Biomanufacturing Skill Standards
(Upstream, Downstream, Microbiology and Chemistry Technicians)

TEXAS WORKFORCE INVESTMENT COUNCIL

BIOMANUFACTURING SKILL STANDARDS

Critical Work Function	Key Activity	Key Activity	Key Activity	Key Activity	Key Activity	Key Activity	Key Activity	Key Activity
1. Follow/write documents and manage records	1.1 Follow Standard Operating Procedures (SOPs)	1.2 Fill out batch records	1.3 Document and analyze data	1.4 Write technical reports	1.5 Maintain equipment logbooks	1.6 Participate in change control activities	1.7.Obtain and review trend and benchmark data	1.8 Assist in execution of validation procedures
2. Clean and maintain environment	2.1 Clean laboratory environment	2.2 Attend company safety and security training	2.3 Report unsafe conditions	2.4 Maintain laboratory security				
3. Clean, maintain, and trouble-shoot equipment	3.1 Clean and maintain basic laboratory equipment	3.2 Clean and maintain cell culture and fermentation equipment	3.3 Perform calibration of instruments	3.4 Perform preventive maintenance and schedule vendor maintenance	3.5 Perform equipment qualification	3.6 Participate in installation and modification of equipment		
4. Prepare items for laboratory and biomanufacturing activities	4.1. Order materials	4.2. Store materials	4.3 Prepare glassware	4.4. Prepare equipment	4.5. Make media, solutions, and buffers	4.6 Store media, solutions, buffers, and reagent batches		
5. Perform cell culture and fermentation	5.1 Prepare working cell bank	5.2 Initiate starter cultures	5.3 Perform scale-up operation	5.4 Inoculate seed reactor and perform media addition	5.5 Monitor culture	5.6 Execute sampling and assess material for process release	5.7 Perform process release for product	
6. Perform testing and data analysis	6.1 Perform microbiology testing	6.2 Perform chemical testing	6.3 Perform upstream testing	6.4 Perform downstream testing	6.5 Troubleshoot aberrant results or parameters			
7. Perform product purification and prepare for shipping	7.1 Prepare purification equipment	7.2 Receive product from upstream processing	7.3 Filter product as necessary	7.4 Perform chromatography steps	7.5 Remove contaminants, and concentrate product as necessary	7.6 Bulk fill purified product for storage	7.7 Complete final formulation	
8. Provide information to and train staff and customers	8.1 Communicate with co-workers to ensure quality work	8.2 Provide technical assistance to customers	8.3 Provide training to co-workers					

BIOMANUFACTURING SKILL STANDARDS

Occupational Title: Biomanufacturing			
Critical Work Function 1: Follow/Write Documents and Manage Records		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
1.1 Follow Standard Operating Procedures (SOPs)	1.1.1 Procedure or product is researched 1.1.2 Quality Assurance (QA) format for SOPs is followed 1.1.3 Procedures are technically written 1.1.4 SOP is clear and readable 1.1.5 Grammar used is technically correct without room for interpretation	Knowledge of appropriate research techniques Knowledge of the functional side of document control Knowledge of SOPs and how the process works. Knowledge of cGMP (Current Good Manufacturing Practices and other related industry practices related to biomanufacturing) Knowledge of Employment Health & Safety Regulations (EH&S), Occupational Safety and Health Administration (OSHA), and other pertinent information	Access to appropriate research materials Company SOPs for indicated activities Appropriate template, software and hardware for writing SOPs cGMP information EH&S, OSHA and other pertinent information
1.2 Fill out batch records	1.2.1 Document provides step-by-step instructions 1.2.2 Document includes space for documenting task 1.2.3 Document includes title, nature, and purpose of procedure 1.2.4 Any correction to batch record is documented with date and signature 1.2.5 Document is reviewed and kept up to date	Knowledge of function of batch records Knowledge of filing process Knowledge of cGMP Knowledge of EH&S, OSHA and other pertinent information	Appropriate batch form template, software and hardware for preparing batch records cGMP information EH&S, OSHA and other pertinent information
1.3 Document and analyze data	1.3.1 Peer assay data is reviewed for accuracy and cGMP compliance 1.3.2 Data is filed in appropriate location based on company policy	Knowledge of cGMP Knowledge of filing process Knowledge of company policies	cGMP information Appropriate software and hardware Company policies

Occupational Title: Biomanufacturing			
Critical Work Function 1: Follow/Write Documents and Manage Records		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
1.4 Write technical reports	1.4.1 Reports are legible and clear 1.4.2 SOP format is followed 1.4.3 Time for applicable project codes is recorded 1.4.4 Data is analyzed using appropriate statistical analysis software	Knowledge of the writing process and software Knowledge of appropriate code for the project Knowledge of cGMP Knowledge of EH&S, OSHA and other pertinent information	Appropriate template, statistical analysis software, and hardware Project code list cGMP information EH&S, OSHA and other pertinent information
1.5 Maintain equipment logbooks	1.5.1 Logbook entries are completed in cGMP manner, including review by appropriate people, as required 1.5.2 Laboratory logbooks are compiled and archived periodically 1.5.3 Calibration/standardizations are recorded 1.5.4 Laboratory equipment activities are documented 1.5.5 Maintenance and out of service are documented	Knowledge of cGMP Knowledge of compiling and archiving logbooks Knowledge of procedures for recording calibration/standardization data Knowledge of procedures for documenting out of service	cGMP information SOP for Logbooks Appropriate logbook template and software is used Company Out of Service Forms
1.6 Participate in change control activities	1.6.1 Input into process changes is given 1.6.2 Changes to document according to approved system are performed 1.6.3 Changes are appropriately justified	Knowledge of process for change control Understanding of required documentation. Knowledge of cGMPs	Company SOPs Company approval forms. cGMP information

Occupational Title: Biomanufacturing			
Critical Work Function 1: Follow/Write Documents and Manage Records		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
1.7 Obtain and review trend and benchmark data	1.7.1 Assay raw data is accurately recorded on paperwork and appropriate data is entered into computer 1.7.2 Environmental action/out-of-spec follow-up reports are prepared 1.7.3 Data from testing results are analyzed with statistical analysis trends 1.7.4 Trend report is prepared 1.7.5 Appropriate Corrective Action and Preventative Action (CAPA) is taken	Ability to Review Reports Knowledge of the paperwork required to record the data. Knowledge of the analysis software and report format Knowledge of CAPA	Company SOPs Data Recording and Analysis Software cGMP information CAPA information
1.8 Assist in execution of validation protocols	1.8.1 Necessary parameters to monitor are identified 1.8.2 Acceptance criteria for equipment and or process specifications are identified 1.8.3 Validation procedure is written 1.8.4 Required approval for validation procedure is obtained 1.8.5 Procedure is validated based on acceptance criteria being met 1.8.6 Needed laboratory studies are performed 1.8.7 Validation report is written 1.8.8 If present during execution of procedure, discrepancies are documented and impact evaluated. 1.8.9 Necessary approval is obtained for validation report to implement change 1.8.10 Updated procedure is validated based on application of proper statistics	Knowledge of validation procedures Knowledge of statistical analysis applicable to this data set Knowledge of SOPs for writing and approval process for qualification report	Applicable SOPs Company approval forms Appropriate statistical software Appropriate hardware for writing validation procedures CGMP information

BIOMANUFACTURING SKILL STANDARDS

Academic and Employability Knowledge and Skill Matrix for Critical Work Function 1: Follow/Write Documents and Manage Records

On a scale of 1 (lowest) to 5 (highest), identify the level of complexity required in each of these skills for the worker to perform the critical work function. Keep in mind that this scale is not for rating an individual's proficiency. It is intended only for rating the level of complexity required to do the work.

Occupational Title: Biomanufacturing																
CWF 1 Follow/Write Documents and Manage Records																
Listening	Speaking	Using Information and Communication Technology	Gathering and analyzing Information	Analyzing and Solving Problems	Making Decisions and Judgments	Organizing and Planning	Using Social Skills	Adaptability	Working in Teams	Leading Others	Building Consensus	Self and Career Development	Writing	Reading	Mathematics	Science
4	3	4	4	3	3	3	3	2	3	2	3	3	4	4	2	4

Statement of Assessment for Critical Work Function 1: Follow/Write Documents and Manage Records

The statements of assessment can do any of several things:

- *Define tools or strategies that industry could use to assess the level of competency a worker has attained in a particular critical work function.*
- *Define for trainers and educators how to assess the level of competency a student has attained relevant to the critical work function.*
- *Define the level of mastery of the critical work function that indicates that a worker or student has achieved an entry-, intermediate-, or advanced level of mastery of a critical work function.*

A. Tests could include:

1) Multiple choice and essay questions that demonstrate an understanding of knowledge being assessed.
2) Preparation and justification of a reasonable solution to a problem scenario.

B. Hands-on exercises or simulations to demonstrate acquisition of knowledge and skills that could:

1) Apply relevant knowledge or skills
2) Focus on the application of knowledge and skills to a new situation
3) Demonstrate an ability to plan, organize, and create a product, service, or an event.
4) Illustrate by individual performance the attained levels of knowledge and skills.
5) Include observation of events, groups, and individuals that focuses on the relevant traits of the skill in question

Occupational Title: Biomanufacturing			
Critical Work Function 2. Clean and maintain environment		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
2.1 Clean laboratory environment	2.1.1 Company SOPs are followed 2.1.2 Personal protection equipment (PPE) such as gloves, eye protection, aprons and respirators are worn as needed 2.1.3 Appropriate gowning is used 2.1.4 Appropriate agent(s) and amounts for cleaning are used 2.1.5 Cleaning is documented	Knowledge of the cleaning agents, pest control and other pertinent information needed to clean and maintain the laboratory environment Knowledge of PPE Knowledge of gowning Knowledge of company EH&S, cGMP, and OSHA Knowledge of documentation Knowledge of basic chemistry	Company SOPs Cleaning Agents Gloves, goggles, apron, respirator Safety SOPs, Safety Data Sheets (SDSs) and related documentation Other PPE as needed Gowning Company safety forms for activity
2.2 Attend company safety and security training	2.2.1 Training records are updated and current 2.2.2 Certifications are obtained where applicable 2.2.3 Application of the training is demonstrated in performance of daily duties 2.2.4 Mandatory training is attended 2.2.5 Training opportunities are assessed and effectively utilized 2.2.6 Emergency procedures are practiced during drills and as part of emergency response teams 2.2.7 Unsafe conditions are identified and appropriate action taken	Knowledge of training opportunities and requirements for emergency and first aid procedures Knowledge of emergency response procedures and policies Knowledge of emergency drill and incident documentation procedures Knowledge of company security policy	Training records and certificates

BIOMANUFACTURING SKILL STANDARDS

Occupational Title: Biomanufacturing			
Critical Work Function 2. Clean and maintain environment		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
2.3 Report unsafe conditions	2.3.1 Lock-out/tag-out and line breaking procedures are followed for equipment 2.3 2 EH&S and OSHA regulations are followed	Knowledge of tag out and line breaking. Knowledge of EH&S and OSHA regulations Knowledge of inside of bioreactor, procedures for sterilization and disinfection.	Laboratory equipment Laboratory and laboratory plans (electrical, water, location of safety equipment, communication equipment) Company SOPs Safety Data Sheets (SDS)
2.4 Maintain laboratory security	2.4.1 Propietary documents are handled according to company security protocols 2.4.2 Communication concerning company documents and procedures is handled according to company security protocols	Knowledge of requirements and training opportunities regarding security Knowledge of posting and communication procedures for security alerts	Company Security protocols

Academic and Employability Knowledge and Skill Matrix for Critical Work Function 2: Clean and Maintain Environment

On a scale of 1 (lowest) to 5 (highest), identify the level of complexity required in each of these skills for the worker to perform the critical work function. Keep in mind that this scale is not for rating an individual's proficiency. It is intended only for rating the level of complexity required to do the work.

Occupational Title: Biomanufacturing																
CWF 2 Clean and Maintain Environment																
Listening	Speaking	Using Information and Communication Technology	Gathering and analyzing Information	Analyzing and Solving Problems	Making Decisions and Judgments	Organizing and Planning	Using Social Skills	Adaptability	Working in Teams	Leading Others	Building Consensus	Self and Career Development	Writing	Reading	Mathematics	Science
4	3	2	2	2	3	3	3	2	3	2	3	3	4	4	2	4

Statement of Assessment for Critical Work Function 2: Clean and maintain environment

The statements of assessment can do any of several things:

- *Define tools or strategies that industry could use to assess the level of competency a worker has attained in a particular critical work function.*
- *Define for trainers and educators how to assess the level of competency a student has attained relevant to the critical work function.*
- *Define the level of mastery of the critical work function that indicates that a worker or student has achieved an entry-, intermediate-, or advanced level of mastery of a critical work function.*

A. Tests could include:

1) Multiple choice and essay questions that demonstrate an understanding of knowledge being assessed.
2) Preparation and justification of a reasonable solution to a problem scenario.

B. Hands-on exercises or simulations to demonstrate acquisition of knowledge and skills that could:

1) Apply relevant knowledge or skills
2) Focus on the application of knowledge and skills to a new situation
3) Demonstrate an ability to plan, organize, and create a product, service, or an event.
4) Illustrate by individual performance the attained levels of knowledge and skills
5) Include observation of events, groups, and individuals that focuses on the relevant traits of the skill in question

Occupational Title: Biomanufacturing			
Critical Work Function 3. Clean, maintain and trouble-shoot equipment		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
3.1 Clean and maintain basic laboratory equipment	3.1.1 Company cleaning and equipment SOPs are followed 3.1.2 Appropriate gowning and PPE are used 3.1.3 Process is documented	Knowledge of glassware cleaning process and documentation Knowledge of equipment cleaning and maintenance	Glasswasher Wrappers Dryer PPE Equipment log books Company SOPs
3.2 Clean and maintain cell culture and fermentation equipment	3.2.1 Appropriate gowning and PPE are used 3.2.2 Equipment is maintained in controlled environment 3.2.3. Clean in Place (CIP) skid is prepared per SOP 3.2.4 Steam in place (SIP) is carried out per SOP 3.2.5 Depyrogenation is carried out per SOP 3.2.6. Clean out of place (COP) equipment such as vessel, transfer lines and sample device/port, are prepared per SOP	Knowledge of appropriate gowning and PPE for controlled environments Knowledge of environmental control that can affect product production Knowledge of cleaning solution, agent, or material Knowledge of necessary documentation Knowledge of COP equipment cleaning process Knowledge of CIP skid cleaning process Knowledge of material to be autoclaved and autoclave process Knowledge of sample device Knowledge of sterilization process Knowledge of required tests for systems Knowledge of run, cool down and valve shutdown. Knowledge of depyrogenation process Knowledge of SIP process	Company SOPs and associated documentation for cleaning and maintaining cell culture and fermentation equipment In place system (bioreactor) Vessels System, especially Device port Autoclaves Hoses Pumps CIP skid Sonicator COP equipment

Occupational Title: Biomanufacturing			
Critical Work Function 3. Clean, maintain and trouble-shoot equipment		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
3.3 Perform calibration of instruments	3.3.1 Appropriate gowning and PPE are used 3.3.2 Calibration schedule and protocol are created/written or followed 3.3.3 Out-of-tolerance/discrepancy is generated when necessary 3.3.4 Calibration results are reviewed and preventive maintenance (PM) schedule and protocol are created/written	Knowledge of calibration methodology and associated documentation	Relevant instruments Company SOPs and forms PPE Gowning cGMP information
3.4 Perform preventive maintenance and schedule vendor maintenance	3.4.1 Appropriate gowning and PPE is used 3.4.2 PM schedule and protocol are created/written or followed 3.4.3 Any required parts are ordered 3.4.4 Maintenance is peer reviewed 3.4.5 Maintenance is documented 3.4.6 Maintenance is coordinated with vendor as needed 3.4.7 Vendor maintenance is reviewed 3.4.8 Vendor maintenance documentation is recorded	Knowledge of preventive maintenance Company SOPs Good communication skills and ability to document maintenance record	Equipment parts Company SOPs Company maintenance forms PM schedules PPE cGMP information

Occupational Title: Biomanufacturing			
Critical Work Function 3. Clean, maintain and trouble-shoot equipment		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
3.5 Perform equipment qualification	3.5.1 Appropriate gowning and PPE is used 3.5.2 Necessary equipment parameters are identified to develop qualification protocol 3.5.3 Qualification protocol is written 3.5.4 Needed approval for qualification protocol is obtained 3.5.5 Protocol is tested and is validated based on application of proper statistics 3.5.6 Discrepancies to qualification protocol are captured and explained 3.5.7 Necessary approval is obtained for qualification report to implement change to procedure	Knowledge of equipment qualification procedures Knowledge of how to prepare installation and operational qualification protocols Knowledge of statistical analysis Knowledge of SOPs for writing and approval process for qualification report	Company SOPs Equipment measuring devices PPE cGMP information
3.6 Participate in installation and modification of equipment	3.6.1 Appropriate gowning and PPE is used 3.6.2. Vendor or appropriate company personnel including technicians, who are responsible for equipment, perform installation and any necessary modifications 3.6.3. Technician is properly trained on equipment 3.6.4 Test run is performed to ensure equipment is running properly 3.6.5 Qualification and calibration procedures are developed for equipment 3.6.6 Maintenance schedule is established	Knowledge of new equipment including installation requirements, operating manuals, and any other information needed to ensure proper operation of equipment	PPE Appropriate equipment manuals Laboratory floor and wiring plans for installation and modification of new equipment Company SOPs cGMP information

Academic and Employability Knowledge and Skill Matrix for Critical Work Function 3: Clean, Maintain and Troubleshoot Equipment

On a scale of 1 (lowest) to 5 (highest), identify the level of complexity required in each of these skills for the worker to perform the critical work function. Keep in mind that this scale is not for rating an individual's proficiency. It is intended only for rating the level of complexity required to do the work.

Occupational Title: Biomanufacturing																
CWF 3 Clean, maintain and troubleshoot equipment																
Listening	Speaking	Using Information and Communication Technology	Gathering and analyzing Information	Analyzing and Solving Problems	Making Decisions and Judgments	Organizing and Planning	Using Social Skills	Adaptability	Working in Teams	Leading Others	Building Consensus	Self and Career Development	Writing	Reading	Mathematics	Science
4	3	4	3	3	2	2	3	2	2	2	2	3	3	3	2	3

Statement of Assessment for Critical Work Function 3: Clean, Maintain, and Troubleshoot Equipment

The statements of assessment can do any of several things:

- *Define tools or strategies that industry could use to assess the level of competency a worker has attained in a particular critical work function.*
- *Define for trainers and educators how to assess the level of competency a student has attained relevant to the critical work function.*
- *Define the level of mastery of the critical work function that indicates that a worker or student has achieved an entry-, intermediate-, or advanced level of mastery of a critical work function.*

A. Tests could include:

1) Multiple choice and essay questions that demonstrate an understanding of knowledge being assessed.
2) Preparation and justification of a reasonable solution to a problem scenario.

B. Hands-on exercises or simulations to demonstrate acquisition of knowledge and skills that could:

1) Apply relevant knowledge or skills
2) Focus on the application of knowledge and skills to a new situation
3) Demonstrate an ability to plan, organize, and create a product, service, or an event.
4) Illustrate by individual performance the attained levels of knowledge and skills
5) Include observation of events, groups, and individuals that focuses on the relevant traits of the skill in question

Occupational Title: Biomanufacturing			
Critical Work Function 4. Prepare items for laboratory and biomanufacturing activities		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
4.1 Order materials	4.1.1 Control and receipt of raw materials is performed properly per company SOP 4.1.2 Stocks are inventoried appropriately per SOP to ensure laboratory is always stocked 4.1.3 Expired materials and items are discarded in accordance with established procedures 4.1.4 Periodic inventory of stock and supplies is taken in compliance with established procedures	Ability to identify expired materials Knowledge of stock supply documentation Knowledge of chemical classification for proper storage Knowledge of cGMP procedures	Company SOPs Company stock supply documentation Company catalogs
4.2 Store materials	4.2.1 Appropriate gowning and PPE are used 4.2.2 Raw materials are stored under specified conditions per SOP 4.2.3 Raw materials are logged 4.2.4 Raw materials are tested and released for use per SOP 4.2.5 Tested materials are stored appropriately per SOP	Knowledge of cGMP procedures Knowledge of Safety Data Sheets (SDSs) Knowledge of safety hazards for materials Knowledge of testing protocols Knowledge of long term proper storage conditions for tested materials	Company SOPs Logs Gowning PPE SDS Storage equipment and area
4.3 Prepare glassware	4.3.1 Appropriate gowning and PPE are used 4.3.2 Glassware is inspected for cracks or chips 4.3.3 Glassware is cleaned per SOP 4.3.4 Glassware is inspected for cleanliness 4.3.5 Glassware is appropriately stored	Knowledge of proper glassware and cleaning procedures Knowledge of proper inspection methods	Company SOPs Glassware Storage equipment and area PPE Gowning

Occupational Title: Biomanufacturing			
Critical Work Function 4. Prepare items for laboratory and biomanufacturing activities		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
4.4 Prepare equipment	4.4.1 Appropriate gowning and PPE are used 4.4.2 Proper repairs and adjustments are made to equipment prior to service 4.4.3 Equipment set-up process meets specifications required by established procedures 4.4.4 Equipment is properly cleaned and sterilized	Ability to make repairs and adjustment to equipment Knowledge of equipment calibration Knowledge of equipment preparation Knowledge of how to properly clean and sterilize equipment	Company SOPs Equipment PPE Gowning
4.5 Make media, solutions, buffers and reagent batches	4.5.1 Appropriate gowning and PPE are used 4.5.2 Components are weighed according to SOPs 4.5.3 Media, solutions and buffers are prepared according to SOPs 4.5.4 Reagent batches are prepared according to SOPs	Knowledge of Safety Data Sheets (SDSs) and how to apply that knowledge to proper handling of chemicals Knowledge of weighing equipment and its validation and calibration. Knowledge of how to document movement of material needed for media, solution or buffer batch preparation Knowledge of inventory control for batch records Knowledge of preparing reagent batch Knowledge of preparing vessel, filtration and storage conditions needed for particular batch	Company SOPs PPE Gowning Batch record Solution prep form Filtration unit Scale Appropriate storage containers Autoclave Equipment for storage such as refrigerators or storage units
4.6 Store media, solutions, buffers, and reagent batches	4.6.1 Appropriate gowning and PPE are used 4.6.2. Media, solutions, buffers and reagent batches are properly labeled 4.6.3 Media, solutions, buffers and reagent batches are kept pure and separate 4.6.4 Proper aseptic techniques are followed 4.6.5 All documentation is done accurately and in a timely manner 4.6.6 Media, solutions and buffers are disposed of according to established procedures and all applicable laws and regulations	Knowledge of media, solutions and buffers documentation procedures Knowledge of safety hazards for each media, solution and buffer Knowledge of specific procedures and associated equipment	Company SOPs PPE Appropriate storage room SDS Gowning

Academic and Employability Knowledge and Skill Matrix for Critical Work Function 4: Prepare Items for Laboratory and Biomanufacturing Activities

On a scale of 1 (lowest) to 5 (highest), identify the level of complexity required in each of these skills for the worker to perform the critical work function. Keep in mind that this scale is not for rating an individual's proficiency. It is intended only for rating the level of complexity required to do the work.

Occupational Title: Biomanufacturing																
CWF 4 Prepare items for laboratory and biomanufacturing activities																
Listening	Speaking	Using Information and Communication Technology	Gathering and analyzing Information	Analyzing and Solving Problems	Making Decisions and Judgments	Organizing and Planning	Using Social Skills	Adaptability	Working in Teams	Leading Others	Building Consensus	Self and Career Development	Writing	Reading	Mathematics	Science
3	3	3	3	3	2	3	2	2	2	2	2	3	4	4	3	4

Statement of Assessment for Critical Work Function 4: Prepare Items for Laboratory and Biomanufacturing Activities

The statements of assessment can do any of several things:

- *Define tools or strategies that industry could use to assess the level of competency a worker has attained in a particular critical work function.*
- *Define for trainers and educators how to assess the level of competency a student has attained relevant to the critical work function.*
- *Define the level of mastery of the critical work function that indicates that a worker or student has achieved an entry-, intermediate-, or advanced level of mastery of a critical work function.*

A. Tests could include:

1) Multiple choice and essay questions that demonstrate an understanding of knowledge being assessed.
2) Preparation and justification of a reasonable solution to a problem scenario.

B. Hands-on exercises or simulations to demonstrate acquisition of knowledge and skills that could:

1) Apply relevant knowledge or skills
2) Focus on the application of knowledge and skills to a new situation
3) Demonstrate an ability to plan, organize, and create a product, service, or an event.
4) Illustrate by individual performance the attained levels of knowledge and skills
5) Include observation of events, groups, and individuals that focuses on the relevant traits of the skill in question

BIOMANUFACTURING SKILL STANDARDS

Occupational Title: Biomanufacturing			
Critical Work Function 5. Perform cell culture and fermentation		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
5.1 Prepare working cell bank	5.1.1 Appropriate PPE and gowning are used 5.1.2. Cultures are properly labeled 5.1.3 Cultures are healthy and viable 5.1.4 Cultures are homogenious and isolated to prevent contamination 5.1.5 Proper aseptic techniques are followed 5.1.6 All documentation is maintained accurately and in a timely manner 5.1.7 Biological cultures are disposed of according to established procedures and all applicable laws and regulations 5.1.8 Vial is properly thawed to maximize cell viability 5.1.9 Media is added to autoclaved spinner flask to maintain sterility 5.1.10 Spinner flask is inoculated with contents of vial maintaining sterility and cell viability 5.1.11 Spinner flask is put in incubator in a timely manner to maintain cell viability 5.1.12 Culture is scaled-up to maintain sterility and cell viability 5.1.13 Culture is sterilely dispensed into vials maximizing cell viability 5.1.14 Vials are prepared for cryo-unit to maximize cell viability	Knowledge of culturing cell process and documentation by batch records Knowledge of materials used for making media Knowledge of sterile technique Knowledge of cell freeze thaw mechanism for purpose of maximizing cell viability Knowledge of PPE for working with cryo-unit Knowledge of gowning for maintaining sterility and	PPE Gowning Autoclave Vials Water baths Sterile hoods Scale up equipment Spinner flasks and associated equipment Pertinent EH&S and OSHA Company policies on proper disposal of biological waste Cryo-Unit Incubator Company Batch Record

BIOMANUFACTURING SKILL STANDARDS

Occupational Title: Biomanufacturing			
Critical Work Function 5. Perform cell culture and fermentation		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
5.2 Initiate starter cultures	5.2.1 Appropriate PPE and gowning are used 5.2.2 Working cell bank vial is taken out of cryo-unit, maintaining cell viability 5.2.3 Vial is thawed maintaining sterility and cell viability 5.2.4 Media is added to autoclaved spinner flask maintaining cell viability and sterility 5.2.5 Spinner flask is inoculated with contents of vial maintaining sterility and cell viability 5.2.6 Spinner is incubated sterilely to maximize growth and cell viability	Knowledge of PPE procedures Knowledge of gowning Knowledge of cell bank inventory system Knowledge of cell freeze-thaw mechanism. Knowledge of materials used for making sterile media Knowledge of cell culture process to maintain cell viability, sterility of culture, and maximization of product formation Knowledge of documentation by batch records	PPE Gowning Spinner flasks and associated equipment Media Sterile hood and associated equipment Autoclave Cryo-Unit and associated equipment Incubator Company batch record
5.3 Perform scale-up operation	5.3.1 Appropriate PPE and gowning are used 5.3.2 Spinner flask is removed from incubator 5.3.3 Media is added aseptically to next larger size spinner flasks 5.3.4 Culture aliquot is transferred aseptically from initial spinner into larger spinner flasks 5.3.5 Larger spinners are incubated to maximize cell growth 5.3.6 Used spinner flasks are sent to equipment prep for turnaround or disposal	Knowledge of culturing cell process Knowledge of documentation by batch records Knowledge of materials used for making sterile media Knowledge of proper disposal or reuse of spinner flasks	PPE Gowning Larger spinner flasks and associated equipment Sterile hood and associated equipment Media Autoclave Incubator Company batch record

Occupational Title: Biomanufacturing			
Critical Work Function 5. Perform cell culture and fermentation		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
5.4 Inoculate seed reactor and perform media addition	5.4.1 Appropriate PPE and gowning are used 5.4.2 Growth media is transferred aseptically to seed reactor 5.4.3 Contents of larger spinner flask are transferred aseptically to seed reactor, maintaining cell viability 5.4.4 Post sterilization of feed port is performed 5.4.5 Used spinner is sent to equipment prep for turnaround or disposal 5.4.6 Media filter assembly and transfer line/feed port are pressure tested to ensure proper use 5.4.7 Filter assembly and transfer line/feed port are sterilized and media is added to reactor 5.4.8 Post-sterilization is performed and filter assembly is disassembled 5.4.9 Media are added sterilely to perfusion reactor 5.4.10 Transfer line is sterilized and checked for positive pressure 5.4.11 Contents of seed reactor are transferred sterilely to perfusion reactor 5.4.12 Post-sterilization of transfer line is performed 5.4.13 Production media are added sterilely to final production reactor 5.4.14 Transfer line is sterilized and checked for positive pressure 5.4.15 Contents of perfusion reactor are transferred aseptically to final production reactor 5.4.16 Post-sterilization of transfer line is performed	Knowledge of PPE procedures and gowning Knowledge of culturing cell process Knowledge of documentation by batch records Knowledge of sterile technique and preparing sterile equipment such as reactors and lines Knowledge of the seed reactor Knowledge of the pumps and lines working to add materials Knowledge of testing lines to ensure proper transfer of materials Knowledge of materials used for making media. Knowledge of perfusion reactor. Knowledge of final production reactor	PPE Gowning Incubator Company Batch Record Hoses Pumps Seed reactor Perfusion reactor Final production reactor Sterile hood and associated equipment Filter assembly

Occupational Title: Biomanufacturing			
Critical Work Function 5. Perform cell culture and fermentation		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
5.5 Monitor culture	5.5.1 Appropriate PPE and gowning are used 5.5.2 Reaction is sampled periodically to determine stage of growth and product production 5.5.3 Culture tests are run to confirm process parameters 5.5.4 Reactor culture is visually inspected to ensure proper operation of reactor and growth of culture 5.5.5 Display and trends are checked for proper process parameter 5.5.6 Set points are adjusted as necessary to optimize culture	Knowledge of PPE procedures Knowledge of gowning Knowledge of culturing cell process Knowledge of sterile technique Knowledge of documentation by batch records Knowledge of sampling Knowledge of adjusting set points	PPE Gowning Company Batch Record Hoses Vials
5.6 Execute sampling and assess material for process release	5.6.1 Sample apparatus is prepared 5.6.2 Samples are aseptically taken using appropriate sampling device 5.6.3 Required samples are aliquoted 5.6.4 Sample is labeled, stored, and submitted 5.6.5 Laboratory Information Management System (LIMS) entries are made as needed. 5.6.6 Sample is submitted to Quality Control (QC)	Knowledge of sampling Knowledge of adjusting set points Knowledge of LIMS Knowledge of QC submission and documentation required to file for QC	PPE Gowning Batch Record Hoses Vials QC forms LIMS

Occupational Title: Biomanufacturing			
Critical Work Function 5. Perform cell culture and fermentation		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
5.7 Perform process release for product	5.7.1 Appropriate PPE and gowning are used 5.7.2 Filter train/collection vessel is assembled, flushed and equilibrated 5.7.3 Solution is charged to filters; filters are bled and monitored for clogging 5.7.4 Centrifuge is set up and bowl is brought up to required speed 5.7.5 Feeding product is started and centrifuge is monitored for speed and temperature 5.7.6 Concentrate is cleared of debris 5.7.7 Centrifuge parts are cleaned and sterilized 5.7.8 Homogenizer is set up, automatically calibrated and started 5.7.9 Feeding to homogenizer is started 5.7.10 Pressure is applied to pistons according to instrument requirement supplied by manufacturer 5.7.11 Two to five feeds are run depending on seed material 5.7.12 Operation is monitored to make sure all desired conditions are met	Knowledge of PPE Knowledge of gowning Knowledge of documentation Knowledge of depth filtration process Knowledge of centrifugation process Knowledge of centrifugation sterilization Knowledge of homogenization process Knowledge of batch records Knowledge of seed material	PPE Gowning Vessel Filters Centrifuge Bottles Homogenizer Feeder Batch records

Academic and Employability Knowledge and Skill Matrix for Critical Work Function 5: Perform cell culture and fermentation

On a scale of 1 (lowest) to 5 (highest), identify the level of complexity required in each of these skills for the worker to perform the critical work function. Keep in mind that this scale is not for rating an individual's proficiency. It is intended only for rating the level of complexity required to do the work.

Occupational Title: Biomanufacturing																
CWF 5 Perform cell culture and fermentation																
Listening	Speaking	Using Information and Communication Technology	Gathering and analyzing Information	Analyzing and Solving Problems	Making Decisions and Judgments	Organizing and Planning	Using Social Skills	Adaptability	Working in Teams	Leading Others	Building Consensus	Self and Career Development	Writing	Reading	Mathematics	Science
3	3	3	3	3	2	3	2	2	3	2	2	3	3	3	2	3

Statement of Assessment for Critical Work Function 5: Perform Cell Culture and Fermentation

The statements of assessment can do any of several things:

- *Define tools or strategies that industry could use to assess the level of competency a worker has attained in a particular critical work function.*
- *Define for trainers and educators how to assess the level of competency a student has attained relevant to the critical work function.*
- *Define the level of mastery of the critical work function that indicates that a worker or student has achieved an entry-, intermediate-, or advanced level of mastery of a critical work function.*

A. Tests could include:

1) Multiple choice and essay questions that demonstrate an understanding of knowledge being assessed.
2) Preparation and justification of a reasonable solution to a problem scenario.

B. Hands-on exercises or simulations to demonstrate acquisition of knowledge and skills that could:

1) Apply relevant knowledge or skills
2) Focus on the application of knowledge and skills to a new situation
3) Demonstrate an ability to plan, organize, and create a product, service, or an event.
4) Illustrate by individual performance the attained levels of knowledge and skills
5) Include observation of events, groups, and individuals that focuses on the relevant traits of the skill in question

Occupational Title: Biomanufacturing			
Critical Work Function 6. Perform testing and data analysis		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
6.1 Perform microbiology testing	6.1.1 Environmental conditions are monitored to ensure bioburden or sterility specifications are met. 6.1.2 Microbial growth is identified 6.1.3 Media is added to autoclaved shaker flask to get the seed culture started 6.1.4 Endotoxin/pyrogen is tested using Limulus Amebocyte Lysate (LAL) (e.g., water, in-process, final product) 6.1.5 Bioburden is tested (e.g., water, in-process, final product) 6.1.6 Biological indicators are tested to ensure viability 6.1.7 Basic microbiology lab techniques are performed 6.1.8 Personnel are monitored by testing for contamination	Knowledge of microbiology such as Gram stain Knowledge of basic microbiology techniques such as counting bacterial colonies, pouring plates, preparing specialized media, staining for identification, isolating and culturing of single colonies, testing for identification, and aseptic techniques Knowledge of pipetting/dilution Knowledge of endotoxin testing Knowledge of biological indicator testing	Particle counter, TSA plates Nam staining strips, Vitek midi strips, selection media, and plates Cape cod LAL assay kit Plates, media, and filter counts for bacteria RODAC Plates, media, pipettes PPE
6.2 Perform chemical testing	6.2.1 Buffer prep log is checked according to company SOPs 6.2.2 pH of solution is checked according to company SOPs 6.2.3 Media prep log is checked according to company SOPs 6.2.4 Upstream and downstream culture monitor log is checked according to company SOPs 6.2.5 Product purity is tested either by appropriate chemical tests or by Enzyme Linked Immunosorbate Assay (ELISA)	Knowledge of SOP for using appropriate equipment to prepare reagent Knowledge of appropriate tests Knowledge of current SOP for testing and documentation Knowledge of SOP for data analysis and validity of test and sample Knowledge of appropriate reporting system and documentation Knowledge of data monitoring and documentation	Forms Software Pipettors Pipettes Tubes pH Meter SOP PPE

Occupational Title: Biomanufacturing			
Critical Work Function 6. Perform testing and data analysis		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
6.3 Perform upstream testing	6.3.1 Appropriate PPE and gowning are used 6.3.2 Filters are integrity tested using approved methods 6.3.3 Probes are tested (pH, DO, 0_2, temperature) 6.3.4 In-process testing is performed 6.3.5 Cell counting is performed	Knowledge of PPE procedures and gowning Knowledge of documentation Knowledge of filter testing process Knowledge of pressure testing process Knowledge of test probes Knowledge of cell counting process and documentation	Company SOPs Bioreactor Pressure gauge Integrity tester unit Cell counter, trypan blue, hemacytometer, microscope [Filter unit PPE Gowning
6.4 Perform downstream testing	6.4.1 Appropriate gowning and PPE are used 6.4.2. Culture is sampled 6.4.3 Optical Density is checked for desired reading before harvesting	Knowledge of documentation by batch records Knowledge of sample vials Knowledge of sample storage conditions	Company SOPs Batch Record Incubator Refrigerator Vials PPE Gowning
6.5 Troubleshoot aberrant results or parameters	6.5.1 Additional tests are conducted to identify potential causes of error 6.5.2 Data is reviewed 6.5.3 Necessity of CAPA is identified	Knowledge of troubleshooting. Knowledge of data analysis Knowledge of appropriate CAPA	Software for data analysis CAPA procedure forms

Academic and Employability Knowledge and Skill Matrix for Critical Work Function 6: Perform Testing and Data Analysis

On a scale of 1 (lowest) to 5 (highest), identify the level of complexity required in each of these skills for the worker to perform the critical work function. Keep in mind that this scale is not for rating an individual's proficiency. It is intended only for rating the level of complexity required to do the work.

Occupational Title: Biomanufacturing																
CWF 6 Perform testing and data analysis																
Listening	Speaking	Using Information and Communication Technology	Gathering and analyzing Information	Analyzing and Solving Problems	Making Decisions and Judgments	Organizing and Planning	Using Social Skills	Adaptability	Working in Teams	Leading Others	Building Consensus	Self and Career Development	Writing	Reading	Mathematics	Science
3	3	4	4	4	2	3	2	2	3	2	2	3	3	3	2	3

Statement of Assessment for Critical Work Function 6 Perform Testing and Data Analysis

The statements of assessment can do any of several things:

- *Define tools or strategies that industry could use to assess the level of competency a worker has attained in a particular critical work function.*
- *Define for trainers and educators how to assess the level of competency a student has attained relevant to the critical work function.*
- *Define the level of mastery of the critical work function that indicates that a worker or student has achieved an entry-, intermediate-, or advanced level of mastery of a critical work function.*

A. Tests could include:

1) Multiple choice and essay questions that demonstrate an understanding of knowledge being assessed.
2) Preparation and justification of a reasonable solution to a problem scenario.

B. Hands-on exercises or simulations to demonstrate acquisition of knowledge and skills that could:

1) Apply relevant knowledge or skills
2) Focus on the application of knowledge and skills to a new situation
3) Demonstrate an ability to plan, organize, and create a product, service, or an event
4) Illustrate by individual performance the attained levels of knowledge and skills
5) Include observation of events, groups, and individuals that focuses on the relevant traits of the skill in question

Occupational Title: Biomanufacturing			
Critical Work Function 7. Perform product purification and prepare for shipping		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
7.1 Prepare purification equipment	7.1.1 Appropriate PPE and gowning are used 7.1.2.Appropriate specifications for column and resin (if required) are used 7.1.3 Column pack is performed by approved by (qualified) procedures 7.1.4 Flow path is sanitized 7.1.5 Column is equilibrated 7.1.6 Appropriate concentration of product is loaded based on column capacity 7.1.7 Appropriate end point is established 7.1.8 Column is cleaned, sanitized, and stored or disposed of 7.1.9 Chromatography process is documented	Knowledge of PPE and gowning Knowledge of documentation Knowledge of approved specifications for column packing Knowledge of resins Knowledge of chromatography separation Knowledge of calculating column asymmetry or High Equivalent Theoretical Plate (HETP) Knowledge of cleaning and sanitizing column Knowledge of data analysis and related software	Columns Resins Software and forms PPE Gowning Company SOPs
7.2 Receive product from upstream processing	7.2.1.Appropriate PPE and gowning are used 7.2.2 Batch record is followed according to company SOPs 7.2.3 Transfer sequence is initiated 7.2.4 Product is mixed 7.2.5 Product is sampled 7.2.6 Tanks and equipment for process steps are prepared 7.2.7 Product is sampled and tested	Knowledge of PPE and gowning Knowledge of SOP required to transfer and mix product and documentation	Company SOPs Batch Record PPE Gowning

Occupational Title: Biomanufacturing			
Critical Work Function 7. Perform product purification and prepare for shipping		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
7.3 Filter product as necessary	7.3.1 Appropriate PPE and gowning are used 7.3.2 Batch record is followed according to company SOPs 7.3.3 Holding tank is pressurized 7.3.4 Filter train is assembled 7.3.5 Air is bled from filter 7.3.6 Transfer is monitored 7.3.7 Test filter is integrity tested once transfer is complete 7.3.8 Process testing is sampled and managed	Knowledge of PPE and gowning Knowledge of depth filtration process, testing and documentation	Company SOPs Filters Filter Train Air Supply PPE Gowning
7.4 Perform chromatography steps	7.4.1 Appropriate PPE and gowning are used 7.4.2 Product recovery is completed according to SOPs 7.4.3 Column is cleaned with appropriate buffer 7.4.4 Column is equilibrated with appropriate buffer 7.4.5 Column is loaded with product 7.4.6 Product is eluted from column 7.4.7 Column is regenerated	Knowledge of PPE and gowning Knowledge of SOP for chromatography separation and documentation Knowledge of post sample loading process and documentation	SOP Columns PPE Gowning Reagents

Occupational Title: Biomanufacturing			
Critical Work Function 7. Perform product purification and prepare for shipping		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
7.5 Remove contaminants and concentrate product as necessary	7.5.1 Appropriate PPE and gowning are used 7.5.2 Filters are assembled into UF skids 7.5.3 Filter is inserted into house 7.5.4 Filters are integrity tested 7.5.5 Skid is cleaned 7.5.6 Buffer is exchanged 7.5.7 Product is concentrated 7.5.8 Difiltration is completed 7.5.9 Process testing is sampled and managed 7.5.10 Filters are integrity tested again 7.5.11 Filter is cleaned, sanitized, and stored or disposed of 7.5.12 Viral removal methods are described 7.5.13 Viral removal steps are performed according to product specifications (PSIs) 7.5.14 Samples are submitted to quality control 7.5.15 Sterility is validated	Knowledge of PPE procedures and gowning Knowledge of how to document process and required documentation for submission to QC Knowledge of filtration using UF skids Knowledge of filters and buffers Knowledge of SOP for viral removal from the product Basic biology of viruses and biology of viral clearance Knowledge of sterility validation	Filters Buffers UF skid Basic Biology SOP Forms PPE Gowning
7.6 Bulk fill purified product for storage	7.6.1 Appropriate PPE and gowning are used. 7.6.2.Bulk product containers are sterilized 7.6.3 Room and Biological Safety Cabinet or Laminar Flow Hood (BSC/LFH) are cleaned. 7.6.4 Bulk product is pooled into bulk containers. 7.6.5 Filters are integrity tested. 7.6.6 Product is transferred for further processing if applicable.	Knowledge of SOP for bulk filling documentation Knowledge of further processing of product	Company SOPs Bulk containers PPE Gowning
7.7 Complete final formulation	7.7.1 Appropriate PPE and gowning are used 7.7.2. Bulk material is adjusted to end product specifications 7.7.3 Chain of custody is followed	Knowledge of end specifications for product formulation Knowledge of proper chain of custody documentation	Company SOPs PPE Gowning

Academic and Employability Knowledge and Skill Matrix for Critical Work Function 7: Perform Product Purification and Prepare for Shipping

On a scale of 1 (lowest) to 5 (highest), identify the level of complexity required in each of these skills for the worker to perform the critical work function. Keep in mind that this scale is not for rating an individual's proficiency. It is intended only for rating the level of complexity required to do the work.

Occupational Title: Biomanufacturing																
CWF 7 Perform product purification and prepare for shipping																
Listening	Speaking	Using Information and Communication Technology	Gathering and analyzing Information	Analyzing and Solving Problems	Making Decisions and Judgments	Organizing and Planning	Using Social Skills	Adaptability	Working in Teams	Leading Others	Building Consensus	Self and Career Development	Writing	Reading	Mathematics	Science
3	3	3	2	3	2	3	2	2	3	2	2	3	3	3	2	3

Statement of Assessment for Critical Work Function 7: Perform Product Purification and Prepare for Shipping

The statements of assessment can do any of several things:

- *Define tools or strategies that industry could use to assess the level of competency a worker has attained in a particular critical work function.*
- *Define for trainers and educators how to assess the level of competency a student has attained relevant to the critical work function.*
- *Define the level of mastery of the critical work function that indicates that a worker or student has achieved an entry-, intermediate-, or advanced level of mastery of a critical work function.*

A. Tests could include:

1) Multiple choice and essay questions that demonstrate an understanding of knowledge being assessed.
2) Preparation and justification of a reasonable solution to a problem scenario.

B. Hands-on exercises or simulations to demonstrate acquisition of knowledge and skills that could:

1) Apply relevant knowledge or skills
2) Focus on the application of knowledge and skills to a new situation
3) Demonstrate an ability to plan, organize, and create a product, service, or an event
4) Illustrate by individual performance the attained levels of knowledge and skills
5) Include observation of events, groups, and individuals that focuses on the relevant traits of the skill in question

Occupational Title: Biomanufacturing			
Critical Work Function 8. Provide Information to and train staff and customers		**Occupational Skills, Knowledge & Conditions**	
Key Activity	**Performance Criteria** *How do we know when the key activity is performed well or performed successfully?*	**Occupational Skills & Knowledge** *What should the technician know and what skills should the technician have in order to do the activity?*	**Conditions** *What tools must the technician use in order to do the activity?*
8.1 Communicate with co-workers to ensure quality work	8.1.1 Customer product requirements are identified 8.1.2 Uses of product or instrumentation/systems suitability for process are explained 8.1.3 Explanation is adequate to meet needs through communication	Good communication skills Knowledge of products and technical specifications	Standard documentation for customers
8.2 Provide technical assistance to customers	8.2.1 Appropriate trainings are given to meet customer needs 8.2.2 Trainings encompass scientific theory, history, and background 8.2.3 Test methods are appropriately identified 8.2.4 Any possible root cause of differences are investigated	Knowledge of products and their technical specifications. Knowledge of SOPs for troubleshooting Good communication skills	Standard Documentation for the customers SOPs
8.3 Provide training to co-workers	8.3.1 Trainee/co-worker is able to read and understand procedure documentation. 8.3.2 Trainee/co-worker is required to observe procedure being performed by co-worker. 8.3.3 Trainee/co-worker is observed while performing procedure. 8.3.4 Trainee/co-worker performs procedure independently of help from co-workers 8.3.5 Aseptic techniques are used 8.3.6 Gowning techniques are used 8.3.7 Trainee/co-worker follows appropriate flow of materials and personnel 8.3.8 Trainee/co-worker complies with specifications for different company areas	Knowledge of procedure for training personnel Knowledge of company policy and procedures	Company training booklet Company SOPs

Academic and Employability Knowledge and Skill Matrix for Critical Work Function 8: Provide Information to and Train Staff and Customers

On a scale of 1 (lowest) to 5 (highest), identify the level of complexity required in each of these skills for the worker to perform the critical work function. Keep in mind that this scale is not for rating an individual's proficiency. It is intended only for rating the level of complexity required to do the work.

Occupational Title: Biomanufacturing																
CWF 8 Provide information to and train staff and customers																
Listening	Speaking	Using Information and Communication Technology	Gathering and analyzing Information	Analyzing and Solving Problems	Making Decisions and Judgments	Organizing and Planning	Using Social Skills	Adaptability	Working in Teams	Leading Others	Building Consensus	Self and Career Development	Writing	Reading	Mathematics	Science
4	4	3	3	4	2	3	3	2	3	2	2	2	3	3	2	3

Statement of Assessment for Critical Work Function 8: Provide Information To and Train Staff and Customers

The statements of assessment can do any of several things:

- *Define tools or strategies that industry could use to assess the level of competency a worker has attained in a particular critical work function.*
- *Define for trainers and educators how to assess the level of competency a student has attained relevant to the critical work function.*
- *Define the level of mastery of the critical work function that indicates that a worker or student has achieved an entry-, intermediate-, or advanced level of mastery of a critical work function.*

A. Tests could include:

1) Multiple choice and essay questions that demonstrate an understanding of knowledge being assessed.
2) Preparation and justification of a reasonable solution to a problem scenario.

B. Hands-on exercises or simulations to demonstrate acquisition of knowledge and skills that could:

1) Apply relevant knowledge or skills
2) Focus on the application of knowledge and skills to a new situation
3) Demonstrate an ability to plan, organize, and create a product, service, or an event
4) Illustrate by individual performance the attained levels of knowledge and skills
5) Include observation of events, groups, and individuals that focuses on the relevant traits of the skill in question