Qualified Person Planta de Salamanca

MSD is a global health care leader with a diversified portfolio of prescription medicines, vaccines and animal health products. The difference between potential and achievement lies in the spark that fuels innovation and inventiveness; this is the space where MSD has codified its 125-year legacy. MSD's success is backed by ethical integrity, forward momentum, and an inspiring mission to achieve new milestones in global healthcare.

Our Manufacturing Division is a team of dedicated, energetic individuals who are committed to being the most trusted supplier of pharmaceuticals and health products worldwide. Our facilities, along with our external contractors, suppliers, and partners, comprise an interdependent global manufacturing network that's committed to delivering a compliant, reliable supply to customers and patients on time, every time, across the globe.

General objective of the position: to ensure that the activities related to the quality of the product comply with the GMP regulations, corporate policies and the established regulatory requirements.

Responsibilities

- Making critical decision for bulk, intermediate and finished veterinary medicinal products
- Ensure that each batch of veterinary medicinal product has been manufactured and controlled in accordance to GMP and other applicable drug legislation, and in particular under the basis of the documentation
- Review and approval of PQR reports related to the products within area of oversight
  - Work in close collaboration with partners in operations, process engineering and planning to Review and evaluation of complaints and deviations related to the products within area of oversight
  - Approval, tracking, assessment, completion and extension of CAPAs
  - Support change management related to the manufacture of the products within area of oversight
  - Review and approval of validation and qualification documentation
  - Create, review and approval of SOPs, specifications and test methods, manufacturing and packaging protocols
- Support the execution of site and quality related projects related to the product in area of oversight as well as other continuous improvement opportunities
- Responsible for Quality Assurance oversight of a key quality activities

Qualifications, Skills & Experience Required -

Qualifications

- Minimum BS degree in pharmacy, or other degree that has attained qualified person certification within Spain
- Minimum 5 years in the pharmaceutical industry
- Majority of experience supporting pharmaceutical manufacturing operations, with a mix of operations and quality experience is preferable
- Minimum 5 years managing a team with proven track record of developing direct reports and departments to address needs or gaps within their organization
- Qualified Person
  - Preferable – Already has attained qualified person certification within Spain
  - Minimal – Has the necessary background experience defined by Spanish Health Authoroties to attain qualified person certification

Skills Required:

- Proven track record of working cross-functionally with other departments and functions to successfully deliver high impact projects and objectives for their organization
- Demonstrated experience with inspections and regulatory authorities also highly desired
- Experience with managing contract manufacturers or external partners also highly desirable
- Advanced knowledge in GMP and applicable Pharmacopoeias.
- Advanced knowledge of Quality System tools (change controls, deviations management, out of specifications, equipment qualification, process validation, product validation, elaboration of risk analysis, annual product reviews, claims, audits, autoinsections , etc.).
- Advanced knowledge in the processes of product manufacturing, equipment and facilities. Experience in the manufacture of biological and sterile products an asset.
- Knowledge in quality control test.
- Fluent in Spanish
- Business Proficient in English

Contact:
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