Estela Alvarez, Ph.D.
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Professional Summary

Organic chemist with over 25 years of experience in quality (QA and QC), project management, manufacturing, and regulatory filings such as Investigational New Drug Application (IND), New Drug Application (NDA) and fillings with FDA and the European Agency for the Evaluation of Medical Products (EMEA). Provided strategic manufacturing and quality planning for supporting global supply of clinical (phase I/III) and commercial products. Conducted quality audit and provided training in current Good Manufacturing Practices (cGMP) and specific quality control methods and operations.
Provided instruction in Chemistry to undergraduate students and junior college students.
Native speaker in Spanish and Intermediate in French

Metrics

- Successfully launched **three** pharmaceutical products from Phase II/ III to the market.
- Wrote and reviewed numerous Standard Operating Procedures, Work Instructions and Forms for companies in phases I/III
- Wrote dozens of characterization reports, development reports, and method validation reports.
- Conducted over **100** GMP audits identified critical compliance gaps. Successfully collaborated with vendors and suppliers to address them.

Areas of Expertise

<table>
<tr><th>Active Pharmaceutical Ingredients (API)/Class</th><th>Dosage Form</th><th>Systems and Operations</th></tr>
<tr><td>Small molecules</td><td>Parenteral</td><td rowspan="4">Quality systems
Change Control
Deviations
CAPAs
Training
Internal and External audits
Quality Agreements
Vendor Management
Investigations
Electronic Document Management systems</td></tr>
<tr><td>Polymers</td><td>Topical</td></tr>
<tr><td>Peptides</td><td>Oral</td></tr>
<tr><td>Proteins</td><td>Transdermal (patch)</td></tr>
<tr><td>Oligonucleotides</td><td>Aerosols</td><td rowspan="2">Laboratory operations
Method development
Method validation
Method Transfer
Reference Standard Program
Stability program
API and Impurity characterization
Equipment qualification
Environmental Program</td></tr>
<tr><td>Vaccines</td><td></td></tr>
<tr><td>Monoclonal antibodies</td><td></td><td></td></tr>
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Professional Experience (Pharmaceutical and Biotech)

EA CMC Consulting (September 2022-present)

Provided technical guidance to pharmaceutical development partners regarding characterization of degradation products, and extractable and leachable compounds. Proposed analytical methods to identify and quantify degradation products. Prepared and implemented policies and standard operating procedures in alignment with regulatory expectations. Conducted audit of suppliers of raw materials, drug substances, drug product, as well as packaging and labeling of clinical trial materials.
System Administrator for Quality documents providing process improvements via configuration changes, testing, and implementation of system changes.

Eicos Sciences Inc. San Mateo CA, December 2020-present
VP of Quality and Analytical Development

Neurona Therapeutics Inc. South San Francisco CA, August 2019-November 2020
VP of Quality Control and Quality Assurance.

Relypsa, Inc. Redwood City CA, September 2013-August 2019
VP, Quality and Analytical Development

Genentech, Inc. South San Francisco CA, June 2013-September 2013
Senior Quality Pharmaceutical Leader

Affymax, Inc. Palo Alto CA, June 2006-June 2013
Executive Director, Quality Control and Analytical Development, 2012-2013
Senior Director Quality Control and Analytical Development, 2006-2011

Vaxgen, Inc. South San Francisco CA, May 2003- May 2006
Director, Quality Control: May 2004- June 2006
Associate Director, Quality Control: April 2003-April 2004

Sugen, Inc. South San Francisco CA, January 2002-April 2003
Group Leader, Quality and Analytical Development

Lynx Therapeutics (currently Illumina). Hayward CA, January1999-January 2002
Quality Manager (QC and QA).

Teaching Experience
Solano Community College, Fairfield CA, 2022-2023
Provided instruction in Chemistry to first year students

Education
Post-doctoral Fellow. National Institutes of Health, NCI. Bethesda MD
Ph.D. Chemistry, University of Maryland, College Park MD
MS. Chemistry, The American University, Washington DC
BS. Chemistry, Iberoamerican University, Mexico City