Kaneka Eurogentec’s Biologics division provides a complete service offering to start-up, biotech, and big pharma companies in the area of injectable biopharmaceutical drugs. As a contract manufacturing organization we are responsible for developing manufacturing process and producing clinical trial material and commercial batches in accordance with cGMP regulatory requirements. The main product classes we manufacture are recombinant proteins, protein conjugates and plasmid DNA. In order to develop services provided by our Biologics division, we are looking for a highly motivated:

**GMP QC Deputy Manager**

As support to the QC Manager, the Scientific and Regulatory Deputy Manager will ensure Quality, Regulatory and Scientific compliance with the QC GMP. The deputy Manager will lead regulatory, delivery, cost and quality strategy. He will ensure that improvement plans and CAPA plans are performed and implemented. He will lead the QC advisor group in order to set up a support group within the QC GMP.

**Main Responsibilities**

**Regulatory, Scientific and Quality mission**

- Ensure that GMP practices are aligned with the current guidance’s and scientific knowledge
- Leads a team of QC advisors
- Lead investigations and corrective and preventive action plans pertaining to non-compliance issues
- Provides scientific and regulatory support to laboratory technicians, project leaders, management
- Back up of the manager during audits, inspections, prospections and follow ups
- Interacts with the QA team in order to develop an effective QMS for the QC
- Review SOPs, protocols and final reports to assure compliance with regulation, and company SOPs
- Attends conferences as well as continuing education and development activities to be up to date.

**Projects Follow up/Continuous improvement**

- Supervise LIMS implementation and follow up (milestones, timelines, people training, troubleshooting,...)
- Supervise continuous improvement projects
- Develop relevant KPI’s in order quality, cost, delivery indicators
- Analyse the main problems, find the root cause, propose action plans and priorities

**Equipments**

- Actively contribute to the qualification and validation process and method transfer
- Accountable for the qualification of lab equipment (URS, protocols, validation plan, reports)
- With his team, he is the referent key user for the software used in the lab

**Qualifications / Required Education / Experience:**

- Master degree in Science
- At least three years in pharma industry experienced in quality and compliance environment
- Preferred GxP auditing skill
- Excellent attention to detail, organizational skill, and previous experience with data review
- Rigorous and reliable
- Proactivity/Autonomy, knowledgeable of Methods: Lean, problem solving...
- Stress resistant
- Problem solver, Out of the box mindset
- Coaching and mentoring, Team player, Management skills
- Good oral and written communication skills and effective interpersonal skills
- Fluent in English
- Willing to work in a fast pace environment
- Knowledgeable of USP, Eu. PH., FDA and EMA guidances, ICH, 21 CFR part 1

Interested ? Please send your C.V. and cover letter Mounia Delhoum, m.delhoum@eurogentec.com

Kaneka Eurogentec SA • Service des Ressources Humaines • LIEGE Science Park
Rue du Bois Saint-Jean, 5 • 4102 Seraing