RONALD J. MAKAR

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QUALITY MANAGEMENT PROFESSIONAL (MEDICAL DEVICES)

Dedicated, well-organized, quality professional with expertise in quality engineering, assurance, control and management as well as product development and commercialization, post-market technical support, regulatory compliance and production management. Multi-faceted with experience in world-class medical device and biotech manufacturing operations.

Extensive background in vitro diagnostic medical devices, digital imaging equipment, neurostimulation devices, interventional devices, bio-based materials, and bio-polymer devices and delivery systems.

- Quality System Development
- Product Development & Design
- Risk Management Integration
- Regulatory Compliance
- Quality Engineering Capabilities
- Supply Chain Management

PROFESSIONAL CERTIFICATIONS

AMERICAN SOCIETY FOR QUALITY (ASQ)

- CERTIFIED BIOMEDICAL AUDITOR (CBA), CERT. NO. 772
- CERTIFIED HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) AUDITOR (CHA), CERT. NO. 787
- CERTIFIED MANAGER OF QUALITY & ORGANIZATIONAL EXCELLENCE (CMQ/OE), CERT. NO. 3187
- CERTIFIED SUPPLIER QUALITY PROFESSIONAL (CSQP), CERT. NO. 574
- CERTIFIED QUALITY AUDITOR (CQA), CERT. NO. 10,459
- CERTIFIED QUALITY ENGINEER (CQE), CERT. NO. 35,016

VILLANOVA UNIVERSITY

- CERTIFIED LEAN SENSEI, VILLANOVA UNIVERSITY – LEAN SIX SIGMA (CERT. NO. VU2019216, NOV. 2019)

EXEMPLAR GLOBAL

- QUALIFICATION BASED MEDICAL DEVICE LEAD AUDITOR: MEDICAL DEVICE (ISO 13485:2016) AUDITOR (CERT. NO. 207821)
- QUALIFICATION BASED LEAD INTERNAL AUDITOR: MEDICAL DEVICE SINGLE AUDIT PROGRAM INTERNAL AUDITOR (CERT. NO. 207821)

RELEVANT TRAINING

- EU MDR AUDITOR TRAINING (EU MDR 2017/745) (QUALITY AUDITING, LLC, JANUARY 2023)
- EU MDR AUDITOR TRAINING (EU MDR 2017/745) (ORIEL STAT-A-MATRIX, AUGUST 2020)
- CONDUCTING A REMOTE MEDICAL DEVICE QMS AUDIT (ORIEL STAT-A-MATRIX, JULY 2020)
- ISO 14971:2019 RISK MANAGEMENT TRAINING FOR MEDICAL DEVICES (ORIEL STAT-A-MATRIX, JULY 2020)
- QMS LEAD ASSESSOR COURSE (ISO 9001:2015) INCLUSIVE OF ISO 13485:2016 (ORIEL STAT-A-MATRIX, JUNE 2020)
- MEDICAL DEVICE SINGLE AUDIT PROGRAM CRITERIA FROM ISO 13485:2016 AND DEVICE REGULATIONS FOR MDSAP JURISDICTIONS (ORIEL STAT-A-MATRIX, JUNE 2020)
- EU MDR REGULATION (EU) 2017/745 MEDICAL DEVICE REGULATION (AXEON, FEB. 28, 2020)

PROFESSIONAL EXPERIENCE

INNOVATIVE QUALITY CONSULTING, LLC | WILMINGTON, DE 2015–PRESENT

OWNER, PRINCIPAL CONSULTANT

WWW.IQUALITYCONSULTING.COM

Consultant to domestic and foreign entities in the core arenas of quality, compliance, medical device, product review, regulation/requirement integration, and risk management.

- Independent Contractor
- Lead Auditor (medical devices)
- DEKRA Business Assurance (www.dekra.com)
- FDA remedial quality management system compliance activities, post-market surveillance activities, product complaint reviews, and Medical Device QMS assessments
- Integration of business, U.S. and European medical device quality management regulations and requirements into effective management systems
- 3rd party registration activities to ISO 13485:2016, ISO 14971:2012, MDSAP
- Establishing business-friendly product development and risk management systems

Medical Device Consulting Projects:

- **Conducted Organizational Capability Assessment**, for a pharmaceutical / medical device combination product.
- **Consultant Guide**, for the application of U.S. Title 21 CFR Part 820 (Quality Systems Regulations) and U.S. Title 21 CFR Part 4 (Combination Products) to a pharmaceutical company ensuring products' compliance.
- **Consultant Team Leader**, for world-wide medical device product development and design control process spanning thirteen (13) global product design centers.
  - Developed product launch process, led post-market QA activities and product complaint management.
- **FDA Quality Systems Regulation (QSR) Remediation**, member of a 16-person team. Led corrective action effort bringing the Japan-Headquartered supplier and purchasing controls into QSR compliance.
  - Key Quality Management interface for contract design development and manufacturing organizations.
  - Launched effective application of eQMS, Grand Avenue Software (www.grandavenue.com).
- **Lead Auditor and Reviewer**, for product, process, system, and software validation activity for 3rd party U.S. Title 21 CFR Part 820, U.S. Title 21 Part 211, ISO 13485:2016, ISO 14971:2019, MDSAP, EU MDR 2017/745, and FDA QSIT audit.
- **Management Consultant**, Oriel Stat-A-Matrix (www.orielstat.com) 2021, 2022. Led training classes of ISO 13485:2016 and FDA U.S. 21 CFR Part 820 regulations.
- **Manager, Quality Assurance**, Helius Medical, Inc.
- **Medical Device Consultant**, Consultant team member reporting to a Washington, DC Medical Device legal firm representing a multi-billion-dollar health care supplier. Review organization's supplier management processes providing improvement recommendations.
- **Medical Device Consultant,** Providing guidance, assessment and recommendations to a pharmaceutical company regarding compliance to U.S. Title 21 CFR Part 4, Combination Products.
- **Medical Device Quality Management Systems Auditor**, Quality Auditing, LLC (www.qualityauditing.com) performing 3rd party internal audits and supplier audits for medical device manufacturers.
- **Quality Management Consultant**, to two start-up medical device companies, and Lead Role for identifying, selecting, and implementing two eQMS systems: Qualio (www.qualio.com) and Greenlight Guru (www.greenlightguru.com).

ACTAMAX SURGICAL MATERIALS, LLC | WILMINGTON, DE 2012–2015

DIRECTOR, QUALITY MANAGEMENT

50/50 joint venture between DuPont and DSM Biomedical.

- Managed the Quality Management System creation, establishment, and certification successfully developing an adhesion barrier medical device. Facilitated product development initiatives. Managed one clinical trial site.
- Achieved quality management systems 3rd party certification and registration to ISO 13485:2012, Medical Device Quality System Requirements, and ISO 14971:2012 Application of Risk Management to Medical Device.
- Led quality management integration efforts into the business QMS for the Medical Device Directive (MDD) requirements (Annex II, Annex III and Annex V of the EC-Directive 93/42/EEC of 14 June 1993).

E.I. DUPONT DE NEMOURS & CO., INC. | WILMINGTON, DE 2007–2015

GLOBAL QUALITY MANAGER – INDUSTRIAL BIOSCIENCES BUSINESS UNIT

Led product quality and quality management systems in the New Product Development arena. Simultaneously supported Actamax Surgical Materials, LLC joint venture.

- Established CMO (contract manufacturing organization) critical business processes to facilitate selection, qualification, and support initiatives.
- Led quality management initiative achieving business launch of an all-natural, all vegetarian Omega-3 dietary supplement.
- Created/implemented a product development and commercialization system compliant with FDA food (21 CFR Part 110) and dietary supplement (21 CFR Part 111) regulations.
- Championed EtQ (enterprise quality management) system implementation (www.etq.com) that managed global manufacturing groups' customer complaints as well as corrective and preventive actions.

HOLOGIC, INC. | WILMINGTON, DE 2002–2007

PLANT QUALITY ASSURANCE MANAGER

Guided/supported manufacturing organization's FDA regulatory and ISO quality management systems for successful digital mammography detector assemblies production and release.

- Managed/revised the operations quality and business management systems to ISO 13485:2003 and ISO 14971:2000 standards.

- Led the organization through a successful FDA site inspection.

W.L. GORE & ASSOCIATES, INC. | ELKTON, MD 2000–2002

QUALITY ASSURANCE ASSOCIATE

- Managed quality assurance activities for interventional devices under development.

DADE BEHRING, INC. | WILMINGTON, DE 1980-2000

(FORMERLY **DUPONT MEDICAL PRODUCTS, DIAGNOSTICS DIVISION**)

QUALITY ASSURANCE MANAGER

- Managed multidisciplinary team for pilot phase implementation of Product Data Management system. Demonstrated product development and manufacturing cycle time reduction feasibility.
- Delivered annual manufacturing cost reductions of $100K+.
- Previous roles included:

  QA & Compliance Manager
  Product Quality Management Engineer
  Production Supervisor
  QA Supervisor
  Process Engineer
  Systems Support Engineer
  Development Engineer

EDUCATION

- Master of Engineering (ME), Biomedical Engineering, UNIVERSITY OF VIRGINIA, Charlottesville, VA
- Bachelor of Science (BS), Medical Technology, UNIVERSITY OF BRIDGEPORT, Bridgeport, CT
- Associate in Science (AS), Electrical Engineering Tech. NORWALK STATE TECHNICAL COLLEGE, Norwalk, CT

Version: 7 March 2024