

# Pilar Acedo-Rico

quality assurance · drug product

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## summary

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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

### QUALITY ASSURANCE (QA) SPECIALIST UTILITIES AND ENGINEERING

Florence, Italy

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

### HEALTH AND SAFETY SPECIALIST

Florence, Italy

Feb 13 - Aug 13

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

## Coordinación de Seguridad y Proyectos

### HEALTH AND SAFETY COORDINATOR IN CONSTRUCTION SITES

Madrid, Spain

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

#### BUILDING ENGINEERING (BENG)

Madrid, Spain

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

#### CORPORATE EDUCATION GROUP

Remote

July 21

### Pharmaceutical Quality Management Systems Lead Auditor Diploma

#### NSF PHARMA BIOTECH

York, UK

Sep 17

### Health & Safety Construction Coordinator Certificate

#### IMF UNIVERSIDAD SAN PABLO CEU

Madrid, Spain

Feb 13 - Aug 13

### French Language, Phonetics and Civilization

#### UNIVERSITÉ SORBONNE PARIS

Paris, France

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