

José M. Amorin, III

Senior Quality Systems Specialist

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PROFESSIONAL SUMMARY

Experienced Chemist with extensive background in and thorough knowledge of Pharmaceutical Laboratory System and cGMP/QA Documentation practices. Experienced in reviewing and preparing pharmaceutical documents (e.g., master batch/production records, standard operating procedures (SOPs), specifications, audit reports, deviation investigation reports, laboratory validation) in accordance with cGMPs. Proven successful track-record of executing laboratory method and equipment validation protocols and test plans, supervising and scheduling personal in order to meet deadlines.

AREAS OF EXPERTISE

- ♦ Technical Writing
- ♦ QC Laboratory Testing
- ♦ Otic & Ophthalmic Drug Manufacturing
- ♦ Protocol & Test Plan Execution
- ♦ Computer System Validation
- ♦ Parenteral Drug Manufacturing
- ♦ QA Documentation & Auditing
- ♦ Suspension Products
- ♦ API Drug Manufacturing
- ♦ Regulatory Affairs
- ♦ Compliance & FDA liaison
- ♦ Vendor/Supplier Audits

PROFESSIONAL EXPERIENCE

Engineering, Consulting and Validation Services (ECVS)

2004 – present

Tucson, Arizona

Senior Quality Systems Specialist for engineering and validation consulting firm to the pharmaceutical, biotechnology, and medical device industry. Services to major clients have included: Development and preparation of component & ingredient specifications, validation protocol preparation and execution, production record template development, product release testing program development, quality systems development for manufacturing, SOP writing, internal & external vendor audits, team leadership, and manufacturing and QA personnel training.

Steris Laboratories

1984 - 2000

Phoenix, Arizona

QA-Documentation Review Supervisor, 1998 - 2000

Supervised twelve QA documentation reviewers – batch records, validation packages, specifications, standard operating procedures, and investigation/audit documents.

Scientist III QC/QA – Documentation, 1993 -1998

Responsible for chemistry, stability, R&D analytical, microbiology, validation, laboratory audits and reviews. Laboratory Information Management validation, department reports, product and production investigation reports. Extensive experience in QA-Documentation including standardization of Master Formula Cards, batch records, release review, packaging records, and batch fortification. Interfaced with many other departments including Manufacturing, Packaging, Marketing, Purchasing, Regulatory Affairs, and FDA. Familiar with computerized manufacturing controls. CPCS, APCs, and API.

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Chemistry Control Laboratory Supervisor, 1987-1993

Management skills: Supervised Analytical QC laboratory testing of sterile parenteral, otic, ophthalmic, topical, and suspension products including raw material testing, bulk in-process, final container testing, customer complaint, and special project testing. Participated in and motivated laboratory personnel during successful team effort to achieve FDA validation of new pharmaceutical manufacturing facility for Dec. 87 to July 88. Supervised laboratory during company expansion of \$8 million annual sales (1987) to \$170 million annual sales (1993.) Managed annual laboratory operating budget of approximately \$1 million.

Documentation skills: Responsible for all laboratory SOPs, weekly, monthly, and annual department reports, investigational reports, and revision of product test specifications. Responsible for maintaining QC status reports for raw material, in-process and final container testing, and producing sale/operations product back order reports. Familiar with modern computerized laboratory.

Instrumentation skills: Extensive experience with HPLC, GC, capillary GC, IR, UV-visible, FTIR, AA, DSC thermal analysis, particle counting, and microscopes (light, polarized, IR.) Responsible for laboratory equipment purchases, writing and validation of equipment SOPs, and established equipment cross training programs for Chemists.

Chemist II – Stability Testing, 1986 -1987

Managed Steris commercial stability test program. Organic chemical analysis of product to determine shelf life. Supervised one Chemist I.

Chemist I – QC Analytical Lab, 1984 –1986

Conducted general wet and instrumental analytical quality control testing of sterile parenteral following USP test methods.

Revlon, Inc., Phoenix, AZ

1983 - 1984

QC Analytical Chemist Technician

General wet and instrumental methods of pharmaceutical cosmetics. HPLC, GC, IR, UV-visible, AA.

EDUCATION

Washington and Lee University, Lexington, Virginia B.S. Chemistry, B.S. Natural Science 1980

Professional Development Courses

Management Institute, Tempe, AZ
Agallo and Associates
McCrone Research Institute, Chicago, IL
Woodbadge for the 21st Century

Managing Multiple Priorities
Validation Science
Pharmaceutical Microscopy
Advanced Leadership Training, Contemporary
Leadership Concepts in Corporate America

PROFESSIONAL MEMBERSHIPS

American Chemical Society, national and local chapter

BSA – Boy Scouts of America (Leadership positions in Arizona region)