Anne Holland Curriculum Vitae

Anne Holland Consulting

Anne Holland

CQA, CQE, CMQ/OE, RQAP-GLP, Exemplar Global Lead Auditor, EU MDR 2017/745 Certified Auditor

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Summary

- 35 years of experience in Technical Leadership, Regulatory Compliance, Quality System Development, Consulting, Design Assurance, Auditing, and Regulatory Affairs in the medical device industry
- Started QA Consulting, Inc. and grew client base, consulting expertise and scaled the business from a locally based company to a nationally known firm that holds ISO 13485 Medical Devices- Quality Management Systems certification as well as certifications as an Historically Underutilized Business (HUB) and National Women's Business Enterprise Certification (WBENC).

Core Competencies

Quality System Regulations - Strategic Planning – Design controls – Customer Retention & Interaction - Good Laboratory Practices –Quality System Remediation - Risk Management – Project & People Management – Expert Witness Litigation Support and Testimony

Professional Experience

2000 – Present	CEO and Founder	**QA Consulting, Inc.**	Austin, TX
1993 - 1999	QA Systems Manager Sr. Manufacturing Engineer Sr. Quality Assurance Engineer	**Sulzer Carbomedics**	Austin, TX
1991 - 1993	Project Manager • Design Assurance Engineer	**Ohmeda Monitoring**	Louisville, CO
1987 - 1991	Quality Assurance Project Engineer	**Cobe BCT, Inc.**	Lakewood, CO
1986 - 1987	Quality Assurance Engineer	**Fischer Imaging Corporation**	Denver, CO
1985 - 1986	Project Engineer	**LA BAC Medical Systems**	Englewood, CO

Career Highlights

- The consulting team obtained over thirty 510(k) clearances primarily in orthopedic and cardiac spaces.
- Created Regulatory Strategies for devices ranging from low-risk (US Class I) through high-risk (US Class III). The strategies defined the device classification, regulation, predicate device(s) and test requirements necessary to market the device in the US, EU, Canada or Australia.
- Participated in FDA inspections, GLP audits, Notified Body Audits and FDA 483 remediation efforts in both corporate management and client representative capacities.
- Conducted more than 100 Quality System audits to assess 21 CFR 820, ISO 13485, ISO 17025, 21 CFR 58, 2017/745 EU Medical Device Regulation (MDR), and MDSAP compliance ranging from medical device manufacturers, contract manufacturers, laboratory facilities, sterilization facilities, and molders to animal testing facilities.
- Developed and implemented complete 21 CFR 820, ISO 13485, ISO 14971, ISO 17025 and 2017/745 EU compliant Quality Management Systems for medical device manufacturers and associated service providers. The systems were inspected by FDA and audited by Notified Bodies and proven sound.

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- Led FDA Form 483 remediation efforts for both implantable and non-implantable devices. The comprehensive approach taken prevented escalation of the Observations to Warning Letters due to the systemic focus on design controls, risk management, training, and complaint handling.
- Researched and composed the nonclinical portion of a PMA for a Class III implantable device. Developed 510(k)'s for additional implantable devices.
- Adjunct faculty member for Austin Community College and The National Graduate School's master's program in Quality System Management.
- Developed and performed validation of complex systems such as: liquid chemical/ steam/ VHP/ filter sterilization processes, dye penetrant testers, cleaning and depyrogenation, de-ionized water, laboratory and custom manufacturing instrumentation, tubing sets, and packaging systems.
- Consult with Medical Device C-suite teams to ensure their understanding of regulatory compliance and management's responsibilities. Assisted with non-compliance issues such as corrective and preventive actions (CAPA's) or recalls.
- Volunteered as a Quality Texas Foundation Examiner to identify industry role models based upon Malcolm Baldridge criteria.

Education and Certifications

M.B.A., *University of Colorado,* Denver, CO **1991**

Dean's List, Beta Gamma Sigma Honorary Society

B.S. in Biomedical Engineering, *Vanderbilt University,* Nashville, TN **1985**

Dean's List

American Society for Quality:

- **Certified Quality Auditor**, certification # 12060
- **Certified Quality Engineer**, certification # 15634
- **Certified Manager of Quality/Organizational Excellence**, certification # 2904

Exemplar Global:
- **Quality Management System Lead Auditor**, certification #104799

Society of Quality Assurance:
- **Registered Quality Assurance Professional in Good Laboratory Practice (RQAP-GLP)** 2011- present

Exemplar Global/ Oriel STAT A MATRIX:
- **Certified EU MDR Auditor Europe's Medical Device Regulation 2017/745,** certification # 202420

Representative Seminars

- Certified Quality Engineer Course Instructor, Austin Community College, May 2003
- Risk Management & Medical Devices, Noblitt & Rueland, February 2004
- Quality System Requirements and Industry Practice Course, Association for the Advancement of Medical Instrumentation, November 2005
- Quality Systems Educational Forum: Design Controls, FDA Medical Device Industry Coalition, April 2008
- American Society for Quality, Supplier Quality, Process Control and Risk Course, October 6-7, 2008
- Biomedical Engineering Society Annual Meeting, October 2010
- Fifth Annual FDA Inspections Summit, FDA News, November 3-5, 2010

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- GLPs for Study Directions and Monitors, West Coast Quality Training Institute, April 19-21, 2011
- Professional Development Webinar: Computer System Validation/Part 11, Society of Quality Assurance, July 26, 2011
- Educational Forum on MDR Complaints, and Recalls, Corrections and Removals, FDA Medical Device Industry Coalition, June 15, 2012
- Reprocessing Reusable Medical Devices-Cleaning & Labeling Requirements, Global Compliance Panel, October 23, 2012
- Professional Development Webinar: Good Clinical Laboratory Practices Auditing, Society of Quality Assurance, October 26, 2012
- RAPS Texas Chapter Meeting, Emerging Technologies in Medicine, January 16, 2014
- MMA Roadshow: A Workshop Managing App Development under FDA Regulation, FDA CDRH, April 16, 2014
- 4th Global QA conference/30th SQA Annual Meeting, Society of Quality Assurance, April 6-8, 2014
- 2014 RAPS The Regulatory Convergence, Regulatory Affairs Professional Society, September 27-October 1, 2014
- 5th Annual Medical Device Global Regulatory Intelligence, Q1 Productions, July 27-28, 2015
- Austin Quality Conference, American Society for Quality, November 6, 2015
- Trends in FDA Inspections, RAPS Texas Chapter Meeting, November 6, 2015
- Quality System Survival: Success Strategies for Production and Process Control, and CAPA, FDA Medical Device Industry Coalition, April 15, 2016
- RAPS Texas Chapter: MDSAP – One Audit, Multiple Market Access, June 22, 2017
- ISO 9001:2015 - Transition Assessment (Auditor), October 29, 2017
- RAPS Preparing for MDSAP Audit Success, March 22, 2018

Continuing Education

- EU MDR Training (Axeon)
- ISO 13485:2016 - Transition Training (Exemplar Global College online training)
- EU MDR Transition Training: Europe's Medical Device Regulation 2017/745 (Oriel STAT A MATRIX)
- Understanding the Brazilian Regulatory Environment for Medical Devices (Compliance Online)
- ISO 14971:2019 and AAMI/ISO TR 24971:2020 Training (PowerPoint presentation conducted by Silas Minnick)
- EU-MDR Soft Transition (FDANews)
- EU-MDR: Are You Ready? Series Part 1-3 (FDANews)
- ISO 13485:2016 Training (online training provided by CALISO Corporation)
- Medical Devices Regulation in Australia (Australian Regulatory Requirements for Medical Devices)
- Preparing for MDSAP Audit Process (FDANews)
- The European In-Vitro Device Regulation IVDR (Compliance Online)
- Understanding How Medical Devices are Regulated in Canada (Device Advice: e-Learning tool)
- MDSAP Foundation Training, (Comply Guru)

Publications and Presentations

- "Automated Extraction of Activity Features in Linear Envelopes of Locomotor Electromyographic Patterns", R. Shiavi, J. Bourne, A. Holland, IEEE Transactions of Biomedical Engineering, 33(6):594-600, June 1986.
- "Risk Management Methods for Medical Devices", Texas A&M University Department of Biomedical Engineering, 2001.
- "Implement ISO 13485:2003 Successfully", Webinar Paton Professionals, March 2007
- "Introduction to Process Validation", Two Day Workshop, September 2007
- "Design Verification and Validation", FDA Industry Coalition, April 2008
- "Risk Management for Cardiac Valves", One Day Workshop, March 2009
- "Supply Chain Risk Management" Presentation, April 2010
- "Quality Assurance and Regulatory Affairs", Texas A&M Guest Lecturer, April 2013 and February 2014
- "Biomedical Engineering and Process Validation", Texas A&M Guest Lecturer, February 2014

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- "Entrepreneurship", Biomedical Engineering Society, Texas A&M, February 2014
- "Current Trends in FDA Inspections", Austin Quality Conference, RAPS Texas Chapter Event, November 2015
- "Efficient Validation Strategies and VMPs", FDA Medical Device Industry Coalition Big Event, April 2016
- "Medical Device Quality" Presentation, TMCx Accelerator Program, September 2016
- "Applying Risk Management Concepts throughout Your QMS", ASQ Austin, May 2017
- "Risk Based Approach for Medical Devices Quality Management" Article, Quality Magazine, October 2017
- "Four Dangerous Myths about Quality that May Cost Lives" Article, Quality Magazine, April 2019
- "Trials and Triumphs of Complaint Handling", Greenlight Guru Panelist, May 2022
- "How to Survive an FDA Inspection", ASQ Austin, May 2022
- "Current Trends in FDA Inspection and 483's", ASQ Medical Device Division, November 2022
- "Management Responsibility", ASQ Medical Device Division, November 2022

Expert Witness and Litigation Support

Case History Upon Request

Professional Societies

- Women in Bio, Vice Chair of Communications Committee, 2015
- Society of Quality Assurance, since March 2011
- Biomedical Engineering Society 2010-2011
- Regulatory Affairs Professionals Society, since 2008
- Association for the Advancement of Medical Instrumentation, since 2007
- American Society for Quality, Chair of Austin Section 2004-2005
- American Society for Quality, Senior Member, since 2004, Member since 1990

Awards and Recognition

- Selected by President of Ohmeda Monitoring as 'Key Player', top two percent (2%) of performers, 1992
- Recognition of Dedication and Effort Towards the First Clinical Implant of the Photofix Pericardial Valve, Carbomedics, 1994
- Appreciation Award, Exceeding Expectations in the Hunt Valley Product Transfer, Encore
- Certificate of Appreciation, Current Trends in FDA Inspections, RAPS Texas Chapter, 2015