

Profile for Quality Head at Lonza-Octane Biotech

General Description of role

- Leads quality organization (QA, QC) at the Kingston Site
- Assures that the site remains under control with respect to GMP/ISO 9001 and 13485 compliance
- Accomplishes corporate business objectives by developing and maintaining business-appropriate site quality systems and ensuring compliance
- Leads & supports customer audits at the Site
- Develops manufacturing and process controls and improves quality systems
- Supports R+D organization
- Member of the Kingston Site Leadership team
- Collaborates with Lonza Cell and Gene Therapy CMO sites and process development teams globally

Desired profile:

More than 10 years experience in a Quality leadership role in Medical Devices (FDA Class 2 or above), medical equipment or laboratory analytical or diagnostic instrument manufacturing.

Working knowledge of USFDA 21CFR820 medical device quality system requirements, including:

- Design Controls,
- Device History File/Records
- Manufacturing related documentation, including materials and specification
- Management of non-conformances and complaints,
- Supplier quality, incoming materials inspection and release, materials qualification
- Supplier audits
- Employee training,
- Manufacturing facility design, facility controls and related systems, pertaining to cleanrooms and assembly of clean components to be sterilized.
- Validation/qualification requirements for production/assembly lines/process and software.
- FMEA
- Process trending/control methodology
- Management of ISO 7/Grade C cleanrooms and related requirements
- Management of sterilization services and related qualification/validation of sterilization methods.

Experience interacting with customers

Experience in Quality role in a matrix organization during product development

Experience in cell based biologics manufacturing is a plus.

Education: Bachelor's Degree in Life Sciences or related Engineering field.

How to apply:

Application should be submitted to Binit Gohel email: Binit.Gohel@lonza.com.