



Russell Johnson

Senior Consultant, Quality Assurance & Regulatory Affairs

EXPERIENCE:

- Regulatory Affairs, Orthofix Inc.
- Regulatory Affairs, DJO Chattanooga

AREAS OF EXPERTISE:

Including, but not limited to

Products:

- Orthopedic
- Cervical/Spinal Traction
- Bone Growth
- Electrotherapy
- Diathermy
- Lasers
- Patient Beds
- Exercise / Trauma Recovery
- Biologics
- Laboratory
- Information Technology / Patient Data Management

Disciplines:

- New Product Development Regulatory Strategy
- US FDA 510(k) and PMA Annual and Change Submissions
- Canadian File Submissions
- European CE File Submissions
- Asian File Submissions
- South America Submissions
- FDA Quality System Regulations – 21 CFR Part 820
- FDA Design Control 21 CFR Part 820.30
- FDA Medical Device Reporting – 21 CFR Part 803
- ISO 13485 Quality Management Systems
- ISO 14971 Risk Management Systems
- Biocompatibility and Sterilization
- IEC 60601, 3rd Edition Electrical Safety Standards
- IEC 60601-1-2 Electromagnetic Compatibility
- IEC 60601-1-4 and 62304 Medical Device Software
- Additional Performance Standards involving ASTM, ANSI, and IEC metrics for electrical, mechanical and software diagnoses and dosage devices.
- IQ/OQ/PQ
- Verification and Validation





EDUCATION:

- B.Sc. Electronic Engineering Technology, DeVry Institute

TRAINING and CERTIFICATIONS:

- FDA and ISO Design Control Certificate of Achievement
- Project Management Certificate of Achievement
- Risk Management Certificate of Achievement
- Certified Quality Engineer (CQE) Certificate of Achievement
- Quality System Regulation Certificate of Achievement