DENISE HOLLIDAY

Medical Device, Regulatory Compliance, and Risk Management Expert

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SUMMARY

Denise Holliday is a litigation and expert witness consultant for Capwell Consulting Group LLC. Ms. Holliday lends her expertise to her clients from her career spanning over 2 decades in the highly regulated field of medical device quality management systems, international regulatory compliance, quality assurance, and medical device risk management. As a medical device regulatory consultant for Capwell Consulting Group, she provides strategic litigation support to medical technology businesses, healthcare organizations, and startups. She conducts ISO 13485 Medical Device and ISO 9001 Quality Management certification audits, spearheads quality management system implementations, and manages regulatory assessments. She delivers expert testimony for medical device litigation, guiding attorneys and organizations through the complexities of the global medical device industry.

SUBJECT EXPERTISE

US FDA 21 CFR
MDSAP
Auditing
Verification and Validation
Clinical Evaluation and Trials
Post Market Surveillance
Quality Management Systems
ISO13485
ISO 14971
Health Canada SOR/98-282
EU MDD/ MDR
Risk Management Process
Design Development
Recalls and Reports
Training
Global Regulatory Analysis
Program Management
ISO 9001

PRODUCT EXPERTISE

Ophthalmology
Cardiology
Orthopedic
In-Vitro Diagnostics
Neurology
Non-Active Implants
General Surgical Equipment
Software
Spinal Implants
Ventilators
Gynecology/Obstetrics
Dental
Prosthetics
General Hospital
Sterilization Processes

REGULATORY AND COMPLIANCE EXPERTISE

483 and Warning Letter Issuance
Consent Decree Litigation
FDA Registration and Listing Matters
FDA Approval and Clearance Disputes

PROFESSIONAL EXPERIENCE

CONSULTANT

Capwell Consulting Group | Saint Augustine, FL | April 2024 – Present

Capwell Consulting Group is an expert witness and litigation consulting firm that offers nationwide litigation support services in the field of medical devices, regulatory compliance, medical quality assurance and risk management solutions. Ms. Holliday's responsibilities include strategic consulting in medical device manufacturing, compliance, litigation support and expert testimony within the regulatory compliance framework.

- Provides expert testimony and reporting for litigation involving medical device quality, manufacturing, auditing, and global regulatory analysis.
- Expert consultant within the international medical device, regulatory compliance, and risk management industries.
- Specializes in quality management systems, international regulatory compliance, risk management, and technical documentation for all classes of medical devices.
- Certified and experienced auditor adept at analyzing compliance with Food and Drug Administration (FDA) and global regulations, including interactions, licensing, certifications, submissions, and reporting.
- Consults on the development, implementation, management, and continual improvement of ISO 13485 Medical Device Quality Management Systems – Requirements for regulatory purposes.
- Consults on the development, implementation, management, and continual improvement of ISO 9001 Quality Management System (QMS) Standards.

PRESIDENT AND CEO

Schuler Medical Device, Inc. | Frisco, TX | April **2015 – Present**

Schuler Medical Device is a consulting firm providing quality and regulatory expertise to medical device organizations across the globe.

- Conducts ISO 13485:2016 and ISO 9001:2015 certification audits.
- Performs internal, supplier, and Medical Device Single Audit Program (MDSAP) audits.
- Reviews and author technical article for Quality Progress magazine.
- Manages and direct quality and regulatory departments.
- Implements and maintains Quality Management Systems (QMS).
- Conducts comprehensive regulatory assessments for compliance.
- Performs Standards GAP Assessments to identify compliance and procedure failures.
- Manages 510(k) and Premarket Approval (PMA) regulatory submissions.
- Prepares EU MDR Medical Device Regulation technical file submissions.
- Handles registration, listing, and licensing for medical devices.
- Assists in design development for medical device prototypes.
- Provide recall and remediation support to ensure regulatory compliance.

DIRECTOR OF QUALITY

Hound Labs, Inc. | Freemont, CA | August **2022 - September 2023**

Hound Labs is a biotech company that developed the first breath testing solution to specifically target THC molecules, limiting cannabis detection to the workday.

- Responsible for developing, establishing, and maintaining quality systems needed for manufacturing and R&D operations.
- Led the implementation of advanced quality systems for product planning and manufacturing processes in a medical device-regulated environment.
- Ensured compliance of products and processes from development through post-market, maintaining adherence to regulatory standards.
- Developed, implemented, and managed the company's Background Screening Agency Accreditation Program (BSAAP) Accreditation Certification in accordance with industry standards.
- Managed quality assurance team in the establishment, implementation and maintenance of a QMS in accordance with ISO 9001:2015 and ISO 13485:2016.

SENIOR QUALITY ENGINEER

Nypro Healthcare (Jabil) | Coppell, TX | August 2015 - January 2017

Nypro Healthcare, a Jabil company was a design and development center providing medical device companies with development and production services. Medical device products included implantable drug delivery devices, surgical ophthalmology devices, and their accessories.

- Project lead for design and development activities for Class I, II, and III medical devices and accessories such as Installation, Operational, and Performance Process Qualifications (IQ/OQ/PQ), sterilization, Design Verification and Validation, and clinical builds/studies.
- Prepared and implemented design and development documentation including risk and Failure Mode Effects Analysis (pFMEA, dFMEA), Preliminary Hazard Analysis (PHA), quality and validation plans, Design Input Output Matrix (DIOM), product specifications, supplier evaluation, Design History File (DHF), Device History Record (DHR).
- Engineering studies include statistical analysis, protocols and summary reports for qualifications and validation activities.
- Managed non-project related activities such as training program, complaint handling, Corrective and Preventive Action (CAPA), Non-Conforming Material Review (NCMR), and Management Review Board (MRB) responsibilities across multiple facilities.

SENIOR MANAGER OF QUALITY AND REGULATORY

Austco | Coppell, TX | May 2014 **– August 2015**

Austco provides healthcare communication services including nurse call systems, enterprise reporting, and analytical tools for caregivers and clinical staff.

- Established and managed QA and Regulatory departments, including personnel, systems, and functions for a small Australian manufacturer of Class II hospital communication systems that relocated to the US.
- Established, implemented, and managed entire QMS per FDA, ISO 13485, Canada and Medical Device Directive regulations (MDD), including complaints, post-market surveillance, returns, supplier and internal audits, corrective and preventive actions (CAPAs), non-conforming material, management reviews, documentation, validations, equipment and environmental controls, and labeling.
- Continuous implementation of global regulatory plans associated with changes to current product as dictated through the product development process (PDP).

DIRECTOR OF QUALITY AND REGULATORY

AutoMedx | Flower mound, TX | January 2011 **– May 2014**

AutoMedx is a veteran-owned automated ventilator manufacturer primarily for use by combat medics in field hospitals.

- Established and managed QA and Regulatory departments, including personnel and systems, for small manufacturer of Class II automated ventilation systems, accessories, and software in accordance with FDA, ISO 13485, Canada and MDD regulations.
- Prepared and compiled CE Technical File Submission, 510(k), and DHFs for design development projects, and achieved ISO 13485 and CE certification.
- Managed all FDA and regulatory audits, interactions, licensing, certifications, submissions, and reporting activities, including adverse events and vigilance.
- Ensured daily QA manufacturing requirements are met, including inspections (incoming, in-process and final), record approvals, and issuance.

DIRECTOR OF QUALITY AND REGULATORY

Avail Medical (Flextronics/FLEX Medical) | Dallas, TX | June 2008 **– Dec 2010**

Avail Medical, acquired and operated by Flextronics's medical device division Flex Medical, operated as a design and development center for all classes of medical device products. Medical device products included blood regulation devices, tourniquets, and wound care kits and accessories.

- Oversaw all design and development activities for Class I, II, and III medical devices such as IQ/OQ/PQ, sterilization, Design Verification and Validation, and clinical builds/studies.
- Prepared and implemented design and development documentation including risk/failure analysis (pFMEA, dFMEA and PHA), quality and validation plans, DIOM, product specifications, supplier evaluation, DHF, DHR, engineering studies including statistical analysis, and protocols and summary reports for qualifications and validation activities.

LICENSES AND CERTIFICATIONS

Regulatory Affairs Certification RAC-DEVICES 2021**, Regulatory Affairs Professionals Society (RAPS)**
BSI Group
ISO 13485:2016 Lead Auditor Certification 2018
ISO 9001:2015 Lead Auditor Certification
Certified Quality Auditor Certification 2010, American Society for Quality
Certified Quality Engineer Certification 2009, American Society for Quality
Six Sigma Green Belt

EDUCATION

Doctorate Regulatory Science - University of Southern California
Expected June 2027
Master of Science, Regulatory Science - The Johns Hopkins University
May 2025
Bachelor of Science, Chemical and Biomedical Engineering – University of California, Irvine 1998-2003
Minor: Biomedical Engineering - University of California, Irvine 1998 – 2003

ACCOLADES AND MEMBERSHIPS

Adjunct Professor - Educating on regulatory and quality standards and processes
Received Outstanding Professor Award
University of North Texas, 2024
American Society for Quality
(ASQ), member since 2009
Regulatory Affairs Professional Society
(RAPS), member since 2016