RA Manager

Job ID
REQ-10037248

1月 19, 2025

Uzbekistan

摘要

Implementation of registration processes based on a marketing strategy in Uzbekistan. Compliance with and control of compliance of the registered material (information) with the requirements of local Legislation and the Company's Global Standards.

About the Role

Major accountabilities:

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  · Initiation of powers of attorney from company divisions for execution of contracts with the National Center for Expertise of Medicines, Medical Devices and Medical Equipment
  · Execution and conclusion of annual contracts with the National Center, brokers, translation and notarization agencies.
  · Communication with the marketing department to confirm the need for a new product

registration or re-registration
· Timely completion of company trainings
· Communication with the certification department in order to eliminate inconsistencies in the approved packaging and instructions for drugs imported into the territory of the Republic of Uzbekistan.
· Communication with the marketing and logistics department in order to inform about upcoming regulatory processes (re-registration, changes) for successful supply planning and stock creation.
· Preparation of documents for customs clearance of samples and standards
· Ordering originals of CPP and GMP
· Preparation of instructions according to CDS, SmPC communication with medical department and marketing department
· Compilation of dossiers in electronic and paper form
· Development of a packaging layout (drawing up text in the state and Russian languages)

· Reconciliation of the identity of the English and Uzbek texts of instructions for the medical use of drugs
· Receipt of invoices for payment for the process of registration, re-registration, amendments and submission of applications for their payment
· Elimination of comments received at different stages of registration (request for additional documentation from the manufacturer, execution of a letter in response to comments), provision of additional documentation, packages for correction, letters to the National Center for Expertise and Standardization of Medicines, Medical Devices and Medical technology

· Working with the database of the National Center for Expertise and Standardization of Medicines, Medical Devices and Medical Equipment (tracking registration stages, checking loaded packages, instructions, delays in receiving comments, issuing orders for registration approval)
· Regular updating of the database (shared folder) for internal divisions (updated registration documents, updating the status of drugs by division)
· Financial reporting (request, receipt, return to the National Center for Expertise and Standardization of Medicines, medical devices and medical equipment of closing documents, reconciliation acts)
· Preparation of approved instructions for medical use, transfer them for translation: description and upload to REDI-GO
· Strictly comply with all internal and external regulations, orders and procedures, including, but not limited to: Code of Ethics, Anti-Bribery Policy, Doing business ethically policy, Conflict of Interests policy etc.
· Be responsible for proper and appropriate reporting of Adverse Events in order to meet all regulatory requirements and ethical obligations, including timely submission of all spontaneous reports to the local person responsible for drug safety.
· Comply with the GxP quality requirements applicable to his/her area of responsibility, incl. but not limited to proper reporting of adverse events and customer complaints, samples handling as well as any incident that may adversely affect the quality, safety, identity, strength, purity, availability or efficacy of a commercial product or clinical trial material and/or may compromise the Novartis Quality System and the global Novartis reputation.

Key performance indicators:

- Implementation of current processes of registration, re-registration or amendments on time,

according to the set plan
Receipt of re-registration without interrupting the term of the Registration Certificate.
Full, clear and timely awareness of dependent departments (internal divisions) regarding the planned or current processes for the company's drugs, with feedback from them
Compliance of the registered material (packaging material, instructions for medical use, local analytical document) with local legislation and Global requirements of the company
Provision of reports and timely updating of electronic databases within the time limits set by the Company, depending on the division

Minimum Requirements:

Higher medical or pharmaceutical education

3 years (as minimum) of experience as a Registration Manager
Experienced user of MS Office

Skills:

- Data Analysis.
- Documentation Management.
- Project Management.
- Regulatory Compliance.

Languages :

- English.
- Russian
- Uzbek

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部门
Development

Business Unit
Innovative Medicines

地点
Uzbekistan

站点
Uzbekistan

Company / Legal Entity
UZP0 (FCRS = CH024) NPHS AG, RO Tashkent

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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