Bio Process Engineer Theory

LFS/N0247 : Provide operational support for daily manufacturing activities

PC1. provide technical support for the evaluation of raw material to ensure manufacturing processes are robust, safe and adequate
PC2. assist improvements in raw material testing regimes to ensure that the critical functional attributes are evaluated
PC3 provide support to manufacturing to meet production demands

1. Which of the following document is used as a reference for testing APIs?
    a. **Respective monographs**
    b. In-house specifications
    c. Safety data sheets
    d. Batch manufacturing records

PC4 operate small-scale cell culture areas and systems by operating cleaning, set up, and maintaining batch reefed fermenters; inoculating and maintaining spinner seed cultures using aseptic techniques, maintaining cell banks; and performing general seed lab operation
PC5. operate large scale column chromatography systems
PC6. comply with safety requirements, GMP, SOP and manufacturing guidelines

2. Which is the most reliable method to check for the purity of cultures?
    a. Biochemical tests
    b. **Molecular identification**
    c. Microscopic examination
    d. Examination of cultural characteristics

PC7. assist in the use of automation to perform production operations
PC8. participate in continuous operational improvement of the manufacturing process
PC9. apply the concepts in commercial-scale drug substance manufacturing

3. Which part of the fermenter assists in preventing vortex?
    a. Spargers
    b. Impellers
    c. **Baffles**
    d. Agitators

PC10. anticipate potential problems and takes preventative action PC11 provide day-to-day bioprocess engineering support to upstream / downstream manufacturing operations

PC12. support and participate in commissioning and start-up activities of biotech unit operations and equipment.

4. Identify the procedure that is not performed during upstream processing.
    a. Preparation of media
    b. **Separation of cells from fermentation broth**
    c. Strain improvement of the microbe
    d. Removal of inhibitory agents from the media

PC13. initiate and implement facility and equipment upgrades to improve plant productivity and throughput
PC14. facilitate the introduction of new products with associated new unit operations and equipment and ensure the bio-processing at the site stays current with emerging processing and equipment innovations

5. Which of these recent developments in downstream processing holds promise in cutting down production time and costs?
    a. **Continuous processing**
    b. Use downstream processing systems of larger capacities
    c. Use alternative downstream processing systems
    d. Use of advanced systems for data analysis

PC15. assemble and prepare equipment for production
PC16. prepare solutions for the production process
PC17. troubleshoot equipment and process problems

6. What temperature is generally maintained for continuous sterilization of solutions?
    a. 131 °C
    b. 125 °C
    c. **140 °C**
    d. 121 °C

PC18. operate systems that clean and sterilize tanks and filtration systems
PC19. operate fermenters, centrifuges, other harvest systems and protein purifications units

7. Which method is best suitable for cleaning tanks and filtration systems?
    a. Clean-out-of-place (COP)
    b. **Clean-in-place (CIP)**
    c. Manual cleaning
    d. Semi-automatic procedures

PC20. interact with internal and external business partners to remain updated on emerging technologies to best position the operations team with a competitive advantage in delivering products of the highest quality at the lowest cost
PC21. develop recommendations for improvements to existing commercial-scale manufacturing processes to ensure reliability, robustness, and regulatory compliance

8. Which of the following types of valve should be suggested for use in aseptic operations?
    a. Gate valves
    b. Globe valves
    c. **Piston valves**
    d. Needle valves

LFS/N0248 : Support R&D capabilities

PC1. establish process development scale-up to extend the company's research and development capabilities
PC2. optimize growth and productivity parameters of suspension cell lines and assist, as needed, in the hands-on experiments to define these variables

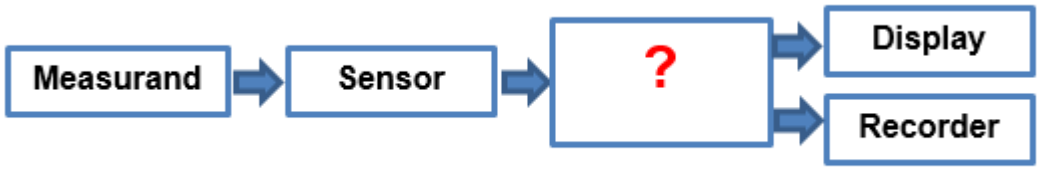
9. Which of these culture flasks are best suited for the culture of small volumes of suspension cells?
    a. Shaker flasks that are tissue-culture treated
    b. Shaker flasks that are not tissue-culture treated
    c. Shaker flasks with baffles
    d. **Spinner flasks**

PC3. conduct research along with life scientists, chemists, and medical scientists, on the engineering aspects of the biological systems of humans and animals

10. Auscultatory method of blood pressure measurement is an invasive technique.
    a. True
    b. **False**

PC4. diagnose and interpret bioelectric data, using signal processing techniques
PC5. design and develop medical diagnostic and clinical instrumentation, equipment, and procedures, using the principles of engineering and bio-behavioural sciences

11. Identify the device in the general representation of a biomedical instrumentation shown below.



    a. Signal converter
    b. Signal transducer
    c. Signal transmitter
    d. **Signal conditioner**

PC6. develop models or computer simulations of human bio-behavioural systems to obtain data for measuring or controlling life processes

12. Which of the following is a controlling biomedical instrument?
    a. Electromyograph machine
    b. Foetal monitor
    c. **Defibrillator**
    d. Blood flow meter

PC7. assist in design, development, and evaluation of biological and health systems and products, such as artificial organs, prostheses, instrumentation, medical information systems, and health management and care delivery systems

13. Which of the statements regarding precision of instruments is true?
    a. **Cannot be improved**
    b. Can be improved
    c. Is the same as accuracy
    d. Is a measure of how close the measured value is to the true value

PC8. participate in the creation, development and design of the organization's novel technologies by interfacing with vector design, downstream and analytical teams
PC9. research new materials to be used for products, such as implanted artificial organs

14. Which of the following organ restores the function of cochlear implants?
    a. Eyes
    b. **Ears**
    c. Liver
    d. Thymus

LFS/N0249 : Assist in development and execution of technical transfer plans, process transfer and validation protocols

PC1. contribute technical support to develop and execute technical transfer plans (including transfer of existing products or new products under development), which includes preparation of process transfer protocols, process validation protocols, and supporting regulatory documents.

15. Which of the following is ideally the first step in process validation?
    a. Process qualification
    b. Process quantification
    c. Continued process verification
    d. **Process design**

PC2. provide technical guidance to R&D cell-line development and media optimization functions to ensure manufacturing suitability and regulatory compliance of proposed strategies while maximizing process yields and/or reducing cost of goods

16. Which of the following statement is true regarding media optimization?
    a. Different types of media can be used in a single batch process
    b. **Different types of media can be used in a fed batch process**
    c. Growth medium has enriched nutrient concentrations
    d. Production medium has lower nutrient concentrations

PC3. serve as technical support on capital projects related to manufacturing processes and equipment, and as a bioprocessing functional area subject matter expert on the internal mammalian cell culture manufacturing

17. Which is the ideal phase for mammalian cells to be subcultured?
    a. **Log phase before they reach confluence**
    b. Log phase after they reach confluence
    c. Lag phase
    d. Stationary phase

PC4. assist in design and execution of test protocols to optimize unit operations
PC5. assist in processing data to manufacturing performance management meetings to establish and monitor process metrics, extract key learnings

18. Which of the following equation is most commonly used to calculate flow rate in filtration systems?
    a. Buckley-Leverett equation
    b. **Kozeny-Carman equation**
    c. Cahn-Hilliard equation
    d. Haaland equation

LFS/N0250 : Carry out reporting and documentation for bioprocessing activities

PC1. support the team in technical transfer of data, processes and technical specifications to CMOs for the implementation of large-scale manufacturing operations for clinical and commercial development of targeted products

PC2. follow reporting procedures as prescribed by the company

19. Identify the procedures which a bioprocess engineer should ideally follow while reporting?
    a. **Company procedures**
    b. Self-set procedures
    c. Local laws and regulations
    d. Procedures followed by your colleague

PC3. identify and report defects/anomalies to the appropriate authority

20. A large amount of foam is observed in the bioreactor. What should the bioprocess engineer do?
    a. Increase the agitation rate
    b. Decrease the agitation rate
    c. **Check if an antifoaming agent has been added or not**
    d. Stop the production immediately

PC4. prepare comprehensive summaries of bioprocessing information and other documents necessary for regulatory submission

PC5. maintain, update and archive study related files and documents

21. After the revision of existing version of the document, what is the action to be taken w.r.t the superseded version of the document?
    a. Master and controlled copies of superseded shall be destroyed
    b. **Master copy shall be superseded and archived; controlled copies shall be retrieved and destroyed.**
    c. Master copy of the superseded version shall be destroyed.
    d. No actions are required as both the documents are kept under QA department control

PC6. identify documentation to be completed relating to one's role

PC7. record details accurately in the appropriate format

PC8. ensure that the final document meets regulatory and compliance requirements

22. Which of these statements comply with good documentation practices (GDP)?
    a. Changes can be made in pencil
    b. Handmade changes need not be dated
    c. Changes can be made in delible ink
    d. **Handmade changes need to be dated and signed**

PC9. perform review of records and other documentation for compliance to established procedures and good documentation practices

PC10. respond to requests for information in an appropriate manner whilst following organizational procedures

PC11. inform the appropriate authority of requests for information received

23. When there is a request for testing information from a contract manufacturing organization (CMO), what should a Bio process engineer do?
    a. Provide information immediately
    b. **Confirm and then provide information**
    c. Refuse the request
    d. Provide information after waiting for sometime

LFS/N0251 : Coordinate with manager and team members to carry out bioprocessing activities

PC1. receive work instructions from reporting manager
PC2. communicate to reporting supervisor about process-flow improvements and quality defects received from manufacturing activities

24. Fluctuation is observed in the agitation speed of a bioreactor in an API production unit. What should be the action of a Bio - process engineer?
    a. Stop the production immediately
    b. Check if it is affecting the quality of the product
    c. **Inform Supervisor and act on his advice**
    d. Try and repair the agitator

PC3. investigate, bring to the manager's attention and suggest possible solutions to problems arising within the department resulting from faulty equipment, dated SOP or human error
PC4. communicate any potential hazards or expected process disruptions

25. There is an increase in bioburden observed in fermenters post the CIP process. What can be suggested to overcome this problem?
    a. **Inclusion of steam in place (SIP) at the end of CIP process**
    b. Inclusion of more chemicals in CIP process
    c. Decrease the flow rate in CIP process
    d. Increase the flow rate in CIP process

PC5. provide requisite information, documents, clarifications to manager during actual audits
PC6. collaborate with the manufacturing department in updating manufacturing procedures and policies

26. Which of these documents are not required during audits for a Bio - process engineer ?
    a. Justifications for changes made in protocols
    b. Out of specification (OOS)/out of trend (OOT) reports
    c. Batch manufacturing records
    d. **Warehouse records**

PC7. work as a team with colleagues and share work as per their own workload and skills
PC8. support team members to support internal and external audit activities as per instructions of superiors/supervisor
PC9. provide documented shift handovers to the next person in the shift
PC10. communicate and discuss work flow related difficulties in order to find solutions with mutual agreement

27. After completion of one's shift, what should a Bio - process engineer do without fail?
    a. Inform your supervisor and leave
    b. Inform other team members and leave
    c. **Handover data to the person in next shift**
    d. Handover data to any of your team members