MyQACoach.com

Michael Dempsey
QA Coach

QA Superpowers: Corrective & Preventive Action, Problem Solving & Root Cause Analysis, Quality Auditing, Process and Analytical Method Validation, Quality Management System Leadership

Summary

A senior Quality professional with over 35 years of experience in all aspects of pharmaceutical industrial quality functions. Experienced in quality engineering and quality auditing applications. Demonstrated track record of building effective teams to maintain the quality operations in several companies.

Career History

PD Pharmatech
Manager of Quality Assurance
Responsible for all Quality functions of the company as outlined in facility SOPs.
Responsible for review of manufacturing documentation for product release and management of all cGMP documentation functions.
Managed the quality staff of four Quality Auditors and one Document Coordinator.

Eli Lilly and Company
QA Representative Auditor
Responsible for early stage product supplier and contractor audits and assessments internal, domestic and international.
Auditing included scheduling, preparing, conducting and reporting audits of internal and external facilities, procedures and processes globally to assess the level of compliance with corporate, national and international regulatory requirements.
Establishment and maintenance of a comprehensive knowledge of all applicable regulations globally.
Provided technical expertise in identifying, formulating, assembling and delivering quality and compliance education to customers, as appropriate.

COOK PHARMICA, LLC
Quality Audit Manager
Managed vendor qualification and internal and external audit schedules.
Assessed quality risk in activities and processes according to regulations, guidelines and procedures.
Managed and lead external audit teams in evaluation of vendors.
Primary contact for client and regulatory agency inspections of site.
Trained auditors and provided coaching and mentoring.
Managed the controlled document management system
Managed three auditors, one document control supervisor and seven document specialists.

VESTA PHARMACEUTICALS, INC.
Director of QA/QC
Managed all Quality functions of the company as outlined in facility SOPs.
Researched and developed new product documentation for manufacturing and Quality functions for this start up pharmaceutical company.
Reviewed and approved all GMP Documentation.
Supported validation efforts to include drafting, reviewing, and approving protocols and final reports.
Managed contractors on site at Eli Lilly Company
Interpreted cGMPs for facility and responsible for training programs.
Prepared, reviewed, and implemented SOPs and enforced compliance.
Developed and administered operational Quality budgets.
Represented the company when dealing with FDA, DEA, suppliers, and vendors.

COLORCON, INC.
QA/QC Manager
Led a team of 10 Quality professionals in testing, paperwork review and releasing of product to market for a global pharmaceutical excipient manufacturer.
Managed all QA and QC functions for the facility's two product lines.
Managed the development of the ISO certification plan.
Acknowledged, investigated and responded to global customer's complaints and CAPA.
Developed and administered the departmental budget of over $1MM annual.
Hosted all customer site audits.
Planned and managed renovation of laboratory and construction of new office complex.
Reworked the entire SOP system for site

THEORIS LIFE SCIENCES
Senior Quality and Compliance Consultant
Developed Standard Operating Procedures for Clients to meet cGMP requirements
Updated training manuals for customer processes
Performed quality reviews of all documents written for cGMP compliance.
Wrote several operational manuals for new and existing process systems for client

XANODYNE PHARMACEUTICALS, INC.
Director of Quality
Managed all Quality functions of the company as outlined in facility SOPs.
Reviewed and approved all GMP Documentation.
Acknowledged, investigated and responded to customer's complaints and CAPA.
Supported validation efforts to include drafting, reviewing, and approving protocols and final reports.
Prepared, reviewed, and implemented SOPs and enforced compliance.
Managed in Product Recall strategies for site location.
Reviewed and audited the final release functions for site location.
Developed and administered operational Quality budgets.
Represented the company when dealing with FDA, DEA, suppliers, and vendors.

CGMP VALIDATION, LLC
Project Manager
Managed several validation projects for clients' new biopharmaceutical facilities in excess of three million dollars revenue for cGMP Validation.
Developed, wrote and executed installation, operation and performance protocols for the qualification of process equipment in compliance with cGMPs and client requirements.
Managed teams varying from two to fifteen professionals on five projects.

SCHWARZ PHARMA MANUFACTURING, INC.
QA Supervisor Documentation
Managed QA document review and control process of all GMP documents generated.
Supervised five persons in various document-related activities.
Performed as primary contact for DEA interactions and as host for DEA site inspection.
Team member for FDA inspections.
Revamped the documentation system to allow for better retrieval and control

BURROUGHS WELLCOME CO.
Quality Engineer
Prepared the analytical data portion of the Annual Product Review.
Participated as a member of QA team for FDA inspection of BW systems.
Acted as an internal consultant on process and quality related opportunities for improvement through data analysis and process review.

PERRIGO COMPANY OF SC
QC Incoming materials Supervisor
Managed incoming material flow to manufacturing and packaging departments.
Developed and managed the OSHA HazComm and SARA Title III programs for plant.
Supervised three Raw Material chemists and one sampler.

GENERAL NUTRITION CORP.
Audit Supervisor
Performed line audit of all production departments and batch record review.
Performed wet chemical assays of incoming raw materials.

SANDOZ PHARMACEUTICAL COMPANY
Kilo Lab Technician III Process Development
Performed process scale up of pharmaceutically active compounds.
Produced active compounds for clinical trial studies.

Education and Credentials

- B.S. Chemistry, Clemson University, Clemson, SC
- ASQ Certified Quality Engineer (CQE)
- ASQ Certified Quality Auditor (CQA)
- ASQ Certified Biomedical Auditor (CBA)
- ASQ Certified Manager of Quality / Organizational Excellence (CMQ/OE)
- RAB Quality Systems Lead Auditor
- RABQSA Provisional Auditor QMS

Achievements and Contributions to the Profession

American Society for Quality: Member 1981 to Present

Section 1126	Board Member – 1990-1995
	Section Chairperson, 1994-95
Audit Division -	Membership Chair, 1993 – 1999
	Region 9 Councilor 2007 - 2013
FD&C Division –	Membership Chair – 2006 – 2012
	Region 9 Councilor 2007 - 2012
Inspection Division –	Division Secretary - 2008 - 2010
	Education Chair – 2008 – 2012
Section 920 -	Secretary 2006 – 2008,
	Membership Chair 2007 – 2010

- Presented a public course of ASQ CQA refresher training - 1994
- Eastern Quality Council of the NC Quality Leadership Foundation Founding Member
- Senior examiner for the North Carolina Quality Leadership Award, 1993-1996
- Pitt County Quality Network Founding Member
- Regulatory Affairs Professional Society – Indy-Cincy Chapter Co-Chair 2004 – 2005

Patents and Publications

- US Patent "*Prenatal Multivitamin/multimineral Supplement*" (US 7994217 B2)