

InfanDx AG is a privately owned company that specializes in the development and commercialization of diagnostic solutions for newborns. The company's lead product in clinical development is the InfanDx HypoxE-Test®, that aims at the early and reliable diagnosis of Hypoxic-Ischemic Encephalopathy (HIE). HIE as a consequence of oxygen deprivation during birth (perinatal Asphyxia) can result in lifelong impairments and disabilities of the affected children that can be mitigated or even prevented by an appropriate therapy initiated within the first hours after birth. While current standard diagnostic methods do not provide a definitive diagnosis within this critical time window, the rapid InfanDx HypoxyE-Test® is designed to aid clinicians in a timely treatment decision.

InfanDx is located at the BioCampus Cologne in the West of Cologne, Germany.

To strengthen our dynamic and rapidly growing team we are looking for a

Quality Manager (w/m/d)

at the earliest possible convenience working full-time at our Cologne headquarters.

The position reports to the QMB.

What we expect of you ...

- You actively contribute to the further development and implementation of our EN ISO 13485 and 21 CFR 820 compliant QMS
- You ensure the appropriate management of documents and records
- You manage corrective and preventive actions (CAPAs)
- You organize and perform QMS trainings
- You coordinate the internal audit program and perform audits
- You support audits by notified bodies
- You prepare management reviews
- You work closely with the R&D department to ensure quality of results and their documentation

What you offer ...

- A completed vocational training or academic degree in a technical discipline
- At least five years of professional experience of which at least two are in the area of quality management
- Experience in working in a EN ISO 13485 and/or 21 CFR 820 controlled environment
- An independent, self-starting and structured work style focused on delivering solutions
- Very good oral and written English language skills; German language skills are of benefit but not required
- Professional command of MS-Office programs
- Strong communication capabilities
- A friendly, yet confident demeanor towards superiors, colleagues and external parties
- A robust, calm, and well-humored temper

What we offer...

- An exciting job in an innovative, growth-oriented enterprise with flat hierarchy and rapid decision-making
- Flexible working hours

- A fair and competitive compensation
- Excellent personal development opportunity in a dynamically growing company
- An inspiring working environment in a team that successfully combines seasoned industry experts with young high-potentials

Do you recognize yourself in this job profile? If yes, we are looking forward to your application by email including all relevant documents. Please also include the reference number below, your earliest availability and your salary expectations.

Reference Number: HR2021_007
Date: 01.09.2021

Contact

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