

At Assystem Care, we embrace your most complex challenges and anticipate new regulatory and technology paradigms in the life science industry. Our unique advisory offer integrates end-to-end engineering, quality and performance management throughout your whole industrial life cycle, with a transverse vision of systems engineering: from conception & engineering to batch release and operations optimization. Starting from your challenges, our team of experts develops the customized solutions you need based on our methodologies and our own first-of-a-kind smart tools.

Our team of 450 specialists located in Belgium, France and Switzerland offers support to both pharmaceutical and biotechnological enterprises throughout their project's lifecycle.

The Belgian team is currently looking for a Quality Control Specialist.

Quality Control Specialist

Your Role:

As a Quality Control Specialist you are responsible for the successful execution of the assignments that you are responsible for:

- Managing QC tests to support commercial manufacturing
- Coordinating and/or performing QC checks and remediation actions specified in Annual Quality Plan
- Monitoring progress and effectiveness of remediation actions
- You actively contribute to the establishment and implementation of lab compliance related CAPAs resulting from audit observations (external and internal) or from adverse events (e.g. deviations)
- Providing support in case of audits (internal and customer audits) and inspections for health authorities
- Writing and taking ownership for SOPs related to testing programs, laboratory operations and/or equipment operations
- Participating in root cause analysis; lead and write laboratory investigations
- Investigating laboratory quality issues and recommending sound corrective actions and resolutions
- Performing and reviewing equipment calibration and maintenance; instrument advocate and subject matter expert
- Managing complex technical and/or production problems, evaluate potential impact on product quality and escalate to management
- Ensuring quality systems (deviation, OOS investigation, CAPA, documentation, training, chance control, validation activities, maintenance and calibration activities) are in place/in use and handled in a timely manner
- Communicating quality control information to all relevant organizational departments, outside vendors, or contractors



Your Profile:

- You possess a master degree in sciences (micriobiology, bio engineering, biotechnology, pharmacology, etc.) or equivalent through experience
- You have at least 3 years professional experience in the pharmaceutical/biotech/medical device industry including QC related experience
- You are familiar with analytical techniques like HPLC, PCR, GC, ...
- You have an analytical mind and are able to translate complex processes into clear, efficient and compliant procedures
- You are fluent in French and/or Dutch and a good level of English.
- You organise your work efficiently and know how to deal with pressure and deadlines

Our Offer:

- A salary in line with your experience
- A competitive package of extra-legal benefits (car, fuel card, insurance, meal vouchers, entertainment expenses, ...)
- Career opportunities both in Belgium and abroad
- Clear objectives and challenges!
- A people focused and motivating work environment

To apply:	
Dutch speaking: mjoye@assystem.com	
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