equipment and technology which are or will be required for competency in research and development entry level work.

Finally, the focus group discussed job trends.

Results of the focus group are found in the Research Outcomes section of this document.

**Step Four:  
Revise the Regulatory Affairs  
and Clinical Trials Skill Standards**

The research from step one determined that the changes in the entry level work of regulatory affairs and clinical trials was related solely to the use of Information Technology (IT). Out of advances in computer hardware and software technology emerged the new field of life science informatics.

In 2006, Bellevue Community College published the Life Science Informatics Skill Standards. These, combined with the National Workforce Center for Emerging Technologies (NWCET) Information Technology Skill Standards provided the content for skill standards expert Terryll Bailey to infuse this added dimension into the Biotechnology & Biomedical Regulatory Affairs and Clinical Trials Skill Standards.

These were reviewed and approved by Ron Manger, Biotechnology & Biomedical thought leader and member of the Shoreline Community College Advisory Committee. The revised skill standards are found in the Research Outcomes section of this document.

**Step Five:  
Manufacturing Cluster Interviews  
with Subject Matter Experts**

On June 13, 2007 a conference call was held with three subject matter experts in the field of Biotechnology & Biomedical Manufacturing. They were asked to discuss the following topics:

- Biotechnology Manufacturing industry trends
- Biotechnology Manufacturing job market trends
- What is the need for skill upgrade? Training on new machines? And what is feasible for a community and technical college on that?

The results of this group interview are found in the Research Outcomes section of this document.

## Definition of Terms

**EACH CHART** in the following skill standards templates contains the following components:

### Clusters

Clusters describe the major areas of work carried out across an industry concentration. They apply across specific industry segments (e.g. automobile manufacturing, furniture manufacturing, airplane manufacturing, etc.) and often cover families of related job titles. “Research, Development”, “Regulatory Affairs and Clinical Trials”, and “Manufacturing” are the concentrations within Biotechnology/Biomedical sector in Puget Sound.

### Critical Work Functions

Critical work functions represent the general areas of responsibility for the front-line worker in Biotechnology/Biomedical. The functions tell us what must be done to achieve the key purpose of an occupation cluster.



### **Employability Skills**

Employability skills are basic academic and personal skills that are needed to build more advanced competencies. They are competencies required by all workers in order to obtain meaningful work and participate in the modern workforce. The level of skill required for biotechnology & biomedical was described in the prior section on SCAN Skills in this document.

### **Key Activities**

Key activities are the tasks related to the functional area of the career cluster and performed by workers in a given occupation. They are made up of work activities which are measurable and observable, and which result in a decision, product or service.

### **Performance Indicators**

Performance indicators are specific behavioral evidence of a worker's achievement of skills, knowledge, and task completion. The question answered is: "How do we know when this key activity is performed well?" Performance indicators provide the standard of performance required to produce the necessary outcomes of key activities.

### **Technical Skills, Knowledge, Abilities and Tools**

Technical skills, knowledge, and abilities are those areas of expertise which workers must have in order to perform a given occupational task with excellence. A collection of skills, knowledge, abilities, and tools make up competencies.

Skills refer to proficiency in an applied activity. This activity could be physical, mental, or interpersonal in nature.

Knowledge is a particular set of information.

Abilities are broad human characteristics that result from natural talent, training, or experience.

Tools are materials, equipment, and implements a worker must be able to use competently to meet the requirements of the job.



# **RESEARCH OUTCOMES: SKILL STANDARDS FOR RESEARCH AND DEVELOPMENT**

**Research Findings  
Typical Job Description and Sample Job Titles  
Scenarios: Routine, Crisis, and Long Term  
Summary of Critical Work Functions and Key Activities  
Skill Standards**

## Research Findings: Research and Development



The industry focus group found that most of the information contained in the 2000 Research and Development Skill Standards was still applicable. It also found some information lacking, particularly in the area of the collection and management of data electronically and bioinformatics, the use of robotics, and technologies such as microscopy, whole body imaging, fluorophores, protein analysis and proteomics, high through-put genomic techniques and flow cytometry.

In addition, the previous version of the biotechnology & biomedical skill standards contained a key activity (A8): Perform routine animal care duties. This key activity was included in the previous version because it was extremely important for a few jobs. Over the past 5 years, requirements for working with animals have changed such that certification by a veterinary board and preclinical group is required. This work is no longer considered entry level, and so it has been deleted from the updated version of the skill standards.

Some entry level work may include performance of routine greenhouse duties for firms that work in the area of genetically engineered food products. However, this does not occur in the Puget Sound region.

The industry group streamlined the skill standards by combining some key activities. In particular, D3, D5 and D6 from 2000 were merged into critical work function A in the 2007 version. This allowed the 2007 critical work function D to shift to an emphasis on data management.

Two new key activities were added, both in the critical work function D (Perform Recordkeeping and Manage Data):

- D3. Enter and manage laboratory information electronically
- D4. Assist with inventory maintenance

### **Typical Job Description for Research, Development, and Manufacturing**

Individuals who work in the area of Research and Development are at the heart of the work in the Biotechnology/Biomedical industry. They work in the laboratories carrying out independent research, working closely with investigators to design, execute, and interpret experiments. Lab work may include such features as preparing culture plates and stock solutions, sectioning, participating in laboratory meetings, journal clubs, and animal care, among other responsibilities. In addition, they perform periodic instrument maintenance and calibration, investigate new technologies, maintain documentation, and order supplies.

Safety is a vital part of the work. Both in terms of personal safety and the safety of co-workers, and in terms of the safety of the public-at-large, individuals take on the contentious responsibility for ensuring that the work environment is safe, that all materials are handled and disposed of in a safe manner, and that the commodities produced meet or exceed all safety and regulatory requirements.

#### **SAMPLE JOB TITLES**

Biological Technician  
Documentation Specialist  
Lab Instrumentation and Calibration Specialist  
Medical Laboratory Technologist (MT)  
Program Assistant  
QA Associate  
Research Assistant/Research Associate  
Research Program Coordinator  
Research Technician  
Research/Medical Scientist  
Scientist

## **Routine Scenario: A Day in Research and Development**

**YOU ARRIVE** at the beginning of your day and schedule out the activities for the day. Nearly everyone will be multi-tasking in an R&D environment. For example, while waiting for cells to grow, other activities may be accomplished. Thus two or three things may be done in parallel while performing tasks such as doing a cell culture. While watching the cell line, you make sure to feed cells at appropriate intervals, monitor cells to be sure they split at appropriate times, and implement appropriate quality control measures to ensure cell lines are not contaminated. At the same time, you could be entering data into the notebook, doing general lab maintenance, or utilizing those cells or other cell lines in experiments. During the day you may have to do literature searches to see if other scientific personnel have done similar experiments. At the close of an experiment you ensure you have data that can be analyzed, and you review the data with a more senior person/data with a more senior person.

### **PRIMARY TASKS AND FUNCTIONS INVOLVED IN THIS SCENARIO**

#### **A. Perform routine laboratory support work**

- A1. Maintain laboratory and equipment
- A3. Operate equipment
- A4. Maintain biological stock cultures
- A5. Clean and prepare items for lab
- A6. Prepare biological and/or chemical materials

#### **B. Assist with research and development**

- B1. Assist in designing experiments
- B2. Perform assays and experiments
- B3. Troubleshoot experiments and equipment
- B4. Perform data analysis
- B5. Communicate results
- B6. Investigate new technologies and methodologies

#### **D. Perform recordkeeping and manage data**

- D1. Maintain lab notebook
- D2. Create documents
- D3. Enter and manage laboratory information electronically
- D4. Assist with inventory maintenance

**Crisis Scenario:  
Calibration**

**THE DATA GATHERED** during an experiment does not come back as expected or as set by quality control, which means the product is outside of tolerances. You must check the equipment and check to see if the correct process was followed. You check documentation to ensure all SOPs (Standard Operating Procedures) were followed. You then follow a systematic approach to safely check the equipment. A representative for the equipment may be called in to recalibrate. Each step along the way is documented and turned in to a senior person in the laboratory.

**PRIMARY TASKS AND FUNCTIONS INVOLVED IN THIS SCENARIO****A. Perform routine laboratory support work**

- A1. Maintain laboratory and equipment service meets requirements

**B. Assist with research and development**

- B2. Perform assays and experiments
- B3. Troubleshoot experiments and equipment
- B4. Perform data analysis
- B5. Communicate results

**C. Maintain a safe and productive work environment**

- C3. Identify unsafe conditions and take corrective action
- C5. Coordinate with work team
- C7. Handle and dispose of hazardous materials
- C8. Maintain Security

**D. Perform recordkeeping and manage data**

- D1. Maintain lab notebook
- D2. Create documents
- D3. Enter and manage laboratory information electronically

**Long-Term Scenario:  
Chemical Spill Team**

**BEING A PART** of a CST (Chemical Spill Team) requires basic understanding of how chemicals react and how safety equipment is used for dealing with chemicals, such as breathing apparatus or special clothing. You attend numerous special trainings so that if a spill arises, the reaction is a planned event and the spill is properly contained. The procedures are documented to ensure clarity, communicate required steps for safety, and train other employees in how to handle chemical spills. Depending on the nature of the chemical—liquid, gas, acid, solvent, or other forms—there are different methods for containing the spill. You meet regularly with the CST, obtain certifications, and practice regular drills with the spill team.

**PRIMARY TASKS AND FUNCTIONS INVOLVED IN THIS SCENARIO****C. Maintain a safe and productive work environment**

- C2. Participate in emergency drills and emergency response teams
- C3. Identify unsafe conditions and take corrective action
- C4. Suggest continuous improvements
- C5. Coordinate with work team
- C7. Handle and dispose of hazardous materials
- C8. Maintain Security
- C9. Send, receive and distribute biological and chemical materials

**D. Perform recordkeeping and manage data**

- D1. Maintain lab notebook
- D2. Create documents
- D3. Enter and manage laboratory information electronically

## Research and Development: Summary of Critical Work Functions and Key Activities

CRITICAL WORK FUNCTIONS	KEY ACTIVITIES									
<b>A.</b> Perform routine laboratory support work	<b>A1</b> Maintain laboratory and equipment	<b>A2</b> Order and stock supplies	<b>A3</b> Operate equipment	<b>A4</b> Maintain biological stock cultures	<b>A5</b> Clean and prepare items for lab	<b>A6</b> Prepare biological and/or chemical materials				
<b>B.</b> Assist with research and development	<b>B1</b> Assist in designing experiments	<b>B2</b> Perform assays and experiments	<b>B3</b> Troubleshoot experiments and equipment	<b>B4</b> Perform data analysis	<b>B5</b> Communicate results	<b>B6</b> Investigate new technologies and methodologies				
<b>C.</b> Maintain a safe and productive work environment	<b>C1</b> Participate in employer-sponsored safety training	<b>C2</b> Participate in emergency drills and emergency response teams	<b>C3</b> Identify unsafe conditions and take corrective action	<b>C4</b> Suggest continuous improvements	<b>C5</b> Coordinate with work team	<b>C6</b> Provide orientation and training for other employees	<b>C7</b> Handle and dispose of hazardous materials	<b>C8</b> Maintain security	<b>C9</b> Send, receive and distribute biological and chemical materials	
<b>D.</b> Perform record keeping and manage data	<b>D1</b> Maintain lab notebook	<b>D2</b> Create documents	<b>D3</b> Enter and manage laboratory information electronically	<b>D4</b> Assist with inventory maintenance						

**Black Text** = Skill Standards validated by industry and still current for 2007 project

**Green Text** = New Skill Standards identified and validated by industry for 2007 project

## CONCENTRATION: RESEARCH AND DEVELOPMENT

## Critical Work Function – A. Perform routine laboratory support work

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<p><b>A1.</b> <b>Maintain laboratory and equipment</b></p>	<ul style="list-style-type: none"> <li>■ Equipment is properly calibrated and functional.</li> <li>■ Laboratory is neat and well organized.</li> <li>■ Equipment malfunction is remedied in a timely manner.</li> <li>■ Scheduled cleanings and PMs (Preventive Maintenance) are performed per established procedures.</li> <li>■ Laboratory procedures are clearly communicated to appropriate personnel.</li> <li>■ Problems and malfunctions are properly escalated, and appropriate technical support personnel are informed.</li> <li>■ Hazardous materials are properly disposed of in accordance with all applicable laws, regulations and procedures.</li> <li>■ Equipment maintenance is documented in compliance with company policies and procedures as well as regulatory and legal entities.</li> <li>■ Documentation is legible, indelible, clear, concise and accurate.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of equipment calibration.</li> <li>■ Knowledge of equipment operation and troubleshooting/repair for equipment such as pipette-aid, pipettmen, micropipettes, pH meter, centrifuge, scale, autoclave or spectrophotometer, cleaning spatulas, stir bars and flow hoods.</li> <li>■ Knowledge of equipment cleaning and PM (Preventive Maintenance) procedures.</li> <li>■ Knowledge of laboratory procedures and systems.</li> <li>■ Knowledge of cleaning agents and procedures.</li> <li>■ Knowledge of hazardous material handling and disposal procedures and laws.</li> <li>■ Knowledge of company policies, procedures, laws and regulations regarding Good Manufacturing Practices, Good Laboratory Practices and Good Clinical Practices.</li> <li>■ Knowledge of Good Manufacturing Practices, Good Laboratory Practices and Good Clinical Practices training opportunities and requirements</li> </ul>	<ul style="list-style-type: none"> <li>■ Performs measurements.</li> <li>■ Uses materials in a safe and efficient manner.</li> <li>■ Identifies and corrects malfunctions/failures.</li> <li>■ Presents basic ideas/information.</li> <li>■ Explains concepts.</li> <li>■ Implements a logical system in the laboratory.</li> <li>■ Records information accurately, completes documentation and summarizes information.</li> <li>■ Performs assigned task, follow rules/policies/procedures and pays attention to details.</li> <li>■ Performs given set of tasks and follows schedule.</li> </ul>
<p><b>A2.</b> <b>Order stock and supplies</b></p>	<ul style="list-style-type: none"> <li>■ Required stocks are anticipated to ensure laboratory is always well stocked.</li> <li>■ Stock and supply documentation is properly maintained.</li> <li>■ Expired materials and items are discarded or reprocessed in accordance with established procedures.</li> <li>■ Periodic inventory of stock and supplies is taken in accordance with established procedures.</li> <li>■ Supplies are ordered on a timely basis.</li> <li>■ Broken lab ware is discarded and replaced as required.</li> <li>■ Records are maintained in an orderly and timely fashion.</li> <li>■ Materials are appropriately recorded in a log book and/or database.</li> <li>■ Stock records are accessible to all relevant personnel.</li> <li>■ Database security is maintained.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of laboratory requirements regarding stocks such as usage rates and laboratory schedules.</li> <li>■ Knowledge of stock record storage locations and procedures.</li> <li>■ Ability to identify expired materials.</li> <li>■ Knowledge of discard and reprocessing procedures.</li> <li>■ Knowledge of stock and supply inventory techniques and ordering procedures.</li> <li>■ Knowledge of chemical classifications for proper storage.</li> <li>■ Knowledge of chemical safety.</li> <li>■ Knowledge of chemical/biological stocks inventory procedures.</li> <li>■ Knowledge of logbook and database management procedures.</li> <li>■ Knowledge of database security protocols.</li> </ul>	<ul style="list-style-type: none"> <li>■ Orders and maintains inventory.</li> <li>■ Monitors safe and efficient utilization of materials.</li> <li>■ Follows rules/policies/procedures.</li> <li>■ Selects/obtains data/information relevant to the task.</li> <li>■ Performs given set of tasks.</li> <li>■ Analyzes organization of information and transfers information between formats.</li> <li>■ Records information accurately, completes documentation, and summarizes information.</li> <li>■ Maintains inventory and monitors safe and efficient use of materials.</li> <li>■ Recognizes ethical issues and demonstrates trustworthiness.</li> </ul>

## CONCENTRATION: RESEARCH AND DEVELOPMENT

## Critical Work Function – A. Perform routine laboratory support work

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<p><b>A3. Operate equipment</b></p>	<ul style="list-style-type: none"> <li>■ Training on equipment operation is obtained and kept current as required.</li> <li>■ Equipment is operated properly in accordance with established procedures.</li> <li>■ Equipment is operated safely.</li> <li>■ All personal protective equipment is worn in accordance with company policies and procedures.</li> <li>■ Equipment is kept clean and in good operating condition.</li> <li>■ Equipment logbooks are maintained by user and include daily usage and any instrument malfunction, calibration, cleaning, and preventative maintenance in accordance with established procedures.</li> <li>■ Service dates and pertinent data are included.</li> <li>■ Logbooks are properly archived in accordance with established procedures.</li> <li>■ Robotic liquid handlers are utilized and operated properly.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of equipment operation training opportunities and requirements.</li> <li>■ Knowledge of equipment operation and procedures for equipment such as pipette-aid, pipettmen, micropipettes, pH meter, centrifuge, scale, autoclave, or spectrophotometer, cleaning spatulas, stir bars and flow hoods.</li> <li>■ Knowledge of equipment operation safety procedures and requirements.</li> <li>■ Knowledge of and ability to use personal protective equipment.</li> <li>■ Knowledge of company policies.</li> <li>■ Knowledge of equipment cleaning procedures and ability to keep equipment in good operating condition.</li> <li>■ Knowledge of procedures for equipment logbooks.</li> <li>■ Ability to identify and document malfunction, calibration, cleaning, and preventive maintenance activities, and knowledge of associated terminology.</li> <li>■ Knowledge of robotic liquid handlers.</li> <li>■ Knowledge of microscopy, whole body imaging, fluorophores.</li> </ul>	<ul style="list-style-type: none"> <li>■ Recalls basic rules/principals.</li> <li>■ Follows rules/policies/procedures.</li> <li>■ Pays attention to details.</li> <li>■ Understands operation/interaction of equipment.</li> <li>■ Follows rules/policies/procedures and pays attention to details.</li> <li>■ Outlines and follows specified maintenance procedures.</li> <li>■ Records information accurately, completes documentation, and summarizes information.</li> <li>■ Knows available technology, identifies appropriate technology, and understands requirements of the task and technological results.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Performs given set of tasks and follows schedules.</li> </ul>

## CONCENTRATION: RESEARCH AND DEVELOPMENT

## Critical Work Function – A. Perform routine laboratory support work

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<p><b>A4.</b> <b>Maintain biological stock cultures</b></p>	<ul style="list-style-type: none"> <li>■ Cultures are properly labeled.</li> <li>■ Cultures are healthy and viable.</li> <li>■ Proper aseptic technique is consistently followed.</li> <li>■ Cultures are kept pure and separate.</li> <li>■ The needs of laboratory personnel regarding biological cultures are anticipated and met.</li> <li>■ Routine care of cultures is performed on a timely basis.</li> <li>■ Cultures are kept current in accordance with established procedures.</li> <li>■ Biological cultures are disposed of according to established procedures and all applicable laws and regulations.</li> <li>■ Materials are appropriately recorded in a log book and/or database accurately and in a timely manner.</li> <li>■ Inventory is performed routinely.</li> <li>■ Stock records are accessible to all relevant personnel.</li> <li>■ Database security is maintained.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of culture labeling protocols.</li> <li>■ Knowledge of care and feeding procedures for biological cultures to keep them healthy and viable.</li> <li>■ Knowledge of aseptic techniques.</li> <li>■ Knowledge of specific culture procedures and associated tools and equipment.</li> <li>■ Knowledge of the requirements of laboratory personnel and the projects for which they are responsible with respect to biological stock cultures.</li> <li>■ Knowledge of biological stock culture documentation procedures.</li> <li>■ Knowledge of safety hazards for each culture.</li> <li>■ Knowledge of basic microscopy.</li> <li>■ Knowledge of biological culture disposal procedures and law/regulations.</li> <li>■ Knowledge of basic bloodborne pathogens and biohazards.</li> <li>■ Knowledge of logbook and database management procedures.</li> <li>■ Knowledge of chemical/biological stocks inventory procedures.</li> <li>■ Knowledge of stock record storage locations and procedures.</li> <li>■ Knowledge of database security protocols.</li> </ul>	<ul style="list-style-type: none"> <li>■ Utilizes mathematical techniques/formulas/processes.</li> <li>■ Follows rules/policies/procedures and pays attention to details.</li> <li>■ Recognizes ethical issues and demonstrates trustworthiness.</li> <li>■ Performs given set of tasks and follows schedule.</li> <li>■ Analyzes organization of information and transfers information between formats.</li> <li>■ Records information accurately, completes documentation, and summarizes information.</li> <li>■ Maintains inventory and monitors safe and efficient use of materials.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures and pays attention to details.</li> <li>■ Adheres to standards.</li> </ul>
<p><b>A5.</b> <b>Clean and prepare items for lab</b></p>	<ul style="list-style-type: none"> <li>■ The needs of laboratory personnel are anticipated and met regarding lab ware and equipment.</li> <li>■ Lab ware is washed in a timely manner and in accordance with established procedures.</li> <li>■ Lab ware is properly staged in accordance with established procedures.</li> <li>■ Where applicable, lab ware is sterilized in accordance with established procedures.</li> <li>■ Lab ware is properly stored.</li> <li>■ Special requests are handled efficiently and courteously.</li> <li>■ Priorities are correctly evaluated and adjusted in accordance with work needs.</li> <li>■ All safety procedures are followed.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of the requirements of laboratory personnel and the projects for which they are responsible with respect to lab ware.</li> <li>■ Knowledge of lab ware washing, staging, and sterilization procedures.</li> <li>■ Knowledge of lab ware storage locations and procedures.</li> <li>■ Knowledge of laboratory project priorities and ability to prioritize special requests.</li> <li>■ Knowledge of hazards, pathogen transfer, and safe handling practices.</li> <li>■ Knowledge of properties of lab ware materials and proper handling.</li> </ul>	<ul style="list-style-type: none"> <li>■ Makes connections between old and new and recognizes patterns/relationships.</li> <li>■ Follows rules/policies/procedures and pays attention to details.</li> <li>■ Outlines and follows specified maintenance procedures.</li> <li>■ Recognizes and responds to customer needs.</li> <li>■ Prioritizes daily tasks and adjusts schedule as required by supervisor.</li> </ul>

## CONCENTRATION: RESEARCH AND DEVELOPMENT

**Critical Work Function – A. Perform routine laboratory support work**

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>A6. Prepare biological and/or chemical materials</b>	<ul style="list-style-type: none"> <li>■ Training on preparation of materials is obtained and kept current.</li> <li>■ Materials are prepared in accordance with established procedures.</li> <li>■ Materials are properly labeled and stored.</li> <li>■ Materials are handled in a safe manner.</li> <li>■ All hazardous materials procedures are followed in accordance with all applicable laws and regulations.</li> <li>■ Prepared materials are tested to ensure that they meet specifications.</li> <li>■ Expired materials are properly disposed of and/or dispositioned.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of basic biology.</li> <li>■ Knowledge of basic bloodborne pathogens and biohazards.</li> <li>■ Knowledge of material preparation training opportunities and requirements.</li> <li>■ Knowledge of material preparation procedures.</li> <li>■ Knowledge of labeling protocols, and storage areas, and procedures for biological and chemical materials.</li> <li>■ Knowledge of material handling procedures.</li> <li>■ Knowledge of hazardous materials and disposal procedures.</li> <li>■ Knowledge of basic chemistry, including buffers and pH.</li> </ul>	<ul style="list-style-type: none"> <li>■ Utilizes mathematical techniques/formulas/processes.</li> <li>■ Follows rules/policies/procedures and pays attention to details.</li> <li>■ Recognizes ethical issues and demonstrates trustworthiness.</li> <li>■ Uses materials in a safe and efficient manner.</li> </ul>

## CONCENTRATION: RESEARCH AND DEVELOPMENT

## Critical Work Function — B. Assist with research and development

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<p><b>B1.</b> <b>Assist in designing experiments</b></p>	<ul style="list-style-type: none"> <li>■ Appropriate resources are researched prior to method development to ensure design represents best practices.</li> <li>■ Design is approved prior to execution.</li> <li>■ Proposed protocols are properly documented.</li> <li>■ Design includes consideration of resources and equipment requirements and availability.</li> <li>■ Proposed final design is offered for validation.</li> <li>■ Recommendations are practical based on time, budget, and resources.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of design resources including Internet, journals, product literature, and colleagues.</li> <li>■ Knowledge of design approval and validation processes.</li> <li>■ Knowledge of protocol documentation procedures.</li> <li>■ Knowledge of the components and discipline of design of experiments including reproducibility, controls, conditions and variables.</li> </ul>	<ul style="list-style-type: none"> <li>■ Identifies facts and principles and applies them to processes/procedures and uses logic to draw conclusions.</li> <li>■ Records information accurately, completes documentation and summarizes information.</li> <li>■ Knows available technology, identifies appropriate technology, and understands requirements of the task and technological results.</li> <li>■ Defends own viewpoints, accepts constructive criticism, and understands own impact on others.</li> <li>■ Sets well-defined/realistic goals; analyzes and adjusts goals.</li> </ul>
<p><b>B2.</b> <b>Perform assays and experiments</b></p>	<ul style="list-style-type: none"> <li>■ Assays are performed as per protocol.</li> <li>■ Proper experimental design is followed.</li> <li>■ Proper reagents are used.</li> <li>■ Assays and experiments are completed on a timely basis.</li> <li>■ All assay and experimental data are properly documented.</li> <li>■ Proper controls and parameters are used.</li> <li>■ Inventories are checked to ensure that required supplies are available and, if not, orders are placed in time to obtain the supplies prior to the start of the experiment.</li> <li>■ Proper analysis is used for the experiment.</li> <li>■ Laboratory citizenship principles are followed.</li> <li>■ Trouble shooting procedures are utilized when necessary.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of assay protocols and experimental design.</li> <li>■ Knowledge of reagents.</li> <li>■ Knowledge of experiment documentation procedures.</li> <li>■ Knowledge of experiment controls.</li> <li>■ Knowledge of current, state-of-the-art protocols or procedures.</li> <li>■ Knowledge of basic chemistry, biology, biochemistry, molecular biology, microbiology or immunology as applicable to the company product or project.</li> <li>■ Knowledge of high through-put genomic techniques.</li> <li>■ Knowledge of ELISA (Enzyme Linked Immunosorbent Assay).</li> <li>■ Knowledge of mammalian and insect cell culture and sterile techniques.</li> <li>■ Knowledge of flow cytometry.</li> <li>■ Knowledge of supply ordering procedures and lead times.</li> <li>■ Knowledge of sequences and design primers and the ability to assemble sequences.</li> <li>■ Knowledge of protein analysis and proteomics.</li> <li>■ Knowledge of basics of bioinformatics (generating and managing data, analyzing data and making models of systems based on data).</li> <li>■ Knowledge of laboratory citizenship principles.</li> <li>■ Ability to troubleshoot experiments.</li> </ul>	<ul style="list-style-type: none"> <li>■ Performs assigned task, follow rules/policies/procedures and pays attention to details.</li> <li>■ Understands requirements of the task.</li> <li>■ Performs given set of tasks and follows schedule.</li> <li>■ Records information accurately, completes documentation and summarizes information.</li> <li>■ Understands and utilizes scientific method.</li> </ul>

## CONCENTRATION: RESEARCH AND DEVELOPMENT

## Critical Work Function — B. Assist with research and development

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>B3.</b> <b>Troubleshoot experiments and equipment</b>	<ul style="list-style-type: none"> <li>■ Proper controls and parameters are used in experiments.</li> <li>■ Equipment is properly calibrated.</li> <li>■ Integrity of reagents is confirmed.</li> <li>■ Experimental data are reviewed and evaluated.</li> <li>■ Co-workers and appropriate resources are consulted regarding experimental results.</li> <li>■ Protocols are thoroughly reviewed and the experiment is repeated when appropriate.</li> <li>■ Appropriate equipment literature is consulted.</li> </ul>	<ul style="list-style-type: none"> <li>■ Ability to use controls and parameters.</li> <li>■ Knowledge of basic chemistry.</li> <li>■ Knowledge of equipment calibration procedures.</li> <li>■ Ability to determine if reagents are expired, degraded, or contaminated.</li> <li>■ Knowledge of company and literature resources available to support the troubleshooting of experiments and equipment.</li> </ul>	<ul style="list-style-type: none"> <li>■ Utilizes mathematical techniques/formulas/processes.</li> <li>■ Performs measurements and converts numerical data.</li> <li>■ Actively participates in team activities.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures and pays attention to details.</li> <li>■ Knows available technology, identifies appropriate technology, and understands requirements of the task and technological results.</li> </ul>
<b>B4.</b> <b>Perform data analysis</b>	<ul style="list-style-type: none"> <li>■ Appropriate tools are used to analyze data.</li> <li>■ Processed data is summarized and properly documented and/or archived.</li> <li>■ Data is thoroughly organized prior to analysis.</li> <li>■ Conclusions are drawn from analysis.</li> <li>■ Data is appropriately used to plan future experiments.</li> <li>■ Proper analysis is used for the experiment.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of and ability to use data analysis tools such as software, graphing, statistical tools, and calculators.</li> <li>■ Knowledge of data summary, documentation, and archive procedures.</li> <li>■ Knowledge of data analysis procedures and protocols for drawing conclusions.</li> <li>■ Knowledge of basic statistical analysis.</li> <li>■ Knowledge of NCBI (National Center for Biotechnology Information (NIH)) and other similar sites.</li> <li>■ Ability to analyze experiment results and incorporate them into experiment planning.</li> <li>■ Knowledge of experiment planning.</li> <li>■ Knowledge of molecular biology and high through-put genomic techniques.</li> <li>■ Knowledge of sequences and design primers and the ability to assemble sequences.</li> <li>■ Knowledge of protein analysis and proteomics.</li> <li>■ Knowledge of basics of bioinformatics (generating and managing data, analyzing data and making models of systems based on data).</li> <li>■ Knowledge of imaging analysis and software.</li> <li>■ Knowledge of 96-384 well assays, versus tubes.</li> </ul>	<ul style="list-style-type: none"> <li>■ Demonstrates creative thinking process while problem solving.</li> <li>■ Selects appropriate categories and applies processes to new information.</li> <li>■ Interprets information and prepares basic summaries.</li> <li>■ Uses logic to draw conclusions.</li> <li>■ Recognizes job tasks.</li> </ul>

CONCENTRATION: RESEARCH AND DEVELOPMENT

**Critical Work Function — B. Assist with research and development**

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
--------------	--	--	--

**B5. Communicate results**

- |   |  |   |
|---|--|---|
| <ul style="list-style-type: none"> <li>■ Data is presented using proper oral presentation techniques.</li> <li>■ Technical reports are written in a thorough manner.</li> <li>■ Information is disseminated to appropriate personnel.</li> <li>■ Appropriate visual aids are created and used.</li> <li>■ Presentation is tailored to target audience.</li> <li>■ Results are communicated in a succinct manner.</li> </ul> | <ul style="list-style-type: none"> <li>■ Knowledge of industry terminology and jargon.</li> <li>■ Knowledge of company procedures regarding communication of results.</li> <li>■ Knowledge of audience and their needs.</li> </ul> | <ul style="list-style-type: none"> <li>■ Knows available technology, identifies appropriate technology, and understands requirements of the task and technological results.</li> <li>■ Communicates appropriate verbal/nonverbal messages and addresses audience/purpose.</li> <li>■ Prepares basic reports and summaries and selects method of communication.</li> <li>■ Knowledge of organizing information.</li> </ul> |
|---|--|---|

**B6. Investigate new technologies and methodologies**

- |   |  |  |
|---|--|--|
| <ul style="list-style-type: none"> <li>■ Appropriate literature is thoroughly reviewed on emerging methods and technologies.</li> <li>■ Comparative evaluations are performed.</li> <li>■ New methodologies and technologies are presented to co-workers for evaluation.</li> <li>■ Cost analysis is performed and availability of resources is evaluated.</li> </ul> | <ul style="list-style-type: none"> <li>■ Knowledge of literature sources regarding emerging methods and technologies.</li> <li>■ Knowledge of current and new methodologies.</li> <li>■ Knowledge of industry terminology for technologies and methodologies.</li> </ul> | <ul style="list-style-type: none"> <li>■ Probes to gain information and interprets and summarizes it.</li> <li>■ Summarizes, integrates and analyzes information.</li> <li>■ Manipulates techniques/formulas and interprets mathematical data.</li> <li>■ Extracts information/data and uses logic to draw conclusions.</li> <li>■ Utilizes previous training experience to predict outcomes.</li> <li>■ Interprets technical information from articles and journals.</li> <li>■ Performs comparative evaluations.</li> <li>■ Utilizes cost analysis methods and evaluates availability of resources.</li> </ul> |
|---|--|--|

## CONCENTRATION: RESEARCH AND DEVELOPMENT

## Critical Work Function – C. Maintain a Safe and Productive Work Environment

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>C1.</b> <b>Participate in employer-sponsored safety training</b>	<ul style="list-style-type: none"> <li>■ Training records are updated and kept current.</li> <li>■ Successful completion results in certification where applicable.</li> <li>■ Application of the training is demonstrated in performance of daily duties.</li> <li>■ Mandatory training is attended.</li> <li>■ Training opportunities are assessed and effectively utilized.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of contents of training records.</li> <li>■ Knowledge of certification processes and procedures.</li> <li>■ Knowledge of safety training opportunities and requirements (e.g. biohazards, radiation, chemical and general laboratory safety).</li> </ul>	<ul style="list-style-type: none"> <li>■ Records information accurately, completes documentation and summarizes information.</li> <li>■ Understands learning process, recalls basic rules/principles, identifies own learning style and draws upon experiences and prior knowledge.</li> <li>■ Applies principles to process/procedure.</li> <li>■ Takes responsibility for own training.</li> </ul>
<b>C2.</b> <b>Participate in emergency drills and emergency response teams</b>	<ul style="list-style-type: none"> <li>■ Training and certification on relevant emergency and first aid procedures is complete and up-to-date.</li> <li>■ Emergency response complies with company and regulatory policies and procedures.</li> <li>■ Emergency drills and incidents are documented promptly according to company and regulatory procedures.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of training opportunities and requirements for emergency and first aid procedures.</li> <li>■ Knowledge of emergency response procedures and policies.</li> <li>■ Knowledge of emergency drill and incident documentation procedures.</li> </ul>	<ul style="list-style-type: none"> <li>■ Records information accurately, completes documentation and summarizes information.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> </ul>
<b>C3.</b> <b>Identify unsafe conditions and take corrective action</b>	<ul style="list-style-type: none"> <li>■ Conditions that present a threat to health, safety, and the environment are identified, reported, and documented promptly.</li> <li>■ Corrective actions are identified.</li> <li>■ Appropriate parties are consulted about corrective actions.</li> <li>■ Corrective actions are taken promptly according to company procedures.</li> <li>■ Ongoing safety concerns are tracked and reported until corrective action is taken.</li> <li>■ Accidents are promptly reported to appropriate personnel and departments.</li> <li>■ Local, state, federal, and company guidelines are followed in handling of biological materials.</li> </ul>	<ul style="list-style-type: none"> <li>■ Ability to identify conditions that present a threat to health, safety, and the environment.</li> <li>■ Knowledge of unsafe condition and accident documentation and reporting procedures.</li> <li>■ Knowledge of company and personnel assistance for correcting unsafe conditions.</li> <li>■ Knowledge of procedures for taking corrective actions.</li> <li>■ Knowledge of safety tracking procedures.</li> <li>■ Knowledge of local state, federal, and company guidelines.</li> <li>■ Ability to locate and interpret MSDS forms.</li> </ul>	<ul style="list-style-type: none"> <li>■ Recognizes ethical issues and demonstrates trustworthiness.</li> <li>■ Uses previous training/experience to predict outcomes.</li> <li>■ Analyzes situations, considers risks and implications, and compiles multiple viewpoints.</li> <li>■ Records information accurately, completes documentation, and summarizes information.</li> <li>■ Develops creative solutions and applies them to new situations.</li> <li>■ Presents complex ideas/information and poses critical questions.</li> </ul>

## CONCENTRATION: RESEARCH AND DEVELOPMENT

## Critical Work Function – C. Maintain a Safe and Productive Work Environment

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<p><b>C4.</b> <b>Suggest continuous improvements</b></p>	<ul style="list-style-type: none"> <li>■ Suggestions for improvements are generated through observation and data analysis.</li> <li>■ Suggestions communicate measurable and data-driven benefits to the company, its customers, and employees.</li> <li>■ Suggestions are made according to proper procedures and documentation.</li> <li>■ Suggestions are not ignored due to status or hierarchy.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of current procedures.</li> <li>■ Ability to identify measurable, data-driven benefits to the company, customers, and employees.</li> <li>■ Knowledge of procedures for making suggestions.</li> </ul>	<ul style="list-style-type: none"> <li>■ Responds assertively, accepts responsibility for own behavior, and understands own impact on others.</li> <li>■ Responds appropriately to others.</li> <li>■ Understands continuous improvement process and suggests system motivations and improvements.</li> <li>■ Recognizes the organizational system and follows processes and procedures.</li> <li>■ Recommends ethical courses of action.</li> </ul>
<p><b>C5.</b> <b>Coordinate with work team</b></p>	<ul style="list-style-type: none"> <li>■ Time estimates are communicated to appropriate personnel upon request.</li> <li>■ Team goals are specific, measurable, achievable, and time-bound.</li> <li>■ Timelines are met effectively.</li> <li>■ Team members are notified of project or production requirements in a timely way.</li> <li>■ Production workflow runs efficiently.</li> <li>■ Relationships with others facilitate effective workflow.</li> <li>■ Workers actively participate in meetings and problem-solving groups.</li> <li>■ Problems/delays are communicated to the team in a timely manner.</li> <li>■ Communication is clear and timely.</li> <li>■ Relevant information is disseminated to appropriate personnel.</li> <li>■ Laboratory systems for communicating information are followed and kept up.</li> </ul>	<ul style="list-style-type: none"> <li>■ Ability to accurately estimate completion times.</li> <li>■ Knowledge of goal-setting techniques.</li> <li>■ Knowledge of scheduling procedures.</li> <li>■ Knowledge of production workflow and timelines.</li> <li>■ Knowledge of project and product.</li> <li>■ Knowledge of laboratory common systems.</li> <li>■ Knowledge of roles of co-workers and current projects.</li> <li>■ Knowledge of communication protocols and channels and reporting procedures.</li> </ul>	<ul style="list-style-type: none"> <li>■ Presents basic ideas/information.</li> <li>■ Applies self-management skills and appropriately modifies goals.</li> <li>■ Recognizes job tasks.</li> <li>■ Performs given set of tasks, prioritizes daily tasks, and monitors/adjusts task sequence.</li> <li>■ Analyzes situation/information and considers implications.</li> <li>■ Applies principles to process/procedure and uses logic to draw conclusions.</li> <li>■ Communicates appropriate verbal/nonverbal messages and presents basic ideas/information.</li> <li>■ Interprets, clarifies, and influences communication.</li> <li>■ Responds appropriately to others and establishes rapport with co-workers and customers.</li> <li>■ Recognizes laboratory systems and understands system principles/terminology.</li> </ul>
<p><b>C6.</b> <b>Provide orientation and training for other employees</b></p>	<ul style="list-style-type: none"> <li>■ Cross-training is provided as appropriate.</li> <li>■ Training needs are assessed regularly.</li> <li>■ New requirements and training issues are identified.</li> <li>■ Training goals are achieved through effective approaches</li> <li>■ Training outcomes are documented.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of overall work flow and production goals.</li> <li>■ Knowledge of documentation procedures for training outcomes.</li> </ul>	<ul style="list-style-type: none"> <li>■ Identifies training needs and conducts task specific training.</li> <li>■ Records information accurately, completes documentation, and summarizes information.</li> <li>■ Responds to verbal/nonverbal communication and confirms information.</li> <li>■ Presents complex ideas/information and analyzes group individual responses.</li> </ul>

## CONCENTRATION: RESEARCH AND DEVELOPMENT

## Critical Work Function — C. Maintain a Safe and Productive Work Environment

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>C7.</b> <b>Handle and dispose of hazardous materials</b>	<ul style="list-style-type: none"> <li>■ Hazardous materials are handled and disposed of in accordance with established procedures.</li> <li>■ All hazardous materials documentation is thoroughly completed and filed in accordance with company policies and procedures, and in accordance with all applicable laws and regulations.</li> <li>■ Deviations from correct hazardous materials handling procedures are reported and/or corrected promptly to appropriate personnel.</li> <li>■ MSDS are consulted as needed.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of hazardous materials handling and documentation procedures.</li> <li>■ Knowledge of MSDS.</li> <li>■ Knowledge of company policies and laws and regulations regarding hazardous materials.</li> <li>■ Ability to identify deviations from correct hazardous materials procedures and knowledge of reporting and documentation procedures for deviations.</li> <li>■ Knowledge of basic chemistry and biology.</li> </ul>	<ul style="list-style-type: none"> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Recognizes ethical issues and demonstrates trustworthiness.</li> <li>■ Records information accurately, completes documentation, and summarizes information.</li> <li>■ Identifies relevant details, facts, and specifications.</li> <li>■ Follows set of instructions.</li> </ul>
<b>C8.</b> <b>Maintain security</b>	<ul style="list-style-type: none"> <li>■ Training is obtained regarding security.</li> <li>■ Security breaches are promptly reported to appropriate personnel.</li> <li>■ Proprietary documents and information are handled in accordance with company policies and procedures and remain on the premises.</li> <li>■ Controlled materials cabinets and storage areas are kept locked at all times.</li> <li>■ Security alerts are properly posted and communicated.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of training opportunities and requirements regarding security.</li> <li>■ Ability to identify security breaches and knowledge of reporting procedures.</li> <li>■ Knowledge of company policies and procedures regarding proprietary documents and information.</li> <li>■ Knowledge of access procedures to restricted storage areas.</li> <li>■ Knowledge of posting and communication procedures for security alerts.</li> </ul>	<ul style="list-style-type: none"> <li>■ Understands learning process, recalls basic rules/principles, and identifies own learning style.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Recognizes ethical issues and demonstrates trustworthiness.</li> </ul>
<b>C9.</b> <b>Send, receive, and distribute biological and chemical materials</b>	<ul style="list-style-type: none"> <li>■ Training on sending, receiving, and distributing materials is maintained and kept current.</li> <li>■ Adequate supply of shipping materials is maintained.</li> <li>■ Material is properly packaged and labeled prior to sending in accordance with established procedures and in accordance with all applicable laws and regulations.</li> <li>■ Shipping, receiving, and distribution records are kept accurate and current.</li> <li>■ Inventory database and/or records are updated.</li> <li>■ Materials are shipped and distributed under the proper conditions and in a timely manner.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of training opportunities and requirements for biological and chemical material transport and receiving.</li> <li>■ Knowledge of supply requirements for shipping materials.</li> <li>■ Knowledge of packaging and labeling protocols and laws and regulations governing sending, receiving, and transporting biological and chemical materials.</li> <li>■ Knowledge of record keeping procedures for shipping, receiving, and distribution procedures.</li> <li>■ Ability to update inventory database or records.</li> <li>■ Knowledge of various conditions for shipping and the ability to select appropriate conditions for biological and chemical materials.</li> </ul>	<ul style="list-style-type: none"> <li>■ Understands learning process, recalls basic rules/principles and identifies own learning style.</li> <li>■ Orders and maintains inventory.</li> <li>■ Follows rules/policies/procedures and pays attention to details.</li> <li>■ Records information accurately and completes documentation.</li> <li>■ Follows schedule and performs given set of tasks.</li> </ul>

## CONCENTRATION: RESEARCH AND DEVELOPMENT

## Critical Work Function — D. Perform Recordkeeping and Manage Data

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<p><b>D1.</b> <b>Maintain lab notebook</b></p>	<ul style="list-style-type: none"> <li>■ Notebook is legible, current, and witnessed in accordance with all established policies and procedures.</li> <li>■ All company policies and procedures are followed.</li> <li>■ Notebooks are kept accessible to appropriate personnel.</li> <li>■ Notebooks are archived as in accordance with all established policies and procedures.</li> <li>■ Structure of lab notebook is effective and efficient.</li> <li>■ Lab notebook contains both raw data and calculations.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of company policies, procedures, and protocols regarding laboratory notebooks.</li> <li>■ Knowledge of storage and archiving locations and procedures for lab notebooks.</li> <li>■ Knowledge of how to organize data in an experiment so the linear progression can be easily followed.</li> <li>■ Knowledge of lab notebook structures.</li> </ul>	<ul style="list-style-type: none"> <li>■ Records information accurately, completes documentation, and summarizes information.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Selects appropriate categories, analyzes organization of information, and transfers information between formats.</li> </ul>
<p><b>D2.</b> <b>Create documents</b></p>	<ul style="list-style-type: none"> <li>■ Appropriate formats/templates are used in accordance with all established policies and procedures.</li> <li>■ Documents are legible, indelible, clear and concise.</li> <li>■ The integrity of the original documents is maintained and all copies are disposed of in accordance with all established policies and procedures.</li> <li>■ All documentation is in compliance with company policies and procedures as well as regulatory and legal entities.</li> <li>■ All documentation is signed by appropriate personnel and dated.</li> <li>■ Work is revised using feedback and suggestions from co-workers.</li> <li>■ Reports are written within time constraints.</li> <li>■ Reports include the appropriate references.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of report formats and ability to use templates.</li> <li>■ Ability to maintain the integrity of original documents.</li> <li>■ Knowledge of copy disposal policies and procedures.</li> <li>■ Knowledge of company policies and procedures and laws and regulations regarding Good Manufacturing Practices, Good Laboratory Practices and Good Clinical Practices.</li> <li>■ Knowledge of Good Manufacturing Practices, Good Laboratory Practices and Good Clinical Practices training opportunities and requirements.</li> <li>■ Knowledge of established policies and procedures.</li> <li>■ Knowledge of appropriate references.</li> </ul>	<ul style="list-style-type: none"> <li>■ Understands computer operations, performs basic data entry, locates and retrieves information, and utilizes networks.</li> <li>■ Analyzes organization of information and transfers information between formats.</li> <li>■ Selects information relevant to the task, integrates multiple items of data, and contrasts conflicting data.</li> <li>■ Recognizes ethical issues and demonstrates trustworthiness.</li> <li>■ Records information accurately, completes documentation and summarizes information.</li> <li>■ Performs assigned task, follow rules/policies/procedures and pays attention to details.</li> <li>■ Performs given set of tasks and follows schedule.</li> <li>■ Summarizes/paraphrases information and creates original documents.</li> <li>■ Accepts constructive criticism.</li> <li>■ Pays attention to details.</li> <li>■ Identifies relevant details and follows a set of instructions.</li> </ul>

## CONCENTRATION: RESEARCH AND DEVELOPMENT

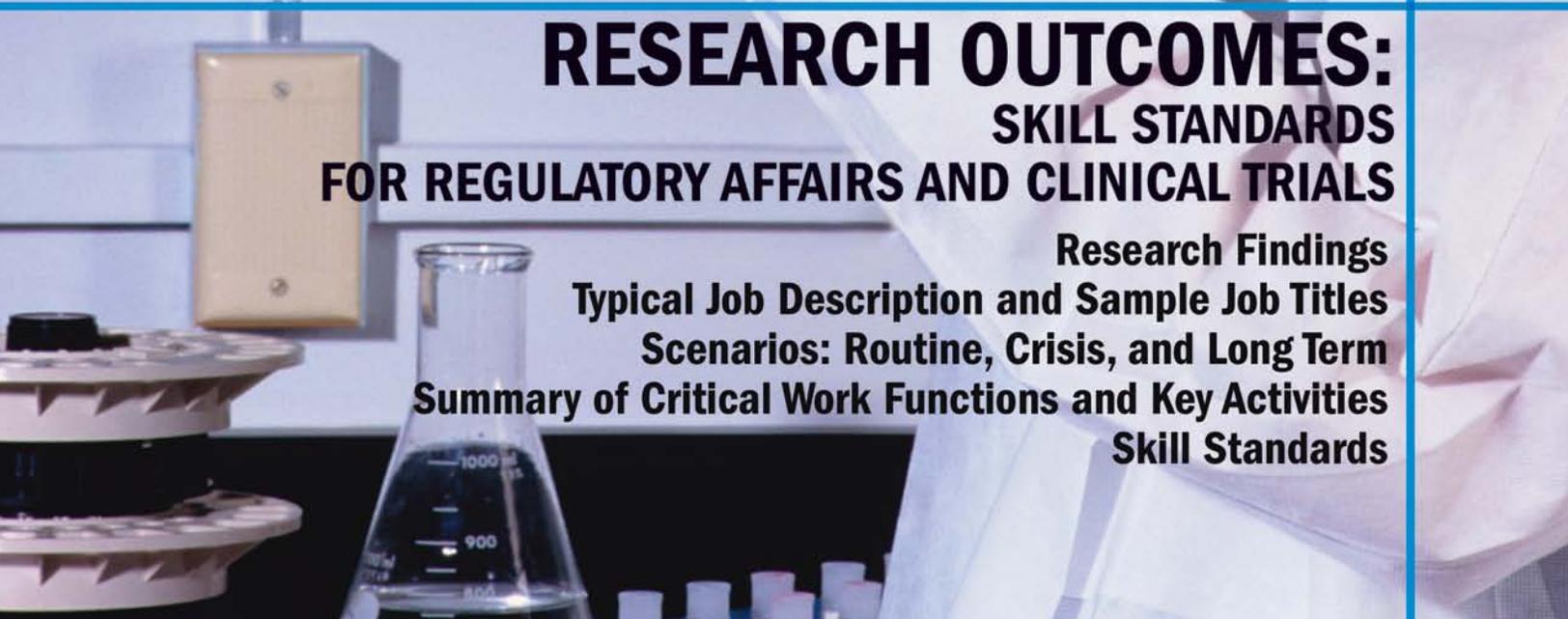
**Critical Work Function – D. Perform Recordkeeping and Manage Data**

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<p><b>D3.</b> <b>Enter and manage laboratory information electronically</b></p>	<ul style="list-style-type: none"> <li>■ Data is entered accurately.</li> <li>■ Data is correctly cross-referenced, and aligns with the linear progression of the work and the experiment methodologies and outcomes.</li> <li>■ LIM (Laboratory Information Management) system is correctly utilized.</li> <li>■ Reference Management System is appropriately accessed.</li> <li>■ NCBI (National Center for Biotechnology Information) is appropriately accessed.</li> </ul>	<ul style="list-style-type: none"> <li>■ Ability to perform data entry using public and proprietary software.</li> <li>■ Knowledge of cross referencing used in experiments and the ability to follow the linear progression of the work.</li> <li>■ Understanding of the experiment and its outcomes.</li> <li>■ Knowledge of the LIM (Laboratory Information Management) system and its requirements.</li> <li>■ Knowledge of systems for archiving imaging data</li> <li>■ Ability to use a Reference Management System (e.g. End Note, RefMan).</li> <li>■ Knowledge of basics of bioinformatics (generating and managing data, analyzing data and making models of systems based on data).</li> <li>■ Knowledge of NCBI (National Center for Biotechnology Information).</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of computers, windows, Linux and office suite software.</li> <li>■ Manipulates, integrates, and modifies information; uses networks</li> <li>■ Analyzes organization of information and transfers information between formats</li> <li>■ Identifies data/information and predicts outcomes</li> <li>■ Interprets information, prepares basic summaries and reports</li> </ul>
<p><b>D4.</b> <b>Assist with inventory maintenance</b></p>	<ul style="list-style-type: none"> <li>■ Requests are tracked and communicated to appropriate personnel in a timely manner.</li> <li>■ Data management system is properly utilized.</li> </ul>	<ul style="list-style-type: none"> <li>■ Ability to manage cell lines that are stored in liquid nitrogen.</li> <li>■ Ability to track what needs to be grown.</li> <li>■ Ability to utilize data management system.</li> <li>■ Knowledge of data entry procedures.</li> <li>■ Knowledge of cell line and enzyme inventory procedures.</li> <li>■ Knowledge of the requirements of the laboratory.</li> </ul>	<ul style="list-style-type: none"> <li>■ Identifies, corrects, and troubleshoots malfunctions and failures</li> <li>■ Understands operation/interaction and manipulates technology for desired results.</li> <li>■ Manipulates, integrates, and modifies information; uses networks</li> <li>■ Acquires/distributes supplies and equipment Demonstrates sensitivity to customer concerns/interests</li> </ul>



# **RESEARCH OUTCOMES: SKILL STANDARDS FOR REGULATORY AFFAIRS AND CLINICAL TRIALS**

**Research Findings  
Typical Job Description and Sample Job Titles  
Scenarios: Routine, Crisis, and Long Term  
Summary of Critical Work Functions and Key Activities  
Skill Standards**



## Research Findings: Regulatory Affairs and Clinical Trials



Industry input, confirmed by internet research determined that changes in the entry level work of regulatory affairs and clinical trials was related solely to the use of information technology (IT). Out of advances in computer hardware and software technology emerged the new field of life science informatics.

In 2006, Bellevue Community College published the Life Science Informatics Skill Standards. These, combined with the NWCET Information Technology Skill Standards provided the content for skill standards expert Terryll Bailey to infuse this added dimension to the biotechnology & biomedical regulatory affairs and clinical trials skill standards.

The Life Science Informatics Skill Standards<sup>1</sup> identified three clusters<sup>2</sup>:

**Bioinformatics:** The application of informatics tools and processes to solving biological problems

**Clinical Trials Data Management:** The application of database management tools and processes to support the acquisition, organization and analysis of clinical trial information

**Life Science Software Validation:** The application of software validation and testing tools and processes as an integral part of development of software to serve the biomedical and biotechnology industries.

Based in particular on the skill standards information contained in the Life Science Clinical Trials Data Management cluster, and the Networking, Database and Technical Support clusters in the NWCET IT skill standards, the following key activities were added to the 2000 biotechnology Regulatory Affairs and Clinical Trials skill standards.

Two new key activities were added to critical work function A (Support Clinical Research):

- A9. Import data collected from investigative sites
- A10. Provide support to personnel at data collection sites

The name of the second critical work function B was changed from Review, Process and Communicate Data to Support Collection and Management of Data.

In addition, four new key activities were added to this critical work function:

- B6. Generate listings, reports and quality control documentation
- B7. Implement processes for transferring and receiving clinical data
- B8. Make database corrections and/or updates
- B9. Document updates to the clinical trial database

<sup>1</sup>To order or download the Life Science Informatics Skill Standards, contact Bellevue Community College, Life Science Informatics Center online at [www.bcc.ctc.edu/informatics](http://www.bcc.ctc.edu/informatics) or [informatics@bcc.ctc.edu](mailto:informatics@bcc.ctc.edu).

<sup>2</sup>Life Science Informatics Skill Standards, Bellevue Community College, 2006. p. 18

Two new critical work functions and associated key activities were added as follows:

**E. Perform system/application administration and support**

- E1. Perform routine installation, configuration and upgrade of existing systems/applications
- E2. Perform system/application security and compliance administration
- E3. Perform system / application operation, monitoring, optimization and maintenance
- E4. Contribute to functional and user testing of clinical trial databases
- E5. Execute software validation methodologies to verify software functionality
- E6. Document changes and maintain version control procedures for data management systems
- E7. Support documentation of data management procedures

**F. Perform coding of clinical trials data**

- F1. Encode clinical trial data
- F2. Interface with project teams to resolve coding problems and issues
- F3. Access, load and update medical coding dictionaries

The associated performance indicators, occupational technical knowledge and skills and academic and employability were derived from the BCC Life Science Informatics Skill Standards and the NWCEIT Information Technology Skill Standards, and approved by a representative of the Industry Advisory Committee for the Biotechnology Program at Shoreline Community College.

### **Typical Job Description for Regulatory Affairs and Clinical Trials**

Individuals who work in the area of Regulatory Affairs and Clinical Trials make sure that all the work of the company meets regulatory requirements. Under the direction of a Senior Associate or Manager, the Regulatory Affairs Associate is responsible for gathering information and assembling regulatory submissions. They are also responsible for projects such as literature searches and report preparation. Submissions may include annual reports, addition of new investigators to clinical protocols, Certificates of Analysis, amendments providing for changes in the clinical program manufacture of a product, and routine and supplemental filings. These individuals assist with and prepare for FDA meetings, inspections, and audits from regulatory agencies. Keeping current on regulations, laws, and guidelines is a very important aspect of this work. Companies rely on reports from these individuals to ensure compliance.

With respect to clinical trials, the primary focus of these individuals' work is on the implementation of clinical studies, with emphasis on study monitoring. Additional responsibilities include assisting with study drug management and reviewing data from clinical trials. These individuals may also be responsible for the review of labeling, promotional, and advertising materials in compliance with regulations and guidelines. They prepare regulatory reports and clinical documents, and coordinate data collection and reporting with other departments.

#### **SAMPLE JOB TITLES**

Bioinformatics Analyst  
Biostatistician  
Clinical Coordinator  
Clinical Data Specialist  
Clinical Programmer  
Clinical Research Administrator  
Clinical Research Associate  
Documentation Specialist  
Drug Experience Coordinator  
Flow Cytometry Specialist  
Histological Technician  
Labeling Compliance Associate  
Laboratory Aide  
Quality Control Manager/ Analyst  
Regulatory Affairs Associate or Specialist  
Research Technician  
Safety Associate  
Technical or Medical Writer

**Routine Scenario:  
Tracking Changes in Regulations  
and Guidelines**

**AS A REGULATORY AFFAIRS** professional, you are often responsible for tracking changes in regulatory guidelines as they may occur. In order to do this, you must take the initiative to keep current on all changes in regulations. For example, you might check the FDA Web site and read professional journals. You might also learn about new guidelines from peers at work or by attending a conference.

All changes in regulations must be documented in the manner required by the company. Changes must also be interpreted and communicated to appropriate people in the company, including management. Management may then determine what changes in company procedures and process may be required to stay in compliance. You may be involved with coordinating and implementing the changes.

**PRIMARY TASKS AND FUNCTIONS INVOLVED IN THIS SCENARIO****B. Support collection and management of data**

- B1. Record and organize data
- B2. Conduct simple analyses of data and process information
- B3. Flag problems and issues
- B4. Track approvals and renewals
- B5. Draft reports
- B6. Generate listings, reports and quality control documentation

**C. Coordinate with manufacturing and other departments regarding regulatory and compliance practices**

- C1. Prepare updates on laws, regulations, and guidelines for distribution to company personnel
- C2. Monitor and evaluate manufacturing process changes
- C3. Review data and reports for compliance
- C6. Support quality assurance
- C8. Assist with resolution of quality issues

**D. Participate in interactions with regulatory agencies**

- D1. Perform literature searches
- D2. Assist with submission preparation and international documents and licenses
- D3. Assist with regulatory document control

**E. Perform system/application administration and support**

- E6. Perform document control

**Crisis Scenario:  
Notified of a Product Failure**

**THE COMPANY IS NOTIFIED** of an adverse event at a clinical trial, which means that a patient had a potential reaction to the test article. Once notified, you collect data about the event to allow the company to evaluate the reaction. The data is turned over to a medical professional to evaluate and determine whether or not the adverse reaction may have been related to the product.

You also ask the medical professional whether he or she felt it was a severe or life-threatening reaction. If it is a severe reaction and is related to the product, then you have reporting responsibilities to FDA.

Depending on the situation and the regulatory requirements, you may be required to call the FDA or to submit a report in writing. You would also notify individuals in your company and other medical investigators at the clinical sites. These actions could lead to a decision whether or not to stop the clinical trial, or simply enter the data as part of the trial.

**PRIMARY TASKS AND FUNCTIONS INVOLVED IN THIS SCENARIO****A. Support clinical research**

- A1. Perform record keeping
- A2. Assist with and coordinate development of clinical trial support documents
- A4. Report on status of clinical trials
- A5. Facilitate communication with IRB (Internal Review Board)
- A6. Monitor clinical sites
- A7. Assist with study drug management
- A8. Review data from clinical trials

**B. Support collection and management of data**

- B1. Record and organize data
- B2. Conduct simple analyses of data and process information
- B3. Flag problems and issues
- B4. Track approvals and renewals
- B5. Draft reports
- B6. Generate listings, reports and quality control documentation
- B9. Document updates to the clinical trial database

**Long-Term Scenario:  
Assist With Training**

**THE COMPANY HAS HIRED** new workers in the Regulatory Affairs Department, and you have been asked to assist with training the workers. You might be asked to give a formal presentation, some on-the-job training, or an assignment for the new individuals to learn on their own. The first step is to gather information about what the new workers will be doing and determine what the content of the training should be. The content could include information about FDA requirements and the company protocols as they apply to the work the new-hires will be doing. Often the training may include job shadowing, in which the new employee spends a few days with you to get oriented to the work in this particular company. You may be asked to monitor and evaluate the work or progress of the new employee and to determine what further training is required. If employees make errors and require additional training, you may provide one-on-one training in specific areas.

**PRIMARY TASKS AND FUNCTIONS INVOLVED IN THIS SCENARIO**

**B. Support collection and management of data**

- B1. Record and organize data
- B2. Conduct simple analyses of data and process information

**C. Coordinate with manufacturing and other departments regarding regulatory and compliance practices**

- C7. Assist in training programs

## Regulatory Affairs and Clinical Trials: Summary of Critical Work Functions and Key Activities

CRITICAL WORK FUNCTIONS	KEY ACTIVITIES									
<b>A. Support clinical research</b>	<b>A1</b> Perform record keeping	<b>A2</b> Assist with and coordinate development of clinical trial support documents	<b>A3</b> Research current literature regarding clinical trials	<b>A4</b> Report on status of clinical trials	<b>A5</b> Facilitate communication with IRB (Internal Review Board)	<b>A6</b> Monitor clinical sites	<b>A7</b> Assist with study drug management	<b>A8</b> Review data from clinical trials	<b>A9</b> Import data collected from investigative sites	<b>A10</b> Provide support to personnel at data collection sites
<b>B. Support collection and management of data</b>	<b>B1</b> Record and organize data	<b>B2</b> Conduct simple analyses of data and process information	<b>B3</b> Flag problems and issues	<b>B4</b> Track approvals and renewals	<b>B5</b> Draft reports	<b>B6</b> Generate listings, reports and quality control documentation	<b>B7</b> Implement processes for transferring and receiving clinical data	<b>B8</b> Make database corrections and/or updates	<b>B9</b> Document updates to the clinical trial database	
<b>C. Coordinate with manufacturing and other departments regarding regulatory and compliance practices</b>	<b>C1</b> Prepare updates on laws, regulations and guidelines for distribution to company personnel	<b>C2</b> Monitor and evaluate manufacturing process changes	<b>C3</b> Review data and reports for compliance	<b>C4</b> Conduct audits	<b>C5</b> Review promotional media to ensure compliance	<b>C6</b> Support quality assurance	<b>C7</b> Assist in training programs	<b>C8</b> Assist with resolution of quality issues		
<b>D. Participate in interactions with regulatory agencies</b>	<b>D1</b> Perform literature searches	<b>D2</b> Assist with submission preparation and with international documents and licenses	<b>D3</b> Assist with regulatory document control	<b>D4</b> Assist with preparation for FDA meetings	<b>D5</b> Keep current on regulatory requirements	<b>D6</b> Assist with inspections and audits from regulatory agencies				
<b>E. Perform system/application administration and support</b>	<b>E1</b> Perform routine installation, configuration and upgrade of existing systems/applications	<b>E2</b> Perform system/application security and compliance administration	<b>E3</b> Perform system/application operation, monitoring, optimization and maintenance	<b>E4</b> Contribute to functional and user testing of clinical trial databases	<b>E5</b> Execute software validation methodologies to verify software functionality	<b>E6</b> Perform document control	<b>E7</b> Support documentation of data management procedures			
<b>F. Perform coding of clinical trials data</b>	<b>F1</b> Encode clinical trial data	<b>F2</b> Interface with project teams to resolve coding problems and issues	<b>F3</b> Access, load and update medical coding dictionaries							

**Black Text** = Skill Standards validated by industry and still current for 2007 project

**Green Text** =New Skill Standards identified and validated by industry for 2007 project

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

## Critical Work Function – A. Support clinical research

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>A1.</b> <b>Perform record keeping</b>	<ul style="list-style-type: none"> <li>■ Data forms are complete, accurate, and legible and are completed in a timely manner.</li> <li>■ Data integrity is maintained.</li> <li>■ Data entry is accurate and timely.</li> <li>■ Data are retrievable.</li> <li>■ Record keeping is completed in compliance with company procedures and regulatory requirements.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of regulatory agency requirements regarding record keeping.</li> <li>■ Knowledge of company procedures regarding record keeping.</li> <li>■ Knowledge of company filing system.</li> </ul>	<ul style="list-style-type: none"> <li>■ Records information accurately, completes documentation, and summarizes information.</li> <li>■ Examines information/data for relevance and accuracy.</li> <li>■ Understands computer operations, utilizes integrated / multiple software, locates and retrieves information/data and utilizes networks.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> </ul>
<b>A2.</b> <b>Assist with and coordinate development of clinical trial support documents</b>	<ul style="list-style-type: none"> <li>■ All documents are available to appropriate personnel.</li> <li>■ Revision control is maintained.</li> <li>■ Case report forms accurately reflect protocol requirements.</li> <li>■ Support documents are accurately prepared and assembled.</li> <li>■ Site documents are provided to sponsor according to prescribed timelines.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of document filing system and location.</li> <li>■ Knowledge of revision control techniques.</li> <li>■ Ability to prepare support documents.</li> <li>■ Knowledge of Code of Federal Regulations (CFR).</li> <li>■ Knowledge of site documents and the ability to locate timelines and sponsor addresses.</li> </ul>	<ul style="list-style-type: none"> <li>■ Analyzes organization of information and transfers information between formats.</li> <li>■ Examines information/data for relevance and accuracy.</li> <li>■ Prepares basic summaries and reports.</li> <li>■ Performs given set of tasks and follows schedules.</li> </ul>
<b>A3.</b> <b>Research current literature regarding clinical trials</b>	<ul style="list-style-type: none"> <li>■ Research is pertinent to the assigned topic.</li> <li>■ Research includes bibliography.</li> <li>■ Research is complete and accurate in accordance with request.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of the topic.</li> <li>■ Knowledge of current literature sources.</li> <li>■ Knowledge of Web and electronic search techniques.</li> </ul>	<ul style="list-style-type: none"> <li>■ Understands computer operations, utilizes integrated/multiple software, locates and retrieves information/data, and utilizes networks.</li> <li>■ Identifies data/information, analyzes it, and integrates multiple items of data.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> </ul>
<b>A4.</b> <b>Report on status of clinical trials</b>	<ul style="list-style-type: none"> <li>■ Report is completed in a timely manner.</li> <li>■ Report is well organized and includes a logical flow of information.</li> <li>■ Report includes an executive summary.</li> <li>■ The report includes assessment of protocol.</li> <li>■ The report is complete and accurate.</li> <li>■ The report includes issues and flags problems.</li> <li>■ The report is grammatically correct and uses the proper format.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of protocol assessment.</li> <li>■ Ability to identify problems and issues.</li> <li>■ Knowledge of medical and industry terminology, jargon, and acronyms.</li> </ul>	<ul style="list-style-type: none"> <li>■ Performs given set of tasks and follows schedules.</li> <li>■ Summarizes/paraphrases information and creates original documents.</li> <li>■ Analyzes data, integrates multiple items of data, and contrasts conflicting data.</li> <li>■ Examines information/data for relevance and accuracy.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

## Critical Work Function – A. Support clinical research

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<p><b>A5.</b> <b>Facilitate communication with IRB</b></p>	<ul style="list-style-type: none"> <li>■ Adverse events are forwarded to IRB.</li> <li>■ Protocols are approved by IRB prior to study initiation.</li> <li>■ All communication is documented in accordance with company policy.</li> <li>■ IRB meetings are communicated to appropriate personnel.</li> <li>■ Draft responses are complete and prepared in a timely manner and are submitted for internal review.</li> <li>■ Copies of IRB correspondence are retained and organized in a retrievable manner.</li> </ul>	<ul style="list-style-type: none"> <li>■ Ability to identify reportable adverse events using clinical site reports and protocols (case report forms).</li> <li>■ Knowledge of medical industry terminology and jargon.</li> <li>■ Ability to locate IRB approvals.</li> <li>■ Knowledge of IRB meetings.</li> <li>■ Knowledge of roles of personnel.</li> <li>■ Knowledge of regulatory agency requirements.</li> <li>■ Knowledge of filing system.</li> <li>■ Knowledge of protocol requirements.</li> </ul>	<ul style="list-style-type: none"> <li>■ Demonstrates commitment to social improvement, analyzes implications of decisions, and recommends ethical courses of action.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Records information accurately, completes documentation, and summarizes information.</li> <li>■ Summarizes/paraphrases information and creates original documents.</li> <li>■ Presents basic ideas/information.</li> <li>■ Understands system organization and follows processes and procedures.</li> </ul>
<p><b>A6.</b> <b>Monitor clinical sites</b></p>	<ul style="list-style-type: none"> <li>■ Clinical site is verified as having required documents and records.</li> <li>■ Site documents and records accurately reflect the requirements defined in the contract and the protocols.</li> <li>■ Clinical sites are monitored in accordance with established schedule.</li> <li>■ Written report documenting the site visit is prepared in a timely manner and is complete and accurate.</li> <li>■ Site is monitored for informed consent records, patient data forms, adherence to protocols, compliance with all relevant regulations and IRB approval of changes.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of required documents and records.</li> <li>■ Ability to interpret contracts and protocols.</li> <li>■ Knowledge of medical and industry terminology, jargon, and acronyms.</li> <li>■ Knowledge of contents of site visit reports.</li> <li>■ Knowledge of proper completion of informed consent records and patient data forms.</li> <li>■ Knowledge of protocols and IRB approvals.</li> <li>■ Ability to identify reportable adverse events from patient data forms.</li> </ul>	<ul style="list-style-type: none"> <li>■ Analyzes data, integrates multiple items of data, and contrasts conflicting data.</li> <li>■ Applies principles to processes/procedures and uses logic to draw conclusions.</li> <li>■ Performs given set of tasks and follows schedules.</li> <li>■ Records information accurately, summarizes/paraphrases information, and creates original documents.</li> <li>■ Collects data and identifies discrepancies.</li> </ul>
<p><b>A7.</b> <b>Assist with study drug and device management</b></p>	<ul style="list-style-type: none"> <li>■ Correct storage and labeling of study drug are confirmed.</li> <li>■ Study drugs and device management are accurately counted and reconciled to previous inventory.</li> <li>■ Storage, labeling, and counts are properly documented.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of study drug and device labeling and storage procedures.</li> <li>■ Knowledge of documentation procedures.</li> <li>■ Knowledge of protocols and 21 CFR 312.</li> <li>■ Ability to locate storage facility.</li> <li>■ Knowledge of how environmental conditions are controlled, maintained, and documented.</li> <li>■ Ability to reconcile the devices used against inventory.</li> </ul>	<ul style="list-style-type: none"> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Obtains data, performs measurements, and converts numerical data.</li> <li>■ Records information accurately, completes documentation, and summarizes information.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

## Critical Work Function – A. Support clinical research

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>A8.</b> <b>Review data from clinical trials</b>	<ul style="list-style-type: none"> <li>■ Missing data are identified and sites are contacted for explanation of any missing data.</li> <li>■ Source documentation is compared with database print-out to verify accuracy.</li> <li>■ Source documentation is reviewed for credibility and data integrity.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of data requirements of clinical trial.</li> <li>■ Ability to obtain source documentation from multiple departments and files.</li> <li>■ Knowledge of contents of source documentation.</li> <li>■ Ability to identify elements of data integrity.</li> </ul>	<ul style="list-style-type: none"> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Examines information/data for relevance and accuracy.</li> <li>■ Analyzes data, integrates multiple items of data, and contrasts conflicting data.</li> <li>■ Responds to verbal/nonverbal communication and confirms information.</li> </ul>
<b>A9.</b> <b>Import data collected from investigative sites</b>	<ul style="list-style-type: none"> <li>■ Data is collected and properly imported from central lab databases, specialty groups utilized on projects and investigative sites.</li> <li>■ Proper import procedures are utilized.</li> <li>■ Imported data is validated and QA procedures are properly executed.</li> <li>■ All FDA guidelines and regulations are followed.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of data export and import processes and tools.</li> <li>■ Knowledge of data validation and QA processes and tools.</li> <li>■ Knowledge of data sampling techniques.</li> <li>■ Knowledge of data collection procedures.</li> <li>■ Knowledge of FDA guidelines and regulations regarding collection and import of data.</li> <li>■ Knowledge of security protocols.</li> <li>■ Knowledge of web-based access to databases and data access methodologies and tools.</li> </ul>	<ul style="list-style-type: none"> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> <li>■ Identifies data/information and predicts outcomes.</li> <li>■ Understands and adheres to standards; demonstrates commitment to excellence.</li> <li>■ Works with minimal supervision and pays attention to details.</li> </ul>
<b>A10.</b> <b>Provide support to personnel at data collection sites</b>	<ul style="list-style-type: none"> <li>■ Training is provided to personnel at data collection sites as required.</li> <li>■ Problems are analyzed and solutions are researched in a complete and timely manner.</li> <li>■ Problems are escalated or referred when appropriate.</li> <li>■ Technical solutions and implementation processes are communicated in a clear and timely manner.</li> <li>■ Hardware, software and user problems and resolutions are documented in a complete and timely manner.</li> <li>■ Research assistants and other research personnel feedback and requests are documented, communicated and resolved in an effective manner.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of data collection and management processes.</li> <li>■ Knowledge of sources of relevant technical data.</li> <li>■ Knowledge of escalation procedures.</li> <li>■ Ability to identify and resolve technical conflicts.</li> <li>■ Knowledge of documentation procedures and requirements.</li> <li>■ Knowledge of networks and online tools and resources.</li> <li>■ Knowledge of research personnel quality issues.</li> </ul>	<ul style="list-style-type: none"> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> <li>■ Understands requirements of the task and technological results.</li> <li>■ Understands operation/interaction and manipulates technology for desired results.</li> <li>■ Adjusts and monitors system operation and troubleshoots system malfunction/failure.</li> <li>■ Demonstrates sensitivity to customer concerns/interests.</li> <li>■ Takes active interest in others and establishes rapport.</li> <li>■ Conducts task-specific training and coaches others to apply related concepts.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

**Critical Work Function – B. Support collection and management of data**

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>B1. Record and organize data</b>	<ul style="list-style-type: none"> <li>■ Data is accurately compiled and formatted in accordance with assignment.</li> <li>■ Record and format are legible.</li> <li>■ Data is properly organized and categorized.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of data formats and recording procedures.</li> <li>■ Ability to perform searches on regulatory agency databases in order to compile data.</li> <li>■ Knowledge of data categories and purpose.</li> </ul>	<ul style="list-style-type: none"> <li>■ Analyzes organization of information and transfers information between formats.</li> <li>■ Summarizes/integrates information.</li> <li>■ Records information accurately, completes documentation, and summarizes information.</li> <li>■ Analyzes data and integrates multiple items of data.</li> <li>■ Examines information/data for relevance and accuracy.</li> </ul>
<b>B2. Conduct simple analyses of data and process information</b>	<ul style="list-style-type: none"> <li>■ Mathematical formulae are correctly selected and applied.</li> <li>■ Correct data set is used.</li> <li>■ Calculations are properly documented.</li> <li>■ Data integrity is preserved.</li> <li>■ Out-of-range or out-of-specification results are identified.</li> <li>■ Trends are identified.</li> </ul>	<ul style="list-style-type: none"> <li>■ Ability to match the correct mathematical formula with the purpose of the analysis.</li> <li>■ Ability to identify data sets and match them to the analysis being performed.</li> <li>■ Knowledge of documentation procedures.</li> <li>■ Ability to identify out-of-range or out-of-specification results.</li> <li>■ Knowledge of the goals and components of the study being analyzed.</li> </ul>	<ul style="list-style-type: none"> <li>■ Manipulates techniques/formulas/processes and interprets mathematical data.</li> <li>■ Selects/obtains data relevant to the task and identifies the need for data.</li> <li>■ Converts numerical data and predicts arithmetic results.</li> </ul>
<b>B3. Flag problems and issues</b>	<ul style="list-style-type: none"> <li>■ Out-of-range or out-of-specification results are identified.</li> <li>■ Errors are identified, documented, and reported to supervisor.</li> <li>■ Questionable data integrity is identified and reported to supervisor.</li> </ul>	<ul style="list-style-type: none"> <li>■ Ability to identify out-of-range or out-of-specification results.</li> <li>■ Knowledge of basic probability and statistics.</li> <li>■ Knowledge of eligibility requirements of data.</li> </ul>	<ul style="list-style-type: none"> <li>■ Converts numerical data and predicts arithmetic results.</li> <li>■ Examines information/data for relevance and accuracy.</li> </ul>
<b>B4. Track approvals and renewals</b>	<ul style="list-style-type: none"> <li>■ Permits are renewed prior to expiration dates.</li> <li>■ Regulatory agency required reports are prepared for submission prior to due date in accordance with company formats.</li> <li>■ Upcoming due dates are anticipated and communicated to other departments in a timely manner.</li> <li>■ Sources are consulted to keep current on new drug, devices, and biological approvals, and results are effectively communicated to appropriate personnel and departments.</li> </ul>	<ul style="list-style-type: none"> <li>■ Ability to locate permits.</li> <li>■ Knowledge of regulatory agency requirements.</li> <li>■ Knowledge of company formats.</li> <li>■ Knowledge of roles of departments and the approvals they require.</li> <li>■ Knowledge of sources of information for new drug, devices, and biological approvals.</li> <li>■ Knowledge of industry terminology, jargon, and acronyms.</li> </ul>	<ul style="list-style-type: none"> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Writes simple documents.</li> <li>■ Recognizes patterns/relationships.</li> <li>■ Uses previous training/experience to predict outcomes.</li> <li>■ Presents complete ideas/information and poses critical questions.</li> <li>■ Probes to gain knowledge/information, qualifies/analyzes information and interprets and summarizes information.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

**Critical Work Function – B. Support collection and management of data**

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>B5.</b> <b>Draft reports</b>	<ul style="list-style-type: none"> <li>■ Report is completed in a timely manner.</li> <li>■ Report is well organized and includes a logical flow of information.</li> <li>■ The report is complete and accurate.</li> <li>■ The report includes issues and flags problems.</li> <li>■ The report is grammatically correct and uses the proper format.</li> <li>■ The report is formatted in accordance with regulatory agency preferences.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of the contents required in the report.</li> <li>■ Ability to identify issues and problems.</li> <li>■ Knowledge of industry terminology, jargon, and acronyms.</li> <li>■ Knowledge of regulatory agency preferred formatting and structure.</li> <li>■ Knowledge of technical writing.</li> </ul>	<ul style="list-style-type: none"> <li>■ Records information accurately, summarizes/paraphrases information, and creates original documents.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Examines information/data for relevance and accuracy.</li> <li>■ Applies principles to process/procedure and uses logic to draw conclusions.</li> </ul>
<b>B6.</b> <b>Generate listings, reports and quality control documentation</b>	<ul style="list-style-type: none"> <li>■ Proper protocols are followed.</li> <li>■ Documentation is reviewed for the purpose of facilitating validation of the clinical database.</li> <li>■ HIPAA and FDA regulations regarding privacy and handling of clinical data are followed.</li> <li>■ QA/QC procedures are followed.</li> <li>■ Reports are disseminated to appropriate departments and personnel in a timely manner.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of data tracking methods.</li> <li>■ Knowledge of clinical databases.</li> <li>■ Knowledge of electronic and paper CRFs (case report forms).</li> <li>■ Knowledge of HIPAA and other regulations governing privacy and handling of clinical data.</li> <li>■ Knowledge of backup procedures.</li> <li>■ Knowledge of electronic data capture systems, tools and processes.</li> <li>■ Knowledge of structure databases and search tools such as PDB, file format, VAST and DALI.</li> <li>■ Knowledge of database reporting tools and practices and database report design and testing.</li> </ul>	<ul style="list-style-type: none"> <li>■ Identifies data/information and predicts outcomes.</li> <li>■ Analyzes organization of information and transfers information between formats.</li> <li>■ Interprets information, prepares basic summaries and reports.</li> <li>■ Works with minimal supervision and pays attention to details.</li> <li>■ Understands system organization and follows processes and procedures</li> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> </ul>
<b>B7.</b> <b>Implement processes for transferring and receiving clinical data</b>	<ul style="list-style-type: none"> <li>■ Correct processes for transferring and receiving clinical data, including data formats and structures to be used are used.</li> <li>■ Data is accurately tracked.</li> <li>■ Proper data validation and QA procedures are followed.</li> <li>■ HIPAA and FDA regulations regarding privacy and handling of clinical data are followed.</li> <li>■ QA/QC procedures are followed.</li> <li>■ Transfer and receipt of clinical data is properly documented in accordance with all applicable policies, laws and regulations.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of data tracking methods.</li> <li>■ Knowledge of data export and import processes and tools.</li> <li>■ Knowledge of data validation and QA procedures.</li> <li>■ Knowledge of lock and export databases.</li> <li>■ Knowledge of documentation requirements and procedures.</li> <li>■ Knowledge of security protocols and clinical data transfer policies and procedures.</li> </ul>	<ul style="list-style-type: none"> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> <li>■ Understands operation/interaction and manipulates technology for desired results.</li> <li>■ Works with minimal supervision and pays attention to details.</li> <li>■ Understands and adheres to standards; demonstrates commitment to excellence.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

**Critical Work Function – B. Support collection and management of data**

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<p><b>B8.</b> <b>Make database corrections and/or updates</b></p>	<ul style="list-style-type: none"> <li>■ Query resolution and/or data review is properly used.</li> <li>■ Data modifications to resolve data quality issues are properly tracking and documented.</li> <li>■ Corrections and/or updates are completed with no adverse impact to the system or data and minimal disruption to users.</li> <li>■ Database is tested following corrections and/or updates to ensure performance and data integrity criteria are met.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of query and query resolutions.</li> <li>■ Knowledge of data review processes.</li> <li>■ Knowledge of data tracking methods.</li> <li>■ Knowledge of data audits.</li> <li>■ Knowledge of data sampling and trend analysis.</li> <li>■ Knowledge of database structure, components and functions.</li> <li>■ Knowledge of database validation and quality assurance processes and tools.</li> <li>■ Knowledge of database performance and optimization.</li> </ul>	<ul style="list-style-type: none"> <li>■ Adjusts and monitors system operation and troubleshoots system malfunction/failure.</li> <li>■ Understands requirements of the task and technological results.</li> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> </ul>
<p><b>B9.</b> <b>Document updates to the clinical trial database</b></p>	<ul style="list-style-type: none"> <li>■ Updates are accurately and completely documented.</li> <li>■ All organization policies and procedures and all applicable laws and regulations are followed.</li> <li>■ Documentation is distributed to appropriate departments and personnel in a timely manner.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of documentation standards, practices and regulations.</li> <li>■ Knowledge of testing and quality assurance processes and criteria.</li> <li>■ Knowledge of documentation control processes and systems.</li> <li>■ Knowledge of documentation retrieval and archival processes.</li> </ul>	<ul style="list-style-type: none"> <li>■ Analyzes organization of information and transfers information between formats.</li> <li>■ Identifies data/information and predicts outcomes.</li> <li>■ Composes and edits documents for appropriate audience and purpose.</li> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> <li>■ Understands system organization and follows processes and procedures.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

**Critical Work Function — C. Communicate with manufacturing and other departments regarding regulatory and compliance practices**

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>C1.</b> <b>Prepare updates on laws, regulations, and guidelines for distribution to company personnel</b>	<ul style="list-style-type: none"> <li>■ Sources for regulatory updates and proposals are thoroughly reviewed.</li> <li>■ A variety of sources and media are searched.</li> <li>■ Appropriate personnel are informed effectively and in a timely manner.</li> <li>■ Updates are prepared and issued in accordance with company policies and procedures.</li> <li>■ FOI sources are regularly contacted for pertinent updates in a timely manner.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of laws, regulations, and guidelines.</li> <li>■ Knowledge of sources of media.</li> <li>■ Knowledge of company policies and procedures regarding updates.</li> <li>■ Knowledge of FOI sources and how to contact them.</li> </ul>	<ul style="list-style-type: none"> <li>■ Probes to gain knowledge/information, qualifies/analyzes information, and interprets and summarizes information.</li> <li>■ Examines information/data for relevance and accuracy.</li> <li>■ Presents basic ideas/information.</li> <li>■ Records information accurately, summarizes/paraphrases information, and creates original documents.</li> <li>■ Confirms information.</li> </ul>
<b>C2.</b> <b>Monitor and evaluate design and manufacturing process changes</b>	<ul style="list-style-type: none"> <li>■ Manufacturing design and process changes are identified and categorized.</li> <li>■ Design and process changes are sent to the appropriate regulatory body.</li> <li>■ Design and manufacturing process changes are assessed against regulatory commitments, and results are reported to supervisor.</li> <li>■ Documentation of review is properly completed.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of design and manufacturing process changes.</li> <li>■ Knowledge of categories of change.</li> <li>■ Knowledge of regulatory commitments.</li> <li>■ Knowledge of documentation procedures.</li> </ul>	<ul style="list-style-type: none"> <li>■ Applies principles to processes/procedures and uses logic to draw conclusions.</li> <li>■ Analyzes situation/information, considers risks/implications, and compiles multiple viewpoints.</li> <li>■ Examines information/data and recommends action plan.</li> <li>■ Develops creative solutions.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Demonstrates commitment to social improvement, analyzes implications of decisions, and recommends ethical courses of action.</li> </ul>
<b>C3.</b> <b>Review data and reports for compliance</b>	<ul style="list-style-type: none"> <li>■ Documentation standards are thoroughly checked against requirements.</li> <li>■ Data referenced in support of conclusions is checked for completeness, relevance, and accuracy.</li> <li>■ Outcome of review is communicated to the report author or supervisor as required.</li> <li>■ Calculations are audited for accuracy.</li> <li>■ Reports and data are reviewed to ensure they are complete and in compliance with regulations.</li> </ul>	<ul style="list-style-type: none"> <li>■ Ability to interpret and assess production records.</li> <li>■ Ability to assess the adequacy of validation reports.</li> <li>■ Knowledge of regulations.</li> <li>■ Knowledge of documentation standards.</li> <li>■ Knowledge of validation report requirements.</li> </ul>	<ul style="list-style-type: none"> <li>■ Adheres to standards.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures and pays attention to details.</li> <li>■ Applies principles to processes/procedures and uses logic to draw conclusions.</li> <li>■ Presents complex ideas/information and poses critical questions.</li> <li>■ Manipulates techniques/formulas/processes and interprets mathematical data.</li> <li>■ Predicts arithmetic results.</li> <li>■ Identifies relevant details, facts and specifications, qualifies information, and interprets and summarizes information.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

**Critical Work Function – C. Communicate with manufacturing and other departments regarding regulatory and compliance practices**

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<p><b>C4.</b> <b>Conduct audits</b></p>	<ul style="list-style-type: none"> <li>■ Company audit procedures are followed.</li> <li>■ Findings and reports are clearly documented.</li> <li>■ Issues are communicated to and followed up with departments and personnel audited.</li> <li>■ Audit results are communicated to appropriate personnel effectively and in a timely manner.</li> <li>■ Audit reports contain correct grammar, appropriate format, and use neutral language.</li> <li>■ Findings are specific, functional, descriptive and non-editorial.</li> <li>■ Audit logs are accurately maintained.</li> <li>■ Audit process scheduling is coordinated with internal personnel and external consultants in an effective manner.</li> <li>■ Audit findings and reports are released only to appropriate parties.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of company audit procedures.</li> <li>■ Knowledge of documentation procedures.</li> <li>■ Ability to identify issues which need follow-up.</li> <li>■ Knowledge of contents of audit reports.</li> <li>■ Knowledge of audit interviewing techniques.</li> <li>■ Knowledge of regulatory agency requirements.</li> <li>■ Knowledge of CFR references.</li> <li>■ Knowledge of how to document a finding and reference it.</li> </ul>	<ul style="list-style-type: none"> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Records information accurately, summarizes/paraphrases information, and creates original documents and technical reports.</li> <li>■ Presents complex ideas/information and poses critical questions.</li> <li>■ Examines information/data, analyzes possible causes/reasons and recommends action plan.</li> <li>■ Analyzes situation/information, considers risks/implications, and compiles multiple viewpoints.</li> <li>■ Demonstrates commitment to social improvement, analyzes implications of decisions, and recommends ethical courses of action.</li> </ul>
<p><b>C5.</b> <b>Review promotional media to ensure compliance</b></p>	<ul style="list-style-type: none"> <li>■ Promotional piece artwork and copy are compared to the approved specification.</li> <li>■ Errors are identified and communicated to appropriate personnel effectively and in a timely manner.</li> <li>■ Claims for the product are reviewed to ensure they match with approved use.</li> <li>■ Results of review and all approvals and rejections are properly documented and communicated to appropriate personnel.</li> <li>■ Original documents are properly archived.</li> <li>■ Final copies of promotional media are sent to the FDA in accordance with regulatory agency requirements or requests for labeling.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of approved specifications.</li> <li>■ Knowledge of approved use.</li> <li>■ Knowledge of documentation procedures for reviews, approvals, and rejections.</li> <li>■ Knowledge of archiving procedures.</li> <li>■ Knowledge of regulatory agency requirements.</li> </ul>	<ul style="list-style-type: none"> <li>■ Analyzes data, integrates multiple items of data, and contrasts conflicting data.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Presents complex ideas/information and poses critical questions.</li> <li>■ Probes to gain knowledge/information, qualifies/analyzes information, and interprets and summarizes information.</li> <li>■ Records information accurately, summarizes/paraphrases information, and creates original documents.</li> <li>■ Examines information/data for relevance and accuracy.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

**Critical Work Function — C. Communicate with manufacturing and other departments regarding regulatory and compliance practices**

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>C6.</b> <b>Support quality assurance</b>	<ul style="list-style-type: none"> <li>■ QA processes and reports are reviewed or audited to ensure they are in compliance with internal procedures and regulatory requirements.</li> <li>■ QA generated data is reviewed for compliance with regulatory filings or commitments.</li> <li>■ Regulatory requirements are interpreted and communicated to appropriate QA personnel.</li> <li>■ Quality System is followed and continuous improvement suggestions are made.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of QA processes.</li> <li>■ Knowledge of internal procedures and regulatory requirements.</li> <li>■ Knowledge of regulatory filings and commitments.</li> <li>■ Ability to interpret regulatory requirements.</li> <li>■ Knowledge of Quality Systems.</li> </ul>	<ul style="list-style-type: none"> <li>■ Probes to gain knowledge/information, qualifies/analyzes information, and interprets and summarizes information.</li> <li>■ Examines information/data for relevance and accuracy.</li> <li>■ Analyzes data, integrates multiple items of data and contrasts conflicting data.</li> <li>■ Presents complex ideas/information and poses critical questions.</li> <li>■ Compares multiple viewpoints, relates intent of occupational/technical desired results and analyzes communication.</li> <li>■ Demonstrates sensitivity to customer concerns/interests.</li> <li>■ Understands continuous improvement process and suggests system improvements/modifications.</li> </ul>
<b>C7.</b> <b>Assist in training programs</b>	<ul style="list-style-type: none"> <li>■ Training on regulatory compliance is provided to employees.</li> <li>■ Training records are reviewed or audited to ensure training is up-to-date.</li> <li>■ Deviations are reviewed to identify trends.</li> <li>■ Summary of deviations and trends is complete, accurate, and submitted to appropriate party.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of regulatory compliance.</li> <li>■ Knowledge of training records and training requirements.</li> <li>■ Knowledge of medical and industry terminology, jargon, and acronyms.</li> <li>■ Knowledge of the data contained in the discrepancy reports.</li> </ul>	<ul style="list-style-type: none"> <li>■ Identifies training needs, conducts task-specific training, and coaches others to apply related concepts.</li> <li>■ Compares multiple viewpoints and relates intent to desired results.</li> <li>■ Uses previous training/experience to predict outcomes.</li> <li>■ Analyzes data, integrates multiple items of data, and contrasts conflicting data.</li> <li>■ Presents complex ideas/information and poses critical questions.</li> <li>■ Demonstrates creative thinking process while problem solving.</li> <li>■ Records information accurately, completes documentation, and summarizes information.</li> </ul>
<b>C8.</b> <b>Assist with resolution of quality issues</b>	<ul style="list-style-type: none"> <li>■ Existing investigation records and reports are reviewed or investigation is initiated.</li> <li>■ Investigation is performed and completed in accordance with company policies and procedures in a timely manner.</li> <li>■ Investigation team members are communicated with effectively.</li> <li>■ Proposed corrective action is reviewed to ensure compliance with regulatory requirements.</li> </ul>	<ul style="list-style-type: none"> <li>■ Ability to locate existing investigation records and reports.</li> <li>■ Knowledge of company policies and procedures regarding investigations.</li> <li>■ Knowledge of regulatory requirements.</li> </ul>	<ul style="list-style-type: none"> <li>■ Probes to gain knowledge/information, qualifies/analyzes information, and interprets and summarizes information.</li> <li>■ Analyzes data, integrates multiple items of data, and contrasts conflicting data.</li> <li>■ Recognizes ethical issues and demonstrates trustworthiness.</li> <li>■ Presents complex ideas/information and poses critical questions.</li> <li>■ Performs given set of tasks and follows schedules.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

## Critical Work Function – D. Participate in interactions with regulatory agencies

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>D1.</b> <b>Perform literature searches on regulatory requirements</b>	<ul style="list-style-type: none"> <li>■ Search is pertinent to the assigned topic.</li> <li>■ Search includes bibliography.</li> <li>■ Search is complete and accurate in accordance with request.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of the topic.</li> <li>■ Knowledge of current literature sources.</li> <li>■ Ability to utilize electronic search tools.</li> </ul>	<ul style="list-style-type: none"> <li>■ Selects/obtains data/information relevant to the task.</li> <li>■ Records information accurately, completes documentation, and summarizes information.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures and pays attention to details.</li> </ul>
<b>D2.</b> <b>Assist with submission, preparation, and with international documents and licenses</b>	<ul style="list-style-type: none"> <li>■ Submission plan is generated and assignments and timelines are communicated to appropriate personnel.</li> <li>■ Critical milestones are identified and tracked, reminders are sent to contributors, and timeline slippage is communicated to supervisor.</li> <li>■ Submission is properly compiled, paginated, copied, and bound, with proper cross-references included.</li> <li>■ Submission is in compliance with regulatory requirements and company policies and procedures.</li> <li>■ Initial draft is issued for internal review, and comments are collated.</li> <li>■ Where applicable, input from technical staff is formatted into appropriate draft.</li> <li>■ Final draft of submission is proofed and all errors are corrected.</li> <li>■ Submission is built on previous submissions and clearances.</li> <li>■ Procedures for international documents and licenses are completely followed.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of processes, timelines, and procedures for preparing submissions.</li> <li>■ Knowledge of critical milestones for preparing submissions.</li> <li>■ Ability to compile, paginate, copy, bind, and cross-reference submission.</li> <li>■ Knowledge of regulatory requirements and company policies and procedures.</li> <li>■ Knowledge of internal review procedures.</li> <li>■ Knowledge of contents of submissions.</li> <li>■ Knowledge of previous submissions and clearances.</li> <li>■ Knowledge of procedures for international documents and licenses.</li> </ul>	<ul style="list-style-type: none"> <li>■ Prepares and organizes multiple schedules, manages timelines, and recommends timeline adjustments.</li> <li>■ Examines information/data and recommends action plan.</li> <li>■ Presents complex ideas/information and poses critical questions.</li> <li>■ Records information accurately, summarizes/paraphrases information, and creates original documents.</li> <li>■ Analyzes data, integrates multiple items of data, and contrasts conflicting data.</li> <li>■ Uses previous training/experience to predict outcomes.</li> <li>■ Performs assigned tasks, follows rules/policies/procedures and pays attention to details.</li> </ul>
<b>D3.</b> <b>Assist with regulatory document control</b>	<ul style="list-style-type: none"> <li>■ Final version of submission is properly archived and distributed.</li> <li>■ Supporting documentation is retained in accordance with company policies and procedures and regulatory agency requirements.</li> <li>■ Receipt of submission is tracked as assigned.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of archival and distribution procedures.</li> <li>■ Knowledge of company policies and procedures and regulatory agency requirements.</li> <li>■ Knowledge of receipt tracking procedures.</li> </ul>	<ul style="list-style-type: none"> <li>■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.</li> <li>■ Analyzes data, integrates multiple items of data, and contrasts conflicting data.</li> <li>■ Analyzes organization of information and transfers information between formats.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

## Critical Work Function – D. Participate in interactions with regulatory agencies

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<p><b>D4.</b> <b>Assist with preparation for FDA meetings</b></p>	<ul style="list-style-type: none"> <li>■ Plan to develop pre-meeting document is generated and assignments and timelines are communicated to appropriate personnel.</li> <li>■ Critical milestones are identified and tracked, reminders are sent to contributors, and timeline slippage is communicated to supervisor.</li> <li>■ Pre-meeting document is properly compiled, paginated, copied, and bound, with proper cross-references included.</li> <li>■ Pre-meeting document is in compliance with company policies and procedures.</li> <li>■ Initial draft is issued for internal review and comments are collated.</li> <li>■ Where applicable, input from technical staff is formatted into appropriate draft.</li> <li>■ Final draft of document is proofed and all errors are corrected.</li> <li>■ All meeting logistics are set up as assigned.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of processes, timelines and procedures for preparing document.</li> <li>■ Knowledge of critical milestones for preparing document.</li> <li>■ Ability to compile, paginate, copy, bind and cross-reference document.</li> <li>■ Knowledge of regulatory requirements and company policies and procedures.</li> <li>■ Knowledge of internal review procedures.</li> <li>■ Knowledge of contents of document.</li> </ul>	<ul style="list-style-type: none"> <li>■ Examines information/data and recommends action plan.</li> <li>■ Analyzes situation/information, considers risks/implications, and compiles multiple viewpoints.</li> <li>■ Recognizes job tasks and distributes work assignments.</li> <li>■ Encourages/supports team members.</li> <li>■ Records information accurately, summarizes/paraphrases information and creates original documents.</li> <li>■ Presents complex ideas/information and poses critical questions.</li> <li>■ Pays attention to details.</li> </ul>
<p><b>D5.</b> <b>Keep current on regulatory requirements</b></p>	<ul style="list-style-type: none"> <li>■ Sources for regulatory updates and proposals are thoroughly reviewed.</li> <li>■ All relevant sources and media are searched.</li> <li>■ Appropriate personnel are informed effectively and in a timely manner.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of sources for regulatory updates and proposals.</li> <li>■ Ability to locate sources.</li> <li>■ Knowledge of the Web and electronic search techniques.</li> </ul>	<ul style="list-style-type: none"> <li>■ Probes to gain knowledge/information, qualifies/analyzes information, and interprets and summarizes information.</li> <li>■ Understands computer operations, utilizes integrated/multiple software, locates and retrieves information/data and utilizes networks.</li> <li>■ Presents basic ideas/information.</li> <li>■ Performs given sets of tasks and follows schedules.</li> </ul>
<p><b>D6.</b> <b>Assist with inspections and audits from regulatory agencies</b></p>	<ul style="list-style-type: none"> <li>■ Requested documentation is obtained and delivered to appropriate personnel.</li> <li>■ All company policies are followed.</li> <li>■ Confidentiality is maintained in accordance with company policy.</li> <li>■ Upon request, notes are taken of the inspection.</li> </ul>	<ul style="list-style-type: none"> <li>■ Ability to obtain documentation.</li> <li>■ Knowledge of company policies.</li> <li>■ Knowledge of confidentiality policies.</li> </ul>	<ul style="list-style-type: none"> <li>■ Selects/obtains data/information relevant to the task.</li> <li>■ Understands the organization and follows processes and procedures.</li> <li>■ Recognizes ethical issues and demonstrates trustworthiness.</li> <li>■ Records information accurately, completes documentation, and summarizes information.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

## Critical Work Function – E. Perform system/application administration and support

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>E1.</b> <b>Perform routine installation, configuration and upgrade of existing systems/applications</b>	<ul style="list-style-type: none"> <li>■ Operating and application software, and upgrades are installed and configured according to specifications.</li> <li>■ Software configuration is refined to meet user needs.</li> <li>■ Software is configured for optimum system and user efficiency.</li> <li>■ System is tested for performance and compatibility.</li> <li>■ Installation/configuration plan is properly tested and implemented.</li> <li>■ Installation, configuration and upgrade of systems and applications is completed with no adverse impact on the system or data, and with minimal disruption to users.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of features of systems and software applications.</li> <li>■ Knowledge of system components and functions.</li> <li>■ Knowledge of software installation and configuration practices.</li> <li>■ Ability to use test programs and other aids to analyze system operation.</li> <li>■ Knowledge of hardware and software troubleshooting and adjustment techniques and practices.</li> <li>■ Knowledge of applications programs.</li> <li>■ Knowledge of system optimization practices.</li> </ul>	<ul style="list-style-type: none"> <li>■ Adjusts and monitors system operation and troubleshoots system malfunction/failure.</li> <li>■ Identifies, corrects, and troubleshoots malfunctions and failures.</li> <li>■ Understands requirements of the task and technological results</li> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> </ul>
<b>E2.</b> <b>Perform system/application security and compliance administration</b>	<ul style="list-style-type: none"> <li>■ Levels of access and security are clearly identified, standardized and communicated.</li> <li>■ Implementation of security measures minimizes unauthorized access and addresses security tradeoffs and risks.</li> <li>■ Users are notified about changes in their security access in accordance with company procedures.</li> <li>■ Accounts are properly audited to determine that security requirements are being met.</li> <li>■ Security breaches are accurately identified and communicated effectively to appropriate personnel.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of system and network security and firewalls.</li> <li>■ Knowledge of database and data repository access and security.</li> <li>■ Knowledge of database security procedures and implementation.</li> <li>■ Ability to collect security breach details and communicate to appropriate personnel.</li> <li>■ Knowledge of network and operating systems.</li> </ul>	<ul style="list-style-type: none"> <li>■ Adjusts and monitors system operation and troubleshoots system malfunction/failure.</li> <li>■ Identifies, corrects, and troubleshoots malfunctions and failures.</li> <li>■ Understands requirements of the task and technological results</li> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> <li>■ Understands and adheres to standards; demonstrates commitment to excellence.</li> <li>■ Works with minimal supervision and pays attention to details</li> <li>■ Takes active interest in others and establishes rapport.</li> </ul>
<b>E3.</b> <b>Perform system/application operation, monitoring, optimization and maintenance</b>	<ul style="list-style-type: none"> <li>■ Diagnostics are completed in a timely manner.</li> <li>■ System performance is monitored according to procedures.</li> <li>■ Problems are identified and resolved or reported in a timely manner.</li> <li>■ System performance is compared to baseline performance for discrepancies.</li> <li>■ Hardware and software are evaluated to facilitate support of organizational goals.</li> <li>■ Monitoring, optimization and maintenance are properly documented.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of system monitoring and diagnostic tools and procedures.</li> <li>■ Ability to detect, evaluate and appropriately alleviate problems.</li> <li>■ Knowledge of performance measurement tools and procedures.</li> <li>■ Knowledge of maintenance procedures and processes.</li> <li>■ Knowledge of documentation procedures.</li> </ul>	<ul style="list-style-type: none"> <li>■ Adjusts and monitors system operation and troubleshoots system malfunction/failure.</li> <li>■ Identifies, corrects, and troubleshoots malfunctions and failures.</li> <li>■ Understands requirements of the task and technological results.</li> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> <li>■ Analyzes organization of information and transfers information between formats.</li> <li>■ Suggests system modifications and improvements.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

## Critical Work Function – E. Perform system/application administration and support

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<p><b>E4.</b> Contribute to functional and user testing of clinical trial databases</p>	<ul style="list-style-type: none"> <li>■ Edit check programs, data entry instruments, and ensure data capture and data transfer application are correctly tested in accordance with all applicable laws and regulations and organization policies and procedures.</li> <li>■ Databases and data structures conform to standards for clinical trials set forth in government and industry standards, including security standards.</li> <li>■ Test results are properly documented and communicated to appropriate personnel and departments.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of clinical trial databases, edit check programs, data entry instruments, and data capture and data transfer applications.</li> <li>■ Knowledge of database testing processes and tools.</li> <li>■ Knowledge of data modeling and normalization.</li> <li>■ Knowledge of data formats and data conversion.</li> <li>■ Knowledge of system and ability to recognize problems identified by test procedure.</li> </ul>	<ul style="list-style-type: none"> <li>■ Takes active interest in others and establishes rapport.</li> <li>■ Demonstrates sensitivity to customer concerns/interests.</li> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> <li>■ Understands requirements of the task and technological results.</li> <li>■ Adjusts and monitors system operation and troubleshoots system malfunction/failure.</li> <li>■ Understands operation/interaction and manipulates technology for desired results.</li> </ul>
<p><b>E5.</b> Execute software validation methodologies to verify software functionality</p>	<ul style="list-style-type: none"> <li>■ User acceptance testing on EDC (Electronic Data Capture) systems is completed to ensure that trial software performs as specified and leads to high data entry accuracy.</li> <li>■ Software is validated to ensure that it handles data in accordance with industry and government standards.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of clinical database specs, design, testing and validation.</li> <li>■ Knowledge of data collection, capture and entry procedures.</li> <li>■ Knowledge of applicable laws and regulations.</li> <li>■ Knowledge of electronic data capture systems, tools and processes.</li> <li>■ Knowledge of data management practices, policies and regulations.</li> <li>■ Knowledge of tiered application architecture.</li> <li>■ Ability to integrate subsystem/application units.</li> </ul>	<ul style="list-style-type: none"> <li>■ Identifies, corrects, and troubleshoots malfunctions and failures.</li> <li>■ Understands requirements of the task and technological results.</li> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> <li>■ Analyzes organization of information and transfers information between formats.</li> </ul>
<p><b>E6.</b> Perform document control</p>	<ul style="list-style-type: none"> <li>■ Version control procedures are maintained for data management systems.</li> <li>■ Documents are prepared and distributed in accordance with company policies and procedures.</li> <li>■ The latest version of the document reflects the most current revision, and is distributed in a timely manner.</li> <li>■ Distribution lists are kept current and accurate.</li> <li>■ Previous original document versions are properly archived.</li> <li>■ All security measures and rules are followed.</li> <li>■ Current and retired documentation is maintained as required for ongoing studies and regulatory review.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of version control procedures.</li> <li>■ Knowledge of company policies and procedures regarding document preparation, distribution, and disposal.</li> <li>■ Ability to locate and identify the most current revision.</li> <li>■ Ability to obtain distribution lists.</li> <li>■ Ability to retrieve outdated versions.</li> <li>■ Knowledge of archiving procedures.</li> <li>■ Knowledge of security rules and measures.</li> </ul>	<ul style="list-style-type: none"> <li>■ Sets well defined/realistic goals.</li> <li>■ Manages timelines and recommends timeline adjustments.</li> <li>■ Examines information/data for relevance and accuracy.</li> <li>■ Performs assigned task, follow rules/policies/procedures, and pays attention to details.</li> <li>■ Recognizes ethical issues and demonstrates trustworthiness.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

**Critical Work Function – E. Perform system/application administration and support**

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>E7. Support documentation of data management procedures</b>	<ul style="list-style-type: none"> <li>■ Standard operating procedures and guidelines are correctly documented.</li> <li>■ Procedural changes are accurately and completely documented.</li> <li>■ All organization policies and procedures and all applicable laws and regulations are followed.</li> <li>■ Documentation is distributed to appropriate departments and personnel in a timely manner.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of documentation standards, practices and regulations.</li> <li>■ Knowledge of testing and quality assurance processes and criteria.</li> <li>■ Knowledge of documentation control processes and systems</li> <li>■ Knowledge of documentation retrieval and archival processes.</li> </ul>	<ul style="list-style-type: none"> <li>■ Analyzes organization of information and transfers information between formats.</li> <li>■ Identifies data/information and predicts outcomes.</li> <li>■ Composes and edits documents for appropriate audience and purpose.</li> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> <li>■ Understands system organization and follows processes and procedures.</li> </ul>

## CONCENTRATION: REGULATORY AFFAIRS AND CLINICAL TRIALS

**Critical Work Function – F. Perform coding of clinical trials data**

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS and Academic Knowledge and Skills</i>
<b>F1.</b> <b>Encode clinical trial data</b>	<ul style="list-style-type: none"> <li>■ Adverse events, medical histories, physical examinations, concomitant drugs and other medications are accurately encoded in accordance with commercial and/or study-specific dictionaries.</li> <li>■ Automated tools, systems and manual coding processes are properly used.</li> <li>■ Coding is performed in accordance with all applicable laws and regulations.</li> <li>■ Adverse events are properly documented and reported.</li> <li>■ Issues in data requiring coding to CDAs (clinical document architecture) are identified for potential query generation.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of medical coding dictionaries.</li> <li>■ Knowledge of regulations governing safety monitoring.</li> <li>■ Knowledge of adverse events.</li> <li>■ Knowledge of documentation and reporting procedures for adverse events.</li> <li>■ Knowledge of CDAs.</li> </ul>	<ul style="list-style-type: none"> <li>■ Prepares schedule and prioritizes, monitors, and adjusts tasks. Manipulates, integrates, and modifies information; uses networks.</li> <li>■ Works with minimal supervision and pays attention to details.</li> <li>■ Analyzes logic/principle and examines information for relevance and accuracy.</li> </ul>
<b>F2.</b> <b>Interface with project teams to resolve coding problems and issues</b>	<ul style="list-style-type: none"> <li>■ Coding issues are clearly communicated to appropriate personnel in a timely manner.</li> <li>■ Adverse event data captured in Drug Safety is reconciled with adverse event data captured in the clinical study.</li> <li>■ Meetings are attended with active participation and advance preparation.</li> <li>■ Issues are accurately and thoroughly discussed and solutions are defined.</li> <li>■ Communication is clear and relevant.</li> <li>■ Action items are carried out in a timely manner.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of medical coding dictionaries.</li> <li>■ Knowledge of regulations governing safety monitoring.</li> <li>■ Knowledge of adverse events.</li> <li>■ Knowledge of documentation and reporting procedures for adverse events.</li> </ul>	<ul style="list-style-type: none"> <li>■ Works to improve team skills and encourages/supports team members.</li> <li>■ Understands and adheres to standards; demonstrates commitment to excellence.</li> <li>■ Examines information, analyzes possible causes, recommends action plan.</li> <li>■ Prepares schedule and prioritizes, monitors, and adjusts tasks.</li> <li>■ Takes active interest in others and establishes rapport.</li> <li>■ Accepts responsibility for own behavior and understands impact on others.</li> </ul>
<b>F3.</b> <b>Access, load and update medical coding dictionaries</b>	<ul style="list-style-type: none"> <li>■ Proper procedures are followed.</li> <li>■ Security protocols are maintained.</li> <li>■ Dictionaries are appropriately accessed.</li> </ul>	<ul style="list-style-type: none"> <li>■ Knowledge of medical coding dictionaries.</li> <li>■ Knowledge of data access methodologies and tools.</li> <li>■ Knowledge of web-based access to dictionaries.</li> <li>■ Knowledge of updating procedures.</li> <li>■ Knowledge of system components and functions.</li> <li>■ Knowledge of installation and configuration practices.</li> </ul>	<ul style="list-style-type: none"> <li>■ Manipulates, integrates, and modifies information; uses networks.</li> <li>■ Identifies data/information and predicts outcomes.</li> <li>■ Prepares schedule and prioritizes, monitors, and adjusts tasks.</li> <li>■ Works with minimal supervision and pays attention to details.</li> <li>■ Analyzes logic/principle and examines information for relevance and accuracy.</li> </ul>



**RESEARCH OUTCOMES:  
MANUFACTURING**

**Cluster Structure  
Biotechnology and Biomedical Manufacturing**

## Cluster Structure



Discussions with the Industry Advisory Committee for the Shoreline Community College Biotechnology Program concluded that biotechnology & biomedical research and development are on the rise in the Puget Sound Region. It further concluded that biotechnology & biomedical manufacturing, at least for the time being, is on the decline in this region.

Examination of the 2000 Cluster, Research, Development and Manufacturing showed a distinct grouping of critical work functions for research and development and one for manufacturing.

The 2000 cluster critical work functions and key activities summary appears on the following page.

CRITICAL WORK FUNCTIONS	KEY ACTIVITIES								
	A1	A2	A3	A4	A5	A6	A7	A8	A9
<b>A. Perform routine laboratory support work</b>	<b>A1</b> Maintain laboratory and equipment	<b>A2</b> Order and stock supplies	<b>A3</b> Operate equipment	<b>A4</b> Maintain biological stock cultures	<b>A5</b> Clean and prepare items for lab	<b>A6</b> Prepare biological and/or chemical materials	<b>A7</b> Send, receive and distribute biological and chemical materials	<b>A8</b> Perform routine animal care duties	<b>A9</b> Communicate with co-workers to ensure quality laboratory work
<b>B. Assist with research and development</b>	<b>B1</b> Perform assays and experiments	<b>B2</b> Assist in method development	<b>B3</b> Investigate new technologies and methodologies	<b>B4</b> Perform data analysis	<b>B5</b> Handle and/or maintain biological stock cultures	<b>B6</b> Troubleshoot experiments and equipment	<b>B7</b> Communicate results		
<b>C. Manufacture the product or provide the service</b>	<b>C1</b> Set up equipment for the production process	<b>C2</b> Perform and monitor the process to make the product or provide the service	<b>C3</b> Inspect materials at all stages of process to determine quality or condition	<b>C4</b> Participate in the installation, modification, and upgrade of equipment	<b>C5</b> Prepare final product for shipping or distribution	<b>C6</b> Monitor, maintain, and troubleshoot equipment, tools and workstation	<b>C7</b> Communicate with co-workers and/or customers to ensure production or service meets requirements	<b>C8</b> Coordinate inventory	
<b>D. Maintain a safe and productive work environment</b>	<b>D1</b> Participate in employer-sponsored safety training	<b>D2</b> Participate in emergency drills and emergency response teams	<b>D3</b> Identify unsafe conditions and take corrective action	<b>D4</b> Suggest continuous improvements	<b>D5</b> Coordinate with work team	<b>D6</b> Provide orientation and training for other employees	<b>D7</b> Handle and dispose of hazardous materials	<b>D8</b> Maintain security	
<b>E. Perform documentation</b>	<b>E1</b> Maintain lab notebook	<b>E2</b> Create documents	<b>E3</b> Document Good Manufacturing Practices, Good Laboratory Practices, and Good Clinical Practices	<b>E4</b> Write reports	<b>E5</b> Maintain equipment logbooks	<b>E6</b> Maintain chemical/biological stock records	<b>E7</b> Maintain training documentation		

**Black Text** = Skill Standards validated by industry and still current for 2007 project

Of the five critical work functions from the 2000 study, only C: Manufacture the Product or Provide the Service was found to be exclusive to biotechnology & biomedical manufacturing. Based on the advice of industry and in accordance with the research, Biotechnology & Biomedical Research and Development and Biotechnology & Biomedical Manufacturing were divided into two clusters.

**Findings:**

## **Biotechnology and Biomedical Manufacturing**

The June 13, 2007 group interview with three subject matter experts started by posing questions in the area of biotechnology & biomedical manufacturing in the Puget Sound Region:

1. What is the trend for existing biotechnology manufacturing operations in the Puget Sound region over the next 3 to 5 years?
2. What is possibility of biotechnology/pharmaceutical firms establishing new manufacturing operations in the Puget Sound area in the next 3 to 5 years?

Burlex was recently purchased by Bayer, and their current plant will be decommissioned and a new one will be brought on line. The manufacturing process flow will be the same, but will be more automated. Skills of current employees will be upgraded to accommodate the increase in automation. Manufacturing quality control and product testing will stay in Washington State, but may be outsourced by Bayer. The process science aspect of the operation will move out of state—Bayer plans to hire only to fill natural attrition.

Amgen is having a difficult time at the moment. They have halted all building and canceled all buildings, and will engage in no hiring until the company stock price turns around. This is not a small setback.

Dendreon did not get FDA approval so they are delayed, and Zymogenetics is still on hold. Several manufacturing companies have come and gone and there has been more downsizing than anything else. There are no rumors of new companies coming here. Most likely growth will come from startups getting a drug approved and getting venture capital to develop a manufacturing facility. Most of these startups are a minimum of eight years away.

The one area the interviewees thought might be growing is biomedical device manufacturing.

The second set of questions posed to the interviewees was in the area of biotechnology manufacturing job market trends:

1. Which manufacturing jobs are in demand today?
2. Which manufacturing jobs will you be hiring for in the near future?
3. What level of degree are you hiring for (AS, BA, Masters, PH.D., etc), for manufacturing jobs?
4. How much experience are you requiring?
5. How important is course credit? How important is a degree, versus training/certification?

Most biotechnology and biomedical firms require a minimum of a bachelor's degree. If that degree is not in the biotechnology field, then any bachelor's degree with the SCC biotechnology certificate would be required.

The job market is getting more specialized and there is really no change from prior trends. There are virtually no jobs in the manufacturing arena for which a two-year AA or AS degree is sufficient.

The current WDC brochure for high demand jobs in biotechnology in Washington State lists 12 job titles<sup>3</sup>. Of the twelve, only two are exclusive to biotechnology and biomedical manufacturing, and they are both in the sales and marketing field, and require a bachelor's degree and prior experience. Nine of the other ten high demand jobs are in the areas of Regulatory Affairs and Clinical Trials and Research and Development.

The WBBA (Washington Biotechnology and Medical Association) annual report on employment has no section for manufacturing. It has an extensive section on Research, covering both laboratory research and development and clinical trials.

### **Recommendations**

Based on the labor market demand situation for biotechnology and biomedical manufacturing, the development of skill standards for the manufacturing cluster will be placed on hold. Should biotechnology and biomedical manufacturing start to grow in the Puget Sound Region, the 2000 skill standards would be updated at that time.

The Manufacturing Skill Standards Council identified clusters for manufacturing:

- Production
- Production Process
- Logistics and Inventory Control
- Health, Safety and Environmental Assurance
- Quality Assurance
- Maintenance, Installation and Repair

It is anticipated that the biotechnology and biomedical manufacturing skill standards would include aspects of all of these clusters when and if they are updated.

<sup>3</sup>Biological/Biotechnology Instructors, post secondary; Bioinformatics Analyst; Biological Technician; Clinical Research Coordinator; Documentation Specialist; Medical Laboratory Technologist (MT); Product Marketing Manager; Quality Control Manager/ Analyst; Regulatory Affairs Associate or Specialist; Research/Medical Scientist; Sales Representative (Bio-Medical Device); Technical or Medical Writer



# **INTEGRATION**

**Assessment and Certification:  
A Vital Connection**

**Assessment Strategies  
Assessment Design**

## Assessment and Certification: A Vital Connection



**S**kill standards, while useful on their own, are just one part of a much larger equation. Skill standards establish the standard of competent performance, but they do not tell a person whether he or she has succeeded in meeting that standard.

For this reason, developing skill standards does not end with their publication. Washington State is also working to develop voluntary assessments and certifications which will make it possible for students, workers and any interested persons to determine their strengths and weaknesses based on the standards, and to earn certification showing that they can perform work competently as established by the skill standards.

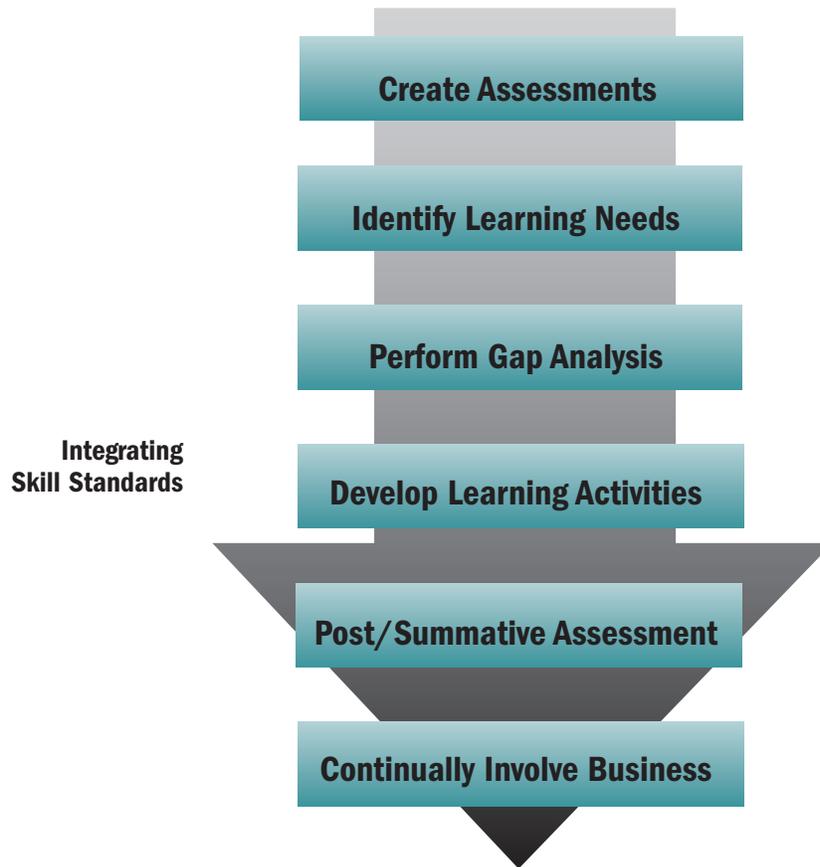
In today's fast-moving technological economy, the necessity for assessments and certification is crucial. The demand for both technical and employability skills is escalating as work becomes more complex. The workforce is more mobile, with workers moving freely between jobs and industries. This job mobility requires that workers must be able to communicate their qualifications to potential employers. As technology changes, workers must keep up with technological change through continuous learning and worker retraining, and must be able to prove they have kept pace. All of these factors mean more training and education for individuals, and the ability to show evidence that this training translates to performance on the job.

Voluntary assessments and certifications based on skill standards will help us address all these needs because of the guiding principles upon which skill standards are based, and because of the stakeholders—employers, educators, workers, students, and government—whose needs skill standards are designed to meet.

Please Note: To ensure the use of standards and their related assessments and certifications do not contradict U.S. employment law, employers will need to conduct an internal validation of the standards before using the skill standards to make hiring and promotion decisions. The purpose of this validation is to ensure that the knowledge, skills, and performance described by the standards are needed for competent performance in an employer's organization. The need to validate the standards internally is a key requirement of U.S. employment law, which seeks to protect individuals from discrimination in hiring and promotion.

The first step toward a statewide system of assessments and certifications is the development of assessments which measure an individual's ability to perform work competently as defined by the skill standards. Once these assessments are developed, curriculum can be reviewed to determine that all necessary topics and practicums sufficiently cover the items in the assessment. Once any gaps are

identified, learning activities and content adjustments can be made, and post/summative assessments can be administered. Finally, it is critical that industry be involved every step of the way, and that standards are continuously reviewed and updated. The diagram below provides a summary of this process.



## Assessment Strategies

**UPON COMPLETION** of the development of skill standards, performance assessment can be created to assess the criteria identified. Sample assessments and standards may be distributed to instructors and curriculum developers who will be educated on the skill standards elements.

Assessments based on the skill standards may include pre-and post-evaluations of the student to measure skill progression and to track the success rate of obtaining certification, where applicable.

Within a skill standards or competency-based system, assessment is the generation and collection of evidence of performance which can be matched to specified explicit standards that reflect expectations of performance in the workplace. **There are two main forms of evidence:**

- Evidence of actual performance
- Evidence of underpinning knowledge, skills and abilities

**The types of evidence may vary and will include:**

- Direct evidence (products and items produced by the performer)
- Indirect evidence (supporting evidence and information about the performer)

Evidence can be collected in a wide variety of educational or business settings. To a large extent, the range of opportunities available for demonstration will determine the most appropriate setting. Often it is difficult to actually perform the task in the authentic work setting. In this case, evidence generated during an educational course or an in-house training session can be collected by individuals and added to their overall portfolios.

By requesting that the student or trainee produce tangible results in the form of take-away products (videos, tapes, paper, and electronic products), the participant will have created real evidence which can be shown to human resource personnel, hiring managers, supervisors or assessors. When assessing these products, **the trained assessor will seek:**

- Validity
- Currency
- Authenticity
- Sufficiency

Therefore, when designing a skill standards-based assessment for an educational course or training session, the assessment process and results will meet four criteria:

**Validity:** The assessment instrument/process clearly relates to the relevant standards.

**Currency:** The assessment instrument/process calls for a demonstration of the current standards in the industry.

**Authenticity:** The individual being assessed produces the assessment results; it is their own work. Team activities will be useful to demonstrate the skills and abilities to work effectively with others, not necessarily the total end results. The individual can, if possible, identify his or her part of the team project to demonstrate evidence of his or her own results.

**Sufficiency:** Enough evidence is collected to match the key task and the performance criteria included in the skill standards.

When designing/revising the curriculum for Biotechnology/Biomedical, students will be assisted in generating high-quality evidence of performance or of underpinning skills, knowledge and abilities which will help them to be successfully assessed as fully competent.

## Assessment Design

### TYPE OF AUTHENTIC ASSESSMENT

### DESCRIPTION OF AUTHENTIC ASSESSMENT STRATEGIES

<b>Project</b>	<ul style="list-style-type: none"> <li>■ Hands-on demonstration of knowledge, skills, and attitudes that reveals a student's ability to plan, organize, and create a product or an event.</li> <li>■ Documentation of process of development from initial steps to final presentation.</li> </ul>
<b>Portfolio</b>	<ul style="list-style-type: none"> <li>■ Collection of pieces of evidence of a student's knowledge, skills, and attitudes.</li> <li>■ Showcase of best work, work-in-progress.</li> <li>■ Record of student's progress over time.</li> <li>■ Content selection by student in collaboration with the teacher.</li> <li>■ Centerpiece for parent conferences.</li> </ul>
<b>On-Demand Demonstrations</b>	<ul style="list-style-type: none"> <li>■ Hands-on performance by a student, which illustrates levels of knowledge, skills, and attitudes.</li> <li>■ Typically involve a "real life" problem or situation to solve.</li> <li>■ Focus on the application of knowledge and skills learned in one situation as it connects to a new and different one.</li> </ul>
<b>Case Studies</b>	<ul style="list-style-type: none"> <li>■ Analysis of events and individuals in light of established criteria.</li> <li>■ Synthesis of evidence to support generalizations based on individual cases.</li> </ul>
<b>Paper/Pencil Tests</b>	<ul style="list-style-type: none"> <li>■ Multiple-choice, essay, true-false questions that rely on extended responses to further clarify a student's understanding of the knowledge being assessed.</li> <li>■ Graphic representations that reveal a student's understanding of connections among ideas.</li> </ul>
<b>Structured Observation</b>	<ul style="list-style-type: none"> <li>■ Observation of events, groups, and individuals that focuses on the salient traits of the skill or attitude being observed.</li> </ul>
<b>Scenarios</b>	<ul style="list-style-type: none"> <li>■ A problematic or challenging situation presented in the context of a career-technical perspective.</li> <li>■ Study required to analyze or evaluate a situation.</li> <li>■ Apply relevant knowledge or skills.</li> <li>■ Prepare and justify a reasonable solution</li> </ul>
<b>Critical Incident</b>	<ul style="list-style-type: none"> <li>■ An interview where the assessee is asked to describe past experiences which demonstrate skill standards.</li> </ul>

From: Center for Occupational Research and Development, November 1996, and *Skill Standards Volume 2: Assessment*, 1999, Washington State Board for Community and Technical Colleges.



## Appendix

## References



*The Biotechnology and Medical Device Industry in Washington State: An Economic Analysis.* Huckell/Weinman Associates, Inc., Prepared for WBBA. 2003. On the Internet at: [http://www.wabio.com/industry/econ\\_dev](http://www.wabio.com/industry/econ_dev)

*Built To Work*, National Skill Standards Board, 2000.

Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook, 2006-07 Edition*, Science Technicians, on the Internet at: <http://www.bls.gov/oco/ocos115.htm> (visited April 1, 2007)

*Clinical Trials Workflow Process, Following the Data.* Bellevue Community College. 2006. On the Internet at: <http://bellevuecollege.edu/informatics/lsicresources.htm>

Colaninno, Peter M. *Career Alternative: Clinical Trials.* *Clinical Laboratory Science*, 2003;16(2):82.

*Diversified Bio-Medics, Inc. Selects Snohomish County for Contract Manufacturing Facility.* Snohomish County EDC Ezine, Volume 1, Issue 32. April 4, 2006. On the Internet at: [http://www.imakenews.com/snocoedc/e\\_article000560171.cfm?x=b11,0,w](http://www.imakenews.com/snocoedc/e_article000560171.cfm?x=b11,0,w)

Dutta, Sandeep. *Drug Development, Clinical Trials and Regulatory Affairs - Opportunity for Strategic Guidance from JUOPAA.* Pharmabiz.com, December 2, 2004. On the Internet at: <http://www.pharmabiz.com/article/detnews.asp?articleid=25040&sectionid=50>

*The Future of Life Science in Washington.* WBBA. 2006. On the Internet at: [http://www.wabio.com/econ\\_dev\\_reports/WA\\_Growth\\_Strategy\\_2006.pdf](http://www.wabio.com/econ_dev_reports/WA_Growth_Strategy_2006.pdf)

*Life Science Informatics Overview.* Bellevue Community College. 2006. On the Internet at: <http://bellevuecollege.edu/informatics/lsicresources.htm>

*Manufacturing Skill Standards*, Manufacturing Skill Standards Council, 2001.

*Skill Standards Guidebook Volumes I and II*, Washington State Board for Community and Technical Colleges. Reprinted June, 1999.

*Washington Biotechnology & Medical Technology Annual Report, 2006.* Washington Biotechnology and Medical Association. 2006. On the Internet at: <http://www.wabio.com>

*Washington State High Demand Jobs in Life Sciences.* King County WDC. 2007. On the Internet at: <http://www.seakingwdc.org/>

*Washington State Workforce Training Report.* Info Resource, Inc. for WBBA. 2006. On the Internet at: <http://www.seakingwdc.org/lssp/wbba-wtrr.pdf>

## Internet References

### Industry

Mediware Information Systems, Inc.: <http://www.mediware.com>

Aerotek, Inc.: <http://www.aerotek.com>

Abt Associates , Contract Research Organization: <http://www.abtassociates.com/>

Human Genome Sciences, Inc.: <http://www.hgsi.com/index.html>

i3 Research: <http://www.i3research.com/en/index.php>

### Education

Foothill College Biotechnology Department:

<http://www.foothill.edu/bio/programs/biotech>

Temple University Certificate in Clinical Trial Management:

[http://www.temple.edu/pharmacy\\_QARA/certificate\\_CM.doc](http://www.temple.edu/pharmacy_QARA/certificate_CM.doc)

Massachusetts College of Pharmacy and Health Sciences:

[http://www.mcphs.edu/careers/career\\_paths/chemistry/biotech\\_research.html](http://www.mcphs.edu/careers/career_paths/chemistry/biotech_research.html)

Gateway Community College Clinical Research Coordinating Program:

<http://healthcare.gatewaycc.edu/NR/rdonlyres/4CB234FE-7C04-4200-960D-548084404F42/0/CRCCOMPKTMAR07.pdf>

Universities.com: [http://www.universities.com/On-](http://www.universities.com/On-Campus/Bachelor_degree_Health_Professions_and_Related_Clinical_Sciences_Pharmacy_Administration_and_Pharmacy_Policy_and_Regulatory_Affairs_MS_PhD.html)

[Campus/Bachelor\\_degree\\_Health\\_Professions\\_and\\_Related\\_Clinical\\_Sciences\\_Pharmacy\\_Administration\\_and\\_Pharmacy\\_Policy\\_and\\_Regulatory\\_Affairs\\_MS\\_PhD.html](http://www.universities.com/On-Campus/Bachelor_degree_Health_Professions_and_Related_Clinical_Sciences_Pharmacy_Administration_and_Pharmacy_Policy_and_Regulatory_Affairs_MS_PhD.html)

Skyline College, Biology:

<http://www.smccd.net/accounts/skyline/smt/biology.html>

Skyline College, Biotechnology:

<http://www.smccd.net/accounts/skyline/smt/biotech.html#courses#courses>

University of Wisconsin Clinical Trials Program:

<http://www.biostat.wisc.edu/clinicaltrialsprogram/index.htm>

UC Irvine, Certified Clinical Research Professional Program:

[http://unex.uci.edu/certificates/life\\_sciences/](http://unex.uci.edu/certificates/life_sciences/)

Keck Graduate Institute 2-Year Program in Applied Life Sciences:

<http://www.kgi.edu/x66.xml>

Southern Illinois University, Carbondale: [www.standards.siu.edu](http://www.standards.siu.edu)

### **Organizations and Government**

Massachusetts Biotechnology Industry Directory: <http://massbio.org>

Career Prospects in Virginia: <http://www.careerprospects.org>

The National Health Museum Resource Center:

[http://www.accessexcellence.org/RC/CC/bio\\_career\\_2.html](http://www.accessexcellence.org/RC/CC/bio_career_2.html)

Biology-Link: <http://www.bio-link.org/>

U.S. Department of Labor, Career Voyages:

<http://www.careervoyages.gov/biotechnology-research.cfm>

Clinical Trials: <http://www.seekingwdc.org/lssp/wbba-wtrr.pdf>.

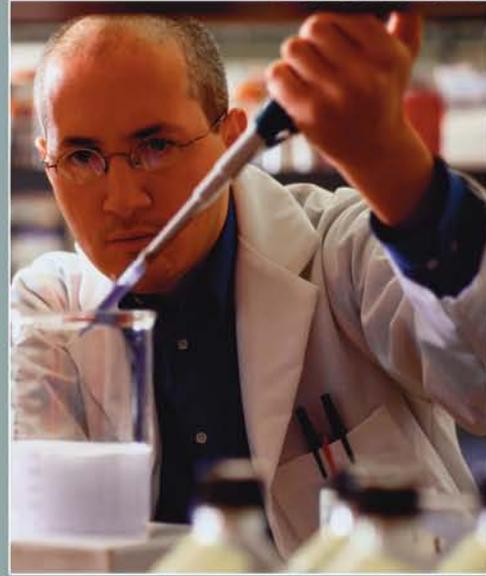
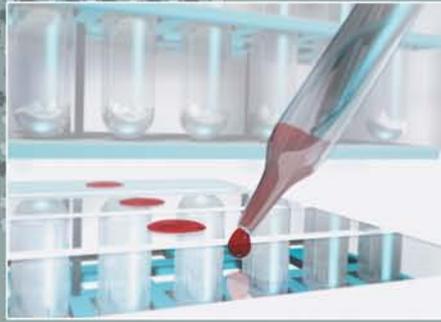
Society of Clinical Research Associates: <http://www.socra.org/>

Bio-Careers: <http://www.bio.com/jobs/browse.jhtml?view=category>

National Center on Education and the Economy: [www.ncee.org](http://www.ncee.org)

American National Standards Institute: [www.ansi.org](http://www.ansi.org)

Clearinghouse on Assessments and Evaluation: [www.ericae.net](http://www.ericae.net)



Shoreline  
COMMUNITY COLLEGE



[www.shoreline.edu](http://www.shoreline.edu)