

Fujirebio – Compliance Officer

In search of a Compliance Officer

In taking up this position you develop and implement quality systems in compliance with the applicable legislation and standards to ensure continuous Quality Management System (QMS) certifications which is key for the sales of our in vitro diagnostics products.

Your key tasks will be to:

- screen the regulatory environment to identify new QMS standards, regulations and guidelines;
- perform and support different departments in the GAP analysis of QMS legislation;
- translate QMS requirements into compliance and cost-efficient QMS documentation;
- plan, prepare, coordinate and act as spokesperson during external audits;
- prepare Management Review Meetings and propose improvements and solutions;
- discuss and follow up actions plans regarding external audits and Management Review Meetings with involved stakeholders;
- supervise the CAPA process within the organization;
- establish the annual GxP training program;
- develop, update and give GxP related trainings;
- supervise the qualification process and ensure the compliant status of the training database;
- stay up to date with the industry practice on QMS standards implementation by reading specialized literature, networking across the industry and interaction with regulatory authorities.

This position is offered as a full-time fixed-term contract of 2 years.

Your Profile

- Master degree in bio-science (pharmacy, biology, biotechnology) or equivalent by experience
- 5 years experience in a high quality environment (ISO, FDA)
- Very good knowledge of applicable GxP regulations
- Excellent communication skills: power of persuasion / impact
- Strong planning & organisation skills
- Good problem solving / problem analysis skills
- Project management
- Customer-oriented

- Creative and innovative
- Open minded, cooperative & taking initiative
- Languages: Dutch & English – good knowledge written & spoken

Why choose Fujirebio?

- A challenging full-time position (fixed-term contract of 2 years) with a competitive salary and attractive benefits package
- A dynamic and stimulating work environment where you contribute daily to advancing healthcare
- A role with rich content and the autonomy to shape and organise your responsibilities independently
- An open and informal company culture that encourages collaboration between scientific, operational, commercial, and support teams
- Plenty of opportunities to develop your knowledge, skills, and talents within a certified *Great Place to Work*

<https://www.fujirebio.com/en>