Metrics of a Medical Device Success Story
New Technology in an Old Industry

Integrated Computer Solutions, Waltham MA

New Technology in an Old Industry

From 2005 to 2009: 56,000 MDRs (Medical Device Reports) for Infusion pumps

- ~30 per day
- 87 pump recalls (~1.5 per month)
- Chief problems: software error messages, **human factors,** broken components, battery failure, alarm failure, over infusion and under infusion

3 Entrenched major infusion pump manufacturers

- Average technology 15 years old
- Low contrast LED displays, delaminating keyboards, no cybersecurity, no human factors studies
- An industry in neglect
- Cash cows – on their last leg

FDA's **Infusion Pump Improvement Initiative** – Final guidance in 2014

- 36 pages of additional guidance for Infusion pumps
- FDA's "Major level of concern"

Infusion Pumps, how hard can this be?

- Control the flow, +/-5%, always. (viscosity, temperature, flow rate, orientation)
- Pump can't touch the fluid - sterility
- **Entrenched competition**
  - $4 disposable – a tube
  - Cheaper pump, low engineering overhead
- **The New Level of Safety**
  - Risk approach "all failures are inevitable" - Fail safe, power/software/processors/notifications
  - Summative human factors testing: with 0 training, complex infusions, 0 use errors
  - Dedicated Safety Processor
  - No single failure can fail silently
  - Safety Assurance Case: comprehensive analysis and justification why every subsystem is safe under all use conditions

Ivenix, Inc.

Ivenix attempting to be the **first, ground-up, redesign** under the new guidance

- Bright, responsive touch screen interface
- Measures Infusate
- Waterproof
- Extensive human factors design (21 studies)

Ivenix, Inc.

Next-generation medical device

- Mobile device compatibility
- Proven EMR connectivity
- Best in class Cybersecurity
- Enterprise Information Management System

Parameters of a no-apologies submission

Submission 9628 pages

Human Factor
Safety Case
Instructions fo
Detailed Desig
Test protocols
Test reports*

103 pounds

Test Group
1438 hours of verification testing (final round only)
7.6 million effective hours of accelerated-life testing

Engineering Test (SW)
6600+ unit tests
500+ system tests
Accelerated testing (Squish): 1.1 million effective pun

Development
Requirements: 550 Specifications: 2500
Design documents: 80 = 32 Pump + 48 IMS

Quality Teams
- Regulatory 3
- QA 4
- Test 10

Total Engineering and Test
- 4 years duration
- **88 person-years effort**

Success Story

Ivenix’s IV pump received FDA clearance in June, 2019!

Thank you.