COMPLIANCE LEADER

Founded in 1987, Corden Pharma Brussels was a member of the Solvay group until being acquired by CordenPharma in October 2013. Peptisyntha has built more than 30 years track record of success in supplying pharmaceutical and biotech companies with small to commercial scale cGMP peptide API manufacturing using world-class cost-effective production processes. Through expertise and capabilities in all synthetic manufacturing technologies, Peptisyntha assesses and customized their manufacturing approach to achieve the most effective manufacturing process for their customers.

Corden Pharma Brussels has developed a portfolio of innovative proprietary technologies with the objective to shorten synthetic processes / reduce the number of steps, control quality, and simplify (or eliminate) HPLC purifications for short peptides.

Function description

The Compliance Leader will be working as part of the Corden Pharma Brussels Quality Assurance Department and ensure that the products are manufactured, stored and packaged in accordance with cGMP regulation.

The Compliance Leader will be working as part of the Quality Unit on site ensuring products are manufactured, stored and packaged in accordance with the cGMP.

Under the direction of the Head of Quality, he/she will be in charge to improve continuously the Quality system regarding the cGMP requirements. He/She will be a QA support in case of quality issues and problem solving techniques to assure the successful outcomes of company and external Health Authority.

He/She will be in direct contact with our customer in case of qualification audit, QA complaint issues and other quality topics.

The Compliance Leader is reporting to the Head of Quality.

Main activities

- **Provide QA support for**:
  - Investigation and closure for the Deviation and the Out Of Specifications
  - Change Control initiation and implementation
  - CAPA initiation and implementation

- **Documentation**:
  - SOP and Policy writing in accordance with the cGMP and Corden Pharma Policies
  - Batch records reviewing and associated documents after production
  - Control Cleaning Records

- **Continuous improvement and project support**:
  - CPB Improvement support and project leader for the new QA project (ex.: new system implementation)
  - Actively contribute to continuous improvement initiatives

- **Customer relationship**:
  - Point of contact in case of customer audit
  - Customer audit contact for the responses

- Customer audit contact for all question regarding the Corden Pharma Brussels compliance aspect

- **Other activities**:
  - TrackWise System Administrator
  - QA KPI implementation and follow-up.
  - QA Trainer (GMP training, Quality issues training, new SOP/Policies,…)
  - Work with relevant departments to ensure timely closure of quality actions
  - Internal auditor
  - Collaborate with the different departments to resolve compliance issues
  - Back-up of the Head of Quality
  - QC Release of raw materials, intermediates products and finish product
  - Technical support during customer audit and regulatory inspections (FDA, AFMPS, other)
  - Coordinate laboratory equipment acquisition, qualification, calibration and preventative maintenance.
  - Leading QC optimization processes and Operational Excellence QC project
  - Ensuring budget follow-up
  - Ensuring good relationship with internal and external stakeholders

Minimum experience required:

- Min.10 years in a QA position

Qualifications:

- Master degree Sciences
- Language requirements: English (written and spoken), French

Specific competences required:

- Perfect knowledge of cGMP in a regulated environment (ICH guidelines)
- Knowledge of quality systems in cGMP environment (21 CFR part 11)
- Excellent accuracy and attention to detail
- Excellent interpersonal skills (Team spirit, Open for the constructive discussion,…)
- Working knowledge of MS office packages (Word, Excel, Power Point) and TrackWise® System is in asset
- Strong problems solving skills, issue resolution and root cause analysis
- Knowledge in Lean Tools is an asset
- Highly Flexible and Adaptable. Able to work independently in a fast paced multitasking environment

Interested and enthusiastic about this job? Please send us your application by email to brussels@cordenpharma.com