Plant Manager, OTC Drug, Cosmetics and Food Mfg.

AREAS OF EXPERTISE

- **ISO 13485**
- **FDA**
- **Medical Devices**
- **Quality System**
- **Validation**
- **Design Control**
- **Biotechnology**
- **Pharmaceutical Industry**
- **Lifesciences**
- **Quality Auditing**
- **GMP**
- **Technology Transfer**
- **CAPA**
- **Regulatory Affairs**

INTRODUCTION:

Consultant has over 30 years' experience in Quality Assurance, Regulatory Affairs, Manufacturing Operations, Project Management and Computerized Systems implementation primarily in FDA regulated industry. Accomplished expert and project manager for development and implementation of process improvement strategies for Quality System remediation projects and quality system integration including compliance with 21 CFR 210, 211, 803, 806, 820, and ISO 13485. Accomplished auditor including supplier audits, third party compliance auditing and quality

WORK EXPERIENCE:

1999 – Present
Industry Consultant
Duties:

- Conducted assessment of current packaging operations for implantable lenses and companion products in Japan. Project manager for initiative to move operations from Japan to consolidate in the client California facility.
- Worked with a Japanese medical device client to implement a Quality Improvement Plan. Provide consultation and compliance support to remediate the clients Complaint Handling and Post Market Surveillance systems. Provide expert input and recommendations to correct noted FDA-483 and Warning Letter observations and improve overall compliance to regulatory requirements, also taking into consideration ISO 13485:2016.
- Providing major capital equipment for the diagnostic imaging sector. Primary responsibilities include remediation of customer service processes and preparation of quality plans and protocols for remediation efforts.
- Duties include quality system remediation including audit CAPA response preparation, integration activities for ANVISA, 21 CFR 210 and 211 compliance, and regulatory inspection readiness training for staff.
- Conducting a series of worldwide quality system gap analysis audits for a major contact lens manufacturer. Delivered audit reports under attorney/client privilege to CEO and Executive Management as the basis for a quality system enhancement project.

- Performing quality system document reviews prior to site approval. Developed protocols and checklists, conducted document reviews, and performed remediation to ensure compliance prior to site approval. All quality system documents at this site were subject to review.
- Integrate revised Novartis quality systems requirements for 21 CFR 210, 211, and 820 into Alcon Laboratories quality system at both the divisional policy and site SOP levels.
- Involved in remediation of complaint handling process with the goal of reducing a backlog of 60,000+ complaints open > 90 days by 90% in 6 months. Helped client achieve goal by bucketing complaints, conducting required investigations including risk analysis and documenting required corrective actions. Complaint investigation process was proceduralized to ensure ongoing compliance.
- Performing gap analyses at both Taiwanese and Chinese facilities for quality system remediation project to bring Taiwanese medical device manufacturer into compliance with 21 CFR 820 regulations. Delivered GMP training to senior management, revised SOPs and provided training for implementation for most quality subsystems, and reviewed documents post-implementation to ensure effectiveness.
- Conducting worldwide 21 CFR 820 compliance gap analyses for Abbott Medical Optics post-acquisition by Abbott Laboratories. Team lead for remediation of identified quality system gaps at the AMO facility in Hangzhou, China, including quality system integration and inspection readiness activities.
- Primarily responsible for definition and implementation of action items designed to implement corrective and preventive actions to bring the quality management system into compliance with 21 CFR 820 requirements.
- Primarily responsible for remediation of all quality compliance aspects of the service department including evaluation of service calls for complaints, maintenance of service parts for consent decree requirements and remediation of service center procedures to meet regulatory requirements.
- Implement a 21 CFR 820 compliant quality system at device manufacturer anticipating entry into the medical diagnostics market. Developed SOPs and associated training for most quality subsystems, assisted with SOP training and implementation, and reviewed documented evidence post-implementation to ensure effectiveness.
- Responsible for remediation and implementation of procedures related to the 21 CFR 820 CAPA quality subsystem including, nonconformances, investigations, risk assessment, CAPA and complaint handling processes.
- Responsible for development of SOPs for several major 21 CFR 820 subsystems and for the revision and implementation of SOPs, Manufacturing Instructions, and Test Methods for the Molecular Genomics business unit.
- Responsible for identification of potential clients and participation in sales cycle to develop consulting business. In addition, provided project management, and lead consultant teams in gap analyses and quality systems remediation.
- Prepared a majority of the audit reports for delivery to client subsequent to approval by the Bio-Reg CEO and Senior Management.

1998 – 1999
Fruit of the Earth, Inc.
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1976 – 1998
Abbott Diagnostics Division, Inc.
Production Manager (1991 – 1998)
Production Supervisor/Planner (1990 – 1991)
Quality Assurance (1989 – 1990)
Research & Development Microbiologist (1976 – 1989)

EDUCATION

The University of Dallas
Master of Business Administration: International Management

The University of Texas at Arlington
Bachelor of Science: Biology

SKILLS

- Responsible for the design and implementation of quality management systems to ensure ongoing compliance with regulations and requirements for medical device and pharmaceutical firms. Established new or remediated current Quality Systems for multiple clients leading to enhanced compliance with regulations. Skilled in the remediation of CAPA systems including root cause investigation of nonconformances, complaints and implementation of corrective and preventive actions.
- Worked with multiple clients on remediation of quality issues including FDA Form 483 observations, Warning Letters and Consent Decrees. Managed planning and implementation of remediation activities leading to successful completion of Consent Decrees, Warning Letters, and 483 remediation projects.
- Experienced auditor performing in-depth compliance audits and gap analyses to assess quality systems and processes for compliance to QSR regulations and ISO 13485. Conduct Third Party Audits as independent auditor and as Member of Audit Executive Team and CAPA System Team. Performed and documented supplier audits for multiple clients.
- Contributed as key member of project team implementing new Quality Systems at several medical device manufacturers. Develop Standard Operating Procedures, Manufacturing and Work Instructions, Test Methods and Test Specifications. Prepare training materials, train staff, and implement procedures to ensure continued compliance. Prepared complaint investigations and remediated complaint handling systems to ensure compliance.
- Provide both direct and indirect support for U.S. FDA Inspections for both domestic and international clients. Directed pre-inspection readiness audits and remediation activities to address identified deficiencies for clients in preparation for regulatory agency audits.
- Lead teams and manage projects for the implementation of Enterprise Resource Planning systems at multiple clients spanning numerous industries including pharmaceutical, automotive, OTC drugs and electro-mechanical assembly. Deliver training on Enterprise Resource Planning system applications.
- Managed multiple production lines producing medical diagnostic instruments and reagents. Responsible for the activities of a multifunctional staff of approximately 150 direct and indirect reports. Accountable for annual manufacturing throughput of approximately $60 MM and budgets exceeding $8.5 MM. Managed training personnel and activities for all manufacturing activities.
- Manage projects for rearrangement and relocation of production lines for medical devices. Projects closed on time and under budget leading to Vice Presidents awards.
- Lead manufacturing team in ISO 9001 implementation and registration. Escort auditors in manufacturing areas.
- Utilize expertise in Enterprise Resource Planning systems for managing materials, production, capacity, standard costs and budgets. Suggest and implement system improvements leading to improved efficiency.
- Supervised workforce, planned materials and production schedule for multiple product lines including diagnostic reagents, disposables, and kits
- Developed new methods and capabilities for reagents and instrumentation for rapid diagnostic microbiology system.

- Analyzed data and assisted in 510(k) submission preparation for in-house and field clinical trials for medical devices.