ORGENTEC Diagnostika GmbH is a leading player in the market of In Vitro Diagnostics specialties. Our strength is autoimmune and infectious disease diagnostics with our own automation and growing family of instruments. Starting out in 1988, ORGENTEC has built a reputation and tradition of bringing new products to the market and successfully grow with a global network of distribution partners.

Our team of 130 colleagues in Mainz needs you to work with us to grow our global business in the position of:

Project Engineer Instrument Development (f/m/d)

to start immediately.

The instrument development engineer will be a member of a team responsible for the successful launch of a new IVD analyzer. The individual will be responsible for identifying requirements, perform planning, oversee the development from a technical perspective and ensures that the equipment meets specifications to fulfill the intended purpose. The candidate collaborates with an external development partner and the internal development team including various functional groups of the company. The job holder will be initially based in Italy with regular travel to Germany.

Responsibilities:

- ✓ Manage and lead all development activities for projects from concept through transfer to production
- ✓ Technical responsibility to ensure compliant generation of technical documentation according IVDR and 21 CFR 820
- ✓ Maintain and communicate project timelines and progress toward key milestones and critical path deliverables
- ✓ Facilitate and ensure on-time delivery of first article parts and validation activities
- ✓ Review test protocols and reports from specifications
- ✓ Identify project constraints and risks; proactively work with appropriate management resources to resolve technical issues for hardware and software
- ✓ Support the external engineering partner
- ✓ Provide design input for manufacturability and reliability
- ✓ Establish and maintain effective communication networks between the third-party developer and ORGENTEC
- ✓ Manage project budgets to quoted estimates
- ✓ Evaluate needed investments and assembly/ testing time to be able to adhere to plan
- ✓ Support marketing activities associated with the project
- ✓ Apply knowledge and past experiences to solve new challenges
- ✓ Participate in the creation and execution of qualification and validation protocols/plans

Requirements:

- ✓ At least Bachelor's engineering degree or equivalent experience
- ✓ At least 5 years of experience with FDA/ EU regulations, IVD instrument development a plus
- ✓ Fluent in Italian and English, additional German advantageous
- ✓ Experience working directly with suppliers
- ✓ Software development experience is advantageous
- ✓ Good understanding of validation methodologies
- ✓ Ability to evaluate system specifications and requirements for completeness and testability
- ✓ Willingness to travel
- ✓ Good computer skills, including MS Office, MS Project, 3D CAD Systems (PRO E, Solid Works) Adobe Acrobat

What ORGENTEC brings to the table:

- ✓ An excellent reputation in the market as an innovative diagnostics manufacturer with products of prime quality.
- ✓ An energetic and team-oriented environment to welcome, support, and challenge you.
- ✓ An exciting product portfolio in reagents and instrumentation with high potential for growth.
- ✓ State-of-the-Art facilities in Mainz – a university-city on the Rhine River with high quality of life.
- ✓ Company fitness program. Good work-life balance.
- ✓ Competitive compensation.

Look forward to a global employer and an attractive salary. Are you interested? Then send us your application today, stating your salary expectations and the possible starting date to **bewerbung@orgentec.com**