Pilar **Acedo-Rico**

quality assurance · drug product

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work experience

Moderna

Madrid, Spain

Manager QA Operations Drug Product

Nov 20 - Present

- Primary QA contact and PIP presence at the fill-finish contract manufacturing organization (CMO).
- QA oversight of CMOs and testing facilities to ensure compliance with internal policies and procedures, specifications and regulatory requirements.
- Review and approve all cGMP documentation, including policies/SOPs, validation protocols/reports, equipment and process validation lifecycle documentation, batch records, deviations and CAPAs.
- Review and coordinate all changes made to the manufacturing, testing, and control processes, including those initiated by the CMO.
- Collaborate with MS&T, QC, QA Systems and Compliance, QA Disposition, Supply Chain to support ongoing operational activities, resolve issues and continuous improvement.
- Quality counterpart for the implementation of new projects at the CMO. Oversight and approval of the validation activities, supporting submission activities.

Carl Zeiss Meditec

Madrid, Spain

Quality and Regulatory Manager

Feb 18 - Nov 20

- Head of the QA and Regulatory Department. Responsible for managing a small team in charge of the Quality, Regulatory and Environment departments.
- SPOC for Quality, Regulatory and Environment topics with the Authorities and the manufacturer (HQ).
- Responsible for implementing and maintaining Quality System Certifications (ISO9001:2015, ISO17025:2017) and the Environmental System Certification (ISO14001:2015).
- Analysis and monitoring KPIs. Lead for Management Review meeting.
- Local Management System Officer. Ensure compliance of the local affiliate QMS to the Global Standards.
- Registration of Medical Devices in Health Authorities.
- Market surveillance of Medical Devices.

Hoffmann-La Roche

Basel, Switzerland

Supplier Quality Manager, Medical Devices

Jun 16 - Dec 17

- Quality oversight of Medical Device CMOs as per the applicable regulations, guidelines, GMP and Roche Standards.
- Evaluate and solve a wide range of complex issues that affect multiple functions/sites related to direct material discrepancies, market complaints and associated investigations.
- Initiate, assess, and manage vendor-initiated change, and third-party actions for Roche initiated change per applicable regulations, guidelines, and Roche standards.
- Supplier Audit.
- Continuous monitoring and trending of the qualified Suppliers. Identify, define and implement supplier corrective and improvement projects.
- Create and Negotiate Quality Agreements. Provide quality requirements and negotiate final Supply specifications.
- Participate in due diligence assessment for Supplier selection, Lead Supplier qualification and maintain its approved state through consistently satisfactory performance.
- Strive to meet company and department goals and metrics.
- Elaboration and revision of Device Design documentation, such as Validation Master Plan, Design History File, OQ/IQ/PQ.

Roche

Madrid, Spain

Quality Assurance (QA) Operations Specialist

Jun 15 - May 16

- Hands-on performing in-process Quality Assurance checks for tablets and capsules.
- Lead deviations and investigations occurred during the production processes, propose corrective and preventive actions (CAPA) to solve problems, reduce recurrences, and monitor effectiveness.
- Develop technical documentation to evaluate product performance, analyze trends, and propose actions, such as Annual Product Quality Reviews (APQR) and Periodic Quality Evaluations (PQE).
- Writing and review of local procedures, Quality Agreements, Global Standards and Specifications.
- Ensure product quality and reliability inside all departments related to product manufacturing.
- Batch record review.
- Complaint management. Investigation and reporting product customer complaints.

Eli Lilly

Florence, Italy

Quality Assurance (QA) Specialist Utilities and Engineering

Sep 13 - Mar 15

- QA of the Clean Utilities used for the production of biotech FP.
- Change control, assessing and investigating deviations, CAPAs, complaints and periodic quality evaluations.
- Monthly monitoring and trending reporting for the Clean Utilities.
- Established new objectives and introduced a quality culture inside the engineering projects, maintenance and facility management.
- QA representative for facility management, pest control and engineering projects.
- SME during external and internal audits.

Eli Lilly

Florence, Italy

Health and Safety Specialist

Feb 13 - Aug 13

- Catastrophic Risk Assessment.
- Site Business Continuity Plan.
- Site Pandemic Plan.
- Chemical Safety.

Coordinación de Seguridad y Proyectos

Madrid, Spain

Health and Safety Coordinator in Construction Sites

Mar 10 - Dec 12

- Management of occupational safety risks on a range of industrial, retail and residential construction sites.
- Identification of hazards and injury reduction through direct dealing with contractors and subcontractors, mediating with the project management.
- Making technical decisions based on applying the safety principles established by law.

education

Escuela Universitaria de Arquitectura Técnica. UPM

Madrid, Spain

Building Engineering (BEng)

Sep 04 - Jun 12

- Thesis title: *Application of Carbon Fiber Panels to the concrete structures in the rehabilitation of a historical building.*

Qualifications

Lean Six Sigma Yellow Belt Course

Remote

Corporate Education Group

July 21

Pharmaceutical Quality Management Systems Lead Auditor Diploma

York, UK

NSF Pharma Biotech

Sep 17

Health & Safety Construction Coordinator Certificate

Madrid, Spain

IMF Universidad San Pablo CEU

Feb 13 - Aug 13

French Language, Phonetics and Civilization

Paris, France

Université Sorbonne Paris

July 10

skills

Languages	Spanish, English, Italian, French (Basic)
Computer Skills	MS Office, Power BI, AutoCAD
Professional Software	CRM, SAP, Salesforce, Trackwise, Smartlab, Regulus, Gmars, Darwin