QA SPECIALIST

(BIOPHARMACEUTICAL MANUFACTURING PLANT)

JOB SUMMARY: This person is responsible for the continuous development and administration of Helvetic Biopharma Quality Assurance System under full GMP conditions. The place of employment shall be Mezzovico, Ticino, Switzerland.

ABOUT HELVETIC BIOPHARMA: Helvetic Biopharma SA (www.helveticbio.com) is a new Biopharmaceutical company located in Mezzovico, Ticino, Switzerland and has assembled a team of biotechnology professionals with expertise in development and manufacturing of recombinant proteins for therapeutic use. Lead products will mainly include biosimilars monoclonal antibodies and functional proteins active in different therapeutic areas.

MAIN ACCOUNTABILITIES:

The main responsibilities will include but are not limited to:

- Author, revise and review SOPs and the other documents required to develop and maintain the Quality Management System.
- Provide training to the personnel on the Quality Management Systems.
- Manage internal and external auditing programs. Conduct GMP audits of internal departments, contract manufacturing organizations, outside testing laboratories, and other outside providers.
- Primary company interface during the authority and custom GMP inspections.
- Manage vendor qualification program.
- Lead batch disposition activities. Review of Batch Records and Laboratory Test Records and generation of documents needed for release e.g. COA, Compliance Statement, Release Notification, etc.
- Lead investigations and CAPA program. Work with cross-functional teams to investigate quality events (deviations and quality incidents), CAPA implementation, closures and evaluate CAPA effectiveness.
- Perform trend analysis of Quality Event, internal and external audit finding and generate trend reports. Report trends identified to Quality Management and recommend CAPA and improvements to eliminate or decrease the risk/impact associated with the trends.
- Lead or be part of the quality team that is managing the manufacturing and testing facility commissioning, including facility validation, and equipment validation.

PREFERRED QUALICATIONS:

- BS/MS in the life sciences (e.g. Biotechnology, Biochemistry, Chemistry, Chemical Engineering, Biology, Pharmacy, related field).
- At least 5 years of Quality Assurance experience in regulated industry (pharma/biotech) in a full GMP environment.
- Experience conducting internal audits, external audits (CMO, vendors).
- Strong working knowledge in GMP regulations, including FDA and EMA guidelines applicable to biologics manufacturing.
- Able to proactively work within cross functional teams, maintain good and collaborative communication and relationship with all staff, contractor, and consultants.
- Able to independently interpret complex results and situations, recognize risk, and develop recommendations for solutions.
- Fluent in Italian and English.

COMPETENCIES:

- Commitment to ethical scientific investigations and rigorous experimental methods.
- Ability and desire to multitask and function in a fast-paced entrepreneurial environment.
- Demonstrated ability to think critically and analyze and interpret data independently.
- Sense of urgency in performance of duties.
- Interpersonal skills that promote a collaborative and productive environment.
- Effective and efficient written and oral communication skills.

Please send your CV at : hbp-jobs@helveticbio.com