



Accumedix provides complete services to develop your ideas into innovative medical devices. We have been in operation since 2001 and are located in Grayslake, IL. Our Accumedix facility is FDA registered and has obtained ISO 13485 & ISO 13485 CMDCAS certifications for European Notified Body, DQS, Medical Device Directive, Canadian Medical Devices Conformity Assessment System and FDA Quality System Reg. 21 CFR Part 820.

Accumedix also provides consulting expertise to its customers on product design, development and manufacturing regulatory compliance through its partnership with [Vantage Consulting](#)

### **What We Do:**

#### **Product Design and Regulatory Submission Assistance**

- Design for cost and manufacturability
- Packaging design
- 510K and other regulatory submissions and device listings
- Regulatory facility registrations
- Regulatory consulting services

#### **Process Development**

- Manufacturing and assembly procedures
- Testing procedures
- Design control processes
- Tooling and fixtures
- Equipment validations including IQ, OQ & PQ
- Validation protocol development, testing and final reports
- Packaging testing
- Sterilization validation

#### **Material Procurement and Control**

- Vendor selection, audit and approval
- Inventory management
- Raw material and component purchasing
- Incoming receiving and inspection
- Warehousing with full lot control

#### **Manufacturing and Assembly**

- Clean room and non-clean room manufacturing
- Clinical trial through full production scale
- Full lot control and/or serialization
- In-process and final quality assurance

#### **Packaging and Sterilization**

- Sterile packaging
- Sterilization coordination

#### **Order Fulfillment**

- Receive orders into ERP
- Finished goods warehousing
- Ship product globally

#### **Quality Management**

- Device master record/Device history record
- Act as management representative to FDA and other regulatory agencies
- Device manufacturing documentation
- Work order history
- Full lot control
- Quality consulting services

