RONALD J. MAKAR

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QUALITY MANAGEMENT PROFESSIONAL

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, JULY 2020)
- QUALIFICATION BASED LEAD INTERNAL AUDITOR: MEDICAL DEVICE SINGLE AUDIT PROGRAM INTERNAL AUDITOR (CERT. NO. 207821, JULY 2020)

CURRENT TRAINING

- 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 www.iQualityConsulting.com 2015 to current

Owner, Principal Consultant

Core Capabilities:

- Independent contract, Lead Auditor (medical devices), DEKRA Business Assurance (www.dekra.com)
- FDA remedial quality management system compliance activities, post market surveillance activities, including product complaint review, Medical Device QMS assessment\
- Integration of business, U.S. and European medical device quality management regulations and requirements into effective management systems
- Pre-certification and internal auditing, including facilitation of 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 (2015 through present):

- Management Consultant, Oriel Stat-A-Matrix (www.orielstat.com) 2021, 2022. Have lead training classes of ISO 13485:2016 and FDA U.S. 21 CFR Part 820 regulations.
- Provided consulting guidance in 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, seeking to ensure their combination products are compliant to the combination product regulations.
- Provided Quality Management consulting to two start-up medical device companies, taking a lead role in identifying, selecting, and implementing two eQMS systems: Qualio (www.qualio.com) and Greenlight Guru (www.greenlightguru.com)
- Performing medical device quality management systems audits for Quality Auditing, LLC (www.qualityauditing.com)
- Medical Device Consultant, March 2020 – present. As a member of a four (4) consultant team reporting to a Washington D.C. Medical Device legal firm representing multi-billion-dollar health care supplier, am reviewing the organizations supplier management processes and providing improvement recommendations.
- Manager, Quality Assurance (Contract): Helius Medical, Inc., Newtown, PA, Dec. 2018 – March 2020. Developed product launch process, responsible for post market QA activities, including product complaint management. Key Quality Management interface to contract design development and contract manufacturing organizations. Responsible for the effective application of its eQMS, Grand Avenue Software (www.grandavenue.com)
- Performed a pharmaceutical / medical device combination product organizational capability assessment.
- Provided quality management system process improvement guidance and training to an international medical device company to U.S. Title 21 CFR Part 820 and FDA QSIT audit technique
- Provided process and system assessment, process map and recommendations to promote a more effective service and repair operation for an international medical device company
- Lead auditor, 3rd party FDA 21 CFR Part 820, ISO 13485, ISO 14971 and FDA QSIT audit, including a review of product, process, system and software validation activity.
- As a member of a sixteen (16) person FDA Quality Systems Regulation (QSR) remediation team, led corrective action effort to bring into QSR compliance supplier and purchasing controls of an international medical device company headquartered in Japan.
- Consultant team leader, world-wide medical device product development and design control process of an international medical device company across thirteen (13) global product design centers.

ACTAMAX SURGICAL MATERIALS, LLC, Wilmington, DE 2012 to 2015
(Actamax Surgical Materials, LLC, was a 50/50 joint venture between DuPont and DSM Biomedical)
Director, Quality Management
Managed the creation, effective establishment and certification of the quality management system, enabling the successful development of an adhesion barrier medical device. Facilitated product development initiatives, including management of one clinical trial site.

- Achieved 3rd party certification and registration of the quality management systems to ISO 13485:2012, Medical Device Quality System Requirements and ISO 14971:2012, Application of Risk Management to Medical Device.
- Led quality management efforts to integrate Medical Device Directive (MDD) requirements (Annex II, Annex III and Annex V of the EC-Directive 93/42/EEC of 14 June 1993) into the business QMS.

E.I. DUPONT DE NEMOURS & CO., INC., Wilmington, DE 2007 to 2015
Global Quality Manager (Industrial Biosciences Business Unit)
Led product quality and quality management system efforts in the development of new products. Established business processes to facilitate the selection, qualification and support of critical contract manufacturing organizations (CMOs). Also supported the Actamax Surgical Materials, LLC joint venture.

- Led quality management efforts resulting in business launch of an all-natural, all vegetarian Omega-3 dietary supplement.

- Developed and implemented a product development and commercialization system compliant with FDA food (21 CFR Part 110) and dietary supplement (21 CFR Part 111) regulations.
- Championed effort to implement EtQ enterprise quality management system (www.etq.com) to manage customer complaints and corrective and preventive actions among world-wide manufacturing groups.

HOLOGIC, INC., Wilmington, DE 2002 to 2007
Plant Quality Assurance Manager
Provided FDA regulatory and ISO quality management systems guidance and support to the manufacturing organization, ensuring effective production and release of digital mammography detector assemblies.

- Managed successful revision of the operations quality and business management system to ISO 13485:2003 and ISO 14971:2000. Led the organization through a successful FDA site inspection.

ADDITIONAL RELEVANT EXPERIENCE

W.L. GORE & ASSOCIATES, INC., Elkton, MD
Quality Assurance Associate
Managed quality assurance activities for interventional devices under development.

DADE BEHRING, INC. (formerly **DuPont Medical Products, Diagnostics Division**), Wilmington, DE
Quality Assurance Manager
Managed multi-disciplined team effort to implement pilot phase of Product Data Management system. Demonstrated product development and manufacturing cycle time reduction feasibility and annual manufacturing cost reduction of over $100,000.

Previous roles include **QA & Compliance Manager, Product Quality Management Engineer, Production Supervisor, QA Supervisor, Process, Systems Support** and **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

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