

QUALITY AUDITOR EMEA

Multiple Locations



THE COMPANY

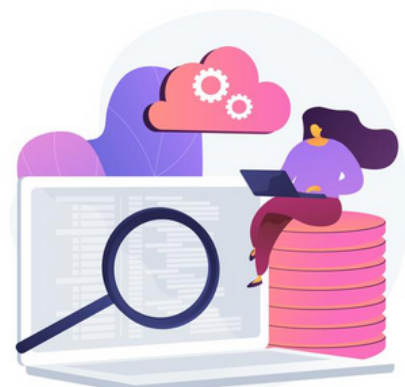
WWe are partners to a globally leading medical device company based all around the world who are currently searching for their next quality auditor EMEA. Do you want to be part of one of the world's biggest healthcare companies?

With an extremely dynamic growth strategy, and great future prospects, this is for sure a company where you won't get bored! This is an opportunity to join and have oversight of the biggest and best performing market segment for the company; which has enjoyed double digit growth in the last year.

Due to this growth - a completely new role as Quality Auditor has been created. The goal; play a critical global role concerning all internal audits, by leading and evaluating.

THE OPPORTUNITY

This is a brand new role, which you will have the chance to shape yourself from the beginning, giving you maximum impact! It's all about being able to prioritise multiple high profile requests and playing a critical role in the audits across multiple sites. If you are passionate about working with multiple cultures and enjoy collaborative environments, this is the career step for you!



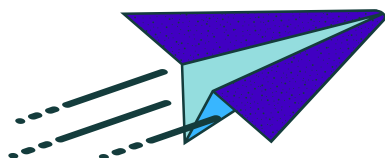
CONTACT US IF YOU HAVE...

- Minimum of 5 years of experience in auditing compliance from the medical device or pharmaceutical industry;
- Extensive knowledge and ability to apply international regulations and standards of FDA QSR, ISO 13485, EU MDR/IVDR, and ISO 14971 standards.
- Expertise within the IVD industry will also be accepted.
- You must have one of the following certifications or equivalent from an accredited organization: Certified Quality Auditor/ISO Lead Auditor Certified, Certified Quality Engineer, or Certified Quality Manager.
- Good knowledge with CAPA, Root Cause Investigation; Validation (Process, Test Method, Software, and Design); Environmental Monitoring; MDSAP; Sterilization (EtO, Irradiation).
- Ability to travel domestically and internationally; there are some home based options available in this role.

- You can be based everywhere in Europe except in: France, Spain, UK, Germany, Swiss
- Excellent communication skills in English, both written and spoken. Fluency in any other European language would be a bonus.

IN THIS NEW AND EXCITING STAFF QUALITY AUDITOR ROLE YOU WILL:

- Conduct Corporate Quality Internal Audits to assure compliance with domestic and international medical device standards and regulations, local procedures, and corporate policies/procedures.
- Follow up with the auditee as required to compile information relating to the audits.
- Provide periodic reports to management based on the audit statuses and defined metrics.
- Travel about 30-50% to the sites. Directly work with the team in the USA.



If you think you can bring any of the above to Elemed we would LOVE to hear from you!

Send your CV to **monia@elemed.eu** for a confidential career discussion. Good Luck!