Accumedix, Inc.

Medical Device Contract Manufacturing

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

Accumedix also provides consulting expertise to its customers on product design, development, manufacturing, quality and regulatory compliance.

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 white 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

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

Quality Management

- Device master record/Device history record
- Device manufacturing documentation
- Work order history
- Full lot control
- Quality consulting services