Document Control Specialist (m/f/d)

PENZBERG, GERMANY

Foundation Medicine dedicated to transforming the way in which patients with cancer are diagnosed and treated. At Foundation Medicine you will work with everyone fighting the disease—patients and their families, payers, physicians, drug developers—to raise awareness about the ongoing evolution in cancer care and to ensure we are delivering the analytic tools and molecular information required to bring the promise of personalized cancer care into routine clinical practice. As a member of our International Product Development department, you will be responsible for distilling the latest advances in genomic science, technology and clinical data into innovative, best-in-class clinical diagnostic tools and data products that will enable oncologists to determine the best treatment throughout each patient's journey with cancer.

Summary of Position:

FMI Germany GmbH in Penzberg, Germany is seeking a Quality Assurance (QA) **Documentation Control Specialist** to assist with administrative activities such as the organization of QA documents, training schedules, as well as the set up and maintenance of the QA/RA Masterfiles. The function will also include training, implementation, deployment and administration of the electronic Quality Management System(s). In addition, the person will provide support and contribute to other QA activities as needed.

Responsibilities:

- Follow and enforce company policies and applicable procedures.
- Qualify and act as site administrator for electronic Quality Management System(s)(QMS)
- Execute work with adherence to legal requirements and applicable regulations including but not limited to GxP, ISO standards, or in-vitro diagnostics.
- Be responsible for maintaining, updating and versioning of policies and protocols.
- Support and improve Good Documentation Practices across different departments.
- Partner with the laboratory operations team to manage QMS documents.
- Manage employee training files.

Qualifications:

- Must be detail oriented with excellent prioritization and organizational skills
- Must have experience and passion for documentation management
- Must be able to deliver results on schedule in a fast-paced, dynamic environment
- Experience in the diagnostics industry strongly desired
- Must have the ability to communicate clearly and concisely with all stakeholders.
- High level MS office skills, including SharePoint
- You must be able to self-organize and operate effectively without significant day to day oversight while staying tightly connected to key leaders and team across departments
- Must be fluent in German and English

Desired Skills and Background:

- Knowledge of requirements in a regulated environment, ideally GCLP, ISO 15189, ISO 13485, or IVDD/IVDR
- Working experience with electronic documentation (eDMS, SharePoint) and electronic quality management systems (eQMS), like MasterControl, Cornerstone or Pilgrim.

Education:

- Bachelor's degree with at least 2 years of experience in the pharmaceutical, biotechnology, medical device, or diagnostic industries, which should include QA experience or equivalent.

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How to Apply:
Please send your application documents by email to tholtschke@foundationmedicine.com

Who should I contact if I have any questions?
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