

Process Engineer

INCOG BioPharma is searching for a Process Engineer to join their growing organization, and deliver exceptional results.

The Project Engineer will provide technical assessment, approval, and documentation for engineering and process changes, equipment life cycles, and other qualification activities. They will also be ready to adapt and understand the changing needs of a CDMO.

Key Responsibilities:

- Monitor and analyze manufacturing data to provide support for process improvement and investigations.
- Participate and support process FMEAs to understand the risks as a prerequisite for process validation.
- Mentor and train other team members.
- Ensure successful manufacturing process comparability and process validation runs by assessing risk, setting preventative measures in place, investigating, and troubleshooting equipment and process issues.
- Lead and ensure systematic DMAIC based approach utilization for process/product related investigations to identify root cause and provide impact assessment to maintain routine manufacturing operations and determine process improvements for manufacturing.
- Participate and report to a cross-functional team to advance production activities.
- Participate in evaluation of new technology and process automation for introduction into GMP manufacturing.
- Write technical documentation (protocols & reports for equipment/instrument qualifications, comparability, process, and manufacturing process validation testing)
- Execute engineering studies, recipe development, and validation test cases.
- Work with vendors and suppliers to define requirements and understand functional specifications.
- Understand manufacturing needs and adapt to the changing needs of the manufacturing environment.
- Work flexible hours for the coverage of the production facility.

Education and Experience Requirements:

- Bachelor's degree or higher in chemical engineering, biochemistry, bioengineering, or related scientific field.
- 3+ years' experience in biopharmaceutical or other GXP regulated industry.
- Knowledge of data management tools and RCM.

Preferred Qualifications (not essential):

- CMO/CDMO experience
- Technical and/or lean six sigma certifications

Don't meet all the requirements? Don't sweat! We're always looking for an excuse to discuss your next opportunity. You might just surprise yourself...

Lead Candidate wholeheartedly supports Equality and Diversity in employment and opposes all forms of unlawful or unfair discrimination on the grounds of age, disability, sex, gender reassignment, sexual orientation, pregnancy and maternity, race, religion or belief and marriage and civil partnerships.