Job Description: «PCP» Biologics Trainee
Job Title: PCP Trainee- Biotechnologist, Mammalian Manufacturing
Department: Mammalian Manufacturing

Responsibilities

The Biotechnologist is responsibe for the manufacutre of therapeutic proteins under cGMP conditions. Expectations for each position are built upon those described in the preceding level.

This position reports to the Senior/ Section Lead/ Manager of the Manufacturing Large Scale, Small Scale or Centralized Operations Team.

Equipment Expertise (All sections)

- Learn & perform well defined procedures
- Pursue ongoing training to increase knowledge & understanding
- Attain basic understanding of cGMP requirements & compliance within a GMP manufacturing setting
- Perform assigned tasks (by Section Lead/ Manager) both with and without supervision
- Perform equipment monitoring & and basic 6S housekeeping
- Perform basic laboratory tasks (eg: sampling, pH/ conductivity/ osmolality measurements etc.)
- Perform routine sanitization tasks to maintain facility standards
- Achieve & consistently maintain a training status of ≥ 90%
- 100% trained & signed off on Performnace Measures (PMs) relating to CIP/ SIP/ basic tank & instrument operations
- Demonstrate aseptic technique in the handling of product materials
- Perform tasks independently in ≥ 80% of manufacturing areas assigned eg. USP/ DSP/ PST
- Perform basic process & equipment troubleshooting
- Able to multi-task on equipment preparations & operations to ensure adherence schedule
- Attain full competency in the performance of all operations relevant to manufacturing areas assigned
- 100% trained in all related manufacturing operations
- Display basic process & equipment troubleshooting ability under routine scenarios.

Technical Process Expertise (All sections)

- Exhibit basic understanding of critical process/ operational parameters and target/ acceptable ranges
- Exhibit basic understanding of the entire process eg. interactions between different process parameters.
- Understand process flow from scheduling & resource loading perspective.
- Display basic awareness of operational factors, which influence the process
- Work effectively interdepartmentally, providing manufacturing insights & support to MSAT, Lot Review and Deviation Investigation groups.

Systems & cGMP Expertise (All Sections)

- Use Standard Operating Procedures (SOPs), logbooks & Batch Records (BRs) effectively & competently.
- Understand in general the Lot Review process/ workflow
- LIMS (Laboratory Information Management System) trained & competent in the submission of samples via LIMS
- Attain operating knowledge of PWCS (Plant Wide Control System)
- Understand the deviation system/ workflow overview

- Understand the Kanban system overview & competent in ordering of consumables, BRs traceable & logbooks
- Perform logbook & 1st level BR review effectively & competently
- Operate PWCS independently for daily routines.
- Understand emergency materials requisition process/ workflow.
- Execute validation activities as per instructed.

Specific Skillset

Buffer/ Media preparations

- Understand there are different setup and equipment use between customers for different operations. Eg. CIPs and buffer/ media transfer.
- Able to identify and install the different set up and equipment for different customers for different operations. Eg. CIPs and buffer/ media transfer.
- Understand the criticality of setting up the right path and equipment for different customers.
- Understand the different set up and the equipment use between single use and the conventional stainless steel equipment.

Dispensing/ Sampling/ Autoclave/ Equipment Wash

- Able to identify the correct materials by part number and FEFO lots.
- Select appropriate Dispensing Booth's Hoods and Weight balance.
- Identify sampling requirements based on material RMS.
- Assemble Autoclave assembly per SOP.
- Able to perform equipment wash without stain and residues.

Cell Culture (Upstream small/ large scale)

- Basic skill and knowledge of aseptic technique for subculture stages example using culture flask, spinners, wave bioreactors, etc.
- Basic technical knowledge on the bioreactor culture control example pH/ DO control, CO2/ O2 control, cell performance and metabolites analysis.

Purification (Downstream small/ large scale)

- Basic skill and knowledge of column chromatograpy techniques, tangential flow, filtration techniques, micro/ Nano filtration techniques. pH/ Conductivity adjustment techniques, aseptic techniques.
- Basic technical knowledge on the chromatography operating interface example using UNICORN software and various DeltaV control parameters for chromatography and UF operation.
- Basic knowledge in single use applications for the respective processes.

Problem Analysis/ Decision Making (All sections)

- Make basic decisions eg. know when to seek help & who to contact
- Identify situations which may require further escalation to Section Lead/ Manager.
- Provide appropriate immediate actions in situations, which will require further escalation.
- Recognize abnormal and/ or potential events, which affect operations, product quality and/ or safety & escalate to the appropriate level of attention.

Planning/ Comunication (All sections)

- Organize & plan assigned daily activities to ensure timely completion of all assignments
- Document all work as it occurs
- Ensure all BRs related materials eg. dispensing, consumables, traceable, cleaned/ autoclaved parts etc. are available in advance of scheduled usage.
- Ensure all equipment are ready for production use (ie. within CIP/ SIP expires) in advance of scheduled usage.

- Communicate to a level where appropriate questions are asked to increase understanding of role.
- Present facts in a logical, concise & accurate manner while checking for understanding.
- Offer suggestions/ options to Section Lead/ Manager on process/ scheduling issues.
- Draft shift notes.
- Support Operational Excellence (OE) visual management tools & systems.
- Write & perform shift exchange in the absence of Section Lead/ Manager.
- Support multiple and/ or changing priorities of floor activities.
- Support upcoming suite activities & actively coordinate with other departments.
- Offer and implement improvement suggestions relating to process/ scheduling/ costs/ operational workflows.

Supervision Received (All sections)

- Report to Section Lead/ Manager
- Receive daily supervision on routine work & detailed instructions on new assignments.
- Able to work indelendently to perform manufacturing activities.
- Receive minimal supervision and ensure job assignments are progressing per schedule.
- Any other duties as assigned by your Supervisor Manager.

Education & Experience

- Degree/ Diploma/ NITEC in a related Science/ Engineering discipline
- Fresh graduates are welcome
- Individual without prior working experience in the biopharmaceutical manufacturing industry is encouraged to apply as training will be provided
- Knowledge of cGMP applications
- Positive team oriented attitude
- Strong communication and interpersonal skills
- Willing to perform rotating 12-hour shift pattern
- Able to perform physical activities in a clean room environment. Individual will be on the feet most of the time, and will be required to perform manual work (> 60% of activities) in a buddy system that includes standing, carrying items that weigh up to 12 kg, or moving equipment.

Competencies

- Business Acumen
- Customer Focus
- Driving Results
- Leadership
- Collaboration
- Agility

Others

- Two-way company transport is provided to various pick-up and drop-off points island wide.