At Biocon Biologics, we are creating a model for the future of healthcare for all. We are a leading company in the biosimilars revolution where patients come first. Our ambition is to impact a billion lives and we do this by fostering a culture of affordable innovation, patient-centricity, and disruptive thinking. We are a multicultural global company where employees have a purpose and passion to work closely with partners and patients. We have a long-term commitment to bringing high-quality affordable biosimilars to patients all over the globe. We have proven end-to-end expertise from clone development, manufacturing, clinical development, and regulatory approvals to commercialization.

About the Role:

We are seeking a candidate for the Qualified Person Role who will be responsible for supporting Quality Europe. The primary role of the successful candidate will be to review and QP certify imported batches in preparation for release onto European markets and to carry out associated support activities. The person will also be responsible to support the maintenance of the MIA under which the import and certification activities occur, participating in inspections, executing inspection follow up (CAPA) and supporting inspection readiness activities. This position will partner with key internal business stakeholders and will work cross functionally on continuous improvement activities to drive effective, compliant, and sustainable solutions. This role demands an understanding of the regulatory requirements governing pharmaceutical products in Europe.

ROLES & RESPONSIBILITIES

Batch Review and Certification

Ensure that every batch of medicinal product to which the Manufacturers/Importers Authorization (MIA) relates has been manufactured and checked in compliance with:

- The requirements of Good Manufacturing Practice
- The provisions of the Marketing Authorization (MA)
- The laws in force in the Member State where certification takes place.
- Ensure the requirements of the MA relating to a product imported from non-EU/EEA country are complied with before each batch is released for sale within the EU.

Quality Management System (QMS)

Ensure that a QMS is maintained to support the review and certification activities.

Manufacturing Authorisation (MIA)

- Be conversant with conditions attached to the MIA and ensure that conditions are observed in operations of the manufacturer.
- Ensure that the competent authority is informed in advance of any proposed changes which will affect the MIA.
- Ensure that there are formal procedures for the effective communication between the product licensing authorities and manufacturing departments in all regulatory matters.
- Be involved during regulatory and customer inspections of the MIA site.

MA Compliance

- Ensure that the manufacturing and control procedures are not changed unless these have been approved by the relevant competent authority. Be aware of any amendments to the MA and ensure that these are implemented on the agreed date.

Competencies

- Meets the educational requirements for EU Qualified Person as defined in Article 49 of Directive 2001/81/EC.
- Minimum of 5 years of experience working as a QP, with at least 3 years performing QP release of sterile or biological products.
- Excellent communication, collaboration, and problem-solving abilities.
- Confident and professional.
- Credible in liaising with clients, customers, suppliers and regulators.
- Strong organizational skills, with the ability to effectively prioritize and manage multiple projects and tasks, with attention to detail.

Preferred Skills

- Self-motivated and demonstrated success in working with cross-functional teams.
- Excellent time management skills with a proven ability to meet deadlines.
- Detail oriented with proven abilities to meet deadlines and time management skills.

Applications:

Please send your application with CV
to barry.heelan@biocon.com or surabhi.parihar@biocon.com