CQV Coordinator - Manager NSYNC Project (FTC)

Today Lonza is a global leader in life sciences. We are more than 15,000 employees in more than 100 locations around the world. While we work in science, there's no magic formula to how we do it. Our greatest scientific solution is talented people working together, devising ideas that help businesses to help people. In exchange, we let our people own their careers. Their ideas, big and small, genuinely improve the world. And that's the kind of work we want to be part of.
We are currently looking for a Commissioning, Qualification and Validation (CQV) Coordinator for the NSYNC Project to plan the CQV activities, coordinate the process and the involvement of all parties involved to ensure a timely execution within budget and meeting the expected quality of the execution.

Key responsibilities:

- Development of commissioning and validation strategies and plans, risk assessments, project procedure and templates
- Responsible for site commissioning and qualification procedures for building and process systems, cGMP equipment and systems (IQ, OQ, PQ)
- Responsible for scheduling/ management of commissioning qualification and process validation activities to achieve defined production start dates
- Manage CQV support of projects and manufacturing including financial tracking and reporting
- Responsible for auditing of various department structures to procedural guidelines and cGMP/ regulatory compliance
- Writing of position papers, rationales and process validation documentation for cleaning validation, intermediate hold time and life time studies for varying process purification techniques
- Providing strong leadership, direction, coaching and organizational planning for the team

Key requirements:

- Bachelor's degree in Engineering, Bioprocessing, technical or science related field.
- extensive experience of progressive experience in operations, qualification, validation and quality management of pharmaceutical/biotechnical operations obtain within a pharmaceutical manufacturing and multimillion-dollar CAPEX project environments;
- Specific project experience in primary active pharmaceutical ingredients (API's), secondary (Tablet), Cell Culture, plasma protein purification and vaccination manufacturing facilities.
- Demonstrated working knowledge of validation principles and cGMP, FDA, EMA, TGA, ICH and PICs regulatory requirements, compendia and guidelines such as ISPE
- Exceptional interpersonal and communication skills including mentoring, collaborating and negotiating in a multicultural environment.
- Project Quality Management Experience in several large-scale CAPEX pharmaceuticals projects.

People come to Lonza for the challenge and creativity of solving complex problems and developing new ideas in life sciences. In return, we offer the satisfaction that comes with improving lives all around the world. The satisfaction that comes with making a meaningful difference.