FRESENIUS MEDICAL CARE

(Senior) Expert (m/f/d) IT Quality »

Within Fresenius Medical Care, the QREM Department (Quality, Regulatory Affairs & Management Systems) has the key responsibility to ensure that the company maintains and receives its marketing authorizations (e.g. CE-marks or drug registrations). Having identified legal requirements and regulations for the company, QREM works with different departments guiding them and ensuring that regulatory compliance and regulatory prerequisites for medical devices & drugs are met.

Your assignments

As a (Senior) Expert (m/f/d) IT Quality, you will render support the assurance of regulatory compliance of business processes within a regulated IT environment (in particular GxP, ISO 13485, GAMP 5). The focus here is to ensure compliance with the requirements of the European Medical Device and Pharmaceutical Regulation and the associated requirements governing quality management systems.

Your role entails monitoring and participating in the implementation of state of the art technology in regulated IT environment (in accordance with EU regulations such as GxP, ISO 13485, GAMP 5). You will act as an interface between the business units Quality Management System (QMS) and IT or IT service providers. Implementation of quality assurance measures in the corresponding business areas (e.g. IT compliance audits) will be part of your task in this position.

While supporting the quality assurance unit in fulfilling relevant documentation requirements, you will draft, verify or evaluate user requirements specifications, functional specifications and validate documentation for regulated computerized systems.

Furthermore, you will render support in the implementation of risk management, of IT QA processes and you will assist in staff trainings focusing on IT quality. Moreover, you will act as an interface to other Fresenius legal entities to harmonize requirements of the Fresenius Group.

Your profile

As a (Senior) Expert (m/f/d) IT Quality, we expect you to have a graduate degree in technical/scientific/ IT/ and or quality management studies or similar educational background with relevant professional expertise in a similar function.

You will bring in your experience in IT Audit, IT Validation or IT System compliance exhibiting knowhow in regulatory IT compliance (EU-GxP) and in the validation of regulated computer-based systems according to EU-GMP Annex 11 and GAMP 5.

Your expertise in the EU regulatory requirements within the pharmaceuticals and medical devices industries (e.g. Directive EU 2001/83/EC, AMG, Regulation EU 2017/745/EU & Quality Management Systems ISO 9001/13485, EU-GDP, EU-GMP as well as GAMP 5) is something you are eager to demonstrate. Cross-organizational assertiveness and strong communication skills round off your profile.

Your intercultural diplomatic competence as well as your professional demeanor will surely come in handy in this expert role.

If you enjoy using your proficient German and English language skills (orally and written) and you have willingness to travel then we look forward to getting your application.

Your contact

Fresenius Medical Care Deutschland GmbH

Bad Homburg

Ref. number: 31059

FRESENIUS MEDICAL CARE