Medistri

Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.

An Opportunity to Join Medistri

Quality Engineer

Medistri is Europe's largest independent sterilization company, and your work will have an impact by helping businesses in the healthcare sector achieve their greatest ambitions, overcome their challenges, and bring their innovations to life.

Medistri's mission has remained the same since our founding in 2006: to facilitate innovation in global healthcare.

We are a growing company that upholds its core values:

Honesty, Efficiency, and Success.

By joining our team, you will benefit from coaching and training to ease your integration. Coaching and feedback are fundamental principles at Medistri and will be part of your ongoing development.

Profile sought:

- Fluent in written and spoken Hungarian and English.
- Strong computer proficiency (MS Office, internal systems).
- Good understanding of administrative processes.
- Engineering degree or equivalent technical qualification.
- Experience with Quality Assurance in an industrial environment (preferably in food, pharmaceutical, or medical device industry).

Your mission :

- Release of routine sterilization cycles; placing non-compliant cycles on "HOLD"
- Release of laboratory tests; placing non-compliant analyses on "HOLD"
- Release of purchases of "critical" consumables or services
- Assisting the Quality Manager in daily tasks
- Preparing items for transport and completing delivery notes.
- Acting as point of contact for all routine quality-related questions.
- IQ-OQ approval of equipment and annual reviews.
- Release of equipment calibrations; placing non-compliant calibrations on "HOLD".
- Development and update of specifications for critical products and services.
- Supporting the Validation Manager in releasing lab analyses, cycle parameters, and validation documentation.

Quality Management System (QMS) Tasks :

- Opening, tracking, execution, and implementation of MCRs (change control and procedure updates)
- Opening, tracking, execution, and implementation of trainings (TRNs)
- Monitoring and management of customer cards
- Delivering initial quality training for new employees
- Monitoring and implementing CAPAs in line with scheduled timelines
- Ongoing regulatory monitoring and updating of the Quality Management System
- Participation in various departmental projects (e.g., studies, reporting)
- Organization and hosting of external audits (clients, regulatory authorities)
- Conducting internal audits according to the F117 internal audit schedule

Site: Medistri Kft – Székesfehérvár, Hungary

Team: Quality

Work Load: 80 - 100%

About Medistri:

Founded in 2006, Medistri has focused on building infrastructure for the healthcare sector. Companies of all sizes, from start-ups and university projects to Fortune 500 companies, use our services to save time, grow their business, and focus on what they do best.

Medistri reduces barriers to the development and growth of healthcare products. We provide infrastructure to new businesses when they launch and to established companies to help them scale globally.

Medistri's headquarters is located in the heart of Switzerland. In 2024, we expanded to Hungary with the opening of our site in Székesfehérvár, where our team contributes directly to Medistri's global mission of facilitating innovation in healthcare.

Send us your application today and join a growing international team.

job.hu@medistri.com

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Validation Tasks:

- Monitoring and updating the validation review schedule; sending reminders and communication to clients
- Organizing validation cycles in collaboration with the Production team (support with sample setup, retrieval, etc.)
- Drafting validation protocols (EtO sterilization, steam, packaging)
- Writing validation reports as required
- Coordinating interdepartmental validation tasks and reporting to the Quality Manager
- Preparation and follow-up of internal orders
- Programming, reading, maintaining, and replacing batteries of sensors
- Participation in various validation-related projects as needed

We look forward to receiving your application.

At Medistri, we are looking for passionate, ambitious, and honest people. We encourage you to apply even if your experience doesn't exactly match the job description. Your skills and passion will set you apart, especially if your career has taken extraordinary turns. At Medistri, we welcome diverse perspectives and people who think rigorously. Join us

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