

Linda Magill

Summary

Quality Systems Professional with over 25 years combined successful pharmaceutical/medical device/OTC drug /cosmetic manufacturing experience encompassing both management and technical aspects. Proven ability to set goals logically, establish systems, handle change and follow through effectively. Demonstrated leadership and performance encompassing: Quality Systems, Regulatory Compliance, 510(k) Submissions, MDRs and Product Complaint Handling, Staff Development/Training, Product Commercialization, Project Management, Budget Preparation and SOX Financial Controls, Validation/Qualification, Internal/External Audit, Investigations/ CAPA.

Selected Accomplishments

- ◆ Implemented Quality Systems resulting in a medical device company going from a Warning Letter to a follow-up inspection with zero FDA 483 observations and a compliance status of NAI (no action indicated).
- ◆ Implemented Quality Systems/hired and trained staff resulting in an OTC drug company going from the threat of an FDA Warning Letter to an FDA inspection with zero FDA 483 observations.
- ◆ Provided guidance and expertise to a start-up pharmaceutical company being prosecuted by the FDA successfully avoiding a Consent Decree.
- ◆ Qualified a newly constructed 235,000 square foot pharmaceutical manufacturing campus including facility, utilities and equipment ensuring on time start-up for new product launches.
- ◆ Implemented an internal auditing program providing executive management visibility into areas requiring improvements resulting in appropriate prioritization of activities to ensure critical issues were addressed promptly.
- ◆ Created, reviewed and approved product master formulae and manufacturing procedures, product specifications, quality standards and packaging specifications supporting expansion of product line.
- ◆ Facilitated the implementation of a multi-site CAPA system improving visibility and reducing investigation and CAPA cycle times.
- ◆ Implemented Quality Metrics that monitored trends for deviations, documentation errors, out-of-specification results and release cycle times reducing backlogs and providing appropriate senior management oversight and remediation.
- ◆ Planned, validated and implemented a random warehouse release system ensuring cGMP compliance and eliminating 30% of the warehouse positions.
- ◆ Organized and implemented a Total Quality Management (TQM) system by facilitating multiple task teams, thus ensuring employee involvement and commitment to quality.
- ◆ Coordinated multi-department projects from developmental stage through marketing stage and ensured the completion of new products, contributing to an increase in sales of 25% to 50% per year.

Experience

Mergen Medical Solutions, Coconut Creek, FL

2008 to 2009

Medical Devices

Director of Quality and Regulatory Affairs (2008 to Present)

Responsible for Regulatory Affairs, 510(k)s, Quality Systems, Quality Assurance, Quality Control, CAPAs, Complaints and Medical Device Reporting, Document Control, Internal/External Audits and ISO 13485 Certification. Member of New Product Team and assist in the preparation of Risk Analysis and Design History Files.

Selected Accomplishments: Implement corrective actions to obtain FDA compliance and resolve FDA Warning Letter status resulting in an FDA Inspection with zero FDA 483 observations. Expanded company product line by successfully preparing and submitting 510(k) submissions. Implemented improvements to Quality System Procedures: CAPA, Complaint Handling, MDR Reporting, Design Controls, Supplier Qualifications, Internal Audit Program resulting in FDA

compliant procedures and improved processes. Prepared Management Review Reports and engaged management in the Quality Systems. Established Quarterly Complaint trend reports and presented to senior management. Successfully enhanced CAPA system resulting in appropriate root cause investigations and corrective actions/preventive actions resulting in a reduction in product complaints.

SOLAR COSMETIC LABS, INC., Miami Gardens, FL 2005 to 2008
OTC Drug Manufacturer
Vice President Quality, Regulatory and Technical Services (2007 to 2008)

Responsible for Technical Services, Regulatory Affairs, Quality Systems, Quality Assurance, Quality Control Laboratory, Document Control, Stability and Validation.

Selected Accomplishments: Implemented a program to evaluate product formulations resulting in improved manufacturing processes and product stability. Evaluated multiple manufacturing companies and prepared a plan to outsource manufacturing functions and reduced cost due to seasonality of product and financial constraints.

Director Quality (2005 – 2007)

Responsible for all Quality functions including Quality Systems, Quality Assurance, Quality Control Laboratory, Document Control and Validation.

Selected Accomplishments: Hired to resolve FDA compliance issues resulting in the company going from the threat of a Warning Letter to an FDA Inspection with zero FDA 483 observations. Prepared all responses to FDA 483 which resulted in the FDA not issuing the company a Warning Letter. Prepared and implemented standard operating procedures required per 21 CFR Parts 211. Implemented validation program and validated analytical test methods and products. Established quality metrics. Prepared Annual Product Reviews increasing senior management's awareness of the products performance.

ANDRX PHARMACEUTICALS INC, Fort Lauderdale, FL 2001 to 2005
Director Quality Assurance (2001 to 2005)

Responsible for all Quality Assurance functions. Active member of facility and equipment qualification, new product and process validation teams.

Selected Accomplishments: Qualified newly constructed 235,000 square foot pharmaceutical manufacturing campus including facility, utilities and equipment ensuring on time start-up for new product launches. Facilitated the implementation of a multi-site CAPA system improving visibility and reducing investigation and CAPA cycle times. Implemented Quality Metrics to monitor trends for deviations, documentation errors, out-of-specification results and release cycle times reducing backlogs and providing appropriate senior management oversight and remediation.

Associate Director Quality Assurance (2001)

Managed all Quality Assurance functions. Promoted after three months on the job to Director Quality Assurance.

BAUSCH & LOMB PHARMACEUTICALS, Tampa, FL 1999 to 2001
Senior Manager Quality Assurance (2000 to 2001)

Responsible for Quality Assurance functions. Active member of the Steering Committee for the Quality Teams.

Selected Accomplishments: Assisted teams in the implementation of manufacturing execution system (MES) and laboratory information management system (LIMS).

Senior Manager Quality Systems (1999 to 2000)

Responsible for evaluating, developing and implementing improvements to the quality systems.

Selected Accomplishments: Lead team in preparation for CFR 21 Part II compliance. Prepared and executed protocols to validated ERP system. Planned, validated and implemented a random warehouse release system ensuring cGMP compliance and eliminating 30% of the warehouse positions. Provided corporate training for 21 CFR Parts 820 Quality Systems. Prepared process flows for current procedures in order to improve process efficiencies and ensure process compliance.

MAGILL CONSULTING SERVICES

1997 to Present

Quality/Regulatory Consultant

Responsible for evaluating, developing and implementing programs to improve quality in a manufacturing environment while working closely with management to achieve company goals. Provided direction and support to Operations, Technical Services, Regulatory Affairs and Quality Assurance/Control to various manufacturing companies and enhanced and/or created systems, policies and procedures increasing both efficiencies and compliance.

Selected Accomplishments: Provided guidance and expertise to a start-up pharmaceutical company being prosecuted by the FDA successfully avoiding a Consent Decree. Prepared analytical and process validation programs for various companies. Reviewed, enhanced and/or prepared standard operating procedures. Trained employees on cGMPs and Quality Systems.

ZENITH GOLDLINE PHARMACEUTICALS/IVAX, Shreveport, LA

1983 to 1997

(A Subsidiary of IVAX Corporation)

Vice President Quality Assurance, Zenith Goldline Pharmaceuticals (1992 to 1997)

Quality Assurance Manager, LuChem Pharmaceuticals (1990 to 1992)

Quality Control Laboratory Manager, LuChem Pharmaceuticals (1989 to 1990)

Research and Development Formulation Manager, LuChem Pharmaceuticals (1987 to 1989)

Quality Control Laboratory Supervisor, LuChem Pharmaceuticals (1985 to 1987)

Chemist, LuChem Pharmaceuticals (1984 to 1985)

Quality Assurance Inspector, LuChem Pharmaceuticals (1983 to 1984)

Education

M.B.A., Centenary College, Shreveport, LA

B.A., Science, Louisiana State University, Shreveport, LA

Professional Development

Complaints, MDRs, Reports of Removals and Corrections and Recalls (Kimberly Trautman); Integrating Complaint Handling and CAPA (K. Trautman); Quality Systems Regulations 21CFR820 (K. Trautman); FDA Overview of Regulatory Requirements, Medical Devices (Bill Sutton); 510K Submission Requirements, Contents and Options (J. Kasoff); Regulatory Compliance; Aseptic Manufacturing; ISO; Kepner Tregoe Problem Solving; Project Management; Process Validation; Cleaning Validation; Equipment and Facility Qualification; Computer Validation; Documentation Management and Control; Change Control; Drug Product Stability and Shelf Life; Leadership Development; Visual Workplace Techniques; Internal Audits and FDA Inspections; Time Management; Good Automated Manufacturing Practices; Dale Carnegie