

Regulatory affairs, Corporate regulatory affairs

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Company: Michael Page

Location: Bogota

Category: business-and-financial-operations

Descripción

Create and maintain regulatory distribution control rules to enable compliant product release in light to product changes, expiration dates, Country of Origin, manufacturing transfers, and supplier changes.

Create and maintain regulatory affairs registrations and licenses in RIMS/GTS distribution control systems in support of regulatory controls for global product distribution.

Release and management of RA blocks.

Generate and communicate GTS/distribution control reports in a timely fashion.

Maintain records (objective evidence) per established procedures.

Maintain GTS/distribution control block tracker.

Perform and support User Acceptance Testing (UAT) as needed for RIMS and GTS.

Work closely with global RA teams and Global Customer Operations to resolve issues related to GTS/distribution control blocks, batch determination rules, and maintenance of objective evidence.

Upload and maintain RA data in RIMS, Batch Determination, and GTS system using automated upload tools and troubleshoot data errors as needed.

Perfil buscado (h/m)

We are looking for our next << Corporate Regulatory Affairs Systems specialist >> who is going to provide support for the maintenance and implementation of RA systems, with particular focus on Regulatory Information Management System (RIMS) and Regulatory Distribution Controls through SAP. This person will create and maintain regulatory affairs registrations and licenses in RIMS/GTS distribution control systems in support of regulatory controls for global product distribution.

Candidate must be:

Bilingual (English B2 or above)

Bachelor's degree (or non-US equivalent) required; concentration in life sciences, technical/engineering or related field, preferred

A minimum of 3-5 years of experience in Regulatory Affairs, Engineering, Quality, or related field required.

Have knowledge of EU, EMEA, APAC, LATAM, or US regulations pertinent to medical devices, biologics, drugs and combination products.

Software Skills- SAP modules, SAP GTS, ERP systems, Microsoft Office Suite, Adobe Professional and Excel for data analytics

Attention to detail and capable of working in an organized and consistent manner.

Qué Ofrecemos

Great and competitive salary and benefits package.

Good company's culture and work environment.

Hybrid work model

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