A. Introduction

The Partnership for Biotechnology Workforce Training is a joint endeavor of the North Carolina Community College System and the North Carolina Biotechnology Center to provide education and training for North Carolina's bioprocess manufacturing industries. The Process Technician Certification examination is available to individuals who have completed the biotechnology/biowork process technician training program offered through the North Carolina Community College System.

B. Application Deadlines and Certification Examination Schedule

Applications will be accepted on a rolling basis. Currently, paper-and-pencil examinations will be administered. Computer-based examinations may be utilized in the future. Examination administrations are scheduled following the completion of each BioWorks course. The testing window will be three to four weeks in length, and the testing window will begin no less than 30 days after the last class meeting of the latest BioWorks course scheduled across the North Carolina Community College System. For example, if the last class ends January 15, then the testing window will begin no sooner than February 15.

For additional information on test dates and locations, please contact the BioWorks course professor or Castle Worldwide, Inc., the testing company contracted to administer the examination.

C. Application Fees

Currently, the application fee is $55. The fee must be paid in U.S. funds. Please make all checks payable to the Castle Worldwide, Inc., the testing company contracted to administer the examination. Refund requests must be received in writing three weeks prior to the test date and are subject to a $25 processing fee.

All fees are subject to change. If such a change occurs before the reprinting of this candidate handbook, a notice of the change will be inserted into the application. Be aware of the importance of any notices inserted.

D. Application Submission

Send your completed application and application fee directly to Castle Worldwide, Inc., the testing company contracted to administer the examination. Castle Worldwide, Inc. receives and processes all applications. Please mail the application if it includes payment by check or money order. Applications that include payment by credit card may be faxed. An application will not be processed until it is complete. An application that is still missing pertinent information one year after it was originally received will be closed, and the application fee will be forfeited. In that circumstance, the applicant who still wishes to pursue the credential must update and resubmit all application materials and a new application fee.

Send all materials to the following address:

Castle Worldwide, Inc.
Attention: Process Technician Certification
P.O. Box 570, Morrisville, NC 27560
telephone: 919.572.6680 / fax: 919.361.2426

Applications must be received at least 30 days prior to the examination administration date.

E. Application Process Overview

To sit for the Process Technician Certification examination, applicants must have successfully completed the BioWorks course through the North Carolina Community College System. The application steps include:

1. **Review the candidate handbook prior to completing the application.** Follow the instructions given, and address any questions to Castle Worldwide, Inc. Failure to follow the instructions can lead to the denial of an application.

2. **Review the competency requirements.** To sit for the Process Technician Certification examination, an applicant must have successfully completed the BioWorks course through the North Carolina Community College System.

3. **Compete and mail the application.** The completed application must include a copy of the applicant’s BioWorks course certificate or the applicant’s college/course transcript indicating completion of the BioWorks course. All these materials will be held in strictest confidence.

4. **Mail the application and application fee.** A completed application must be received at Castle Worldwide, Inc. before processing begins. Applications must be received at least 30 days prior to the examination administration date. Applications incomplete after one year from the date of submission will be moved to a closed file and must be resubmitted along with the application fee.

5. **Allow sufficient time for application review.** Applicants are encouraged to submit their applications and collateral materials as early as possible to allow for any unanticipated delays. Major delays are often caused by incomplete applications or missing payments and collateral information.
6. **Sit for the examination.** If an applicant is approved to sit for the Process Technician Certification examination, he or she will be informed in writing that he or she is now eligible to sit for the examination. Examination administrations are scheduled following the completion of each BioWorks course. The testing window will be three to four weeks in length, and the testing window will begin no less than 30 days after the last class meeting of the latest BioWorks course scheduled. For example, if the last class ends January 15, then the testing window will begin no sooner than February 15.

For additional information on test dates and locations, please contact the BioWorks course professor or Castle Worldwide, Inc., the testing company contracted to administer the examination.

7. **Wait for the examination results.** In order for statistical analyses to be completed on the Process Technician Certification examination, examination results will be mailed approximately six weeks after the examination date. 

Exam results will be released in writing by mail only. Exam results will not be given via telephone or fax.

**F. Competency Requirements**

To sit for the Process Technician Certification examination, applicants must have successfully completed the BioWorks course through the North Carolina Community College System.

The application must include a copy of the applicant’s BioWorks course certificate or the applicant’s college/course transcript indicating completion of the BioWorks course. All these materials will be held in strictest confidence.

**G. Additional Application Information**

**PERSONAL INFORMATION:** Complete all sections of the application that pertain to personal information. This information is needed in order to facilitate communication with the applicant. Applicants should include maiden names if they are needed to confirm education. Provide complete information including all zip codes, telephone numbers, and e-mail addresses in order to expedite processing. During the application and certification process, it is the applicant’s responsibility to keep Castle Worldwide, Inc. informed of current addresses so that he or she will continue to receive all certification updates, training information, and renewal notices.

**ORIGINAL SIGNATURE AND VERIFICATION OF INFORMATION:** An original signature must be on the application. Applicants are expected to provide truthful and complete information. Any application missing information or found to be dishonest will not be considered for the certification program.

**H. Certification Examination Registration**

If a candidate is approved to sit for the examination, he or she will be informed in writing. The examination admission letter will include an examination administration schedule (reporting times, test times) as well as the test location.

Examination administrations are scheduled following the completion of each BioWorks course. The testing window will be three to four weeks in length, and the testing window will begin no less that 30 days after the last class meeting of the latest BioWorks course scheduled. For example, if the last class ends January 15, then the testing window will begin no sooner than February 15.

For additional information on test dates and locations, please contact the BioWorks course professor or Castle Worldwide, Inc., the testing company contracted to administer the examination.

**I. Certification Examination Information**

**EXAMINATION DEVELOPMENT:** The Partnership for Biotechnology Workforce Training has contracted with Castle Worldwide, Inc. to develop the certification examination. Castle Worldwide is a full-service testing company providing licensure, certification, and specialty examinations, including practical and written simulation tests, for associations, state boards, government agencies, and corporations.

The development of a valid examination for the Partnership for Biotechnology Workforce Training certification process begins with a clear and concise definition of the knowledge, skills, and abilities needed for competent job performance. Using interviews, surveys, observation, and group discussions, Castle Worldwide, Inc. works with subject matter experts to delineate critical job components.

**EXAMINATION CONTENT:** Eight units of the BioWorks course account for the examination’s content. These units, as well as the task statements for each unit, are listed below.

**Unit 2: Working Safely**

1. Identify the people you are responsible for keeping safe while you are on the job.
2. Identify common hazards related to materials, equipment, and surroundings in chemical and biological...
process manufacturing. For example, hazards related to chemicals and heavy equipment and biohazards.

3. Explain what the letters PPE stand for and identify PPE items that process technicians might need to perform their work.

4. Describe OSHA’s regulation on hazard communication.

5. Explain the purpose of lockout.

6. Explain the purpose of an MSDS.

7. Demonstrate proper lifting procedure.

8. List five examples things you must be aware of to keep yourself and co-workers safe.

9. Identify examples of using your senses to detect hazards and potential hazards.

Unit 3: Building Quality into the Product
1. Explain the meaning of the following phrases:
   • Understand customer needs.
   • Say what you do.
   • Do what you say.
   • Prove it.
   • Improve it.

2. Identify consequences of failure to follow quality standards in manufacturing.

3. Explain the difference between quality control and quality assurance.

4. Explain how the following process technician tasks impact quality:
   • Monitoring the process.
   • Communicating and working as a team.
   • Following procedures.
   • Keeping records.
   • Sampling and testing.
   • Solving problems and improving the process.

5. Follow documentation standards for writing date and time and for making corrections.

6. Explain the purpose of a batch production record and an SOP.

7. Briefly define cGMP, ISO 9000, TQM, and Continuous Improvement.

8. State the purpose of FDA regulation of pharmaceutical manufacturing.


10. Describe the general procedure for raw material handling in a cGMP facility.

11. State the purpose of validation.

12. State the purpose of an audit.

Unit 4: Measuring Process Variables
1. Metric System
   A. Measure length, volume, and mass using the metric system.
   B. Convert between units in the metric system.
   C. Give rough English equivalents of the following metric system unit:
      • Meter
      • Kilometer
      • Gram
      • Kilogram
      • Liter
   D. Use formulas that are provided to convert measurements from metric to English units and vice versa.
   E. Identify by name and be able to use common laboratory glassware and pipettes.
   F. Use a balance.

2. Mass, Volume, and Density
   A. Calculate the third factor if two of the following factors are known (mass, volume, or density).

3. Measurement Concepts
   A. Determine how many decimal places to use in reporting a measurement that is made with a particular measuring device.
   B. Select an instrument with a range that is appropriate for a particular task.

4. Temperature
   A. Identify common instruments for measuring temperature and describe in basic terms how they work.
   B. Give rough Fahrenheit equivalents of the Celsius reading for the following:
      • Human body temperature
      • Temperature at which water freezes
      • Temperature at which water boils

5. Pressure
   A. Describe how volume and temperature affect gas pressure in a container.
   B. List safety precautions for working with high-pressure steam and gases.
C. Describe proper procedures for working with gas cylinders.
D. Describe steam collapse and how it can be prevented.
E. Identify common instruments for measuring pressure and describe how they work.
F. Identify units of measure for expressing pressure.
G. Convert between different units for measuring pressure.
H. Define vacuum.
I. Explain the difference between absolute and gauge pressure.

6. Flow and Level Measurement
A. Identify common instruments for measuring flow rate and describe in basic terms how they work.
B. Identify units of measure for gas flow and for liquid flow.
C. Identify factors that increase or decrease flow rate.
D. Perform flow rate calculations, given the formulas.
E. Identify ways to measure the flow of solid materials in an industrial process.
F. Identify common instruments for measuring level and describe in basic terms how they work.

Unit 5: Transforming Matter

1. Regulation of Chemicals and Basic Chemical Safety
A. List basic safety precautions required to handle the following types of materials: flammable, toxic, corrosive, air and water reactive.
B. Define terms commonly used in information about chemical hazards.
C. Describe types of information contained in an MSDS.
D. Read an MSDS for a chemical commonly found in process manufacturing and state the hazards and precautions to be taken in handling it.
E. Explain the basic steps an employee without chemical emergency response training should take to respond to chemical spills.
F. Explain the hazard level (rank) of a chemical indicated by the NFPA (National Fire Protection Association) diamond symbol.

2. What Everything Is Made Of
A. Define element, atom, molecule, and compound.
B. List names and symbols for 10 common elements.
C. Given the formula for common chemical compounds, provide the name of the compound. (Or, given the compound name, provide the formula.)
D. State that the chemical composition of a substance affects its physical nature and how it interacts with other substances.
E. Describe the physical appearance of five different common elements or simple compounds, provide the chemical formula or symbol, and describe where the substances might be found in everyday life. (For example, salt is sodium chloride and looks like white grains or powder, sulfur is white powder, hydrogen peroxide is clear liquid.)

3. Families of Chemical Compounds
A. Define acid and base, and identify household or industrial examples of each.
B. Describe the hazards typically associated with acids and bases.
C. Describe precautions to take in mixing acids and bases with water and with each other.
D. Describe what pH measures, and specify the acidic and basic range of values for pH.
E. Measure pH and adjust the pH of a solution.
F. State that carbon can make a large variety of compounds and that some of these compounds make up living things.
G. State that the variety of organic compounds is due to:
   • Which atoms make up the compound.
   • How these atoms are arranged in space.
H. Identify common organic compounds used around the house or in manufacturing.
I. List hazards typically associated with organic compounds, especially hydrocarbons and oxygen-containing organic solvents such as alcohols, ethers, esters, and ketones.
J. Explain what an oxidizing agent is, and identify an example of one.
K. Identify hazards that may result from oxidation reactions.

4. Chemical Reactions
A. Explain the difference between theoretical and actual yield.
B. Explain the difference between endothermic and exothermic reactions and identify examples of each.
C. Identify hazards that may result from exothermic reactions.
D. Describe how temperature, pressure, and concentrations of reactants affect chemical reactions.
E. Describe the role of catalysts in chemical reactions.
F. Explain the difference between reversible and irreversible chemical reactions.

5. Solutions
A. Define solubility, solvent, and solute.
B. Explain the difference between reversible and irreversible chemical reactions.
C. Correctly express percentage concentration of a solution.
D. Calculate amounts of solute to use in making percentage solutions and correctly make v/v, w/v, and w/w percent solutions.
E. Dilute a stock solution to make the desired concentration of a reagent.
F. Define these properties of solutions: refractive index and concentration.
G. State that concentration of different kinds of solutes affects refractive index and conductivity.
H. Use a hand-held refractometer.
I. Make conductivity measurements.

6. Separation Technology
A. Describe the following in basic terms and identify an example of each as used in an industrial process:
   • Evaporation
   • Distillation
   • Precipitation
   • Crystallization
   • Filtration
   • Liquid extraction
   • Chromatography

Unit 6: Learning the Nuts and Bolts
1. Chemical, Pharmaceutical, and Bioprocess Manufacturing
   A. From a basic description of a manufacturing process, identify starting materials, unit operations, and inputs, outputs, and waste products from each operation.
   B. Read and draw simple process flow diagrams using a legend with a limited set of equipment symbols.
   C. Explain the difference between a batch and continuous process.
   D. Define process stream and waste stream.

2. Plant Utilities and Waste Treatment
   A. List the utilities commonly serving a process manufacturing plant and briefly describe their uses: water, steam, compressed air, other gases, CIP solutions, heating/cooling fluids, electricity, and hydraulics.
   B. For each plant utility, describe potential hazards and identify key parameters (such as temperature, pressure, conductivity) that process technicians must monitor.
   C. Describe the different types of water used in process manufacturing (deionized, WFI, USP purified, and incoming plant water) and identify an example of how each might be used.
   D. Identify examples of potentially hazardous plant wastes in solid, liquid, and gas waste streams.
   E. Explain in basic terms why biological wastes may need to be inactivated before release into the environment and why the amount of biological waste released must be controlled.
   F. Identify examples of wastes for which of the following methods of handling would be appropriate: sanitary sewers, on-site waste treatment, off-site hazardous waste disposal, landfill.
   G. Describe at least two precautions that must be observed in treating waste materials from bioprocess manufacturing prior to their release into the environment.
   H. List precautions (such as replacing frayed cords, pulling on the plug—not the cord, not hosing down areas with electrical components, and being aware of high voltage) for avoiding common electrical hazards of shock, burns, and fires.
   I. Define short circuits, and explain why they are hazardous. Identify causes of short circuits (such as damaged insulation and wet equipment).

3. Plant Equipment
   A. Identify ways process technicians use sight, hearing, touch, and smell to locate problems with equipment (tanks, pumps, valves, piping, connections, or motors).
   B. Explain why it is important to consider the compatibility of a fluid with the construction material of the parts or equipment the fluid will contact.
   C. Identify the following tank parts on a diagram and explain their purpose:
      • Inlet and outlet valves
      • Manways
      • Inspection ports
      • Agitators
      • Baffles
      • Spray balls
      • Spargers
      • Vents
      • Rupture discs
   D. Identify special features of equipment and piping in food or drug manufacturing that prevent microorganisms from growing (sanitary couplings, sloped piping, no sharp 90° bends, no dead ends, stainless steel construction).
   E. Define transfer panel and manifold, and identify examples of use.
   F. Explain in basic terms how the following valves work, and be able to identify them or their important features in diagrams:
      • Ball
      • Globe
      • Butterfly
      • Check
      • Gate
      • Diaphragm
• Plug
• Relief
• Pneumatic control

G. Explain in basic terms how the following pumps work:
• Centrifugal
• Diaphragm
• Lobe

H. Define suction and discharge heads and how they affect pump operation.

4. Unit Operations
   A. Identify unit operations used in chemical, pharmaceutical, or bioprocess manufacturing. (Note: This part of the course material is incomplete at this time. More specific competencies related to this subject will be developed later.)
   B. For described or diagrammed unit operations, list inputs, outputs, and process variables that might be monitored. (Note: This part of the course material is incomplete at this time. More specific competencies related to this subject will be developed later.)

Unit 7: Controlling the Process

1. Process Control: Types and Terms
   A. Identify simple everyday and industrial examples of process control.
   B. Define the following terms and identify them in a process description or diagram:
      • Controlled variable
      • Measured variable
      • Set point deviation
      • Manipulated variable
      • Disturbances

2. Process Control Instruments
   A. Describe the function of the following process control instruments and identify an industrial example of how they might be used:
      • Sensor
      • Transmitter
      • Controller
      • Final control element
      • Recorder
      • Indicator
      • Alarm
      • Interlock

3. Manual and Automatic Control
   A. For a given process example, explain the difference between manual and automatic control.

4. Feedback Control Loop
   A. Given a diagram of a feedback control loop, identify the following in the loop:
      • Controlled variable
      • Measured variable
      • Set point deviation
      • Manipulated variable
      • Disturbances

5. Two-Position and Proportional Control
   A. Describe two-position control, and identify an example.
   B. Describe proportional control, and identify an example.

6. Resistance, Capacitance, Dead Time, and Lag Time
   A. Define lag time, and explain how resistance, capacitance, and dead time contribute to it.

7. Adjust and Wait
   A. State that when making a process change:
      • Make small changes
      • Allow sufficient time between changes for the process to respond.
      • Make sure only one person at a time is making changes.

8. P&IDs
   A. Read a simple P&ID containing a limited set of equipment and instrument symbols and explain why each variable measured is important in the process.

Unit 8: Maintaining Sterile Processes

1. Microorganisms
   A. State that microorganisms are everywhere in the environment and on and within our bodies.
   B. Describe in general terms the characteristics of bacteria, fungi, and viruses.

2. Microorganisms and Disease
   A. List ways that humans can become infected with disease-causing microorganisms (pathogens).
   B. Identify common examples of human diseases caused by bacteria, fungi, and viruses.
   C. Identify common examples of blood-borne pathogens.

3. Microorganisms and Contamination
   A. Identify reasons why microbial contamination can be a problem in certain manufacturing settings and identify typical sources of contamination.
B. Demonstrate one method for sampling a surface for contamination.
C. Explain why proper hand washing is important.
D. State that even a single microorganism can cause a contamination problem.

4. Working Aseptically
   A. Define the following terms:
      • Growth media
      • Liquid media
      • Solid media
      • Inoculation
      • Incubation
   B. List basic safety precautions for working in a microbiology lab.
   C. Define: sterilization, antiseptic, and disinfectant.
   D. Identify examples of sterilization by steam, dry heat, and filtration in manufacturing processes.
   E. List precautions for working with autoclaves.
   F. Demonstrate how to sterilize a liquid by autoclaving and filtration.
   G. List precautions for steam sterilizing-in-place.
   H. List basic guidelines for working with disinfectants.
   I. Define spore, pyrogen, and aerosol, and indicate why they are problems in aseptic manufacturing.
   J. List precautions for aseptic transfer.
   K. Demonstrate proper aseptic technique for performing sterile transfers of liquids.
   L. Explain what a clean room classification defines (allowable particle concentration in the room).
   M. Describe basic precautions workers must take to prevent contamination of clean room environments and state that worker error is the chief cause of contamination.
   N. Demonstrate proper gowning procedures for clean room work.

Unit 9: Growing Living Cells
1. Basic Biochemistry
   A. List the major classes of biological molecules (proteins, nucleic acids, lipids, carbohydrates), and describe in general terms the role they play in cell structure/function.
   B. State that cells must have nutrients with which to synthesize biological molecules and nutrients that supply chemical energy.
   C. State that carbohydrates are broken down to CO₂ and H₂O with the release of chemical energy.
   D. Distinguish between aerobic and anaerobic growth.
   E. State that genes code for proteins.
   F. State that the genetic content of cells can be manipulated through genetic engineering to create cell types that will make a desired product.
   G. Define enzyme; know that enzymes are proteins.
   H. Describe in general terms how enzymes catalyze biological reactions.
   I. State that proteins are large molecules with a great variety of structure.
   J. List environmental factors such as pH, temperature, and salt concentration that affect maintenance of protein structure.

2. Cell Culture in Industry
   A. List common cell types used in production: bacteria, yeast, other fungi, mammalian cells.
   B. Give some examples of useful products that are made by each cell type, especially in North Carolina bioprocessing facilities.
   C. Be able to distinguish between different shapes and appearances of cells to discern contamination of a production culture.

3. Fermentation
   A. List the basic nutrient elements in growth media.
   B. List guidelines for preparing growth media.
   C. Identify problems that can occur if growth media components are not properly prepared.
   D. Describe phases of growth of a microbial culture.
   E. Describe how temperature, dissolved oxygen (DO) and pH affect cells and state that growth of a culture results in changes in these parameters.
   F. Label parts on a diagram of a typical industrial bioreactor and describe their functions.
   G. List typical inputs to a cell culture or fermentation process, and the different process variables that may be monitored.

4. Downstream Processing
   A. Describe process flows for two different product examples.
   B. Describe in basic terms the unit processes often employed in separation and purification of biological products, including at minimum chromatography and filtration.

EXAMINATION TIME LIMITS: Candidates must take the examination on the test administration date scheduled immediately following approval of their applications. Exceptions will be made only for substantiated emergencies. In these cases, candidates can request a refund, minus the $25 processing fee, within 30 days of the test administration date. Refund requests submitted within 30 days of the test administration must include documentation of the emergency, i.e., physician’s note.

REASONABLE ACCOMMODATIONS: Reasonable accommodations provide candidates with disabilities a fair and equal opportunity to demonstrate their knowledge and skill in the essential functions being measured by the examination. Reasonable accommodations are decided upon based on the
individual’s specific request, disability, documentation submitted, and appropriateness of the request. Reasonable accommodations do not include steps that fundamentally alter the purpose or nature of the examination.

A disabled candidate is one who has a physical or mental impairment that substantially limits that person in one or more major life activities (e.g., walking, talking, hearing, performing manual tasks); has a record of such physical or mental impairment; or is regarded as having such a physical or mental impairment.

The candidate must submit documentation provided by an appropriate licensed professional on the professional’s letterhead. The documentation must include a diagnosis of the disability and specific recommendations for accommodations. Requests must be received by Castle Worldwide, Inc. 30 days in advance of the examination date.

EXAMINATION SCHEDULE: Candidates will have four hours to complete the examination. The examination schedule will be noted on the examination admission letter.

All candidates should bring photo identification with signature to the examination site. Acceptable forms of identification include driver’s licenses, passports, and government-issued identification cards. Unacceptable forms of identification include gym memberships, warehouse memberships, school identification cards, and identification with signature only.

Non-communicating, battery-operated, silent, and non-printing calculators are permitted. Calculators with alphanumeric keypads are permitted.

EXAMINATION SCORING: In order for statistical analyses to be completed on the certification examination, examination results will be mailed approximately six weeks after the examination date.

If an individual believes his or her examination results are wrong, he or she may appeal to Castle Worldwide, Inc. To initiate this process, the candidate must do so within 30 days of receiving his or her score report. Castle Worldwide, Inc. will handscore the examination and mail the results to the candidate for a fee of $25.

Castle Worldwide, Inc. will perform a diagnostic report on the examination results for a fee of $35. The diagnostic report includes a breakdown of the score into the major domains in which the candidate was tested, the number of questions the candidate answered correctly, the percentage answered correctly, the average score earned by everyone on that date, the range of scores (low and high), and whether the candidate was strong or weak in those particular domains.

EXAMINATION RETAKES: Candidates who fail the examination at their first test administration date can reapply to take the examination three months after their first test administration date. Candidates who fail the examination at their second examination administration can reapply to take the examination one year after their second test administration date. Candidates can only take the examination three times.

The reapplication process includes submitting a current application and proof that the candidate has successfully passed the BioWorks course through the North Carolina Community College System as well as paying any current examination fees.

EXAMINATION RULES: Castle Worldwide, Inc. follows industry standard testing rules as outlined below.

- No books, papers, or other reference materials may be taken into the examination room. An area will be provided for storage of such materials.
- No electronic devices, including telephones, cameras, signaling devices, pagers, alarms, and recording/playback devices of any kind may be taken into the examination room. An area will be provided for storage of such materials.
- Candidates cannot take examination materials, documents, or memoranda of any type from the testing room.
- The examination will be given only on the date and time noted on the examination admission letter. If an emergency arises, and a candidate is unable to take the examination as scheduled, he or she may send a refund request to Castle Worldwide, Inc. within 30 days of the test administration date. The request must include documentation of the emergency, i.e., physician’s note. All refunds are subject to a $25 processing fee.
- No questions concerning the content of the examination may be asked during the examination period. The candidate should listen carefully to the directions given by the proctor and read the directions carefully in the examination booklet.