



Job Description: Manufacturing Sciences Trainee

Primary Objectives of the Job:

- Support manufacturing operations (Upstream/Downstream) by troubleshooting process/product issues
- Act as technical support for manufacturing operations to resolve process issues, perform root cause analysis and impact assessment for process investigations
- Support evaluation of technologies and execute process improvements
- Support and execute global manufacturing sciences in initiatives
- Support and execute site manufacturing activities such as continuous process verification (CPV) program, technology transfer of new products and process monitoring and trending .
- Perform analytical testing for laboratory experiments, use tests or small-scale investigations. Support manufacturing operations (process investigations, improvement projects) through maintaining analytical methods and performing analytical testing for small scale laboratory studies/experiments.
- Support the implementation of new analytical equipment in the Singapore (SN) Manufacturing Sciences (MSci) lab. Perform maintenance of existing analytical equipments in the SN MSci lab.
- Support the evaluation of analytical methods development and implementation for new product introduction, technology transfer and any feasibility runs in the SN MSci Lab . Support any global initiatives for analytical methods development and implementation.

Primary Responsibilities Include:

Core Responsibilities:

- Complete 8 Core Modules together with elective modules in Biologics conducted in Singapore Polytechnic and On-the-Job Training (OJT) with Takeda
- Executing activities required for process investigation such as performing process impact assessment, participating and performing root cause analysis. Work with cross functional teams for process issues investigation
- Analyzing process trends, monitoring process performances as part of the CPV program. Escalate and perform investigation in event of any out of trend or process issues
- Leading process investigations to identify root cause and implement action plans to correct or prevent re-occurrence
- Executing process improvements and robustness projects
- Providing technical input for equipment qualification,
- Execute cycle development for process parameters where applicable
- Drafting process training slides and providing process training to cross functional teams
- Own change control child tasks a process SME
- Perform impact assessments for relevant change controls



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- Supporting the evaluation of new manufacturing technologies and/or equipment for process improvement or process capabilities build
- Supporting and executing technical transfer activities according to project timelines. Raise change controls where applicable to support the technical transfer
- Monitoring process performance and trending through the site CPV program. Proactively investigate where required to ensure process robustness.
- Performing risk assessment, drafting required technical transfer and process control strategy documents and updating lifecycle documents
- Authoring process validation protocols and reports where needed
- Support the implementation of analytical activities in SN Msci lab from purchase of equipment, commissioning and to method transfer (including feasibility studies) from analytical development and/or Neuchetel and Orth QC labs
- Execute analytical testing for SN MSci lab activities to support global and local process improvements projects or process investigations or material use tests for commercial manufacture. Support the planning of any analytical experiments required for SN MSci lab activities.
- Create laboratory documentation including procedures, forms, protocols and reports for routine analytical activities and / or testing according to relevant quality standards.
- Analyse and summarize analytical testing results. Compile results into laboratory reports where applicable. Draft analytical reports where applicable.
- Perform laboratory analytical equipment maintenance and calibration as per laboratory procedures.
- Support the implementation of analytical methods to support end to end small scale processing for current manufacturing processes on site (for eg, Advate, Rixubis, TAK-755) and for any new manufacturing processes to be transferred to the site (for eg, Vonvendi).
- Support troubleshooting of analytical testing issues, analytical equipment issues within the SN MSci lab.
- Order and stock materials, including consumables and raw materials required for analytical methods maintenance and testing.
- Participate in Community of Practice, where applicable, and support the implementation of new analytical initiatives and /or improvements.
- Support audits, regulatory submissions and responses
- Support and execute global manufacturing sciences initiatives according to project timelines
- Responsibility to adhere to any applicable EHS requirements.
- Commitment to a fair and respectful relationship to others and behavior in accordance with Takeda's Code of Conduct.
- Any other duties as assigned by supervisor.



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Education and Experience Requirements

- Bachelor's Degree in Biochemistry, Chemistry, Chemical Engineering, Biotechnology, Biochemical Engineering with at least 1 year of relevant experience or fresh Master's Degree in the relevant technical area.
- Hands-on experience with cell culture/ upstream processes and/or downstream processes in a manufacturing or development environment is an added advantage.
- Hands-on experience with analytical testing (for eg, HPLC testing, spectroscopy analysis, bioanalytical assays, etc) for biologics processes in a manufacturing or development / small scale lab environment.
- Has knowledge of cGMP

Key Skills and Competencies

- Good technical knowledge and process understanding of biopharmaceutical processes
- Good understanding of problem solving, in identification of potential issues, correlation or cause and effect relationships, root cause analysis methodology
- Willingness to learn
- Team worker/ able to work in matrix environment
- Independent worker/ Self starter