Job Description

Quality Assurance Specialist-QUA008262

Description
Quality Assurance Specialist

MSD Ballydine

Are you ready to Invent, Impact, Inspire?

Join MSD and shape the future of healthcare in Ireland

INTRODUCTION

At MSD Ireland, we are committed to 'Inventing for Life' in all that we do. We keep the patient at the very heart of all that we do and strive to find solutions and treatments for some of the world's most challenging healthcare needs.

THE COMPANY

MSD Ireland is one of the country's leading healthcare companies, having first established here over 50 years ago.
We currently employ over 1,700 employees, across four sites in Ballydine, Co Tipperary, Brinny, Co Cork, Carlow and Dublin and, in addition, operate substantial Human Health and Animal Health businesses.
In total to date, we have invested $2.5 billion in our Irish operations and our annual turnover ranks us as one of Ireland's top 20 companies. Currently, our Irish sites manufacture approximately half of MSD's top twenty products, saving and enhancing lives in over sixty countries around the world.
With almost 70,000 employees operating in more than 140 countries, you will be joining one of the world's largest pharmaceutical companies.

MSD BALLYDINE
MSD Ballydine develops and supplies the active ingredients and final formulated product for a range of innovative medicines at its manufacturing and R&D facilities. The plant, which has been operating in Tipperary for over 40 years, exports to over 25 countries around the world with primary markets being Europe, USA and Japan.
Our highly-skilled local workforce of 500 employees is now leading the way in the development of new medicines, including MSD's treatment for hepatitis C, which is being manufactured in Tipperary for patients around the world.
MSD Ballydine's existing portfolio and future pipeline offers team members the opportunity to operate at the cutting-edge of science and technology, and develop new treatments that positively impact patients across the globe.

JOB DESCRIPTION & SPECIFIC OBJECTIVES

Applications are invited for the position of Quality Assurance Specialist at MSD Ballydine. The role will offer the successful candidate a unique opportunity to work as part of a QA team in the clinical and commercial businesses at our Ballydine facility. This is a 12 month fixed term contract. The Quality Specialist participates as a core member of the Integrated Process Team or as a member of the Quality Centre of Excellence (CoE).

The Quality Specialist will complete:
• Attend and actively contribute to daily Tier meetings.
• Complete pre and post production batch record review
• Support development, clinical and commercial production
• Release incoming materials
• Provide Quality support OOS/deviations, providing detailed knowledge of quality systems in place and ensure that root cause is identified and corrective actions as appropriate are completed.

• Review and approve master cleaning documentation, including; technical assessments, cleaning protocols, inspection protocols and Master Cleaning Batch records.
• Generation of Technical & Quality agreements
• Annual Process and Systems Reviews: Prepare and coordinate the review and approval of the Annual Product Review Schedule. Prepare annual process and systems reviews, including the annual mock recall, as determined by the Annual Product Review (APR) Schedule.
• Investigate Supplier Complaints / Raw Material Deviations / Customer Complaints
• QA Review of Regulatory Data: Review and verify documentation that may be used for regulatory submissions/filings. Assure the accuracy and integrity of all data and information through a timely review program.
• Lead walk down audits
• Participate in the preparation for and hosting of regulatory and customer audits
• Participate in Quality and site projects that may arise.
The position will provide an opportunity to develop strong Quality and Technical understanding of Operations and Compliance requirements in the Pharmaceutical Industry.

Qualifications

Qualification:
• Bachelor's degree or post-graduate qualification in Science, Pharmacy or Engineering field.
Experience:
• Previous experience in Quality Assurance / Compliance.
• Excellent understanding of the current pharmaceutical industry regulations (FDA/EU/ICH).
• Practical experience in the implementation of quality systems in a pharmaceutical manufacturing environment.
Preferred Competencies and Skills:
• Operate as part of a self-directed team in carrying out day to day functions and assigning priorities
• Knowledge of global health authority regulations and quality and compliance requirements with the ability to effectively communicate these requirements.
• Hands-on experience in a investigation root cause analysis
• Demonstrated ability to make and act on decisions
• Ability to provide innovative ideas to improve quality and compliance that create value.
• Experience supporting regulatory inspections
• Analytical problem solving skills applied to issue identification and resolution
• Assertive, a very strong communicator
• Ability to respond to changing priorities
• Inclusion behaviors

Your role at MSD is integral to helping the world meet new breakthroughs that affect generations to come, and we're counting on your skills and inventiveness to help make meaningful contributions to global medical advancement. At MSD, we're inventing for life.

MSD is not accepting unsolicited assistance from search firms for this employment opportunity. Please, no phone calls or emails. All resumes submitted by search firms to any employee at MSD via email, the Internet or in any form and/or method without a valid written search agreement in place for this position will be deemed the sole property of MSD. No fee will be paid in the event the candidate is hired by MSD as a result of the referral or through other means.

Job
: Qual Assurance & Ops Generic

Primary Location
: EMEA-Ireland-Munster-Tipperary

Employee Status
: Regular

Travel
: Yes, 5 % of the Time

Number of Openings
: 1

Closing Date

07 Dec 2018