RONALD J. MAKAR

2523 JUSTIN LANE, WILMINGTON, DE 19810 +1.302.494.5978

ron@iQualityConsulting.com www.iQualityConsulting.com www.linkedin.com/in/ronmakar

CORE QUALIFICATIONS

- 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.
- Multi-faceted with forty (40) years of experience in world-class medical device and biotech manufacturing operations.
- Professional background includes experience in the areas of in-vitro diagnostic medical devices, digital imaging equipment, interventional devices, bio-based materials, and bio-polymer devices and delivery systems.

CORE COMPETENCIES

- Auditing (Lead, Process, Product, System)
- Change Initiatives / Change Controls
- Change & Complaint Management
- Combination Products
- Council Directive 93/42/EEC
- Critical-to-Customer / Critical-to-Quality
- Design Controls & Product Development
- Design & Development Planning
- ISO 9001; 13485; 14971; 17021
- MDSAP, EU MDR
- Process Development / Process Controls
- Process Improvement & Mapping
- Project Management
- Process Validation Assessment (IQ, OQ, PQ))
  - Software, Hardware & Systems Validation
- Quality Engineering, Control and Assurance
- Quality Management
- Risk Management / Hazard Analysis / FMEA
- Supplier Qualification & Supplier QA
- Training
- 21 CFR Parts 4; 11; 803; 806; 807; 810; 812; 814; 820
- U.S. FDA QSR Remediation & QSIT Audit

PROFESSIONAL CERTIFICATIONS (ACTIVE)

ASQ (AMERICAN SOCIETY FOR QUALITY)

- Certified Biomedical Auditor (CBA)
- Certified Hazard Analysis and Critical Control Point (HACCP) Auditor (CHA)
- Certified Manager of Quality/Organizational Excellence (CMQ/OE)
- Certified Supplier Quality Professional (CSQP)
- Certified Quality Auditor (CQA)
- Certified Quality Engineer (CQE)

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 (2020)

- 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 (MDSAP) criteria from ISO 13485:2016 and Device Regulations (ORIEL Stat-A-Matrix, June 2020)
- EU MDR Regulation (EU) 2017/745 Medical Device Regulation (Axeon, Feb. 2020)

CORE CAPABILITIES

Providing creative and effective solutions to the medical device and biotech industries:

- Independent contract, Lead Auditor (medical devices), DEKRA Business Assurance (www.dekra.com).
- FDA remediation quality management system compliance activities, including hardware, software and systems validation review of medical devices and combination products.
- 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 and MDSAP.
- Establishing business-friendly product development and risk management systems.

SELECTED ACCOMPLISHMENTS

Medical Device Consulting (2015 through present)

- Medical Device Consultant, October 2020 – present. As acting Quality Director for a start-up company focused on the manufacture of PPE (personal protective equipment), established an ISO 13485:2016 quality management system using Greenlight Guru (www.grteenlight.guru)
- Medical Device Consultant, March 2020 – October 2020. 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, December 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.
- Lead Auditor (medical devices), DEKRA Business Assurance (www.dekra.com): ISO 9001:2015, ISO 13485:2016.
- Performed a pharmaceutical and medical device combination product organizational capability assessment of a start-up company, valued at $4 billion, focused on the development of an insulin pump.
- Provided quality management system process improvement guidance and training to an international medical device company, including audit, 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, responsible for simplification and harmonization of a world-wide medical device product development and design control process of an international medical device company across thirteen (13) global product design centers.

AUDITING & AUDIT PROCESS MANAGEMENT

- Lead Auditor Trained: ISO 13485:2016 (2017), 2020; ISO 9001:2015 (2018)
- Obtained Lead Auditor training (FDA Quality System Regulation) – (1990), Renewed Training: July 2020
- Obtained MDSAP training – (2018, 2020)
- Performed internal company audits in R&D, manufacturing (consumables, instrumentation, service, software) for DuPont Medical Products, Dade Behring, W.L. Gore Medical Products, Hologic, Inc. – (1990 – 2007).
- Managed internal audit programs, including training of auditors, as a part of quality manager responsibilities (1990 – 2014).
- Performed various biotech and medical device supplier and contract manufacturing audits during roles as Global Quality Manager (DuPont Industrial Biosciences) and Quality Systems Director (Actamax Surgical Materials) – (2008 – 2014).
- Performed various medical device audits as independent consultant for international medical device companies – (2015 – 2018).
- Maintaining three ASQ audit certifications:
    - CERTIFIED BIOMEDICAL AUDITOR (CBA), CERT. NO. 772
    - CERTIFIED HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) AUDITOR (CHA), CERT. NO. 787
    - CERTIFIED QUALITY AUDITOR (CQA), CERT. NO. 10,459
- Primary interface to 3rd party registrars (BSi, UL, DEKRA) as quality management system Management Representative.

CONTINUAL IMPROVEMENT & TRAINING

- Developed and provided hands-on continuous improvement training and guidance in the areas of product development planning, process validation, control and reduction of product and process variability, and product change control.
- Identified and implemented a novel and effective way to present standard operating procedures using information mapping (www.informationmapping.com).

- Managed and directed a multi-disciplined team effort to implement pilot phase of corporate-wide Product Data Management (PDM) system. Through this work, the team was able to demonstrate product development and manufacturing cycle time reduction feasibility and annual manufacturing cost reduction of over $100,000.
- Developed and maintained a customer complaint and CAPA process for medical products businesses.
- Championed effort to implement EtQ enterprise quality management system (www.etq.com), which was utilized for customer complaint handling and CAPA. This resulted in a more effective management of customer complaints, enabling co-located complaint management units to manage customer complaints in a single system.
- Developed and presented a training session titled: The Value of ASQ Certification to corporate quality managers.

LEADERSHIP & MANAGEMENT

- Supervised a production operation of twenty-five assemblers and technicians in the production and quality control of new, remanufactured and refurbished blood chemistry analyzer systems.
- Co-managed the transfer of a production operation from one location to another, with 33% less space, to obtain a greater level of production capacity and output.
- Managed product, process and system audits, non-conforming product failure analysis and product reliability testing activities in a medical device production operation.
- Responsible for the release to market of FDA Class II finished medical device products (blood chemistry analyzer systems), including final review of all product development (DHF) and manufacturing (DMR) records, e.g. design outputs, validation protocols and reports.

POST-MARKET SURVEILLANCE

- Led product problem resolution action and team efforts to analyze and correct customer complaints.
- Worked with field technical support engineers and customers to understand, investigate, analyze and correct issues related to DuPont clinical chemistry analyzer systems.
- Submitted MDRs to FDA, as required.
- Represented quality assurance and regulatory compliance interests in after-market product management team for DuPont clinical chemistry analyzer products and systems.
- Initiated CAPAs, as required, in response to customer complaint investigations.

PRODUCT DESIGN & DEVELOPMENT

- Established a stage/phase gated product development process in accordance with U.S. CFR Title 21 Part 820, ISO 13485:2012, ISO 14971:2012, MDD standards and regulations and business requirements.
- Designed and developed new product electronic circuitry and electro-mechanical subassemblies for in vitro diagnostic blood chemistry analyzer instrumentation.
- As a member of a product team, in the role of Global Quality Manager, successfully launched an all-natural Omega-3 dietary supplement.
- Managed quality assurance compliance activities for an FDA Class II medical device under development.

QUALITY ENGINEERING

- Identified, investigated and resolved production problems for a medical device production operation (FDA Class II, blood chemistry analyzer systems).
- Developed and implemented Statistical Process Control (SPC) analysis methods during final (finished) product testing of the production of blood chemistry analyzer systems. This allowed the production organization to more accurately interpret and diagnose test result variation due to special causes vs. normal, inherent process variation, resulting in cycle time reduction and financial savings.
- Provided medical device technical support and product training to field service engineers and customers. Implemented field service modification protocols.
- Utilizing process capability analysis, developed meaningful and realizable specifications for various products manufactured by contract manufacturing operations.
- Led efforts to validate a Class 10,000 clean room in a medical products development start-up facility.
- Simplified product development, manufacturing and support processes utilizing process mapping techniques.

QUALITY MANAGEMENT SYSTEMS

- As Management Representative, established and maintained several quality management systems to enable the development and commercialization of medical device products compliant to U.S. FDA Quality System Regulation (U.S. CFR Title 21 Part 820), ISO 13485 (2003, 2012), Medical Device Quality System Requirements and ISO 14971 (2000, 2007, 2012), Application of Risk Management to Medical Device.
- Implemented an established quality management system in Microsoft® SharePoint.
- Identified and established a mechanism with an external service to manage documents (standards and regulations) of an external origin.
- Managed resolution of customer complaints with diverse business operations groups, including development and implementation of corrective and preventive actions.
- Managed quality management system compliance of a medical device manufacturer's R&D division to ISO 9001:1994, the FDA Quality System Regulation, and EN46001.
- 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.

REGULATORY COMPLIANCE

- Successfully led business teams to obtain 3rd party certification to ISO 13485:2003, as well as other ISO standards, such as ISO 9001 and ISO 9002.
- Integrated Medical Device Directive (MDD) requirements (Annex II, Annex III and Annex V of the EC-Directive 93/42/EEC of 14 June 1993) into a business quality management system.
- In the role of Quality Assurance & Compliance Manager, assisted Regulatory Affairs Managers in the review and management of regulatory submission data.
- Managed internal auditing programs for several businesses.
- Managed a successful FDA inspection of a medical device manufacturing operation.

RISK MANAGEMENT

- Developed, established and integrated acceptable risk management processes in several quality management systems to ISO 14971 (both 2007 and 2012 versions).
- Facilitated hazard analysis and risk analysis and risk evaluation activities with several medical device development operations.
- In partnerships with critical contract manufacturing operations, ensured that the CMO had performed adequate and effective risk analysis of their manufacturing processes.

SUPPLIER QUALITY

- Managed supplier selection, qualification and approval activities of critical contract manufacturing operations. This included demonstrating supplier capability and obtaining assurance that selected critical suppliers were compliant to applicable FDA and ISO quality system regulations and requirements.
- Managed efforts in the development and execution of quality agreements with critical suppliers.
- Interfaced directly with critical contract manufacturing operations on a regular basis, to review, approve and release production lots.

PROFESSIONAL EXPERIENCE

- Innovative Quality Consulting, LLC, Owner, Principal Consultant (Wilmington, DE); 2015 - present
- Actamax Surgical Products LLC, Director, Quality Management (Wilmington, DE); 2011 - 2015
- E.I. DuPont de Nemours & Co., Inc., Global Quality Manager (Wilmington, DE); 2007 - 2015
- Hologic, Inc., Plant Quality Assurance Manager (Newark, DE); 2002 - 2007
- W.L. Gore & Associates, Inc., Quality Assurance Associate (Elkton, MD); 2000 - 2002
- Dade Behring Inc., Quality Assurance & Compliance Manager (Newark, DE); 1998 - 2000
- E.I. DuPont de Nemours & Co., Inc. (Newark, DE); 1980 - 1998
    - QA & Compliance Manager (Newark, DE)
    - Product Development, Process and Quality Management Engineer (Newark, DE)
    - Production & Product QA Supervisor (Newark, DE)
    - Field Service Technical Support Engineer (Newark, DE)

EDUCATION

- Master in Engineering (Biomedical Engineering), University of Virginia, Charlottesville, VA
- Bachelor of Science (Medical Technology), University of Bridgeport, Bridgeport, CT
- Associate in Science (Electrical Engineering Technology), Norwalk State Technical College, Norwalk, CT

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 (MDSAP) criteria from ISO 13485:2016 and Device Regulations (ORIEL Stat-A-Matrix, June 2020)
- EU MDR Regulation (EU) 2017/745 Medical Device Regulation (Axeon, Feb. 2020)
- Certified Lean Sensei, Villanova University – Lean Six Sigma (Cert. No. VU2019216, Nov. 2019)
- Certified Supplier Quality Professional (CSQP) Exam Prep. – Quality Council of Indiana (Oct. 2018)
- MDSAP and Regulatory Transitions, www.nsf.com (October 2018)
- ISO 9001:2015 Lead Auditor Training, www.caliso.com (June 2018)
- ISO 13485:2016 Lead Auditor Training, www.caliso.com (July 2017)
- ISO 13485:2016 Changes and Implementation Best Practices, ASQ Biomedical Division (May 2016)
- Six Sigma Green Belt Training, E.I. DuPont de Nemours & Co., Inc.
- Six Sigma Greenbelt Overview Series, American Society for Quality
- ISO 14971:2007 [Risk Mgt. for Medical Devices], Assoc. for the Advancement of Medical Instrumentation (AAMI)
- Understanding and Implementing the New ISO 13485:2003 Standard, EXCEL Partnership Inc.
- R&D Risk Management & FMEA, LOGICON
- Understanding Financial Business Management, SMG
- 21 CFR Part 11 - Electronic Records and Signatures, FDA
- Planning and Managing Projects, Integrated Project Systems
- Understanding the New Medical Device GMP, Stat-A-Matrix
- Advanced Auditing Techniques: Process Auditing, Stat-A-Matrix
- Quality Engineering Course, CQE, Total Business Service Center, Inc.
- Quality Auditing Course, CQA, Total Business Service Center, Inc.
- Statistical Process Improvement Techniques for Process Validation, Logicon R&D
- Management Problems of the Technical Person in a Leadership Role, Fred Pryor Seminars
- Collaborative Problem Solving, DuPont Corporate Continuous Improvement Curriculum
- Train the Trainer, Fred Pryor Seminars
- On-The-Job Auditor Training, Batalas
- Product Quality Management System Technology, DuPont Quality Management & Training Center
- Lead Assessor Certification, Batalas
- Deming Philosophy, DuPont Medical Products
- Medical Device GMP's and Regulations - Quality Program Preparation and Audit, Stat-A-Matrix

PROFESSIONAL AFFILIATION

American Society for Quality (ASQ), Senior Member (Member No. 00947837) – 1989 to present

- Delaware ASQ Section Chair – (2000 – 2001)

PUBLICATIONS & PRESENTATIONS

Managing Product Risk from Cradle to Grave
Presented at American Society for Quality (ASQ) World Conference on Quality and Improvement, Dallas, TX, (5/14)

How Healthy is Your Ability to Manage Risk? (Thoughts on Risk Based Thinking Requirements in ISO 9001:2015)
Presented at March 2016 ASQ Delaware Section Dinner Meeting, Wilmington, DE

ISO 13485:2016 - Preparing for the International Medical Device Standard
Presented at the 16th Annual Product Complaints Congress for Life Sciences, June 20, 2018, Arlington, VA