Analytical Development

Job description forthepositionof molecular biology

Key Responsibilities:

- Proficiency in qPCR, RT-PCR, and DNA/RNA extraction techniques.
- Experience in nucleic acid-based assays such as quantitative PCR (qPCR), RT-PCR,
  digital PCR (dPCR), and endpoint PCR.
- Experience in gel electrophoresis (agarose/SDS-PAGE) as part of analytical workflows.
- Prior knowledge on method development, qualification, and validation of molecular
  assays for new or existing products.
- Experience in evaluate product identity, contamination mycoplasma detection, residual
  host cell DNA quantification, or viral safety testing.
- Knowledge of method qualification/validation principles and documentation

Job description for the position of LC-MS

Key Responsibilities:

- Hands on experience in operate and maintain LC-MS/MS, UPLC-MS, and Q-TOF
  systems for quantitative and qualitative analysis.
- Experience in method development, optimization, and validation for pharmaceuticals,
  biologics, or biosimilars following ICH and regulatory guidelines.
- Perform a wide range of sample types including peptides, proteins, monoclonal
  antibodies, metabolites, and impurities.
- Use software such as MassLynx, Analyst, OpenLab, or Skyline for data acquisition and
  processing.
- Experience with intact mass analysis, peptide mapping, glycan profiling, or host cell
  protein (HCP) characterization.
- Exposure to high-resolution MS (Orbitrap/Q-TOF) and proteomics or metabolomics
  workflows.
- Knowledge of deconvolution software, charge state analysis, and spectral interpretation.

Downstream – Manufacturing - Biologics

- **Commissioning & Qualification:** Responsible for commissioning and qualification of equipment associated with DSP cell culture manufacturing.
- **Depth Filtration:** Hands-on experience with depth filtration using Merck Millipore and 3M holders.
- **Chromatography Systems:** Proficient in operating Akta process systems (600 LPH and 2000 LPH) and Akta pilot chromatography systems.

- **Column Packing:** Expertise in packing Quick scale columns (70 to 450 mm) and Isopack columns.
- **Low Bioburden Filtrations:** Good knowledge in performing low bioburden filtrations.
- **TFF Systems:** Skilled in handling TFF systems up to 15 m^2.
- **Documentation:** Responsible for preparing BMRs, SOPs, and protocols.
- **Safety Practices:** Ensures adherence to all safety practices and procedures.
- **Quality Management:** Responsible for QMS activities.

Upstream Manufacturing - Biologics

- Execute and optimize cell culture processes for mammalian systems to support the production of biologics.
- Operate and maintain single use bioreactors, including setup, monitoring, and troubleshooting during cell culture processes.
- Collaborate with cross-functional teams to develop and scale up upstream processes, contributing to process characterization and validation.
- Ensure compliance with Good Manufacturing Practices (GMP) and company standards, performing in-process testing and documentation of results.
- Qualification of upstream process equipment.
- Maintain accurate records of manufacturing, procedures, and results in accordance with regulatory requirements.
- Identify and resolve issues related to cell growth, yield, and product quality, proposing solutions and process improvements.

Upstream Process Development & MSAT

Key Responsibilities

- Plan and design experiments based on project/study requirements with a strong understanding of upstream process parameters.
- Process scale-up and scale-down studies.
- Technology transfer to Mfg. scale, troubleshooting challenges.
- Demonstrate proficiency in aseptic techniques for cell culture operations, media preparation, and sterile filtration.
- Execute process development and optimization studies across various scales including shake flasks, Ambr systems, and bench-top bioreactors.
- Prepare, calibrate, and operate bioreactors efficiently; ensure timely preparation of media, feeds, and buffers in accordance with batch requirements.
- Actively support team members and contribute to a collaborative work environment to achieve shared goals.
- Ensure all process development activities comply with GXP standards and follow ALCOA principles for data integrity.
- Monitor usage and stock levels of raw materials and consumables; coordinate timely ordering and inventory upkeep.
- Maintain accurate and comprehensive records including batch records, lab notebooks, and process development reports.
- Initiate and manage quality system elements such as Change Controls, Deviations, CAPAs, and Risk Assessments as required.

- Collaborate with cross-functional teams (CFTs) to ensure smooth execution of project milestones and deliverables.
- Contribute to the preparation and review of QMS documentation such as URS, DQ, IQ, OQ, and PQ protocols.
- Mentor and train new team members, interns, and junior staff on lab practices, equipment handling, and SOP compliance.
- Adhere to Environmental, Health, Safety, and Security (EHSS) standards and IT/data handling policies at all times.

Downstream Process Development & MSAT

- Key Responsibilities
- Plan and design experiments (DoE) based on project/study requirements
- with a strong understanding of downstream process parameters.
- Demonstrate proficiency in handling Akta pure system, buffer preparation,
- SDS-PAGE, Western Blotting and other associated activities.
  Technology transfer to Mfg. scale, troubleshooting challenges.
  Prepare, calibrate, and operate bioreactors efficiently; ensure timely preparation of media, feeds, and buffers in accordance with batch requirements.
- Actively support team members and contribute to a collaborative work
- environment to achieve shared goals.
- Ensure all process development activities comply with GXP standards and
- follow ALCOA principles for data integrity.
- Monitor usage and stock levels of raw materials and consumables;
- coordinate timely ordering and inventory upkeep.
- Maintain accurate and comprehensive records including batch records, lab
- notebooks, and process development reports.
- Initiate and manage quality system elements such as Change Controls, Deviations, CAPAs, and Risk Assessments as required.
  Collaborate with cross-functional teams (CFTs) to ensure smooth execution of project milestones and deliverables.
  Contribute to the preparation and review of QMS documentation such as URS, DQ, IQ, OQ, and PQ protocols.
  Mentor and train new team members, interns, and junior staff on lab practices, equipment handling, and SOP compliance.
  Adhere to Environmental, Health, Safety, and Security (EHSS) standards and IT/data handling policies at all times.

Downstream Process Development:

- Primary Responsibilities:
  - Responsible for process development activities and designing of
  - experiments. Preparation and review of qualification documents
  - as applicable as per SOP and coordinate with cross functional team for timely review and approval. Ensuring execution of Installation, Operational and performance qualification of process
  - development equipment's. Coordination with internal, external stakeholders and Aragen cross functional teams to expedite the
  - qualification milestones. Upkeep the required stock of consumables for batch activity and take follow-up with respective
  - team for its procurement and timely availability.

- Manage the team and plan daily activities to complete the project on time. Preparation and review of SOPs related to facility and process development equipment's. Adherence to Standard Operating Procedures. Maintenance of Process development equipment in coordination with Maintenance Department. Verification of Process development Equipment calibration and PM/AMC. Checking and Review of process development LNBs and other documents. Preparation, revision, and review of tech transfer protocols, internal protocols, process development reports and master formula records. Review of Quality Department Protocols related to process development lab. Troubleshooting of failure experiments. Compliance with current good documentation practices and keep lab ready all the time as per regulatory requirements. Providing regular work progress update, report creation and summarizing project status. Updating project status during client calls. Completion of training on time.

Quality Control

Quality Control Digitalization:

- Perform the analysis and online documentation as per written procedures.
- Involve in testing of the biochemical related analysis for product related samples.
- Management of chemicals and other reference standards in the QC laboratory.
- Involve in the equipment back up and maintenance with relevant cross functional teams.
- Involve in the material management and waste management in the QC laboratory.
- Preparation of Certificate of analysis (CoA) and ensure batch release.
- Preparation and operation of the LIMS masters and worksheets.
- Preform the calibration and preventive maintenance and qualifications of instruments as per the schedule.
- Ensure in every activity adhere to Data integrity policy.
- Preparation of department documents like; SOPs, STPs, Protocols, Reports etc.
- Involve in change controls, deviations, CAPAs and market compliant investigations.
- Involve in laboratory incidents and out of calibration events.
- Involve in Analytical Method Validations & Method transfers whenever required.
  Any task assigned by Head of the Department.
  To assign and coordinate trainings in department.

Bioassay:

- Perform the analysis and online documentation as per written procedures.
- Involve in testing of the bioassay related cell-based assays for product
- related samples.
  Management of chemicals and other reference standards in the QC laboratory.

- Involve in the equipment back up and maintenance with relevant cross functional teams.
- Involve in the material management and waste management in the QC laboratory.
- Preparation of Certificate of analysis (CoA) and ensure batch release.
- Preparation and operation of the LIMS masters and worksheets.
- Preform the calibration and preventive maintenance and qualifications of instruments as per the schedule.
- Ensure in every activity adhere to Data integrity policy.
- Preparation of department documents like; SOPs, STPs, Protocols, Reports etc.
- Involve in change controls, deviations, CAPAs and market compliant investigations.
- Involve in laboratory incidents and out of calibration events.
- Involve in Analytical Method Validations & Method transfers whenever required.
- Any task assigned by Head of the Department.

In-Process Quality Assurance:

- Manage in-process quality assurance (IPQA) activities throughout the manufacturing process for biologics. Line clearance for the Manufacturing activities.
- Perform real-time quality checks and assessments on ongoing manufacturing processes, ensuring compliance with SOPs, cGMP, and regulatory requirements.
- Review and approve batch records, SOPs, Protocols (Process validation, Gowning qualification, cleaning validation) related to Manufacturing activities.
- Ensure the timely release of materials (Cell Bank)and products in accordance with established quality standards.
- Mentor a team of IPQA associates, ensuring appropriate training and development.
- Organize and conduct regular training sessions on cGMP, quality policies, and in-process procedures for production and quality staff.
- Participate in regulatory and internal audits, providing necessary documentation and guidance on quality systems and processes.
- Support for the Investigations into non-conformances and out-of-specification and Out of Trend (OOS) results related to the manufacturing process.
- Provide technical expertise to troubleshoot issues, identify root causes, and implement corrective actions.

- Ensure that all relevant IPQA documentation, reports, and records are maintained in accordance with cGMP requirements.
- Review and approve documentation related to in-process testing, inspections, and quality assessments.
- Preparation of APQR.
- Responsible for release of the product by ensuring review of relevant audit trial of Manufacturing.
- Strong knowledge of cGMP, ICH guidelines, FDA regulations, and other relevant standards for biologics manufacturing.