TESSA MELLI

(XXX)-XXX-XXXX | first.last@email.com | Longmont, CO | linkedin.com/in/tessamelli/

SUMMARY

Biotechnology Professional with over three (3) years' industry experience in biopharmaceutical manufacturing. Core areas of knowledge include Quality Control, Research, and Manufacturing Sciences and Technology (MS&T/MSAT).

Core competencies: cGMP, GDP, GLP, start-up activities, technology transfer, root-cause analysis, data trending, statistical data analysis, Design of Experiments (DOE), technical writing, aseptic gowning, Lean Principles

EXPERIENCE

AveXis | Longmont, Colorado

Process Science Engineer II | Upstream Tech R&D Lab **September 2019 – Present**

Summary: Execute experiments in support of adherent cell expansion and scale-down reactor models. Analyze data and draft technical reports to enable cross-network decisions on manufacturing process changes and troubleshooting.

- SME of analytical test equipment: understand operation and use, perform instrument maintenance and troubleshooting, train others on sample testing, and interface with vendors for instrument IQOQ and PM activities
- SME of adherent cell expansion: understand passaging technique across multiple adherent cell culture vessels, train individuals on passaging, revise procedures and data capture sheets, and design and implement a strategy to maintain a continuous rolling cell stock to enable inoculation of laboratory reactors per the schedule
- Design and organize the lab space, and continuously assess consumables required to perform laboratory operations

Quality Control Analyst | Analytical Microbiology **April 2019 – September 2019**

Summary: Assisted in method transfer and process implementation in support of site start-up activities for QC.

- Contributed to start-up of the raw material sampling program, including transfer of SOPs, creation of a sampling forecast tool, and assessing operational requirements to avoid additional modifications to the original facility space
- Worked with a multi-site team to achieve alignment in conductivity test practices, that were in compliance with compendial requirements, in order to successfully transfer the method to the site

AstraZeneca | Boulder, Colorado **January 2017 – March 2019**

Quality Control Analyst | Microbiology

Summary: Supported routine and non-routine microbiological analyses and evaluated results against limits and specifications. Drafted, revised, and reviewed controlled documents such as protocols, reports, and SOPs.

- Contributed to site start-up activities in support of a PPQ campaign, including: Cleaning Validation, Performance Qualifications (Clean Utilities, EM, SIP), Process Characterization, and Process Validation
- Leveraged sample matrix information from manufacturing process documentation and MS&T SMEs to execute a strategy that reduced sample type qualification testing for two test methods by 60%
- Compiled data and performed statistical analysis for trending and alert/action limit assessments
- Created automated query tools to reduce time to perform sample forecasting and reconciliation by 75%

Bayer Healthcare | Berkeley, California **June 2015 - August 2015**

Manufacturing Sciences Intern | Drug Product

Summary: Investigated the stability of a therapeutic protein under time/temperature stress and freeze-thaw conditions.

Bowman Research Group | University of Colorado | Boulder, Colorado **August 2014 - May 2015**

Undergraduate Researcher | Materials Science

Summary: Developed and optimized a thermally re-mendable polymeric material with structural integrity retention.

EDUCATION

University of Colorado | Boulder, Colorado **Graduation: August 2016**

- **Chemical and Biological Engineering** | Bachelor of Science | *Cum Laude*
- **Molecular, Cellular, and Developmental Biology** | Bachelor of Arts | *with Distinction*