Aston Life Sciences is the proud leading company in Consulting, Recruitment and Executive Search for the Pharmaceutical, Biotechnology, Medical Devices and Diagnostics industry. Based in Switzerland we serve Eastern and Western Europe, North America and Russia. Life Sciences is our passion and we are committed to successfully support our clients in their quest to improve patient's health all around the world.

For one of our client based in Switzerland, we are looking for a:

Head of QA/QC - Medical devices

Your role:

On behalf of our client - an international company operating in the Medical Devices industry - we are looking for an Experienced Head of Quality Control and Quality Assurance who is motivated to contribute to the development of a highly innovative company as part of a young, talented and ambitious team. In this key position, your role will be to lead the Quality Control Team, IVD Assay Manufacturing and take a leading role in the Quality Assurance for activities related to the development and manufacturing of IVD kits. You will report directly to the Chief Scientific Officer and collaborate very closely with the Head of Production, the NPI Manager and the Head of R&D.

Your tasks:

- Lead the Quality Control Team of the IVD Assay Manufacturing Department: you are responsible to ensure that the quality control activities of incoming material and produced goods are realized in due time and in full compliance with the company procedures. You also prepare the Team to follow future demands in manufacturing activities by implementing and supervising the development of novel quality control methodologies and/or modification of existing ones.
- Track product lot specifications to identify drifts and shifts and develop, together with Production, preventive or corrective actions to correct problems and/or improve processes.
- Develop novel methods to determine product specifications and control the compliance with targeted specifications.
- Participate in Design Review meetings, provide risk assessment expertise and ensure that Company Device Master Files are timely assembled and maintained up-to-date, according to the Company's QMS.
- Monitor compliance with company policies and procedures within the Department and develop and execute organizational and operational policies to accommodate the growth of the Company and its needs to comply with novel quality and regulatory standards. In particular, you support the transition of the company to the novel European IVD Regulation.
- Perform internal audits and prepare reports, including propositions for corrective actions where needed, for Senior Management
- Support the preparation and participate in external audits, as well as auditing of key suppliers. Prepare and ensure timely completion of corrective action plans.
- Take decision regarding the release of manufactured goods and initiate, plan and lead investigations of non-conforming products.

Your profile:

- Education in Life Sciences with at least 8+ of relevant professional experience in Quality Control and Quality Assurance in the Medical Device and/or IVD industries. Advanced degree preferred.
- Strong leadership and proven experience in managing people and multiple projects concomitantly. Excellent capacity to interact with various partners, within the company and externally.
- Previous professional experience in an ISO 13485-certified environment. Good understanding of FDA CFR Part 830 is a plus.
- Good knowledge of bioanalytical methods commonly used in the quality control of biomolecules, in particular of ligand binding assays.
- Attention to details, dedication, and sense of responsibilities.
- Ability to perform work independently

- Fluent verbal and written English, knowledge of French is a plus.

Starting date: 1 July 2019

Location: Lausanne area

Level: Manager

Domain of experience: Medical Devices, QA, QC, management, IVD

Category: Medical devices

Closing date: 01 January 1970