

# ***CURRICULUM VITAE***

## **Melita A. Ball, CQA**

### **Executive Summary**

Ms. Ball is a Regulatory & Quality Systems professional with over 19 years of experience in Life Science Quality Assurance and Regulatory Compliance. She has particular expertise in establishing compliant quality systems based on ISO 13485:2003, ISO 14971:2007, and 21 CFR Parts 11, 801, 803, 806, 809, 810, 812, and 820. She is a recognized expert in providing consulting services for life science companies in the areas of GxP training, auditing, software validation (including electronic records & electronic signatures), business process re-engineering, complaint handling systems, and effective document and change control deployment. Ms. Ball is certified by the American Society for Quality (ASQ) as a Certified Quality Auditor (CQA).

### **Experience and Accomplishments**

#### **MBC & Associates, Tucson, AZ**

##### **Owner/Principal Consultant**

- Consulting firm providing quality system & regulatory compliance services to Life Sciences including:
  - Internal Quality Audit programs & management
  - Supplier Quality Audit programs & management
  - FDA QSIT, ISO assessments & audit preparation
  - MDD, IVDD, CMDR, and FDA Part11 assessments & audit preparation
  - Preparation for customer audits and management
  - Quality System design & deployment
  - Quality System gap analysis & re-engineering
  - Quality System & compliance assessments
  - Customized training programs, instructional design, and delivery
  - Business Process Re-Engineering
  - Software configuration, validation, and deployment
  - Project Management
  - Complaint Management & Vigilance Reporting
  - CAPA programs & management
  - Document & Change Control systems
  - Data & Records Management systems
  - Design Control strategies & assistance
  - Process Validation programs & assistance

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- Recall & Field Correction assistance
- Nonconforming Material programs & management
- GMP support, FDA Facility Registration assistance
- Regulatory Strategies & Submissions
- GCP support, Clinical Study Protocol reviews & assistance
- Provide comprehensive project management services combined with quality system/regulatory compliance leadership for the creation and implementation of individualized business focused quality systems, including any configuration and implementation of software solutions to support those business processes.
- Complete assessments and audit reports including detailed recommendations for system improvement, ways to reduce regulatory risk, and business efficiency based on industry best practices.
- Partner with clients to develop software validation requirements that ensure compliance with Part 11 when automating business and quality systems.
- Support clients in defining system requirements, preparing Requests for Proposals & Quotes (RFP & RFQ), and selecting appropriate software applications to meet individual compliance needs and business goals.
- Provide clients with expertise in automating business processes using industry standard software applications like TrackWise, Livelink, and Agile.
- Instructional design and delivery of a wide variety of quality system and regulatory training courses. Courses can be designed specifically for audiences ranging from the executive board room to manufacturing operators/technicians to field service personnel.
- Develop and author standard operating procedures to support business processes tailored to the needs of individual clients.
- Assist clients with the development of regulatory strategies, IRB protocols, and 510(k) submissions.

### **Third Wave Technologies, Madison, WI**

#### **Director, Quality Assurance & Regulatory Compliance**

- Responsible for the establishment, implementation, and maintenance of the corporate Quality Management System and for regularly reporting on the performance and effectiveness of the Quality System.
- Management responsibilities include directing staff and managing budgets for Quality Auditing (internal, supplier, and regulatory), Quality Engineering, Quality Training, Document & Configuration Control, Quality Control, Complaint Handling, and Final Product Release.
- Provide advice and guidance to product development teams to ensure design controls are properly implemented and product designs are correctly translated into manufacturing.

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- Serve as technical expert for protocols, equipment validation, process validation, and software validation (including Part 11 compliance).
- Serve as instructional designer and trainer for all quality related training courses.
- Lead product improvement initiatives throughout company.
- Direct failure investigations and root cause analyses related to complaints and/or internal nonconformities.
- Implementation of successful CAPA programs.
- Selection, configuration, validation, and successful implementation of automated solution for managing processes and metrics for the Quality Management System.
- Successful Implementation of a business-focused quality system that resulted in registration to ISO13485:2003 through BSI.
- Lead cross-functional teams through the regulatory landscape leading to 510(k) submission and clearance.
- Lead cross-functional teams through regulatory requirements for the creation and control of labeling & packaging including the adoption of international symbols for product labels.

### **Ventana Medical Systems** (division of Roche), **Tucson, AZ**

#### **Manager, Regulatory Compliance**

- Responsible for providing project management and regulatory compliance leadership for quality system and compliance programs and projects.
- Specific responsibilities included managing the Corporate Quality Audit program, identification and implementation of long-term strategies for quality system training, and managing audits from external regulatory agencies and customers.
- Successfully responded to FDA 483 observations and met with the LA District office to keep them apprised of our progress.
- Provided company-wide gap analysis with respect to FDA compliance, facility registration, Medical Device Reporting (MDR) practices and recall management.

### **ALARIS Medical Systems, San Diego, CA** (now Cardinal Health)

#### **Sr. Manager, Corp. Quality System Training & Documentation**

- Led a top-level cross-functional team to develop and implement a streamlined global Quality System resulting in a 70% reduction in audit findings within the first year of implementation and an additional 20% reduction in audit findings within the second year of initial implementation. The improved Quality System significantly enhanced the company's ability to demonstrate regulatory compliance, reduced the time to market new products, and contributed to the financial stability and growth of the company.

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- Successfully reduced turn-around time for Change Orders from an average of 45 days to less than 8 hours by implementing a business-focused change process that facilitated compliance and was easy to grasp and understand.
- Responsible for the identification and implementation of global long-term strategies for quality system training, change control, and document control for both North American and International business units.
- Specific responsibilities included serving as technical consultant for the development and implementation of quality system training courses, business software validations, and engineering change control initiatives.
- Management responsibilities included planning, directing, and managing an international staff (non-exempt and exempt) within the Corporate-wide Document Control and Quality System Training departments.
- Accountable for departmental budget of \$1.5 million related to areas of responsibility. Successfully managed on or under budget for every year of responsibility.

### **Quality System Training Specialist**

- Served as technical consultant for quality system training and related development activities.
- Served as a key team member in the successful development and implementation of an automated tracking and notification tool for quality system training.
- Developed and implemented conceptual training modules to enhance the understanding of the intent of the quality system and other quality, regulatory and business requirements.
- Successfully established and implemented world-wide quality system training programs ranging from foundational to advanced courses supporting cGMPs, US FDA regulations, ISO standards, and European Medical Device Directives.

### **Hollister Incorporated, Stuarts Draft, VA**

#### **Quality Assurance Technician**

- Lead Auditor for FDA Certified and ISO9002 Registered Medical Device Manufacturer.
- Responsible for maintaining cGMPs through the implementation of documented procedures and one-on-one training with employees.
- Wrote and implemented procedures to assure compliance with QSR and ISO9002.
- Responsible for performing product audits on pre-sterilized and post-sterilized product.
- Responsible for placing biological indicators and preparing bio-burden samples for sterilized product.
- Analyzed post-sterilization test data for acceptance.
- Performed WIP, Finished Goods and Quality System Audits.

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- Performed calibration activities for QA measuring & testing devices.
- Responsible for designing and implementing a database tracking methodology for defect reporting that facilitated ongoing analysis of defect trends.
- Provided root cause analysis support for corrective & preventive action.
- Assisted Senior Quality Assurance Engineers in developing and implementing ongoing protocols and SPC projects.

### **Professional Certifications & Affiliations**

- Regulatory Affairs Professional Society (RAPS), Member
- ASQ Certified Quality Auditor (CQA)
- American Society for Quality (ASQ) – Member of the Management, Auditing, & Biomedical Divisions
- ASQ Senior Member
- Certified Quality Engineer Preparation, Certificate
- ISO9001 Lead Auditor, Certificate
- Trainer, ASQ Quality Auditing Body of Knowledge
- Situational Leadership II Training, The Ken Blanchard Companies, Certificate
- Team Top Gun, Effectiveness Dimensions International, Certificate
- Lean Manufacturing Management, Certificate
- Configuration Management, Certificate
- Sterilization & Microbiology Training, Certificate

### **Education**

#### **Bridgewater College**

Bridgewater, VA

- BA
- GPA 3.6/4.0
- Magna Cum Laude Honor Graduate

#### **The George Washington University**

Washington, D.C.

- Graduate Coursework
- GPA 4.0/4.0

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