REGULATORY AFFAIRS & QUALITY ASSURANCE SPECIALIST

AMSTERDAM, THE NETHERLANDS

Get in touch with Monia at monia@elemed.eu

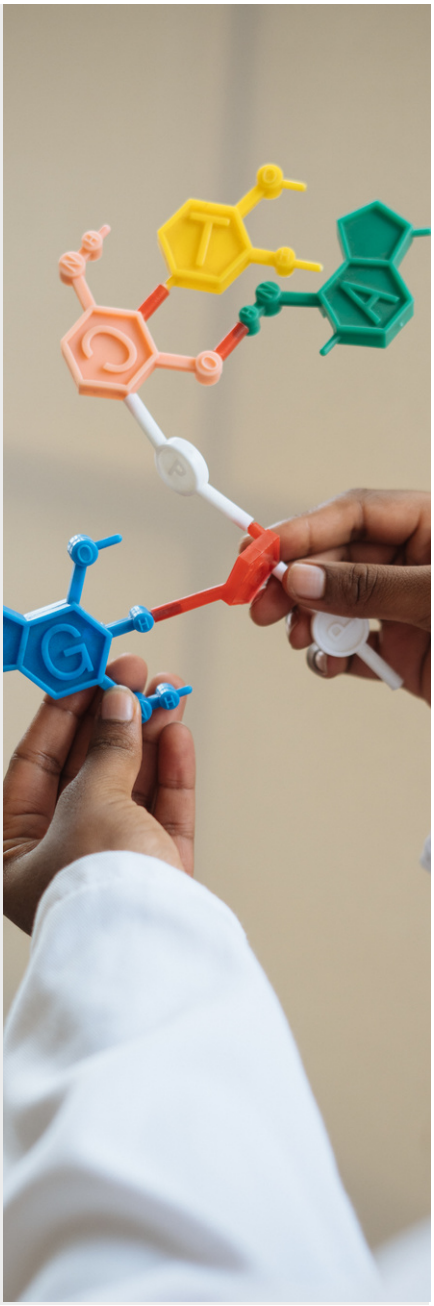
THE COMPANY

Are you someone looking to have a real impact on patients' lives? Do you want to be part of a real changement that will be part of history?

Are you able to use Regulatory and Quality as an enabling tool, rather than a blocker? Are you able to build good business relationships?

This is a fantastic opportunity to join a molecular company focused on breast cancer. As a Regulatory and Quality Specialist you will be based in the Amsterdam office and surrounded by prestigious physicians.

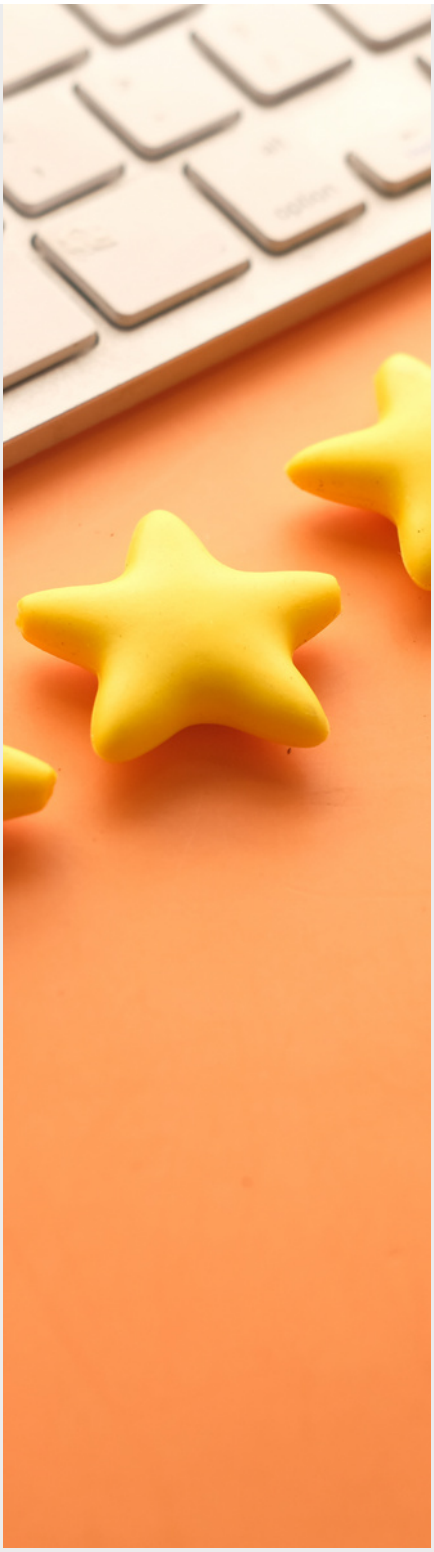
Be part of a company advancing a number of clinical trials through key partnerships that will impact how breast cancer is treated.
They already launched their CE -marked test suite in several continents (Europe, Latin America and Asia) where they are reaching deeper into global markets.



THE OPPORTUNITY

As Regulatory and Quality Specialist, you will

- Develop and maintain Quality Management System in accordance with regulatory requirements, such as ISO13485, FDA 21 CFR 820, IVDD/IVDR, CLIA, CAP
- Support IVDR implementation
- Lead and participate in Quality Management System processes such as CAPA, NCMR, Document Control, Supplier Quality, Management review processes
- Ensures all regulatory compliance, submission and approvals are met
- Collaborate cross functionally with other departments to determine regulatory strategy.
- Prepare and submits regulatory filings with relevant authorities
- Maintain registration database
- Post market surveillance (complaint, trending, post market activities)
- Provide support to various Quality Assurance and/or Regulatory Affairs activities such as but not limited to; training of employees on quality system processes, standards and regulations, complaint handling.



REQUIRED EXPERIENCE

Do you have the following experience? If so, we want to hear from you!

- Minimum of 3 years' experience in Regulatory Affairs in the In Vitro Medical Device (preferred) or Medical Device industry
- Experience with ISO 13485

Interested to explore this further?

Please send your CV to Monia at monia@elemed.eu to arrange a confidential career discussion.