THE COMPANY

This company has been enhancing performance in healthcare across the world for over 150 years so have a huge amount of history behind it including being the first company to mass-produce dressings for wound care. Even though they have developed and manufactured many revolutionary devices, the innovation doesn't stop and is done in-house.

They are always looking for new ways to improve not just what they produce but also how they do business so have recently undergone a huge business transformation. If you are looking for a large, established company that still feels like family, this is the place and the role for you!

THE OPPORTUNITY

This opportunity will give you the chance to join a dynamic team in a healthy environment where you will never have the same day twice! You will have a variety of activities and will never get bored. If playing with numbers gets you excited this position is definitely for you. This position will offer you the possibility to grow vertically or horizontally and be continually stimulated and challenged.

As a Head of Validation, you will manage one Quality Control person under your team. Through your responsibilities, you will also be the Head of Raw Material, Process Validation Owner, and Software validation process coordinator. This position will give you the chance to take all necessary decisions concerning any risks of the products, including stopping operations.

THE RESPONSIBILITIES

As Head of Validation, your role will be very varied and will cover:

Head of Raw material:

- Support adequate documentation for raw material (quality agreements and material specification) and maintain direct contact with suppliers to reach the expected material quality level
- Coordinate the incoming material control activities: QC incoming inspection, reporting, control methods, etc
- Support Raw Material supplier audit program

THE RESPONSIBILITIES

Validation Process Owner:

- Develop and support validation process as part of local QMS, according to ISO standards and global corporate procedures
- Manage appropriate user training
- Maintain the Factory Validation Master Plan (VMP) and keep up-to-date properties list and impact tables
- Provide validation protocols and select the properties to be validated
- Collect data from validation studies and compile the validation report for approval
- Maintain all validation documentation in accordance with local QMS and Process validation summary report in the PLM system
- Act as change control process coordinator for Waremme Factory operations (management of change control notification)

Software validation process coordinator:

- Develop and support software validation process as part of local QMS, according to global corporate procedures
- Maintain the Factory Computerized Validation Master Plan
- Manage appropriate Software Owner training
- Provide input, guidance, and support to software Owners.
- Present validation systems (process & software) during internal and external audits

YOUR QUALIFICATIONS

- Relevant master's degree in Science or Engineering
- A minimum of 5 years of Manufacturing Process Validation experience in an established Quality function in the Pharmaceutical or Medical Devices industry
- Fluent in English and French

INTERESTED TO EXPLORE THIS FURTHER?

If you are interested in this exciting role, please send your application directly to **monia@elemed.eu**

Would you like to find out more about our open opportunities? Visit https://www.elemed.eu/vacancies/