QC SPECIALIST

(BIOPHARMACEUTICAL MANUFACTURING PLANT)

JOB SUMMARY: The QC Specialist will be responsible to carry on the main analyses of recombinant proteins for human therapeutic use. The candidate should be able to autonomously run the laboratory instrumentations and produce the analytical reports. He/she will generate the QC analytical procedures and documentation, like standard management, equipment usage, and/or sampling in a GMP environment.
The job place is 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, manufacturing and analysis 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:

- Perform the QC analysis to support production and release of drug substance and perform a large panel of analysis in good manufacturing/laboratory practices (GMP/GLP);
- Support equipment/system qualification and validation activities within the QC department;
- Maintain controls, reagents and reference standards to support testing, and assure stock of reagents and materials;
- Generate, review and maintain of all required Standard Operating Procedures, Work Instructions, and other quality documents related to areas of responsibility, as well as support other areas as required;
- Take part to the GMP inspections and audits;
- Act as a mentor to more junior team members and lead by example to ensure timely analysis with the appropriate quality level;
- Proactively propose problem resolutions;
- Raise, investigate and close events, deviations and non-conformances;
- Raise and define action for the Change Controls;
- Contribute positively to a strong culture of business integrity and ethics;
- Act within compliance and legal requirements as well as within company guidelines.

PREFERRED QUALIFICATIONS:

- BS/MS in the life sciences (e.g. Biotechnology, Biochemistry, Chemistry, Chemical Engineering, Biology, Pharmacy, related field);
- At least 5 years of Quality Control experience in regulated industry (pharma/biotech) in a full GMP environment;
- Good understanding of analytical technologies and GMP experience;
- Practical and hands-on experience in HPLC analysis is needed;
- Practical experience in bio-analytical testing of proteins and nucleic acids (qPCR, ELISA, SDS-PAGE, Bradford Assay) is a plus;

- Able to proactively work within cross functional teams, maintain good and collaborative communication and relationship with all the staff;
- Able to independently interpret complex results and situations, recognize risk, and develop recommendations for solutions;
- Self-dependent way of working and taking ownership of assigned task to plan and deliver according to agreed timelines;
- Fluent in Italian, good communication skills in 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