ORGENTEC Diagnostika GmbH is the world market leader in the development and production of test systems for the diagnosis of infectious and autoimmune diseases. As part of the Sebia Group, headquartered in Lisses, France, ORGENTEC supplies medical laboratories in over 100 countries with highly specific and innovative devices and test kits. Steady and sustainable growth in an internationally oriented, future-oriented business area characterizes our company.
To strengthen our team at the Mainz location, we are looking for a:

R&D Manger Product Development(m/w/d)

Main tasks :

- Developing and building up an efficient development team for the development of new products and for sustaining/improvement activities of existing products
- Manage resources needs and ensure building up and retention of key knowledge
- Lead the reagent development team by creating appropriate processes to ensure efficiency and good use of the resources
- Responsible for the project management (controlling/coordination/planning/reporting) of development projects in scope, time and budget
- Responsible for compliance to the design control process including documentation, verification and design transfer to manufacturing/QC
- Create, maintain and update the Design History Files
- Review complaints and other experience gained from the devices on the market to identify corrective and preventive actions and for potential product improvement.
- CAPA management in the area of responsibility
- R&D representative during audits (FDA, Notified Body, others)

Knowledge & Technical Skills:

- Master's degree in biology, biotechnology, or biochemistry; advanced graduate degree (PhD) is a plus.
- Minimum of 5 years of post-education experience in product development of assays (ELISA, CLIA, Blots; thereof minimum of 3 years managerial experience)
- Strong project management and leadership skills
- Experience in technical and scientific writing for regulatory audiences such as Notified Bodies, FDA or other authorities
- Deep knowledge of regulations (IVDR) and experience in the application of the relevant ISO standards (14971, 13485, 20916) and FDA guidance documents (510k submissions)
- Careful, accurate and responsible way of working
- Excellent documentation practice
- Excellent verbal and written communication skills (German and English)
- Confident in the use of MS-Office

Benefits:

- An attractive salary
- Permanent employment contract
- an exciting job with creative freedom
- Short communication and decision-making channels
- Excellent transport connections within the Rhine-Main area
- Flexible working hours
- Individual employee development and qualification
- Health promotion/company sports
- Subsidy for company pension schemes
- Company canteen with employer subsidy
- Subsidy for kindergarten
- Free employee parking directly in front of the building

Have we piqued your interest?

Then we look forward to receiving your application (cover letter, curriculum vitae, certificates) by e-mail to jobs@orgentec.com. Please indicate your salary expectations and a possible starting date.

ORGENTEC Diagnostics GmbH
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