



# Medical Device Software

## A developer's perspective


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This presentation focuses on taking medical device software from the lab to the market ...

- What regulations are involved, and what do the regulators want?
- What are the key development issues?



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2. Regulatory Overview
3. Case Study







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1. Introduction

Invetech - 200+ engineers and scientists developing systems for bio-applications since 1988


	Clinical in-vitro diagnostics		Medical devices
	Life sciences & biotechnology		Drug discovery
	Molecular biology		Therapeutic manufacturing

..... providing an 'idea to market' service








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1. Introduction

## Our track record ... 60+ Biomedical Instrument developments

		
Bio-Rad BioPlex 2200 Immunoassay	Gates Foundation Point-of-Care Diagnostics for the 3rd world	bioMérieux easyMAG™ Nucleic acid purification
		
Leica Bond™ In-situ hybridisation and immuno-histo-Chemistry	bioMérieux Provi-Isola™ Microbiology	

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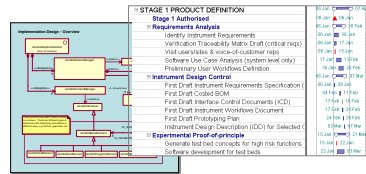
**Most product developments are targeted at US and Europe**

- USA
  - Regulator - Food and Drug Administration (FDA)
  - Regulations specified in Quality System Regulations (21CFR 820)
  - Regulations supplemented by guidance documents
- Europe
  - In-Vitro-Diagnostic Directive (IVDD) & Medical Device Directive (MDD)
  - Requirements specified in international standards

Although the US and Europe have quite different regulatory structures, a similar development approach satisfies both

**Key quality system elements ...**

- Development undertaken in a planned, controlled manner
- The requirements for the development must be clearly specified
- Potential hazards are investigated and mitigated
- Design outputs verified as meeting the requirements
- The process and outputs are validated



**Additionally for software ...**

- FDA analysis - 79 % of software related product recalls caused by changes after product first released
- Software cannot be proven by testing alone

A robust development process is essential for confidence that the software is fit for purpose

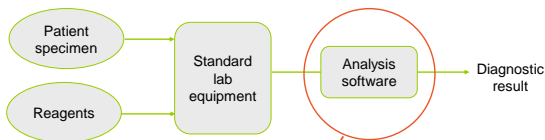
- Additional documentation requirements
- Review code and documentation for completeness and correctness

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**Our clients wanted to take their product from research to market ...**

The product provides a diagnostic result by processing specimens with custom reagents and analysis software

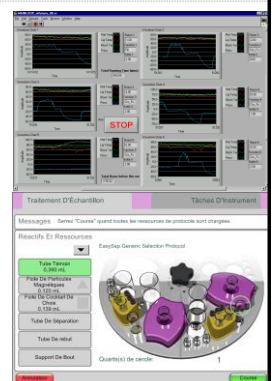


Our role ...

- Take the analysis software from a research tool to "production" software suitable for a clinical lab

**Our activities ...**

- Assist our client define the software requirements to suit a busy clinical lab
- Prepare verification test procedures to enable repeatable testing of each software release
- Conduct formal verification testing
- Assist our client with regulatory issues
- Prepared the User Manual
- Identify potential software hazards and implement mitigations
- Repeatable software build environment, so that the software generated is independent of the developer
- Formal design documentation both as an aid to future development/support and to satisfy the regulators



**The project outputs ...**

The code size has doubled ... and only 25% of the original code remains

- User interface completely re-written to suit clinical laboratory users
- Instrument Interface extended to support additional hardware variants
- Calibration code rewritten to suit a simpler, more rigorous procedure
- Additional code for data cross-checking, error handling and robustness
- Automatic "unit testing" adds confidence that the software has not been broken by later changes

Documentation to support the product (& satisfy the regulators)

- Requirements Specification - 30 pages
- Test Procedure - 150 pages, 80% devoted to error handling
- Hazard Analysis – identification of possible failure modes and mitigations

**Questions?****Thankyou****Web sites**

- Invetech [www.invetech.us](http://www.invetech.us) , [www.invetech.com.au](http://www.invetech.com.au)
- FDA [www.fda.gov](http://www.fda.gov)

**FDA regulations:**

- 21CFR820 – Quality System Regulations (QSR)
- 21CFR11 - Electronic records
- (CFR = Code of Federal Regulations)

**FDA Guidance documents**

- 585 Off the shelf software use in medical devices
- 938 General principles of software validation
- 1553 Cyber security for networked devices etc
- 1497 Risk Management & Human Factors

**International standards**

- ISO13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes
- IEC62304 Medical device software – Software life cycle processes
- ISO14971 Medical devices -- Application of risk management to medical devices