



Carrie Hetrick

Senior Consultant, Regulatory Affairs

EXPERIENCE:

- Vice President, Regulatory Affairs, Grant Dental Technology Corporation
- President and CEO, Hetrick Medical Device Consulting
- Director, Regulatory and Quality Affairs, Kestrel Labs, Inc.
- Senior Medical Device Regulatory Specialist; Senior Product Manager, DENTSPLY, Inc.
- Medical/Technical Writer; Sales/Marketing, TMJ Implants, Inc.

AREAS OF EXPERTISE:

Including, but not limited to

Products:

- Craniofacial devices
- Dental devices
- Orthopedic devices
- Bone Grafting materials and devices (e.g., allografts, autografts, alloplasts and xenografts)
- Patient Monitoring Equipment, single and multi parameter
- Sterilithographic Anatomical (SLA) Modeling

Disciplines:

- FDA Quality System Regulations – 21 CFR Part 820
- FDA Human Cells, Tissues, and Cellular and Tissue Based Products - 21 CFR Part 1271
- US FDA 510(k) and PMA submissions
- CE Marking - Technical Files and Design Dossiers
- COFEPRIS Dossier Preparation
- State Tissue Registration
- Biocompatibility and sterilization
- IEC 60601 electrical safety standards
- ISO 17025 competence of testing and calibration laboratories

EDUCATION:

- D.D.S., University of Colorado Health Science Center, Denver, CO USA
- B.Sc. Biology, Pacific Lutheran University, Tacoma, WA USA

PROFESSIONAL AFFILIATIONS:

- Member, Regulatory Affairs Professional Society (RAPS)
- Member, American Medical Writers Association (AMWA)
- Member, Rocky Mountain Regulatory Affairs Society (RMRAS)

TRAINING AND CERTIFICATIONS:

- ISO 13485 QMS & Lead Auditor



- ISO 17025 QMS & Lead Auditor
- GMP/GLP Certification, University of Denver, CO USA
- CMDR & MDD Certification
- GMP Compliance Certification

PUBLICATIONS AND PRESENTATIONS:

- Britton C, Christensen RW, Curry JT. Use of the Christensen TMJ Fossa-Eminence Prosthesis System: A Retrospective Clinical Study. *Surgical Technology International X*, 2002, pp 273-281.
- Christensen RW, Alexander R, Christensen MS, Britton CJ, Curry JT, Masters TE. Hemi and Total TMJ Reconstruction Using the Christensen TMJ Prostheses: A Retrospective and Prospective Evaluation. *TMJ Prosthesis: A retrospective and Prospective Evaluation*. TMJ Implants, Inc. April 2003
- TMJ Implants, Inc. Christensen TMJ Prosthesis System: The Product of Choice. *Private Hospital Healthcare Europe, Theater, & Surgery*, 2003, pp T 54.