Endorsements

VP of Operations:

- "I couldn't have asked for more."

VP of R&D:

- "You're one of the best program managers I've worked with."

President, Medtronic:

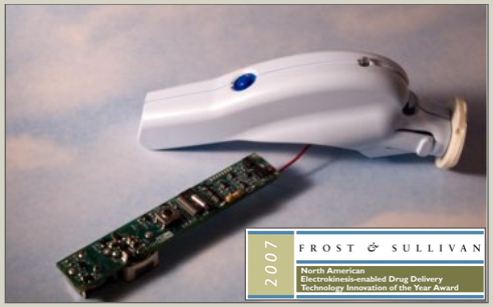
- "The work you and your team did on Thera was outstanding. I was impressed with your ability to always get the task accomplished with the resources given and the time allotted."
- "I am very impressed with how you and your team managed this so effectively. ... Your experience, managerial skill and attention to detail provided the winning formula, thanks again for a terrific job."

VP of R&D:

- "These changes [life cycle] are setting the entire tone of operation for our development efforts over the next 12 months. Mike did an outstanding job …I could not have asked for more. He made a great impression on the teams and showed them that he cares about their issues …"
- "Best quality we've had." "Since [adoption] …we've been on-time with all our commitments."

Team Member, Medtronic:

- "You were one of the best managers I've had here."



60% Cost Reduction

Class III Medical Devices and Software

30 Years of Experience

Vice-President Transfer to Manufacturing
Senior Director of Engineering
Senior Product Development Director
Program Manager
Senior Principal Software Engineer
Analog Design Engineer

Mike Barsness

Medical Device Consulting Inc

mike@barsness-consulting.com
www.barsness-consulting.com

29 Pine Ridge Drive
Oxford, MA 01540
(774) 922-7618

Barsness

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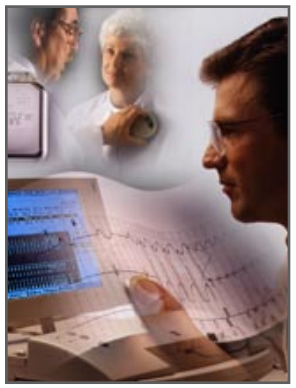

30 Years of Experience

President Barsness Consulting
VP / Director Infusion Pumps
Senior Director Combination Products
Senior Director Medtronic Instruments
Program Manager Medtronic Software

Consulting Services

Program Management
IEC 60601-1 3rd Edition Compliance
Compliant SOP Gap Analysis and Creation
(Risk, Usability, Software, Clause 14)
Wireless Medical Device Approval
Medical Device App Approval
Leading Teams New to Medical

Presym Reliable Heart Health
SANMINA-SCI
fluidnet
GUIDANT
Medtronic When Life Depends on Medical Technology
Boston Scientific Delivering what's next.
Transport Pharmaceuticals, Inc.

Experience

30 Years of medical Device Experience

Developing new electronic medical devices and combination products at Medtronic, Guidant, Boston Scientific, Transport Pharmaceuticals, Sanofi, Presym.

Leading cross-functional teams and organizations as VP of Transfer to Manufacturing, Product Development Director, Program Manager, Engineering Manager, Senior Principal Engineer.

Delivering class II & III products including Pacing & Defibrillation Instruments, Endoscopy Systems, Disposable Cardiac Monitoring Endoscope, IV Pump and Disposables and Iontophoretic Drug Delivery.

Leading internal and external teams, with and without prior medical device experience. Reconciling quality systems between organizations or establishing them when necessary.

Managing product transfer to manufacturing; establishing test regimens, process qualifications and overcoming production issues.

Regulatory Compliance interacting with Notified Bodies, FDA. 3rd Edition Compliance. Hosting on-site audits, compiling technical submissions for Class II and Class III products that repeatedly pass agency reviews with few, if any, questions.

Consulting Services

3rd Edition Compliance

Steps to Compliance

1. Gap Analysis
   - 701 point assessment

2. Upgrade SOP's per:
   - 14971 Risk
   - 62304 Software
   - 62366 Usability
   - Clause 14 PEMS/PESS

3. Map Risk Analysis to over 120 60601 - 1 Clauses

4. Compile Evidence of SOP Compliance
   - Gap Fill, And/Or
   - Analyze Risk of Gaps for Legacy Systems

PEMS: Programmable Electrical Medical System
PESS: Programmable Electronic Sub-System

Wireless

Steps to Compliance

1. Wireless Related Risk Analysis:
   - Functions Implemented Wirelessly
   - Intentional or Foreseeable Misuse
   - Degradation or Loss of Link
   - Essential Performance

2. Wireless Coexistence Testing
   - Potential Sources of Interference
   - Risk Acceptability Criteria

3. EMC Testing
   - with system TX/RX working

4. Security of Wireless Signals & Data

5. Information for Setup and Operation

New to Medical + Medical Apps

Getting Started

1. Establish Quality System
   - Quality Policy
   - Standard Operating Procedures
     - Design Controls per 21 cfr 820
   - Follow EU standards will comply in U.S. too.
     - ISO 13485 Quality System
     - 14971 Risk
     - 62304 Software
     - 62366 Usability
     - 60601-1 Safety/EMC/PEMS
     - 21 cfr 820 FDA Design Controls

2. Establish Development Life Cycle
   - What decisions are made/when?
   - What information is necessary to make those decisions?
   - Align stages with Design Control

3. Clearly define deliverables due per stage
   - Who owns/approves which deliverable?
   - Program Management needs prior medical experience (hire or rent it)
   - Design Control Training Required
     - Quality System
       - Defined Procedures
     - Planning
       - Activities, Responsibilities, Interfaces
     - Design Input
       - User Needs, Product Requirements, Risk Management
     - Design Output
       - CAD, Schematics, Architecture
     - Design Review
       - Technical and Management Review
     - Design Verification
       - Design Implements Requirements
     - Design Validation
       - Design Meets User Needs
     - Design Transfer
       - Design Correctly Transferred to Mfg
     - Change Control
       - Manage Change
     - Design History File
       - Record of Design Effort