Regulatory Affairs Analyst Sr.

Job ID
REQ-10017730
Aug. 07, 2024
Argentinien

Zusammenfassung

Garantiza un sistema de documentación controlado, retención de registros y servicios de información, incluidos los procesos de retención de registros electrónicos de acuerdo con los requisitos reglamentarios. Asegura el cumplimiento de los requisitos de las agencias reguladoras. Mantiene el sistema de cambio de documentación técnica y no técnica. Asegura que existen procedimientos para clasificar y mantener registros. Interpreta y hace cumplir todos los requisitos de formato, estándares, políticas y procedimientos operativos de la documentación. Puede identificar los componentes de presentación, comunicar las normas de documentación y coordinar el montaje de los expedientes reglamentarios. Puede analizar y evaluar datos, extraer información pertinente, preparar resúmenes de información y resúmenes ejecutivos del material buscado. Puede mantener un amplio conocimiento de la información del producto y contactos continuos con clientes locales, regionales y divisionales.

About the Role

Your responsibilities include, but are not limited to:

· Execute Global/Regional strategies for new products (NCE & BLA), new indications, LCM, RMP /Risk Management Plans and PSURs in Argentina. Interface with Regional Project Coordinators/RA New Products Strategy/ RA Regional Heads.

· Local Legislation: collaborate with the RA GDD Head/RA GDD Managers for reporting/informing new legislations, updates and/or modifications of the local legislation to the Local Leadership team and to the Regional/Global RA.

· Responsible for ensuring product quality and GxP standard compliance per the corresponding area of responsibility, including the reporting and escalation of any incident or breach related to product quality or GxP standards.

· Participate in Committee of New Products (CNP).

· Promotional materials: Active participation in the review of promotional activities to ensure policy compliance and its notification to ANMAT.

BD&L: Advise on the regulatory aspects that correspond to each individual case.

· Record Update: Ensure the proper update of records through the assessment of the extent of the changes proposed by Global (Headquarters) in the local records, submission and approval before the HA and subsequent implementation.

· Comply and enforce compliance by the staff with all practices, programs and procedures related to the health, safety and environmental protection. Actively participate in the HSE Management System including, but not limited to, immediately reporting the health and environmental risks, deficiencies in equipment and/or in the work place, HSE events, attending trainings and/or meetings, reporting problems and recommending improvements.

Minimum Requirements:

· Graduated or advanced student in health sciences (pharmacist, biochemist, biotechnologist, biologist, etc.)

· At least 1 year of experience working in the pharmaceutical industry, not exclusive.

· Knowledge of current local regulations.

· Ability to interact effectively across boundaries with other global /local functions using influencing and relationship-building skills.

· Good knowledge of Microsoft tools (Power BI, etc.) & IA tools (ChatGPT, etc.).

· English and Spanish at a fluent level.

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