Anne Holland, BSE, MBA
Medical Device Regulatory, Quality Systems and Implantable Device Testifying Expert

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SUMMARY

Biomedical engineer with more than 35 years experience guiding medical device regulatory, quality systems, and design control systems for clients and medical device manufacturers across the U.S, Asia, Europe and Australia. Substantial testimony experience in complex implantable-device litigation, including U.S. multidistrict litigation and Australian Federal Court proceedings. Expert work includes reports, depositions, and trial testimony involving pelvic mesh, hernia mesh, orthopedic implants, risk management, design controls, complaints/adverse events, audits, and regulatory compliance matters.

Particular expertise in Class III and implantable medical devices, including FDA Quality System Regulation (21 CFR Part 820), ISO 13485, MDSAP, EU MDR, design controls, risk management, CAPA, complaint handling, and the evaluation of quality management systems in product liability and regulatory compliance matters.

EXPERT WITNESS AND TESTIMONY EXPERIENCE

- Testifying expert in U.S. multidistrict litigation and Australian Federal Court proceeding
- Two trial testimonies
- Eight depositions
- Thirteen expert reports
- Multiple forensic consulting engagements
- Matters involving pelvic mesh, hernia mesh, orthopedic implants, complaints/adverse events, risk management, design controls, and quality systems
- Retained by both plaintiff and defense counsel

PROFESSIONAL RESPONSIBILITIES

Anne Holland Consulting, LLC | Santa Fe, NM 2024-Present
Principal
Provide expert witness consulting for medical device litigation involving FDA and international regulatory compliance. Analyze quality systems, design controls, supply chain management, and post-market activities; prepare expert reports; provide deposition and trial testimony regarding potential regulatory and compliance deficiencies related to the subject matter.

QA Consulting, Inc | Austin, TX 2000-Present
Founder and CEO
Direct regulatory, quality, auditing, and remediation initiatives supporting the development and commercialization of medical devices under FDA regulation and Foreign Regulatory Authorities. For over 25years, have provided strategic consulting services to more than 400 medical device manufacturers ranging from heart valves, spinal implants, and total joints to muscle stimulators.

Sulzer Carbomedics | Austin, TX 1993-1999
QA Systems Manager | Sr. Manufacturing Engineer | Sr. Quality Assurance Engineer
Direct manufacturing-floor experience with implantable Class III cardiac devices. Managed Quality Engineering operations for Class III implantable heart valves ensuring compliance of Quality Systems, Design Controls, and CAPA processes with FDA and international regulatory requirements.

Ohmeda Monitoring | Louisville, CO 1991-1993
Design Assurance Engineer
Developed and implemented Design Control systems for Class II oximeter devices to support FDA regulatory and quality system compliance.

Cobe BCT, Inc | Lakewood, CO 1987-1991
Quality Assurance Project Engineer
Developed mixed-model manufacturing flow lines for blood component therapy systems and led technical complaint investigations, root cause analysis, and corrective actions.

Fischer Imaging Corporation | Denver, CO 1986-1987
Quality Assurance Engineer
Developed and managed QA and QC operations for medical device manufacturing, including receiving inspection, Material Review Board (MRB) processes, and final X-ray system acceptance to ensure product quality and compliance.

LA BAC Medical Systems | Englewood, CO 1985-1986
Project Engineer
Conducted quality control and industrial manufacturing processes for advanced quadriplegic wheelchair systems, including machining and production support activities.

EDUCATION

MBA, University of Colorado | Denver, CO
Dean's List, Beta Gamma Sigma Honorary Society

B.S. in Biomedical Engineering, Vanderbilt University| Nashville, TN
Dean's List

CERTIFICATIONS AND REGISTRATIONS

BSI:
- Requirements of the In Vitro Diagnostic Regulation (IVDR), 2026, certification #294444-168923

Exemplar Global:
- Certified EU MDR Auditor Europe's Medical Device Regulation 2017/745**,** 2023, certification #202420

Exemplar Global:
- Medical Device Single Audit Program (MDSAP), 2023, certification #4526
- Quality Management System Lead Auditor, 2012, certification #104799

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

American Society for Quality:
- Certified Manager of Quality/Organizational Excellence, 1997, certification #2904
- Certified Quality Auditor, 1995, certification #12060
- Certified Quality Engineer, 1987, certification #15634

All certifications are current and maintained through continuing education and active professional practice.

PRESENTATIONS

1. Management Responsibility, ASQ Medical Device Division, November 2022
2. Current Trends in FDA Inspection and 483's, ASQ Medical Device Division, November 2022
3. How to Survive an FDA Inspection, ASQ Austin, May 2022
4. Trials and Triumphs of Complaint Handling, Greenlight Guru Panelist, May 2022
5. Applying Risk Management Concepts throughout Your QMS, ASQ Austin, May 2017
6. Medical Device Quality" Presentation, TMCx Accelerator Program, September 2016
7. Efficient Validation Strategies and VMPs, FDA Medical Device Industry Coalition Big Event, April 2016
8. Current Trends in FDA Inspections, Austin Quality Conference, RAPS Texas Chapter Event, November 2015
9. Entrepreneurship, Biomedical Engineering Society, Texas A&M, February 2014
10. Biomedical Engineering and Process Validation, Texas A&M Guest Lecturer, February 2014
11. Quality Assurance and Regulatory Affairs, Texas A&M Guest Lecturer, April 2013, and February 2014
12. Minimizing Supply Chain Risk, Houston, TX and Austin, TX, April 2010
13. Risk Management for Cardiac Valves, One Day Workshop, March 2009
14. Design Verification and Validation, FDA Industry Coalition, April 2008
15. Introduction to Process Validation, Two Day Workshop, September 2007
16. Implement ISO 13485:2003 Successfully, Webinar Paton Professionals, March 2007
17. Risk Management Methods for Medical Devices, Texas A&M University Department of Biomedical Engineering, 2001.

PUBLICATIONS

1. Bringing New Medical Devices to Life: The MedTech Startup Guide to Quality Systems, November 2022, Anne Holland, MedTech Startup Guide
2. Four Dangerous Myths about Quality that May Cost Lives, Quality Magazine, April 2019
3. Risk Based Approach for Medical Devices Quality Management, Quality Magazine, October 2017
4. 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.

GRADUATE INSTRUCTION & PROFESSIONAL EDUCATION

The National Graduate School | Austin, TX | Adjunct Professor- "The Cost of Quality"

Austin Community College | Austin, TX | Adjunct Professor- Quality Auditing

PROFESSIONAL SOCIETIES

- Society of Quality Assurance, 2011-present
- Regulatory Affairs Professionals Society, 2008-present
- Association for the Advancement of Medical Instrumentation, 2007-present
- American Society for Quality, Chair of Austin Section 2004-2005
- American Society for Quality, Senior Member, since 2004, Member 1990-present