QUALITY ENGINEER (M/F)

ABOUT 3D SYSTEMS LEUVEN

3D Systems Leuven, formerly LayerWise, is a dynamic and leading enterprise, specialized in 3D Printing of metal components. 3D Systems Leuven is not only a technology developer but also a technology user. This makes us a strong innovation partner for clients in the industrial, medical and dental sector.

With this technology, we build up material in layers using a high intensity laser until it becomes a solid product. Unlike conventional production techniques, this one does not render any material loss, nor does it require any tooling. It does however, enable the designers to manufacture very complex geometries which are not producible using the traditional techniques.

JOB DESCRIPTION

Our site in Leuven Belgium is looking for a top notch engineer to support the manufacturing of products in the high tech, aerospace and healthcare industries.

The Quality Engineer is responsible for focusing engineering quality as regulated by the ISO 13485, ISO 9001, AS9100 and global requirements such as FDA QSR, MDD and various aerospace regulations. This position is responsible for supporting the development, execution and improvement of manufacturing processes in accordance with the quality system for one or all of 3D Systems' Healthcare product lines.

RESPONSIBILITIES

- Collaboration with project teams as a contributing member by providing quality and process engineering support in the development of new products and processes, and continuously improving 3D Systems' products
- Application development of new technologies to enhance the capabilities of 3D Systems'
- Contributing to the development and execution of verification & validation plans, testing, and generation of test protocols and reports
- Development and contribution to the risk management process
- Development and contribution of process controls and planning
- Participating in the compilation and review of technical documentation for both domestic and international regulatory submissions
- Assisting project teams on compliance with design control requirements per FDA QSR, European MDD, ISO 13485/9001 and other applicable ISO/EN standards
- Facilitating and performing internal QA audits as required
- Participating in the execution, maintenance and improvement of the Quality Management System.
- Analyzing reports and returned products and recommending corrective/preventive actions (CAPAs)
- Leading process improvement initiatives of cross functional teams to address business and quality manufacturing issues

PROFILE

- Master degree, preferably in engineering
- 2-4 years of related work experience in regulated, cGMP environment such as medical device, pharmaceutical or food manufacture.
- Quality assurance and reliability experience supporting product development and/or manufacturing are preferred.
- Working knowledge of GMP and ISO 13485 Quality System preferred
- Ability to read and design engineering specifications across a number of products and materials.
- Ability to analyze and develop engineering processes for use in advanced technology implementations

3D SYSTEMS

• Fluent in English

WE OFFER

- A challenging job in a young and dynamic team
- A competitive salary and additional non-statutory benefits
- Career opportunities in a global company with exponential growth

INTERESTED?

Please send your resume and motivation mail in English to: <u>BelgiumCareers@3dsystems.com</u>