Argentina Jobs Expertini®

Senior Compliance Specialist

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Company: Thermo Fisher Scientific

Location: Argentina

Category: computer-and-mathematical

At Thermo Fisher Scientific, you'll discover meaningful work that makes a positive impact on a global scale. Join our colleagues in bringing our Mission to life - enabling our customers to make the world healthier, cleaner and safer. We provide our teams with the resources needed to achieve individual career goals while taking science a step beyond through research, development and delivery of life-changing therapies. With clinical trials conducted in 100+ countries and ongoing development of novel frameworks for clinical research through our clinical research portfolio, our work spans laboratory, digital and decentralized clinical trial services. Your determination to deliver quality and accuracy will improve health outcomes that people and communities depend on – now and in the future.

As awithin our Quality function, you will execute compliance and quality strategies within the organization as related to document administration. This involves overseeing the creation, periodic review, revision, and retirement of controlled documents. This role will maintain tools and materials, serve as project lead, and provide mentoring and expertise to advance the vision of the department.

Essential Functions:

System Configuration: Impact assessment (project and system), develop business requirements, test in various environments, prepare for validation

Business and account administration for EDMS

Researches and addresses issues, tracks metrics, reporting, and documentation related to

quality and compliance activities.

Communicates to ensure quality and timelines are maintained with respect to compliance activities around documentation procedures.

Leads smaller projects and/or some process/quality improvement initiatives.

Education and Experience:

Bachelor's degree or equivalent and relevant formal academic / vocational qualification

Previous experience that provides the knowledge, skills, and abilities to perform the job (comparable to 5+ years).

Knowledge, Skills and Abilities:

Strong working knowledge of Part 11, GAMP 5, and other industry standard validation standards

Strong working knowledge of document management

Experience working with Electronic Data Management Systems (such as VEEVA, Documentum, Master Control, etc)

Knowledge of GXP regulations

Excellent oral and written communication skills

Strong organizational and time-management skills

Demonstrated problem solving skills

Excellent attention to detail

Strong computer skills: ability to learn and become proficient with appropriate software

Demonstrated ability to multitask and prioritize competing demands/workload

Proven flexibility and adaptability

Our 4i Values:

Our Mission is to enable our customers to make the world healthier, cleaner and safer. Watch as our colleagues explain . As one team of 100,000+ colleagues, we share a common

set of values -**Integrity, Intensity, Innovation and Involvement**- working together to accelerate research, solve complex scientific challenges, drive technological innovation and support patients in need. #StartYourStory with Thermo Fisher Scientific, where diverse experiences, backgrounds and perspectives are valued.

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