



Teresa A. Huddleston

Senior Consultant, Quality Assurance & Regulatory Affairs

EXPERIENCE:

- QA Specialist, Clinical Development, Encysive Pharmaceuticals, Inc.
- Drug Supply Specialist, Clinical Development, Encysive Pharmaceuticals, Inc.
- Senior Regulatory Compliance Auditor, Guidant Corporation
- Quality Assurance Supervisor, Guidant Corporation
- Biology Instructor, Collin County Community College

AREA OF EXPERTISE:

Including, but not limited to

Products:

- Cardiovascular
- Combination
- Ear, nose, and throat
- Gastroenterology/urology
- Implants, non-active
- Mobility aids/equipment
- Ob/Gyn
- Ophthalmic/optical
- Orthopedic
- Patient Monitoring
- Pharmaceuticals
- Protheses
- Radiology
- Reusable Instruments
- Software
- Surgical Instruments
- Therapeutic
- Anesthesia/respiratory
- Biologic Cell Therapy
- Biotech
- Contraceptives
- Cosmetic/plastic surgery
- Dental equipment

Disciplines:

- FDA QSR (21 CFR Part 820) Implementation
- FDA QSR Internal Auditor Training
- ISO 13485 Awareness Training
- 510k/513g submissions



- Due Diligence Audits
- ISO 13485 Implementation
- Sterilization
- Validation (Process, Software)
- CE Marking and CE Marking Training
- Clinical trials in Europe
- ISO 13485 Internal Auditor Training
- Technical File/Design Dossier Preparation
- Auditing to ISO 13485 + CDMR
- Audits for Japan PAL/169 Compliance