Poland Jobs Expertini®

Configuration Engineer (SAP QM), Quality Operations

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Company: Novocure

Location: Poland

Category: architecture-and-engineering

Novocure is a global publicly-traded commercial-stage oncology company developing a profoundly different cancer treatment therapy called tumor treating fields (TTFields) for patients with solid tumors. TTFields therapy is a non-invasive, novel, antimitotic treatment modality which utilizes proprietary technology attempting to slow or reverse tumor progression by inducing tumor cell death. Novocure's commercialized product, Optune, is approved for the treatment of adult patients with glioblastoma (GBM) in the USA, Europe and Israel. Novocure has ongoing or completed clinical trials and is further expanding its efforts into several other solid tumor indications - non-small cell lung cancer, pancreatic cancer and other types of solid cancers.

Novocure Poland is our newest office in Europe and you will be part of a global business services team supporting multiple business functions including finance and payroll and located in Krakow. The global business services organization within Novocure Poland is critical to Novocure's efforts to drive process efficiency, standardizations and drive greater business value as the company prepares for future growth.

To support our team in Krakow, Poland we are looking for a:

Configuration Engineer (SAP QM),

Quality Operations

In this role as Change and Configuration Engineer, Quality Operations you will support Novocure's global quality system activities in the areas of change management, change implementation, document distribution / retention integrity and SAP master data changes in the quality Module. This includes providing process oversight and acting as a process expert to provide consistent, reliable support to global business partners with focuses on cycle times and accuracy.

Your responsibilities:

Perform change control activities in Novocure systems including, but not limited to, SAP Master Data and Mastercontrol.

Create, maintain, and retire e-Route Cards in SAP S4 Hana in support of Quality Control, Service, and Operations in global Operating Centers

Assures locally procured and distributed materials for individual Operating Centers are subject to appropriate specification and document control

Designs and implements new processes and process improvements, particularly in relation to change management and SAP QM/eRoute Card

Participates in internal audits and regulatory authority inspections, as required

Participate in Corrective and Preventive Actions (CAPA), as required

Reviews and provides input into operational QA strategies, and executes for results. Ensures approaches are innovative, industry leading, and meeting the needs of Novocure patients and related Enterprise business strategies

Works with the Change and Configuration Manager, the QA team, and the IT team organization to deliver against strategic goals and improvement plans

Your profile:

At least 2+ year experience in SAP/QM

Demonstrated experience writing, evaluating and improving process procedures

Proven ability to manage projects and influence teams of significant scope and complexity, while

meeting all deliverables and timelines

Outstanding written and oral communication skills in English

Familiarity with Change Control and Quality Risk Management and process validation

Familiarity with Quality System Regulation, Medical Device Directive / Medical Device Regulation, ISO 13485 / FDA is a plus

Benefits:

Financial

Performance related bonus

Life Insurance

Lifestyle

Free fruit & cookies delivered for office staff

Multisport card

Health

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Private Medical care

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