



Christopher Ford
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SKILLS/SPECIAL QUALIFICATIONS:

Fifteen years progressive quality management experience in high-tech manufacturing, primarily in the medical device manufacturing industry and with a specific focus on regulatory compliance in US FDA Class II and III device manufacturers.

Eleven years quality management systems audit experience, as a Certified Quality Auditor (CQA / ASQ) and a certified ISO 13485:2003 Lead Auditor (QSA/RAB), specializing in the US FDA Quality System Regulation, the Sherman Act of the State of California, ISO 13485 / 9001, as well as the EU Medical Device Directive, Health Canada CMDCAS, and the Japanese Ministry of Health, r-PAL requirements. Conducted approximately 400 first, second, and third-party ISO 13485 / 9001 / QSR / MDD audits internationally.

Eight years experience implementing cost-effective and efficient quality management systems solutions and harmonized processes (ISO 13485:2003, US FDA QSR, MDD, CMDCAS, etc.), while focusing on customer satisfaction and efficiency.

Eight years Management Representative experience with direct responsibility for oversight of government inspections. Successfully completed more than ten state (CA Department of Health) and Federal (US FDA) facility inspections, and more than twelve Registrar (ISO 9001/13485) certification and recertification audits, as well as negotiated Form 483 observations and registrar nonconformities.

Eight years experience developing and delivering quality systems training programs for ISO 13485:2003 / ISO 9001, FDA QSR, and other international requirements, as well as specific training programs for CAPA, Complaint Handling, Internal Auditing, Government Inspection, Document Control and Good Documentation Practices.

Knowledge in USC Title 21 CFR Part 820, The Quality System Regulation, ISO 9001:2000-2008, ISO 13485:2003, European Parliament Directive 93/42/EEC, The Medical Device Directive, European Parliament Directive 98/79/EC, CMDR (Canada), SOR/98-282, P.C. 1998-783 May 7, 1998 and amendments, Japanese r-PAL GMP,

Ordinance No. 169, 21 CFR Part 11; Electronic Records; Electronic Signatures, 21 CFR, Parts 50, 54, 56, 812 and 814, Good Clinical Practices Government Code, Division 104, Part 5, State of California, Sherman Food, Drug and Cosmetics Law, Including those parts relative to Home Medical Device Retailer.

Experience with devices in obstetrics/gynecology, clinical chemistry, physical medicine, radiology, neurology, immunology, pathology and hematology, including a tubal occlusion insert (permanent contraception), point of care blood chemistry analyzer and colorimetric reagent test panels, glucometer and insulin delivery system, carboxhymoglobin assay, power inflatable tube massager, medical image (CAD) analyzer, evoked response auditory stimulator, automated cell-locating device, automated image analysis microscope, and differential cell counter.

Regulatory Expertise:

Medical Devices – Durable, Electronics, Implantables, Software, Sterile

Adverse Event (SAE) Evaluation, ASQ Certified Auditor, Audits – Certification,/State Licensing,/ Due Diligence/GCP/GMP (Biologic)/ISO/ Mock/ Pre-Approval Inspection/ Quality System Inspection Technique (QSIT)/Quality System Regulation (QSR)/Supplier, Clinical –Labeling, Electronic Records & Electronic Signatures; 21 CFR Part 11 EPA, FDA - 483 and Warning Letter Responses, Hazard Analysis, ISO - 13485/ 9001/9002/ 9003/14971 (Risk Management) / In-vitro Diagnostic Directive (IVDD)/ Medical Device Directive (MDD), ISO certified auditor, ISO lead auditor, Quality Assurance, Quality Control, Quality Management, Quality Systems Development and Implementation, Regulatory Affairs

Submissions –510(k), PMA

Technical Expertise:

Batch Record Review, Calibration, Computer Validation, Corrective and Preventive Action (CAPA), Design Controls, Development History Report Writing, Document and Records Controls, Engineering - Software/Controls/Design/ Manufacturing/Process/Project, Environmental Monitoring, Equipment Validation, ERP, Facility Validation, Gap Analyses, Lean Manufacturing, Medical Devices, Metrology/Calibration, Non-conformance Investigations, Out-of-Specification (OOS) Investigations, Packaging and Labeling, Pre-Approval Preparation and Inspection, Process Optimization, Process Validation, Program Management, Project Management, Quality Engineering, Risk Analysis – FMEA/FMECA/FTA/HAACP/, Root Cause Analysis, Software - Development Quality Programs, SOP Development and Implementation, Software/Hardware Validation, Supply Chain and Supplier Management, Technical Writing, Training-GMP, QSR, ISO, Validation Protocol and Report Writing

WORK EXPERIENCE:

2009 -Present *Marion Weinreb & Associates, Inc., Mill Valley, CA*
Associate

Works with clients in the medical device, and biotechnology industries to develop quality assurance and regulatory strategies for compliance with FDA regulations and applicable international requirements.

- Conducts assessments of client sites, procedures, and programs to determine compliance. Quickly identifies gaps and weaknesses, and develops strategies to assist the client in developing cost-effective and efficient solutions.
- Conducts and reports quality systems audits, specializing in FDA Class II and III medical device manufacturers.

2006 – 2007 *Game Ready, Berkeley, CA*
Manager, Quality Systems and Regulatory Affairs

- Management representative, and Regulatory point of contact for the company responsible for oversight of the quality management system with specific emphasis on the internal audit system, CAPA, Complaint Handling, and the supplier audit system.
- Established and implemented an ISO 13485:2003 / QSR / CMDCAS / MDD compliant quality management system within 90 days, and developed and delivered associated training materials.
- Established and implemented a Home Medical Device Retailer program, and attained licensing allowing the organization to dispense medical devices to patients.
- Managed a 510(K) application project for submission to FDA.
- Successfully hosted one State (CA Department of Health) and one Federal (US FDA) inspection, minimizing inspectional observations (483) and reducing the company's liability, and developed timely responses and negotiated with FDA to successfully close inspection reports.
- Developed user manuals for CE mark and technical files for submission. Managed certified translation services for all Game Ready brand user communications.

2004 – 2005 *Abbott Laboratories, Abbott Diabetes Care, Alameda, CA*
Manager, QARA Audit

- Developed, implemented and maintained the divisional audit program, including internal quality system compliance, clinical practices, and supplier/contract manufacturer quality
- Audited PMA applications prior to submission.
- Lead and directed staff, and conducted first and second-party audits, including quality system, clinical trials, clinical investigational sites, suppliers, and contract manufacturers for compliance with applicable corporate and divisional policies and regulatory / statutory requirements.

2001 – 2003 *R2 Technology, Inc., Sunnyvale, CA*
Manager, Quality and Continuous Process Improvement

- Management representative, and point of contact for the company responsible for oversight of the quality management system. Directly managed Document Control, Management Review, CAPA, Complaint Handling/Investigation, Inspection, Internal and Supplier Audit, Training (internal and external) Nonconforming Material, and Equipment Controls.
- Established and implemented an ISO 13485:2003 / QSR / CMDCAS / MDD / r-PAL compliant quality management system, and developed and delivered associated training materials. Achieved certification and subsequent recertification with minimal nonconformities noted.
- Successfully hosted two State (CA Department of Health) and two Federal (US FDA) inspections, minimizing inspectional observations (483) and reducing the company's liability, and developed timely responses and negotiated with FDA to successfully close inspection reports.
- Developed and executed validation test protocols to implement the Agile PDM electronic document management system.
- Lead continuous improvement efforts, and participated on cross-functional committees focused on improving performance, cost and speed relative to customer satisfaction.

2000 –2001 *Natus Medical, Inc., San Carlos, CA*
Lead Quality Engineer / QA Manager

- Management representative, and point of contact for the company responsible for oversight of the quality management system. Directly managed Management Review, CAPA, Complaint Handling/Investigation, Inspection, Internal and Supplier Audit, Training (internal and external) Nonconforming Material, and Equipment Controls.
- Established and implemented an ISO 13485:2003 / QSR / CMDCAS / MDD / r-PAL compliant quality management system, and developed and delivered associated training materials. Achieved certification and subsequent recertification with minimal nonconformities noted.
- Successfully hosted two State (CA Department of Health) inspections, minimizing inspectional observations and reducing the company's liability, and developed timely responses to successfully close inspection reports.
- Lead continuous improvement efforts, and participated on cross-functional committees focused on improving performance, cost and speed relative to customer satisfaction.
- Managed, lead and / or conducted approximately 65 supplier audits (ISO 13485/9001/MDD/QSR) internationally.

1991 - 2000

Positions Include:

- Materials / Procurement - Materials Handler, Receiving Clerk, Expeditor / Planner, Buyer, Sr. Buyer, Purchasing Manager
- Quality Systems Management - Document Control Specialist, Technical Writer /

Reviewer - Policies, Procedures, Process Maps, User Manuals, FAQ's, Web Content, Quick Guides, Brochures, Direct Mail pieces, Trade Show booth panels, and other collateral / QA Specialist, Quality Engineer, Sr. Quality Engineer, QA Supervisor, QA Manager

TRAINING:

FDA Sponsored Training

2001 FDA Quality System Inspection Technique (QSIT) – FDA Regional Medical Device Workshop

Other Training

2006 Systematic Problem Solving for Sustained Improvements with Quality Tools - ASQ
2004 Risk Management for Medical Device - ASQ
2004 ISO 13485:2003 Lead Auditor – RABQSA
2004 Quality Tools for Teams – ASQ
2004 Voice of the Customer – ASQ
2003 Managing Customer Satisfaction – ASQ
2003 Mastering the Art of Effective Communications – Tom Hopkins
2003 Transitioning to ISO 13485:2003 – ASQ
2001 New ISO 9001:2000 Standard (Medical Device Industry) – Excel Partnership
2001 Practical Risk Management Strategies – Guidant

PROFESSIONAL AFFILIATIONS:

American Society for Quality (ASQ)
Regulatory Affairs Professionals Society (RAPS)

EDUCATION:

2003 Business Management / Marketing, University of Phoenix, San Francisco, CA
2001 Strategic Planning, California State University, Dominguez Hills, CA
1998 Journalism / Mass Communications, San Jose State University, San Jose, CA