Job description Quality Assurance Officer 80-100%

Reports to:

Qualified person or responsible person

Purpose of the function:

Responsible for planning and execution of daily quality assurance activities while ensuring compliance with international quality requirements as defined by the applicable guidelines (e.g. FDA, EMA, ICH) and all existing GMP standards in the area of responsibility.

Tasks and results:

Plan and execute quality assurance activities (document management, batch records and label issuance, batch record review, equipment and supplier qualifications etc.) including documentation.

Monitor compliance with all applicable GMP and safety standards.

Support the Qualified Person in his role, including audits and quality training.

Write, review and approve documentation (SOP's, manufacturing and quality instructions, validation of protocols and reports, non-conformities, change requests).

Handle, distribute and archive controlled documents.

Prepare data for trending (QRB, Annual Product Review) and support internal and external audits.

Responsibilities and authorizations:

This position involves judgement of batch related documents.

Therefore the position requires a very precise and responsible working attitude.

Knowledge, skills, and competences:

- Intermediate vocational education or BSc in chemistry/biotechnology.
- Knowledge of GMP is an advantage.
- Good communication skills in English.
- Accuracy, tidiness, self-organized, flexible, attention to detail, team player.
- Experience with a Quality Management System and ISO certification