The Power To Change The World

Mylan

Title: Quality Assurance Officer, GCP Lead (m/f/d)
Company: MEDA Pharma GmbH & Co. KG, member of Mylan Group
Location: Bad Homburg, Germany

For Us, It's A Mission

At Mylan, we mean it when we say we work every day to provide access to high quality medicines to the world's 7 billion people. If you are unconventional, relentless and passionate. If you believe in doing what's right, not what's easy. If you are a doer and have a passion for serving others, we want to talk to you.

Make a Difference

At Mylan, each person has the ability to make a difference. From the providers who sell and market our products to the producers who develop and manufacture them and finally to our business partners who support the providers and producers, we all have a mission critical role.

For our **Corporate Quality Assurance Team in Bad Homburg** we are looking for a new and motivated member.
In this Position you will ensure that a comprehensive GCP quality management system (QMS) and associated activities are developed and implemented for Clinical Quality Assurance. Furthermore you ensure that GCP activities meet regulatory requirements and align with Global Clinical Research and Quality requirements.

Your core responsibilities:

- Lead and support the development of the CQA Quality Management System according to relevant applicable laws, regulations or ICH guidance.
- Support the development and maintenance of the training system for CQA. Support the development and maintenance of documentation controls for CQA.
- Lead, support and maintain oversight of clinical activities for assigned projects. Represent CQA in discussions and action plans for assigned projects
- Facilitate any GCP activities identified during Clinical Quality Council CQC meetings (where required).
- Facilitate, review, approve Quality Investigations, CAPAs, and complaints (where applicable) reported during ongoing clinical studies, ensuring GxP compliance is maintained.
- Plan, conduct, report external clinical quality audits, of Clinical Investigators and Contract Research Organisations (CROs) for assigned projects. Assist in the creation, maintenance, review and approval of SOPs as required, ensuring alignment between business lines and Mylan sites, and compliance with current regulations.
- Plan, conduct, report internal clinical quality audits for assigned projects. Assist in the creation, maintenance, review and approval of SOPs as required, ensuring alignment between business lines and Mylan sites, and compliance with current regulations.
- Attend relevant global quality meetings and represent Clinical Quality Assurance during global discussions.
- Collaborate with GCR stakeholders from a GCP advisory role and be the GCP related subject matter expert.
- Ensure strong interface/ communication between Global businesses and CQA.
- Facilitate or host Internal GCP audits and regulatory authority inspections (where required).
- Participate to the review of new regulations, guidelines documents (where required) and support training initiative to promote GCP changing regulatory environment.

- Lead projects, Quality initiatives or parts of the Quality Management System as assigned. This may include multiple business lines within the organisation and may include other Mylan sites or external vendors.
- Ensure activities are carried out in compliance with Mylan Global policy, SOPs and regulatory expectations.
- Ensure Senior Management engagement and visibility to program status and risks through Quality Management Review process.
- Ensure GCP-GMP interface is well managed and maintained.
- Identify opportunities of continuous improvement in the GCR and CQA QMS.

Travel is required for this position (up to 40%)

Make Our Values Your Values

Mylan hires only the best. People who thrive in a culture of innovation and empowerment. People who are active learners and have a positive attitude. People who are leaders and know that by working together we can run faster, reach higher and achieve more. By doing so, we will continue to set new standards in health care.

Here are the minimum qualifications and essential functions for this position:

- Bachelor/ Master degree or equivalent in Science or Healthcare (Nursing, Pharmacy) or medical documentation
- 5+ years' experience in Clinical Quality Assurance or equivalent Clinical Drug Development experience .
- Fluent in English and German
- Knowledge of quality aspects of European regulations and clinical studies
- Experience in clinical audits (onsite audits, clinical investigator CRO audits and documents audits)
- Well experienced in developing, implementing and maintaining SOPs for our Global Key Brands

Why Mylan?

If you want to be part of a global health care company that is making a difference and changing lives, Mylan may be the place for you. With a workforce of more than 35,000 worldwide, we can make a difference. We encourage you to visit Mylan.com to learn more about our unconventional culture, our approach to doing business and how we plan to set new standards in health care.

Mylan offers competitive salary, excellent benefits and an environment conducive to professional growth and advancement. Mylan is an Equal Opportunity Employer

Interested? Please send your complete application documents in English to recruitment.gis@mylan.com

Please note our privacy notice for processing of personal data of applicants.