Quality Systems & Reporting

Craig A. White

Consulting Regulatory Affairs and Quality Systems leadership for medical device manufacturers and their vendors. Ten (10) years experience with design assurance, design control and ISO process writing and product performance analysis and improvement.

EXPERTISE

Regulatory Affairs

- 21 CFR 820 Quality Systems Regulation
- FDA Design Control Guidance, 1997
- Design History File gap analysis, remediation
- New product compliance
- Adverse Incident/Event investigation, reporting
- Product Design & Development process writing
- Recall management
- EU Medical Device Directive, as amended
- EU *In vitro* Device Directive (IVDD)
- EU Technical File generation, remediation

Quality Management Systems

- QMS Registration, Renewal: ISO 13485, 9001
- ISO Internal Audits, Management Review
- ISO External Audit preparation, defense
- Product performance analysis & improvement
- Robust Corrective & Preventive Action
- Process and performance documentation
- Vendor management

CONSULTING EXPERIENCE

Hycor Biomedical, Inc. Garden Grove, California *Medical Device Consulting* 02/2011- Present

Hycor Biomedical designs, develops and sells FDA Class 2 automated electromechanical *in vitro* diagnostic platforms, together with related allergy and autoimmune assay kits. During the contract period ending 12/30/2011, I performed gap analyses on the design history files of two (2) diagnostic platforms and provided related design document compliance assurance.

Added Value In addition, during the contract period, I generated a Technical File for an allergy assay kit.

Contract Extended Hycor has extended my contract to:

- Rewrite the company's design development and design control process and performance documentation.
- Perform an Internal Audit of their Regulatory Affairs and Quality Assurance departments.

Freedom Innovations, LLC Gunnison, Utah *Medical Device Consulting* 01/2010- 10/2010

After their acquisition by a private equity firm, Freedom Innovations, my direct employer for over seven years, hired me as a consultant. I

- Reviewed and approved new product Design History Files at each development gate.
- Performed MHRA Adverse Incident and FDA Adverse Event investigations and reporting.
- Performed a company-wide ISO internal audit, management review and QMS defense at external audit.

DIRECT EMPLOYMENT EXPERIENCE

Freedom Innovations, LLC *Regulatory Affairs & Quality Systems Manager* 10/2002- 12/2009

Irvine, California & Gunnison, Utah

Freedom Innovations, LLC (Freedom) designs, develops, manufactures, sells and distributes FDA Class 1 and Class 2 lower limb prosthetic devices. I served Freedom as Quality Systems and Regulatory Affairs Manager from start-up, and for more than seven (7) years.

REGULATORY AFFAIRS

Compliance

Facilitated and assured Freedom's compliance with all applicable national and international regulations, including 21 CFR 820 Quality Systems Regulation and the Medical Device Directive of the European Union, as amended.

New Medical Device Release

Prepared twenty (20) new medical devices for national and international release. Assured new product compliance with all applicable national and international regulations, standards & requirements, including:

21 CFR 820 Quality System Regulation	ISO 14971 Risk Management
Medical Device Directive, as Amended	IEC 60601 Electrical Safety Standards
[FDA] Design Control Guidance, 1997	ISO 10993 Biological Safety
ISO 9001, ISO 13485	2002/95/EC Hazardous Substances Reduction (RoHS)
ISO 10328 Structural Testing	2002/96/EC Waste Electronics Collection (WEEE)

Design History Files Evaluated the project manager's design history file at each research and development gate to assure compliance with all requirements and to confirm conformity to all related written processes. Documented my gap analysis and facilitated necessary remediation.

CE Marking & Technical Files Filed Declarations of Conformity and generated digital Technical Files for all products sold in the European Union.

Design Control Compliance Informed and guided project managers to compliance with FDA Design Control Guidance, 1997 for two software-automated devices: a microprocessor controlled knee and a knee/ankle/foot assembly.

Adverse Incident Investigations & Reports

Investigated all reported national and international adverse incidents for credibility and reportability. Filed two (2) FORM FDA 3500A and responded dispositively to five (5) MHRA Adverse Incident Reports. Managed an FDA and international Recall to successful conclusion.

Complaints

Trended customer complaints to ascertain the nature and magnitude of customer dissatisfaction with product performance. Championed and facilitated the corporate commitment to resolve complaints to customer's satisfaction.

New and Revised Regulations & Standards

Informed corporate executives of all applicable new and revised regulations and standards, outlined their impact and guided corporate conformity to them (e.g., Amended Medical Device Directive, Massachusetts Medical Device Manufacturer Conduct Law and ISO 9001:2008).

QUALITY MANAGEMENT SYSTEMS

Created & Maintained ISO Quality Management System

Wrote and released Freedom's Quality Management System (QMS) to ISO 9001 and revised it to ISO 13485 for later upgrade. Maintained the QMS with a robust Corrective/Preventive Action regimen, meticulous Internal Audits and comprehensive Management Review. Defended the QMS during five (5) external audits with a single minor nonconformity.

Facilitated Product Performance Improvement

Chaired quarterly product performance conferences with corporate executives, targeting customer-identified issues. Facilitated successful cross-functional product improvement strategies for Freedom's First Generation prosthetic foot line and their electromechanical microprocessor-controlled knee.

Corrective & Preventive Action

Established, facilitated and managed a robust Corrective & Preventive Action regimen.

Process Improvement

During our annual Internal Audits, I reviewed all written processes with department managers and key employees to assure process effectiveness and to capture evolving efficiencies.

ADDITIONAL EXPERIENCE

Position	Employer	Location	Duration
Consulting Technical Writer	*Ossur* [Medical Devices]	Aliso Viejo, CA	06/02- 10/02
President & Founder	*Covenant Judgment Recovery Group*	Tustin, CA	08/99- 10/02
Sales Tax Analyst	*Municipal Resource Consultants*	Tustin, CA	03/91- 08/99
Residential Real Estate Sales	*The Dalebout Association*	Newport Beach, CA	09/84- 03/91

CERTIFICATES, ASSOCIATIONS & EDUCATION

Lead Auditor Training, RABQSA Certificate

American Society for Quality, Member

Two (2) Bachelor of Arts degrees

CONTACT INFORMATION

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