Core Skill Standards for Bioscience Technicians

c3bc
Community College Consortium for Bioscience Credentials

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TAACCCT

ABOUT THIS REPORT

The Community College Consortium for Bioscience Credentials (c^{3}bc) is funded by a Department of Labor (DOL) Trade Adjustment Assistance Community College Career Training (TAACCCT) grant (#TC-23761-12-60-A-37). The consortium includes 12 colleges, organized into four hubs, and is led by Russ H. Read at Forsyth Technical Community College in North Carolina. This report provides information about one of the major objectives of the grant: **Identification of a set of core technical skills and competencies that are held in common across the bioscience industry subsectors of Bioscience Lab Skills, Biomanufacturing and Medical Devices.**

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The Core Skill Standards for Bioscience Technicians were developed to answer the question: What do all bioscience technicians need to know and be able to do to work in the diverse and ever-changing life sciences industry?

> *"These new Core Bioscience Skill Standards will help community colleges across the country develop new Bioscience programs or modify existing programs to meet industry requirements and better prepare students to be successful in the workplace."*

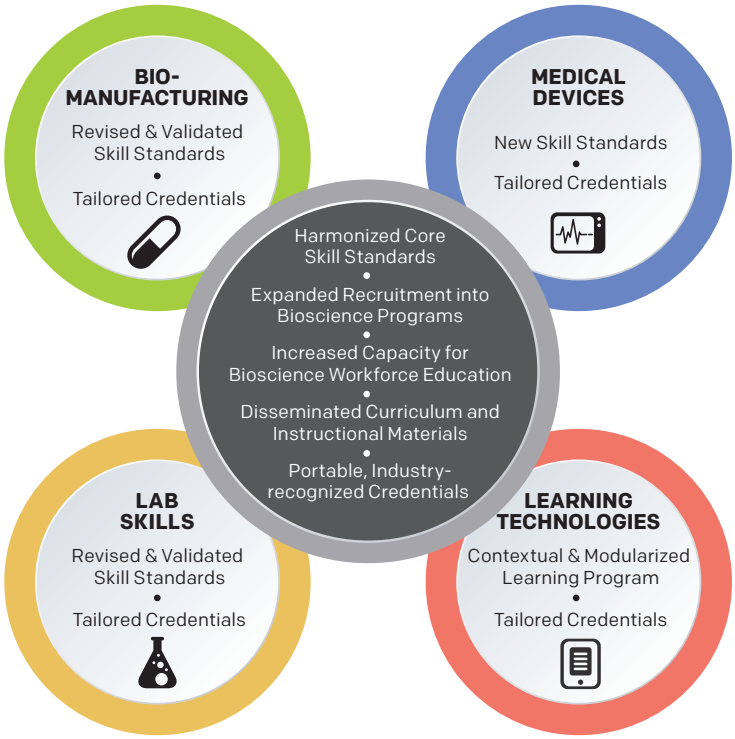
Russ H. Read, Executive Director, National Center for the Biotechnology Workforce, Forsyth Technical Community College

EXECUTIVE SUMMARY

The Core Skill Standards for Bioscience Technicians were developed to answer the question: What do all bioscience technicians need to know and be able to do to work in the diverse and ever-changing life sciences industry? This effort was undertaken to facilitate development of stackable credentials and career pathways in order to build capacity in bioscience technician education (see c³bc Grant Goals below).

This report includes the complete Core Skill Standards for Bioscience Technicians (see Appendix, page 18). Throughout the report, phrases such as "Core Bioscience Skill Standards", "core skill standards", or "skill standards" will be used for convenience, to refer to the Core Skill Standards for Bioscience Technicians.

c³bc Grant Goals



This report also describes the process for establishing these core skill standards and achieving industry recognition, and includes suggestions for how they can be used by educators and employers. Examples are provided to illustrate how the same Key Activity can be taught and assessed differently to prepare students for different industry subsectors.

The c³bc consortium includes 12 colleges, organized into four hubs. As shown in the chart below, three of the four hubs were chosen to represent different subsectors of the bioscience industry. **Biomanufacturing** is an expanding subsector as companies mature into larger scale bioprocessing and production facilities with a need for a technical workforce trained in aseptic technique and Good Manufacturing Practices (cGMP). Although **"Bioscience Lab Skills"** is not usually considered an industry subsector, this grouping was useful in order to include workforce skills needed by research and development laboratories, small-scale production companies, as well as testing laboratories. The **Medical Devices** subsector covers a broad spectrum of industry activities, ranging from instruments as simple as a toothbrush to pacemakers and medical imaging equipment.

The Learning Technologies hub focused on removing barriers to student learning through the design of modularized and flexible learning experiences that could be widely disseminated to college educators and students. Many of these efforts directly address the Core Bioscience Skill Standards (see www.skillscommons.org/handle/taaccct/441). In some cases, these efforts were directed at unemployed workers and veterans to help them understand that many of their skills are transferrable to occupations in the bioscience industry.

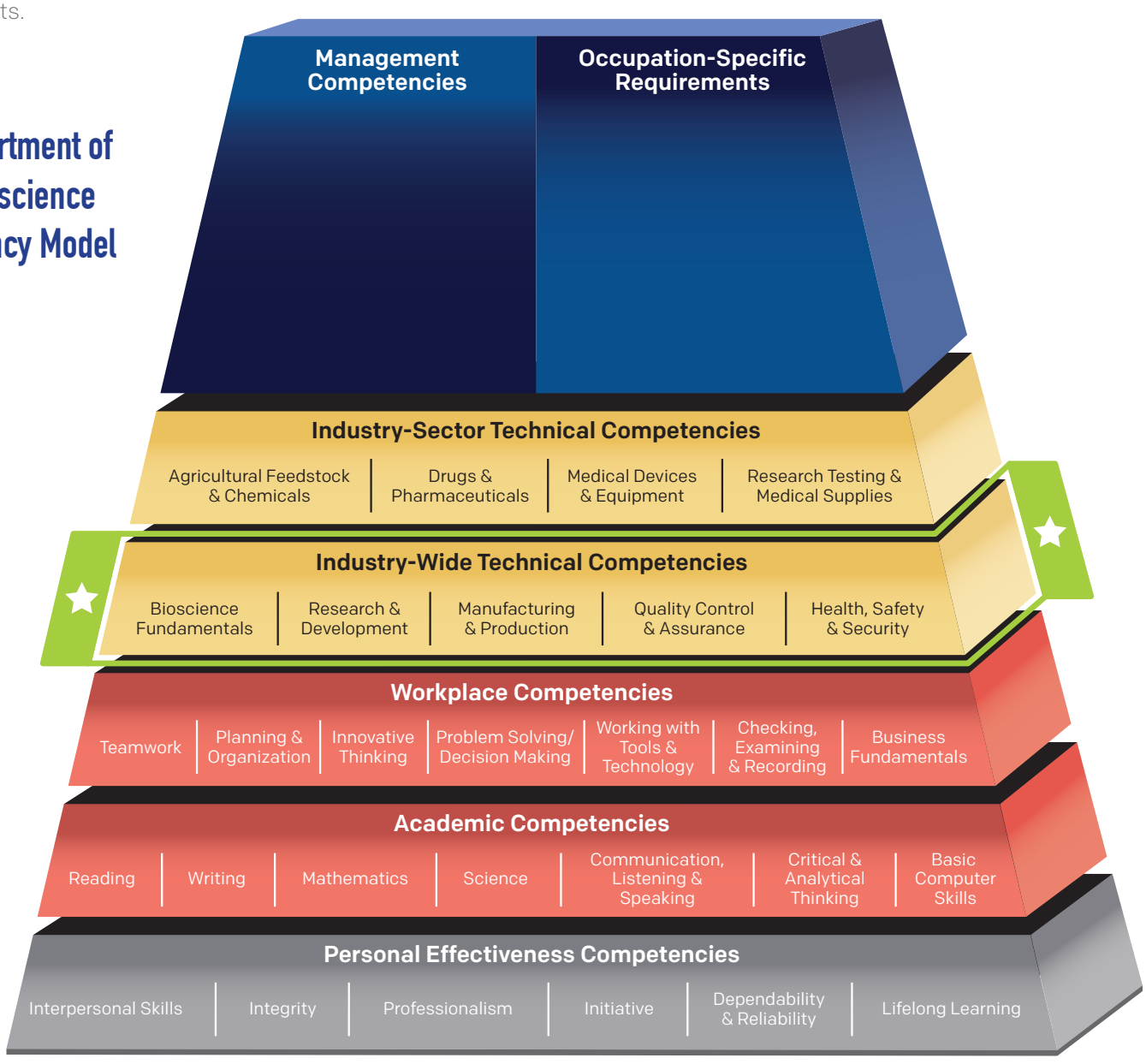
PROCESS FOR ESTABLISHING CORE BIOSCIENCE SKILL STANDARDS

Background and Rationale

Previous sets of bioscience technician skill standards have provided a useful vocabulary for educators, students and industry supervisors (see timeline at bottom of page 6). In recent years, due to the growth and maturation of the bioscience industry, workforce education programs have multiplied to meet industry's need for a technical workforce. This expansion and the variety of job descriptions for technicians presents a challenge for educators as they seek to design curriculum and programming options to prepare students.

Consortium partners recognized the need to focus skill standards efforts on fundamentals that **all** entry-level bioscience technician would need in order to succeed, regardless of industry subsector, geographic location or individual job description. For reference, these "core skills" relate to the "**Industry-Wide Technical Competencies**" that are found in the lower yellow block of the U.S. Department of Labor (USDOL) Bioscience Competency Model (see pyramid below) which was completed in 2008.

U.S. Department of Labor Bioscience Competency Model



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PROCESS FOR ESTABLISHING CORE BIOSCIENCE SKILL STANDARDS

Considerations

As noted, the focus of this effort was on determining skills and knowledge that every entry-level bioscience technician would need, regardless of job description. Due to the enormous range of entry-level technician tasks, from the most basic (e.g. washing glassware) to more sophisticated, such as carrying out experiments and analyzing results in a R&D lab, the *CORE Team* made some decisions about how to approach the task:

1. Consideration was given to skills that most industry employers would reasonably expect an entry-level bioscience technician to have learned in their respective college workforce preparation program.
2. The focus was on **entry-level technicians in industry,** rather than academia, even though academic labs also need entry-level technicians. This was done in order to emphasize familiarity with a regulated environment, and the importance of compliance to applicable industry standards and regulations.
3. Consideration was given to the technician's general need for career development. Even though some entry-level jobs are very basic and quite repetitive, we did not want to neglect the technician's need for a career pathway, so we also considered fundamentals that would form a basis for further education and career development.

Format and Terminology

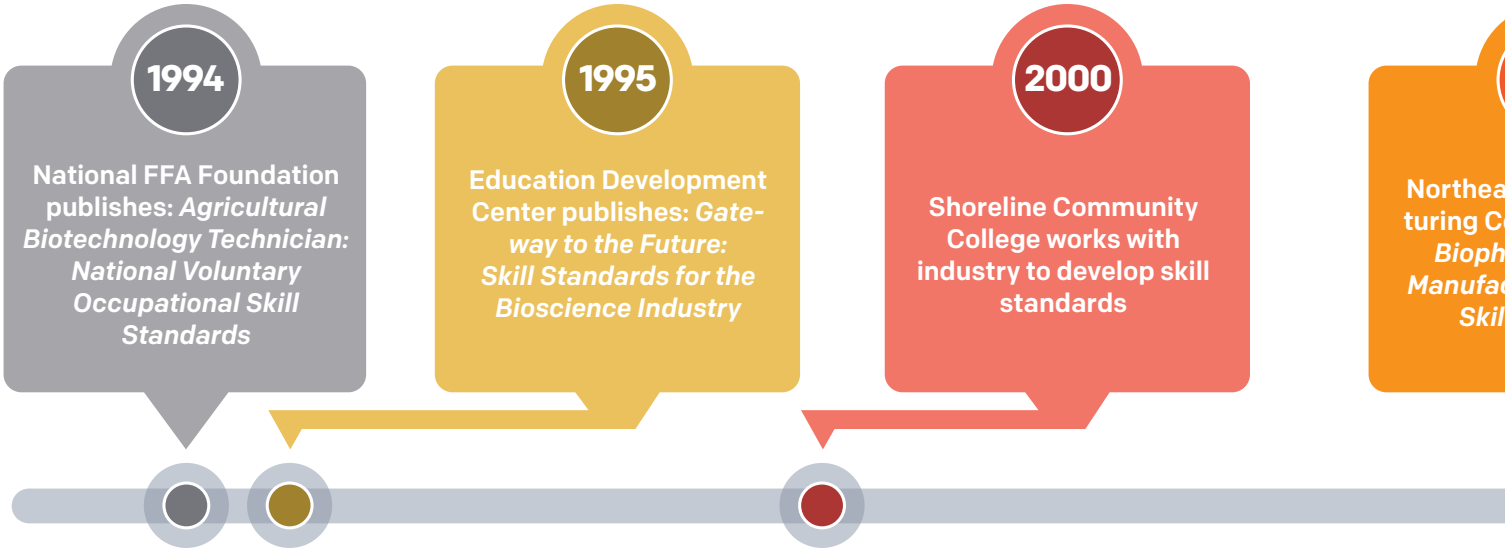
In order to make the Core Bioscience Skill Standards useful to all stakeholders, a format was created that includes the following essential elements:

Critical Work Functions (CWFs) are the broadest areas of responsibility for an entry-level technician. CWFs are general enough that they are included in the job descriptions of the vast majority of entry level technicians.

A Key Activity (KA) is an essential task performed by a worker on a regular basis. KAs are specific enough that students or entry level workers can be assessed to determine their level of mastery.

A **Performance Indicator** is a guide that can be used to determine whether a KA has been performed well.

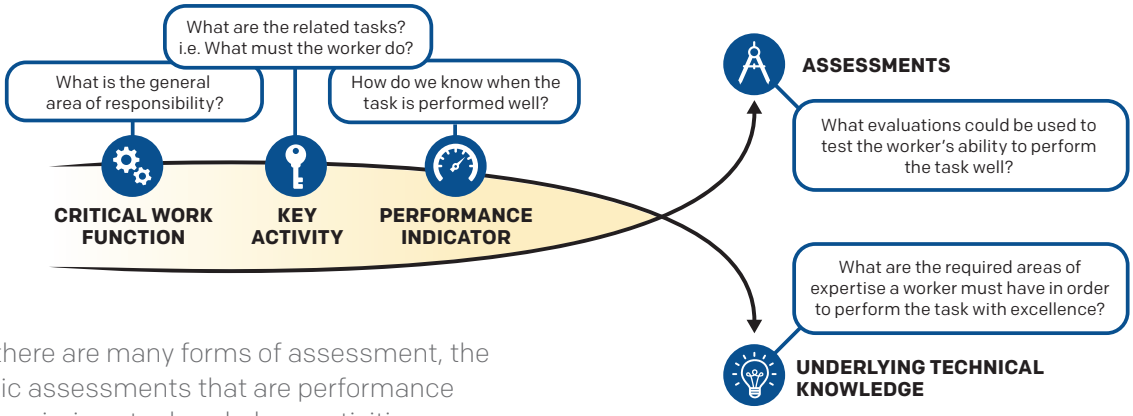
History of Bioscience Skill Standards Development



What are Skill Standards?

Skill standards are performance specifications that identify the knowledge, skills, and abilities that an individual needs to succeed in the workplace. They provide a framework for educators to develop curriculum, courses and credentials as well as measurable learning outcomes. They indicate to students the skills needed in the workplace, and, just as importantly, give them the terminology to describe and discuss their skill set. They offer common language with which educators and industry can discuss training requirements to ensure that industry is provided with the technical workforce it needs to remain competitive.

Underlying Technical Knowledge includes knowledge that a technician must have in order to excel in performing a KA.



An **Assessment** is an exercise that can be undertaken to determine an individual's proficiency in performing a KA. Although there are many forms of assessment, the focus is on identifying authentic assessments that are performance based and that are designed to mimic actual workplace activities as closely as possible in an instructional setting.

The relationship between these terms is illustrated in the figure above.

2006

st Biomanufac-enter publishes: *armaceutical cturing Industry l Standards*

2007

Shoreline Community College publishes: *Biotechnology & Biomanufacturing Skill Standards for Research & Development, Regulatory Affairs & Clinical Trials, Manufacturing*

2008

U.S. Department of Labor develops Bioscience Competency Model

2016

c³bc Consortium publishes: *Core Skill Standards for Bioscience Technicians*

CORE BIOSCIENCE SKILL STANDARDS: CRITICAL WORK FUNCTIONS & KEY ACTIVITIES

The chart below outlines the six **Critical Work Functions** and the **Key Activities** within them, for the Core Bioscience Skill Standards. As might be expected, the Core Skills focus on quality and compliance issues: Documentation, Safety, Calculations, Communication, etc. This chart does not include the **Performance Indicators**, **Underlying Knowledge** and **Assessments** for each of the Key Activities. The complete Core Bioscience Skill Standards document with these sections can be found in the Appendix on page 18 and at the following link: https://sites.google.com/site/c3bcbiosciencesskillstandards/

Critical Work Function: Maintain a safe and productive work environment	
Key Activities	Recognize unsafe conditions and take corrective and/or preventive action(s)
	Follow relevant safety policies, guidelines, and regulation (e.g. company, OSHA[1], EPA[2], CDC[3])
	Access and use MSDS[4] (SDS) and other safety information sources
	Maintain a safe, clean, contamination-free, and clutter-free environment, as appropriate
	Select appropriate PPE to use to protect self from biological, chemical, and/or physical hazards
Critical Work Function: Provide routine facility support	
Key Activities	Monitor, maintain, and troubleshoot/repair equipment
	Use equipment correctly according to manufacturer's guidelines
	Maintain inventory of raw materials, parts, components and/or equipment
	Prepare materials/supplies/equipment for use
Critical Work Function: Perform measurements / tests / assays	
Key Activities	Collect samples according to established procedures and applicable sampling plans
	Prepare samples according to established procedures
	Follow appropriate test procedures/instructions
	Document data & results according to established procedures
	Interpret and/or analyze data & results as appropriate
Critical Work Function: Comply with applicable regulations and standards	
Key Activities	Follow established policies and procedures
	Record information according to established procedures
	Exercise proper document control
	Participate in required training
	Respond to audit-related activities
	Adhere to control principles in accordance with the established quality system
	Adhere to traceability principles
	Participate in validation activities
	Recognize and address nonconformances
Critical Work Function: Manage and communicate information	
Key Activities	Comply with company communication policies
	Communicate information in an appropriate manner
	Assist in reviewing/commenting, revising, and writing technical documents
	Suggest continuous improvements
	Use computer tools effectively
Critical Work Function: Perform mathematical manipulations	
Key Activities	Perform calculations relating to work function
	Perform data analysis

[1] *Occupational Safety and Health Administration*
[2] *Environmental Protection Agency*
[3] *Centers for Disease Control and Prevention*
[4] *Material Safety Data Sheets (Safety Data Sheets)*

Industry Recognition Process

Industry feedback was collected through an online survey and face-to-face meetings. Only industry representatives who had experience directly supervising entry-level technicians participated in the online survey. Although results reported in the table below are grouped according to Critical Work Functions (CWF), reviewers gave feedback on each individual activity within the CWFs.

Direct industry feedback was obtained from the following sources:

- c^{3}bc Consortium National Advisory Council
- Subject Matter Experts (two SMEs reviewed the standards through a preliminary version of the online survey)
- 22 Industry representatives from across the three industry subsectors gave feedback through the final online survey

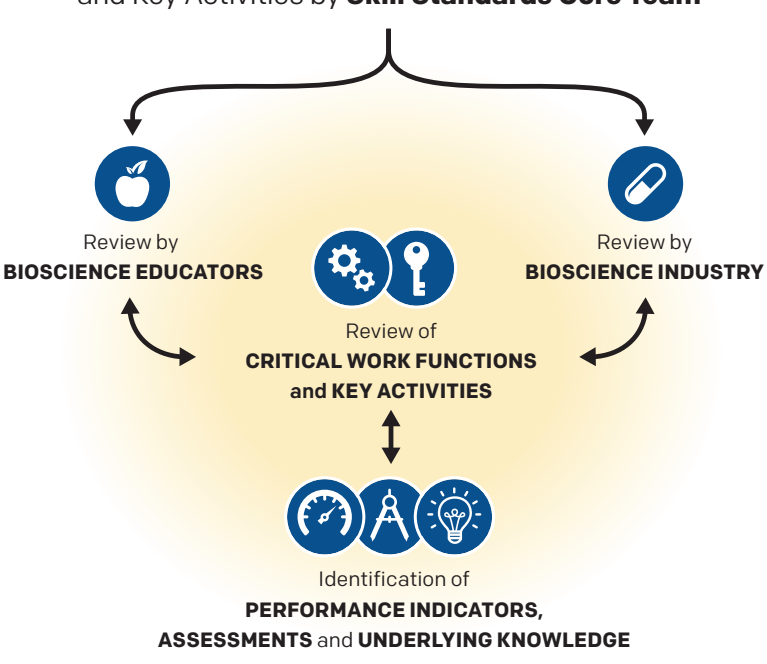
Results from the industry review process indicated the following:

Critical Work Function	% of companies whose employees perform the Key Activities/Tasks comprising the Critical Work Function
Maintain a safe and productive work environment	98.6
Provide routine facility support	91.5
Perform measurements / tests / assays	100
Comply with applicable regulations and standards	93.7
Manage and communicate information	100
Perform mathematical manipulations	100

Formation of Skill Standards Core Team

The Core Team was formed by appointing a representative from each industry subsector hub to identify common skills. Each representative on the Core Team was an experienced bioscience workforce educator with prior industry experience.

Core Bioscience Skill Standards Development Process



HOW EDUCATORS CAN USE THE CORE BIOSCIENCE SKILL STANDARDS

Previous sets of bioscience skill standards were comprehensive and have proved useful as a vocabulary for educators in designing and revising curriculum and in communicating with industry and with students. As the industry matured, workforce needs have expanded with an increased demand for technicians. Because educators have limited time to prepare students for a wide range of workplace settings, placing the emphasis on core skills allows educators to focus their curriculum design and teaching efforts on the fundamentals that get students hired and promoted in the industry.

For example, Forsyth Technical Community College in North Carolina used the new core skill standards to design entry-level courses that are the first step in an educational pathway (stackable credentials). Even if new programs are not developed, the standards can be used to evaluate existing curriculum to ensure that adequate weight is given to basic, but very important workplace competencies. It is important to note that individual hubs also have comprehensive subsector specific skill standards. Information about how to access these skill standards can be found in the Resources section on page 16.

"The core skill standards formed the basis for development of our Biotechnology Laboratory Technician Competency Manual which is used to document student laboratory skills prior to internship placement."

Dr. Mary Ellen Kraus, Biotechnology Program Director, Madison Area Technical College

"The core bioscience skill standards are a valuable tool for educators to use when developing industry relevant skill based courses that will result in well trained and employable graduates. At MCCC we incorporated these standards into the biotechnology and biomanufacturing courses that make up our certificate program."

Dr. Margaret Bryans, Assistant Professor Biotechnology, Montgomery County Community College

"The Core Bioscience Skill Standards that were developed by c³bc has enabled the development of entry level and marketable skills certificates that 4-year, 2-year, and high school students will be able to use to get jobs! "

Linnea Fletcher Ph.D, Biotechnology Department Chair, Austin Community College

CORE Team members outlined suggestions for ways that educators can use the new skill standards:

- To review existing curriculum and ask if these Critical Work Functions and Key Activities are addressed, and if so, determine if adequate weight is being given to them.
- To develop new courses, revise existing ones, and organize existing courses into stackable credentials.
- To serve as a ongoing reminder that although the latest biotechnology techniques are exciting and engaging for faculty and student alike, it is often the fundamentals that get students hired and promoted.
- As a common vocabulary for discussing workplace-relevant skills working with industry advisory boards, students and other educators.
- To promote career awareness about what bioscience technicians do in the workplace, e.g. students will be more likely to see concrete relationships between what they are learning in school and what the workplace requires.
- To engage local employers and/or industry associations in a dialogue about how to address their workforce challenges and hiring needs.
- To work with employers to establish internships and work experience opportunities for students.
- To improve teaching of foundational knowledge and assessment of students' proficiency in performing Key Activities.

"We reviewed all of the major learning outcomes, course objectives, and class activities in each course we developed to ensure that the core bioscience skill standards were embedded wherever applicable. We also developed an alignment matrix to evaluate the overlap between the core skill standards and state curriculum framework from which we developed the AS degree in Biomedical Engineering Technology."

Giovanna A. Taylor, Director, Biomedical Technology/Medical Devices, St. Petersburg College

HOW EMPLOYERS CAN USE THE CORE BIOSCIENCE SKILL STANDARDS

As with previous bioscience skill standards, core standards can, at a minimum, provide a useful vocabulary to advise and evaluate workforce preparation programs and their graduates. Some employers may also choose to use the standards as a guideline for evaluation and design of their own training programs and the structure of student internship opportunities. For example, representatives from Herbalife and Wake Forest Institute for Regenerative Medicine (North Carolina) have expressed interest in using these core skill standards as a tool for training their employees.

Skill Standards: Value To Employers

- Provide a vocabulary for collaboration with educators and employees.
- Identify core competencies and assess workers' abilities to demonstrate competencies.
- Interviews, performance reviews, and productivity can be evaluated and assessed to a higher degree of accuracy and efficacy.
- More easily document employee skills, training needs, and performance criteria.
- Establish or modify employee training programs.
- Developing internships and school-to-work initiatives with community colleges.

"These Core Bioscience Skill Standards and the associated assessments can help to improve the quality of teaching and learning at community colleges, providing our employers with highly qualified candidates who are ready to go to work and contribute to the success of our member companies."

Gardner Carrick, Vice President, Strategic Initiatives, The Manufacturing Institute, National Association of Manufacturers

"Since its inception the Biopharmaceutical industry has hired workers with highly variable training. The Core Bioscience Skill Standards will ensure a uniform skill level for new workers allowing the whole industry to be confident in their human resource investments."

Robert Rehfuss, Ph.D, c^{3}bc National Advisory Council, former Principal Investigator Bristol-Myers Squibb, and Adjunct Professor Bucks County Community College

"All employers train their employees, but it is much easier to train a worker who has been educated in a program that is aligned with the Core Bioscience Skill Standards. It will result in a reduction in training costs and a better quality employee."

Subhash Karkare, Ph.D, Professor of Biotechnology, Moorpark College and former Associate Director of Manufacturing, Amgen

ASSESSMENTS

Authentic Assessments

Although skill standards establish which skills are necessary and provide useful information for stakeholders, skill standards alone do not tell the individual whether they have succeeded in meeting that standard. It is through the design of **"authentic"** assessments that the full potential of these standards can be realized. Authentic assessments are performance based and, in this context, designed to mimic actual workplace activities and desired outcomes as closely as possible. Once appropriate assessments have been identified, curriculum can be reviewed to determine that the necessary topics and foundational skills have been covered sufficiently for the student to succeed. Authentic assessments are challenging to design and implement, but they are critical to adequate workforce preparation. The types of possible "authentic assessments" include performance activities, case studies and scenarios (e.g. mock production lines, audits).

Underlying Knowledge and Preliminary Assessments

Key Activities were chosen because they are a workplace competency; but an educator does not begin by instructing at this level. Considerable learning needs to take place before the student is ready to accomplish this more complex activity.

For example, in the chart on the following page, the Bioscience Lab Skills assessment for the Key Activity "Follow appropriate test procedures/instructions" is execution of a Bradford protein assay. To perform a Bradford protein assay successfully, a student will need to master underlying knowledge and skills so she can choose the appropriate reagents, test tubes and measuring devices; master the skill of pipetting accurately; as well as become familiar with many principles of metrology including types and causes of measurement error, the concept of traceability, and measures of descriptive statistics.

Preliminary assessments for underlying knowledge and skills will therefore be necessary prior to the "performance assessment".

ASSESSMENTS

Industry-Specific Assessments

The Key Activities included in the skill standards are typically performed by technicians working in all three industry subsectors. While the fundamental meaning of a Key Activity is shared, the task itself may vary in its execution among the different bioscience areas. For example, although both Bioscience Lab Skills and Biomanufacturing educators will need to assess the student's ability to prepare multicomponent solutions, the scale of the manufacturing facility will dictate the volume needed and therefore the type of equipment used for assessment. For some activities, these differences are addressed within the skill standards by offering industry-specific Assessments.

An assessment may be developed by the instructor using the Performance Indicator as a guide, or an assessment from the "Assessment Library" may be used (see page 15 for more information on the Assessment Library). Recommended assessments are "authentic assessments" that are most closely related to what a person would do "on the job".

The example below demonstrates how the Key Activity: "Follow appropriate test procedures/instructions" can have different Assessments for each of the industry subsectors.

Critical Work Function: Perform Measurements, Tests, Assays

Key Activity: Follow appropriate test procedures/instructions

	Biomanufacturing	Medical Devices	Lab Skills
Performance Indicator	Biomanufacturing tests are performed according to established procedures and accurate results are obtained.	Medical Devices tests are performed according to established procedures and accurate results are obtained.	Laboratory tests are performed according to established procedures and accurate results are obtained.
Underlying Knowledge	Appropriate use of relevant test equipment including relevant measurement range and sensitivity of different measurement tools; types and causes of measurement error; Distinction between accuracy, precision; appropriate documentation; Science of metrology, Concept of traceability of standards.	Same	Same
Assessment	Endotoxin test on production samples are performed according to established procedure and appropriate results are obtained.	Environmental monitoring such as CFU counts on settled plates or particle counts.	Bradford protein assay: Concentration of a sample is accurately determined using a spectrophotometer assay according to established procedure.

Assessment Library

Consortium members and other educators have begun populating an online "Assessment Library" on the Core Bioscience Skill Standards website: https://sites.google.com/site/c3bcbioscienceskillstandards/.

Assessments are currently being identified and/or developed that will address each Key Activity. In some cases, a single assessment will address multiple Key Activities.

Importantly, educators can contribute assessments or instructional materials to the on-line Assessment Library to help build a robust collection of assessments that will enhance the impact of the Core Bioscience Skill Standards project. The Core Team members hope that the online Assessment Library will continue to grow beyond the life of the c^{3}bc grant.

While there will be many assessments that can be used by all three areas of bioscience, some assessments are subsector specific and will require adaptation for differences in instructional environments.

The following is an example of an Assessment for a Key Activity that can be found at the Assessment Library website: https://sites.google.com/site/c3bcbiosciencesskillstandards/assessments-drafts-1

Critical Work Function: Maintain a safe and productive work environment

Key Activity: Recognize unsafe conditions and take corrective and/or preventative action(s)

Assessment:

Before working in any lab or facility, students should be aware of all of the hazards and safety equipment within that space. Students can be tested on their awareness of these features by asking them to draw a diagram of a laboratory or facility in which they work and asking them to label the diagram with the relevant hazards and safety features. Students' diagrams should include the following:

- Entrance/exit doors
- Fume hoods
- Hazardous waste disposal receptacles
- Fire extinguishers
- Eye wash
- Sink
- Chemical spill kit
- Broom and dust pan (may be included in spill kit)
- Storage locations for hazardous chemicals

Resources for Teaching:

- Seidman, L.A., and C.J. Moore. 2009. Introduction to a Safe Workplace. pp 133-144 In: Basic Laboratory Methods for Biotechnology Pearson Education, Inc., San Francisco, CA.
- Seidman, L.A., and C.J. Moore. 2009. Working Safely in the Laboratory: General Considerations and Physical Hazards. pp 145-160 In: Basic Laboratory Methods for Biotechnology Pearson Education, Inc., San Francisco, CA
- Seidman, L.A., M.E. Kraus, D.L. Brandner, J. Mowery. 2011. Classroom Activity 3: Responding to Emergencies. Pp 9-11 In: Laboratory Manual for Biotechnology and Laboratory Science Pearson Education, Inc., San Francisco, CA.

RESOURCES

For Teaching Core Bioscience Skills

Many resources for teaching Core Bioscience Skills can be found on the Bio-Link and NBC2 websites (see below). Resources that were developed from DOL grant funding, including those developed by the Learning Technologies Hub, are available via the open source repository, https://Skillscommons.org/handle/taaccct/441. In addition, the National Center for the Biotechnology Workforce (NCBW) has many helpful resources that can be found at www.biotechworkforce.org.

Selected resources are listed below according to the three skill categories.

Bioscience Lab Skills

- Bio-Link.org: Courses in a box section. www.bio-link.org/home/courses
- Seidman, L. A. Basic Laboratory Calculations for Biotechnology. San Francisco, CA: Pearson Benjamin Cummings, 2008. Print.
- Seidman, L.A., and C.J. Moore. Basic Laboratory Methods for Biotechnology. San Francisco, CA: Pearson Benjamin Cummings, 2009. Print
- Seidman, L.A., M. E. Kraus, D. L. Brandner, and J. Mowery. Laboratory Manual for Biotechnology and Laboratory Science: The Basics. San Francisco, CA: Benjamin Cummings, 2011. Print.
- Biotech-careers.org

"The Core Skill Standards are very significant as they identify the most fundamental and transferable skills within the broad spectrum of the bioscience industry. The Bioscience Core Skill Standards provided the Medical Device Hub with the valuable framework in developing the first Medical Device industry skill standards."

Dr. Sengyong Lee, Medical Device Hub Leader,
Ivy Tech Community College

Biomanufacturing Skills

- Northeast Biomanufacturing Center (NBC2) http://biomanufacturing.org/ (Curriculum drop-down menu)
- Bryans, M. Introduction to Biomanufacturing. S.I.: Northeast Biomanufacturing Center & Collaborative, 2012. Print. Individual chapters available for download at biomanufacturing.org. Hardcover copy available at Lulu.com
- Bryans, M. Biomanufacturing Laboratory Manual. S.I.: Northeast Biomanufacturing Center & Collaborative, 2011. Individual chapters available for download at biomanufacturing.org. Hardcover copy available at Lulu.com
- Biotech-careers.org

Medical Device Skills

- Atles, L.R. A Practicum for Biomedical Engineering and Technology Management Issues. Dubuque, IA: Kendall Hunt Pub, 2008. Print.
- Ogrodnik, P. J. Medical Device Design: Innovation from Concept to Market. Amsterdam: Elsevier/Academic, 2013. Print.
- Saltzman, W. Mark. Biomedical Engineering: Bridging Medicine and Technology. 2nd ed. Cambridge: Cambridge UP, 2015. Print.
- Villafañe, C. R. Biomed: From the Student's Perspective. 2009. Web. <Techniciansfriend.com>.
- Willson, K. Medical Equipment Management (Series in Medical Physics and Biomedical Engineering). 1st ed. Boca Raton: CRC, 2013. Print.
- Biotech.careers.org

Medical Device courses and course content that were developed with grant funds are available at https://Skillscommons.org/handle/taaccct/441. Topics include: Quality Practices; Product Life Cycle; Root Cause Investigations; Introduction to Inspection Metrology.

Bioscience Skill Standards: Past and Present

Core Bioscience Skill Standards

Links to the complete Core Bioscience Skill Standards can be found at this website. Updates will also be posted here. https://sites.google.com/site/c3bcbioscienceskillstandards/

Links to the Core Skill Standards will also be available through www.biotechworkforce.org; www.ncbionetwork.org; www.skillscommons.org; and www.Bio-Link.org.

Industry Subsector Skill Standards and Past Skill Standards

This page includes skill standards from each subsector hub and links to previous bioscience skill standards.

http://www.bio-link.org/home2/resource/bioscience-skill-standards

References

U.S. Department of Labor's (USDOL) Bioscience Competency Model. www.careeronestop.org/competencymodel/competency-models/bioscience.aspx

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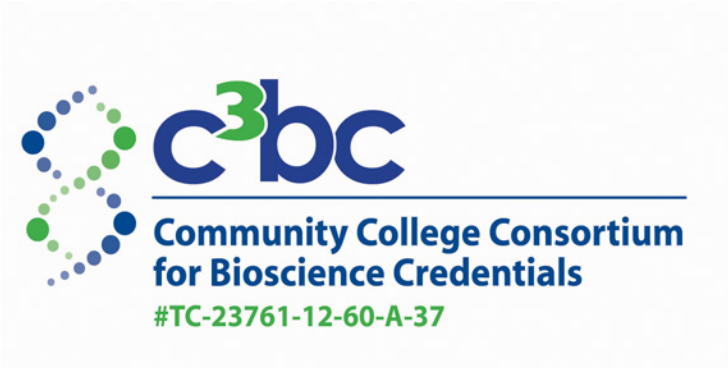
1995: Leff, J. *Gateway to the Future: Skill Standards for the Bioscience Industry*. Education Development Center. https://secure.edc.org/publications/prodview.asp?261

1994: Agricultural Biotechnology Technician; National Voluntary Occupational Skill Standards, National FFA Foundation. files.eric.ed.gov/fulltext/ED413487.pdf



Core Bioscience Skill Standards

for

Biotechnology Laboratory Technicians, Medical Device Technicians, and Biomanufacturing Technicians

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For more detailed assessments, and a glossary for key words, please visit: https://sites.google.com/site/c3bcbiosciencesskillstandards/

CRITICAL WORK FUNCTION: Maintain a safe and productive work environment

Key Activity: Recognize unsafe conditions and take corrective and/or preventative action(s)

Performance Indicators:

- Different types of hazards (biological, chemical, physical, electrical, radiological) are identified
- Emergency procedures are demonstrated

Underlying Knowledge:

- Meaning of safety symbols and signs
- Basic understanding of electricity and electrical hazards
- Types of physical hazards
- "Right to know" laws
- Purpose and proper use of safety equipment (e.g. fire extinguisher operation)
- Proper identification, handling and storage of biological hazards
- Proper handling and storage of radiological hazards
- General procedure one would follow in various emergency situations

Suggested Assessments:

- Have student make a map of all safety equipment in facility/teaching lab.
- Provide students with the following scenario: You walk into the Prep Room and see a bottle had fallen off the shelf and broken on the floor, spilling most of its chemical contents. Demonstrate (or describe) what you would do and why.

Key Activity: Follow relevant safety policies, guidelines, and regulations (e.g. company, OSHA, EPA, CDC)

Performance Indicators:

- LOTO procedures are demonstrated
- Appropriate resources to identify proper disposal/ waste treatment procedures are used

Underlying Knowledge:

- OSHA Hazard Communication Standards (HCS), 29 CFR 1910.1200; OSHA HCS guidance document
- "Right to Know" laws
- Sources of safety information

Suggested Assessments:

- Execute the steps needed, in the correct order, to properly LOTO the piece of equipment in preparation for maintenance.
- Choose a chemical/material and ask student to: (1) retrieve SDS, (2) identify PPE, (3) describe special handling procedures, and (4) describe special hazardous waste and disposal procedures.

CRITICAL WORK FUNCTION: Maintain a safe and productive work environment

Key Activity: Access and use MSDS (SDS) and other safety information sources

Performance Indicators:

- Safe material handling and storage is demonstrated

Underlying Knowledge:

- Know where to find MSDS (SDS) and apply containing information to workplace
- Types of hazardous chemicals
- Routes of entry for toxic chemicals
- Symptoms of exposure to hazardous materials
- Definitions of mutagen, carcinogen, and teratogens
- Toxicity assessment terminology (LD-50, etc)

Suggested Assessments:

- Have student reference a MSDS (SDS) for a particular chemical, specify the PPE needed, the storage considerations, and spill clean-up methods for that chemical.

Key Activity: Maintain a safe, clean, contamination-free and clutter-free environment, as appropriate

Performance Indicators:

- Workspace is wiped down and tidied before and after use
- Workplace organization (e.g. 5S tool: sort, systematic arrangement, shine, standardize, and sustain) philosophy is demonstrated
- Line clearance prior to activity is demonstrated
- Environmental monitoring activities are performed

Underlying Knowledge:

- Nature of contamination and the principles of containment, sterilization, and disinfection
- Knowledge of cleaning agents
- Knowledge of company procedures (based on OSHA, cGMP, etc)

Suggested Assessments:

- Have student demonstrate or describe the appropriate process flow to avoid cross contamination.
- Have student perform air sampling and particulate counting in the tissue culture hood, in the cell culture room, and/or in the biomanufacturing suite (especially near the bioreactor vessels)

Key Activity: Select appropriate PPE to use to protect self from biological, chemical, and/or physical hazards

Performance Indicators:

- Different types of PPE are identified and their function are described

Underlying Knowledge:

- Types of PPE and when to use each

Suggested Assessments:

- Have student identify all required PPE for performing a designated assay or task.

CRITICAL WORK FUNCTION: Provide routine facility support

Key Activity: Monitor, maintain, and troubleshoot equipment

Performance Indicators:

- Preventative maintenance is performed and equipment logbook is maintained
- Monitoring activities are performed and documented according to established procedures
- Basic equipment troubleshooting is performed

Underlying Knowledge:

- Maintenance requirements of different pieces of equipment
- Proper documentation practices

Suggested Assessments:

- Describe a specific piece of equipment that is not working. Have student access user manual and list reasons why equipment is not working.

Key Activity: Use equipment correctly according to manufacturer's guidelines

Performance Indicators:

- Equipment performance is verified prior to use
- Recommended operating conditions of the equipment is used
- Initialization and shutdown of equipment is performed correctly

Underlying Knowledge:

- Concepts of calibration, verification, qualification, validation
- General principles of metrology
- Use of calibration standards and traceability

Suggested Assessments:

- Describe/show what must be considered prior to use of a particular piece of equipment.

CRITICAL WORK FUNCTION: Provide routine facility support

Key Activity: Maintain inventory of raw materials, parts, components and/or equipment

Performance Indicators:

- Periodic inventory of stock/supplies taken in compliance with established procedures
- Material, parts, and equipment inventory are stored appropriately
- Expired materials, parts, and equipment are discarded according to established procedures

Underlying Knowledge:

- Inventory control principles and rules for ordering
- Storage considerations of materials

Suggested Assessments:

- Have student demonstrate how to process incoming materials, parts, components or equipment based on a mock SOP.
- Have student perform an inventory of materials, parts, and equipment, and explain what the next steps should be (e.g. (re)ordering, obsoleting, discarding, expired, etc.) based on the inventory results.

Key Activity: Prepare materials/ supplies/ equipment for use

Performance Indicators:

- Correct selection and quantity of necessary materials/ supplies/ equipment for the activity is gathered
- Materials/ supplies/ equipment are prepared correctly

Underlying Knowledge:

- Impact of preparation and efficiency on task execution
- Knowledge of cleaning agents and procedures
- Knowledge of hazardous material handling and disposal
- Proper glassware cleaning procedures
- Knowledge of sterilization procedures

Suggested Assessments:

- Have student demonstrate the necessary set-up to run a particular test/assay or use of a piece of equipment.

CRITICAL WORK FUNCTION: Perform measurements / tests / assays

Key Activity: Collect samples according to established procedures and applicable sampling plans

Performance Indicators:

- Samples of sufficient quality and quantity are taken

Underlying Knowledge:

- Sampling procedures for the material/ product and sampling plans to be followed for testing
- Chain of custody requirements for samples

Suggested Assessments:

- Have student demonstrate the collection and preparation of samples for testing according to an in-process testing procedure (provided) that has been simulated.

Key Activity: Prepare samples according to established procedures

Performance Indicators:

- Collected samples are handled, labeled, and stored (if necessary) correctly prior to testing
- Manipulation to create test-ready samples is performed as needed

Underlying Knowledge:

- Chain of custody requirements for samples

Key Activity: Follow appropriate test procedures/ instructions

Performance Indicators:

- Tests are performed according to established procedures
- Appropriate measurement/ test tool(s) is(are) chosen for the application
- Measurement/ test tool(s) is(are) used correctly

Underlying Knowledge:

- Appropriate use of applicable test equipment
- Types and causes of measurement error
- Distinction between accuracy and precision
- Relevant measurement range and resolution of different tools
- Uncertainty in measurement
- Importance and purpose of positive and negative controls

Suggested Assessments:

- Have student measure and compare the critical characteristics of a received raw material against the specifications according to established procedures.
- Concentration of a sample is determined accurately using a colorimetric spectrophotometry assay.
- Endotoxin tests on production samples are performed according to established procedures.

CRITICAL WORK FUNCTION: Perform measurements / tests / assays

Key Activity: Document data and results according to established procedures

Performance Indicators:

- Lab notebook is maintained properly
- Batch records are completed properly
- Information is entered correctly in an electronic database

Underlying Knowledge:

- Importance of proper documentation practices

Suggested Assessments

- Student accurately analyzes documentation errors in lab notebook, batch record or other documentation as appropriate for industry subsector

Key Activity: Interpret and/or analyze data and results as appropriate

Performance Indicators:

- Test-specific mathematical calculations are performed
- Data and results are presented in an appropriate manner

Underlying Knowledge:

- Principles of descriptive statistics
- Use of graphs, tables, etc.

Suggested Assessments:

- Have student perform statistical analysis (mean, standard deviation, % error, etc) for test results or fixed set of data.

CRITICAL WORK FUNCTION: Comply with applicable regulations and standards

Key Activity: Follow established policies and procedures

Performance Indicators:

- SOP or procedure is executed correctly and completely
- Deviations are handled appropriately

Underlying Knowledge:

- Familiarity with applicable current federal, state, local and industry regulations and standards
- Familiarity with the FDA (e.g. history, enacted laws/ promulgated regulations, organizational structure, premarket approvals, etc.)
- Consequences of noncompliance
- Types of documents (quality manual, quality policy, standard operating procedures, work instructions, etc.)
- Policy/ procedures for deviations

Suggested Assessments:

- Correctly follow an SOP or procedure and complete a batch record or lab notebook entry to execute a task.

Key Activity: Record information according to established procedures

Performance Indicators:

- Good documentation practices are demonstrated
- Form, record, or notebook (as appropriate) is correctly utilized to capture the necessary information

Underlying Knowledge:

- Knowledge of Good Documentation Practice principles
- Types of records (lab notebooks, batch records, logs, design history files, master records, production records, etc.) and how to properly complete each type

Suggested Assessments:

- Have student complete batch records or lab notebook entries that have been assigned for lab activities.

Key Activity: Exercise proper document control

Performance Indicators:

- Changes to documents are made in accordance to established change control system

Underlying Knowledge:

- Concepts related to document changes, approvals, and distribution/controlled documents

Suggested Assessments:

- Have student make revisions to an existing controlled procedure.

CRITICAL WORK FUNCTION: Comply with applicable regulations and standards

Key Activity: Participate in required training

Performance Indicators:

- Required training is completed by the specified deadline and competencies are demonstrated

Underlying Knowledge:

- Formal training process and mandatory requirements in regulations/ standards
- Training matrix, training policies in effect, re-training frequencies, and consequences of missed (re) training deadlines

Suggested Assessments:

- Present student with the following scenario: You are a manufacturing tech and a new version of the manufacturing procedures was just approved. What does that mean to you? Explain.

Key Activity: Respond to audit-related activities

Performance Indicators:

- Knowledge of position-specific role in the audit process is demonstrated

Underlying Knowledge:

- Types of audits and the audit process

Suggested Assessments:

- Have student demonstrate appropriate behaviors during a mock audit with role playing.

Key Activity: Adhere to traceability principles

Performance Indicators:

- Items (e.g. raw materials, in-process product, final product, samples, etc.) are labeled appropriately
- Material lot numbers/ equipment identification numbers are recorded

Underlying Knowledge:

- Concept and importance of traceability within the bioscience workplace
- Traceability of materials, documentation, and training

Suggested Assessments:

- Have student review a completed batch record for compliance, e.g. lot numbers and equipment ID numbers.

CRITICAL WORK FUNCTION: Comply with applicable regulations and standards

Key Activity: Adhere to control principles in accordance with the established quality system

Performance Indicators:

- Knowledge of change control is demonstrated
- Knowledge of purchasing controls are demonstrated
- Knowledge of production and process controls is demonstrated
- Knowledge of labeling and packaging controls are demonstrated
- Knowledge of materials management/ control is demonstrated

Underlying Knowledge:

- General change control philosophy
- Potential consequences that may arise when change is not controlled
- Supplier relationships, supplier agreements, supplier qualifications, supplier management, supply chain management, purchasing documentation, traceability, and approvals
- General philosophy with consideration of materials, methods, machine, man, and environment; monitoring program; material control and traceability; established procedures and compliance with them; equipment monitoring, inspection, maintenance, and repair; personnel with appropriate and current training; facility and environmental control for product/process quality/ consistency
- Label integrity, appropriate label information content, inspection of labeling, storage and controlled issuance for use, packaging selection considerations
- Incoming raw materials handling (quarantine, acceptance or rejection after inspection/ QC testing, storage for use or disposition of rejected material), FIFO (first in first out), inventory, purchasing

Suggested Assessments:

- Have student propose a design for a cGMP facility that enables appropriate work flow

Key Activity: Participate in validation activities

Performance Indicators:

- Draft procedure is tested and feedback to author is provided

Underlying Knowledge:

- Types of validation: equipment (IQ, OQ, PQ), methods, process

Key Activity: Recognize and address non-conformances

Performance Indicators:

- Appropriate corrective and/or preventative action(s) is(are) taken and documented

Underlying Knowledge:

- Nature of specifications for raw materials and products

CRITICAL WORK FUNCTION: Manage and communicate information

Key Activity: Comply with company communication policies

Performance Indicators:

- Consequences of noncompliance are explained
- Internal and external complaints are routed through the appropriate channels

Underlying Knowledge:

- Purpose of nondisclosure agreements
- Social, legal and ethical issues relating to information and its use

Key Activity: Communicate information in an appropriate manner

Performance Indicators:

- Proper communication method is chosen (e.g. formal reports, memos, e-mail, etc.)
- E-mail responses to a scenario meet assessment criteria
- Formal presentations are delivered according to assessment criteria

Underlying Knowledge:

- Types of communication methods and their best uses
- Safety and security of email (e.g. permanent nature of documented communication)
- Appropriate and inappropriate style and content for electronic correspondence
- Characteristics of an effective presentation (visual and oral)

Suggested Assessments:

- Have student respond to a mock company email.

Key Activity: Assist in reviewing/ commenting, revising, and writing technical documents

Performance Indicators:

- Errors in technical documents are recognized and appropriate changes are suggested
- The typical sections of an SOP are identified and explained

Underlying Knowledge:

- Required components of technical documents

Suggested Assessments:

- Have student review and revise an SOP, report, or other document written by another person.

CRITICAL WORK FUNCTION: Manage and communicate information

Key Activity: Suggest continuous improvements

Performance Indicators:

- Inefficiencies are recognized and appropriate action is taken

Underlying Knowledge:

- Thorough preparation prior to beginning work

Suggested Assessments:

- Require student to set up a work space for a particular assay or task. Evaluate the student's workspace for the necessary materials, tools, and equipment.

Key Activity: Use computer tools effectively

Performance Indicators:

- Basic word processing tasks are performed
- Spreadsheet software is used with reasonable proficiency
- Presentations are created according to recommended guidelines
- Access online information
- Other workplace-relevant software applications are navigated proficiently

Underlying Knowledge:

- Basic features of word processing applications
- Basic features of spreadsheet applications
- Different types of graphs and the scope of use of each type
- Familiarity with the different functions available for formulas
- Basic features of presentation applications
- Characteristics of effective presentations
- Effective search criteria and operators
- Usage and purpose of position-specific applications

CRITICAL WORK FUNCTION: Perform mathematical manipulations

Key Activity: Perform calculations relating to work function

Performance Indicators:

- Basic manipulations involving exponents are performed correctly
- Conversions between standard and scientific notation are performed correctly
- Calculations of logs and antilogs for powers of ten are performed correctly
- Conversions between units of measure (e.g. within the metric system and between metric and US systems) are performed correctly
- Behavior of one variable in an equation with changes in another variable are predicted correctly
- Multiple step problems requiring use of ratios and proportions are solved correctly

Underlying Knowledge:

- Appropriate mathematical handling of exponents and the meaning of significant figures
- Difference between "ratios" and "proportions"
- Common use of log and benefit of using a semi-log plot
- Metric system and common prefixes, US system, and conversion between related units of measure
- Relationships of variables in equations (e.g. directly related versus inversely related)
- Dilution calculations, C1V1=C2V2, solutions containing multiple solutes

Suggested Assessments:

- Ask students to calculate cell density given the number of bacterial colonies on a plate that resulted from serial dilution. Cell density should be reported in scientific notation.
- Give students an equation, such as PV=nRT, and ask students how one variable will be affected when a different variable is increased or decreased.

Key Activity: Perform data analysis

Performance Indicators:

- Data is correctly analyzed using descriptive statistical functions
- Data is graphed using the appropriate graphic method

Underlying Knowledge:

- Purpose of various statistical functions
- Standard curve principles
- Appropriate use of various graphs

Suggested Assessments:

- Provide students with data for constructing a standard curve and evaluate for correct graphing of data points, graph labels, line equations, etc.

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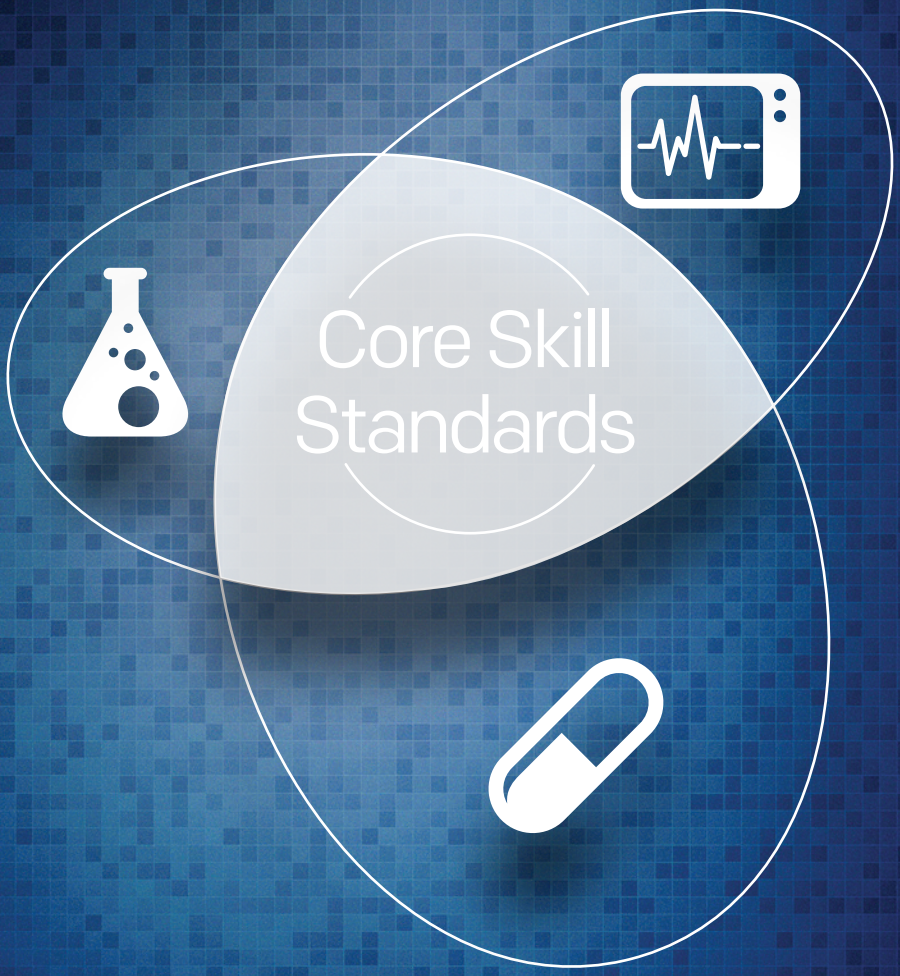

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