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Stephen J. Jerger

QA, QC, RA Coach
Quality Assurance Leadership, Corrective and Preventive Action (CAPA),
Problem Solving & Root Cause Analysis

Summary

A QA/QC/RA professional with diverse GLP/GMP experience in pharmaceuticals (APIs and dosage forms) and medical devices; strong skills in regulatory compliance, problem solving/investigations/CAPA, cost reduction, and management of multi-site manufacturing operations; development of a quality system for a start-up company.

Notable Achievements:

Reduced batch record review from 15+ days to less than 10 days
Reduced batch record errors from 75% to 30%
Developed comprehensive API cleaning validation program based on dose criterion
Conducted international supplier quality audits
Developed tracking/trending databases for investigations and deviations, as well as product defects for a medical device to improve product and processes

Work History:

08/2013 – 04/2014 AmbioPharm; North Augusta, SC
Director of Quality Assurance & Regulatory Affairs
Management of quality system for API manufacturing of peptides; supervision of batch record review for release; generation and submission of Drug Master Files; host for GMP audits; tracking/trending of deviations and OOS investigations

05/2012 – 08/2013 RxBio, Inc.; Memphis, TN
Associate Director of Quality Assurance
Development of SOPs for laboratory equipment, analytical methods, and qualification of equipment for a start-up biotech company; implementation of procedures, qualification, and training to bring test laboratory into GLP compliance; auditing of GLP testing laboratory and a contract API development facility

05/2010 – 02/2012 Zila, Inc.; Batesville, AR
Director of Quality
Management of quality system for medical devices and drug products; host for regulatory inspections; maintain compliance with GMP (210/211, 820, and ISO 13845); supervision of quality activities for plastics injection molding and electronics assembly; review and approval of Risk Assessments, Design Reviews, Validation Protocols, and Validation Reports

07/2007 – 01/2010 Celsis Laboratory Group; St. Louis, MO
Director, Quality Assurance
Management of quality system for contract laboratory testing facility; implementation of a Corrective Action/Preventive Action (CAPA) system; host for client audits and FDA inspections; development of tracking/trending reports for deviations, OOS investigations, and corrected reports; negotiated quality agreements and technical agreements with clients

12/2006 – 06/2007 Tyco Healthcare / Mallinckrodt; St. Louis, MO
Plant QA Manager – Product Release
Management of batch record review and product release for API production facility

10/2004 – 12/2006 Tyco Healthcare / Mallinckrodt; St. Louis, MO
Plant QC Laboratory Manager
Management of QC laboratories (raw materials, in-process, and finished APIs); management of API stability program

04/2002 – 09/2004 Regis Technologies, Inc.; Morton Grove, IL
Director, Quality Assurtance
Management of quality system for an API facility (clinical R&D development and commercial); development/implementation of a comprehensive cleaning validation program; host for client audits and FDA inspections

12/1998 – 03/2002 SPI Polyols / SPI Pharma; New Castle, DE and Grand Haven, MI
Director of Quality
Management of quality system for an API facility (clinical R&D development and commercial); development/implementation of a comprehensive cleaning validation program; host for client audits and FDA inspections

04/2002 – 09/2004 Regis Technologies, Inc.; Morton Grove, IL
Director, Quality Assurance
Management of quality system for an API facility (clinical R&D development and commercial); development/implementation of a comprehensive cleaning validation program; host for client audits and FDA inspections

Most Significant Earlier Work:

11/1197 – 06/1998 Leiner Health Products; Carson, CA
Quality Assurance Director
Management of QA system (receiving inspection, label control, manufacturing/packaging inspection, and batch record review/product release) for a manufacturer/packager of vitamins, nutritional supplements, and OTC products

06/1994 – 10/1997 Ganes Chemicals, Inc.; Pennsville, NJ and Edison, NJ
Quality Assurance Manager
Supervision of QA activities for two API manufacturing facilities; host for client audits and FDA inspections; developed a comprehensive cleaning validation program; conducted supplier quality audits for foreign suppliers of critical intermediates

07/1993 – 05/1994 Boots Pharmaceuticals; Shreveport, LA
Quality Operations Manager
Supervision of receiving inspection, manufacturing/packaging QA inspection, and batch record review/product release for the dosage manufacturing facility

09/1986 – 07/1993 Boots Pharmacueticals; Kingstree, SC
Quality Control Manager
Supervision of QC laboratory and batch record review/product release for an API facility; developed purity and impurity HPLC profiles for APIs; host for FDA inspections

Education and Certifications:
Bachelor of Science, Chemistry; Indiana University – Bloomington (1972)