IEC 62304: SDLC Conformance and Management

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Our Agenda

- Introductions
- IEC 62304 Historical Backdrop
- IEC 62304 Overview
- IEC 62304 Implementation
- Some Things to Watch Out For

Introducing Your Presenter

Rita King - CEO & Senior Consultant

More than 25 years of experience as a regulator, technologist and professional auditor with international reputation as a regulatory expert. Rita is a founding member of the Underwriters Laboratories team that defined, launched, and managed the operations of the first US program to evaluate safety critical software used in commercial and medical devices and developed the ANSI approved Standard for Safety Critical Software, UL 1998.

Rita developed and commercialized InfoStrength Smart Enterprise Suite, a 21 CFR Part 11 Software as a Service content management solution specifically designed for the life science industry and founded her company in 2000.

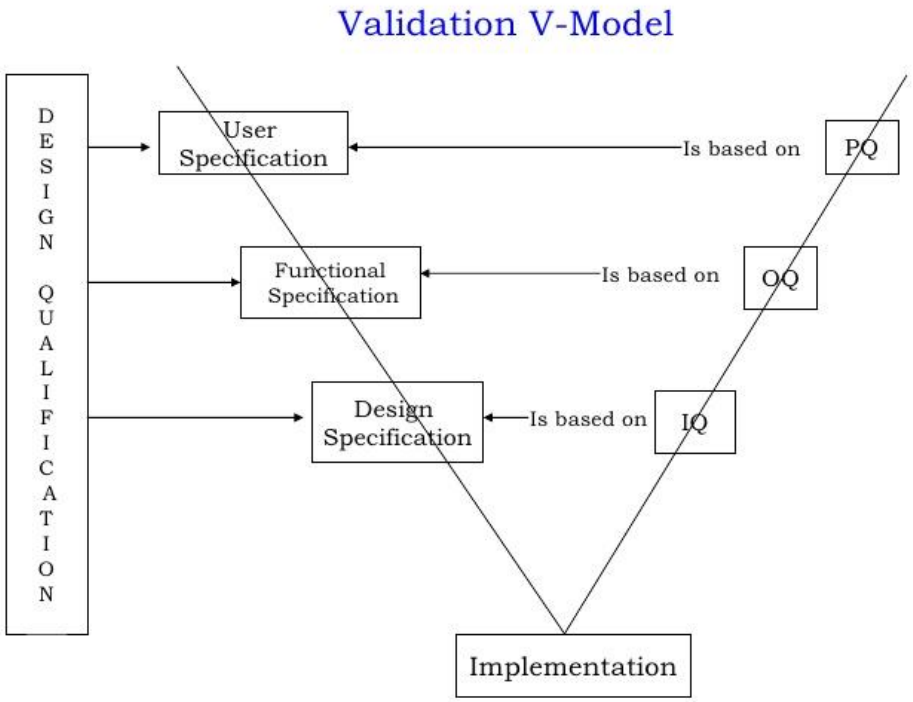
MethodSense is a Life Science service company adding strategic value with integrated expertise:

- InfoStrength Software Solutions
- Regulatory Affairs
- Quality Assurance
- Technology Management
- Business Operations

- **In the mid 1990's the FDA and Underwriters Laboratories (UL) observed a problem:**
  - High percentage of reported incidents of adverse events for medical device software attributed to "user error" by Medical Device Companies
  - Research showed that a significant number of these incidents had their root cause in the quality or unintended performance of the software itself, not "user error"
- **UL response to this problem – UL 1998:**
  - UL developed and published the standard UL 1998 for Safety Critical Software
  - UL 1998 applies to non-networked embedded microprocessor software and addresses the risks unique to product hardware controlled by software in programmable components

- **FDA response to this problem: 21 CFR Part 11**
  - Part 11 requires FDA-regulated industries to implement controls, including audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing electronic data that are:
    - **Required to be maintained by the FDA predicate rules or**
    - **Used to demonstrate compliance to a predicate rule.**
  - Applies to software applications that support Medical Device Businesses, Medical Device Products and software applications that qualify as a Medical Device
- **Part 11 Intent: Establish Safety and Efficacy by Validating or Delivering Evidentiary Demonstration that Software Applications Perform as the User Intends**

- **Classic Validation Representation**



- **Improved Product Quality**

Software, Medical Devices and Managing Risk

- **Additional quality regulations designed to reduce risk and enhance safety**
  - FDA's 21 CFR Part 820 (GMPs)
  - ISO 13485

- **Does the following equation eliminate unacceptable software risk?**

  GMPs / 13485 + Software Validation = Safe Medical Device Software

- **Assessing the equation: GMPs / 13485 + Software Validation = Safe Medical Device Software**
  - **GMPs & 13485 are vague when it comes to software QA**
  - **Validation insufficiently addresses software risk**
  - **FDA Medical Recall Report: FY2003 to FY2012**

"Evaluating the Most Common Cause of Recall – Software Design Failures … Failure to implement software design controls, and where appropriate, testing procedures, as well as increasing complexity of the medical device use environment (with increased connectivity and interoperability) can lead to software anomalies often requiring a correction or removal."

- **GMPs / 13485 and Software Validation do not sufficiently eliminate unacceptable risk in medical devices that are or incorporate software**

- **Enter IEC 62304**
  - **Used by EU since 2008**
  - **Incorporated into IEC 60601-1 3rd Edition Amendment 1 (2014) & required by Clause 14**

  Clause 14 requires manufacturers to comply with IEC 62304 *unless* the device's software has no role in providing basic safety or essential performance or risk analysis demonstrates that a failure of any Programmable Electronic Safety System (PESS) does not lead to an unacceptable risk.

  - **Incorporated into IEC 61010 3rd Edition**

Software, Medical Devices and Managing Risk

- **IEC 62304 enhances medical device safety by tying the Software Development Life Cycle directly into**
  - ISO 14971 and Risk Management
  - Compliant Quality Management System (e.g. ISO 13485)
- **IEC 62304 addresses the risk gap by**
  - Creating specificity for software management where GMPs or ISO 13485 are vague
  - Incorporating ISO 14971 risk management where Part 11 or Validation does not
  - And requiring detail or rigor in software Design, Testing, and Verification

What is IEC 62304?

- **IEC 62304 is the international standard that:**
  - Defines software development lifecycle requirements for medical device software
  - Requires all aspects of the software development life cycle to be scrutinized, including:
    - **Development**
    - **Risk management**
    - **Configuration**
    - **Problem resolution**
    - **Maintenance**
  - Provides a common framework for medical device manufacturers to develop software

What Does Conformance with IEC 62304 Accomplish?

- **Conformance with IEC 62304:**
  - Fulfills the requirements of the EU Medical Device Directive
  - Serves as a benchmark for compliance with regulatory requirements in US because it is recognized by the FDA as a consensus standard
  - Recognized in most countries that use compliance standards to fulfill regulatory requirements
- **Conformance with IEC 62304 has become a part of medical device commercialization roadmap**

Is Conformance with IEC 62304 Required?

- **Is IEC 62304 Required in the US Market?**
  - Technically, "NO" because it is voluntary
  - For all practical purposes, "YES" if you fall into one of these categories
    - IEC 60601-1 3rd Edition Amendment 1 is required
    - The device relies upon software to perform Basic Safety functions
    - The device relies upon software for Essential Performance
- **If you do *not* conform with IEC 62304 and also fall into one of these categories then you *must* demonstrate the software development process used is as good as, or better than, the process presented in IEC 62304, a form of *de facto* compliance**

Is Conformance with IEC 62304 Required?

- **How do I know if IEC 60601-1 3rd Edition Amendment 1 Applies to My Device?**
  - If IEC 60601-1 3rd Edition Amendment 1 Clause 14 applies to the medical device, then
  - Clause 14 requires manufacturers to comply with IEC 62304
    - ***Unless*** the device's software has no role in providing basic safety or
    - Essential Performance or risk analysis demonstrates that a failure of any Programmable Electronic Safety System (PESS) does not lead to an unacceptable risk.

Is Conformance with IEC 62304 Required?

- **How do I know if the device relies on software for basic safety?**
  - If the role of the software includes risk mitigation then the software has a role in providing basic safety
  - Examples:
    - A primary function of the device is controlled by software.
    - Software mitigates a risk if hardware fails
  - A risk analysis will identify your device's level of unacceptable risk and determine the role of software in risk mitigation

Is Conformance with IEC 62304 Required?

- **How do I know if the device relies on software for Essential Performance?**
- **Follow a process of elimination:**
  - List all functional aspects of your device, including accuracy, measurements and its capabilities
  - Determine whether any of these are already covered by the Basic Safety requirements of IEC 60601-1 or whether any item is not part of the device's intended use
  - For every item remaining that is controlled by software, pose the question: "If this item degrades, will it create a risk for the patient?"
  - If "YES" for any item, you must identify how product's functionality must be maintained so the risk is still acceptable (i.e. utilize hardware controls as a back up mechanisms to a potential software failure, include separate software controls, software validation, etc.)
- **This is the device's Essential Performance**

Is Conformance with IEC 62304 Required?

- **Example of software as Essential Performance?**
  - Consider a device that claims its Essential Performance is accurate within 5%.
  - If the device is relying on software to maintain that accuracy or provide an alert when outside of 5%, and that software fails, then the manufacturer will be unable to detect if the device's Essential Performance is being met.
  - This means the software is providing Essential Performance.
- **Once you know your device software is responsible for Essential Performance, you *must* comply with IEC 62304 to ensure there is no unacceptable risk to a patient**

How do You Conform with IEC 62304?

- **IEC 62304 Challenge**
  - The Devil is in the Details……..
  - There are A Lot of Details
- **There are ways to practically tackle this challenge to accommodate your company's needs and satisfy the requirements of the standard for a medical device**

How do You Conform with IEC 62304?

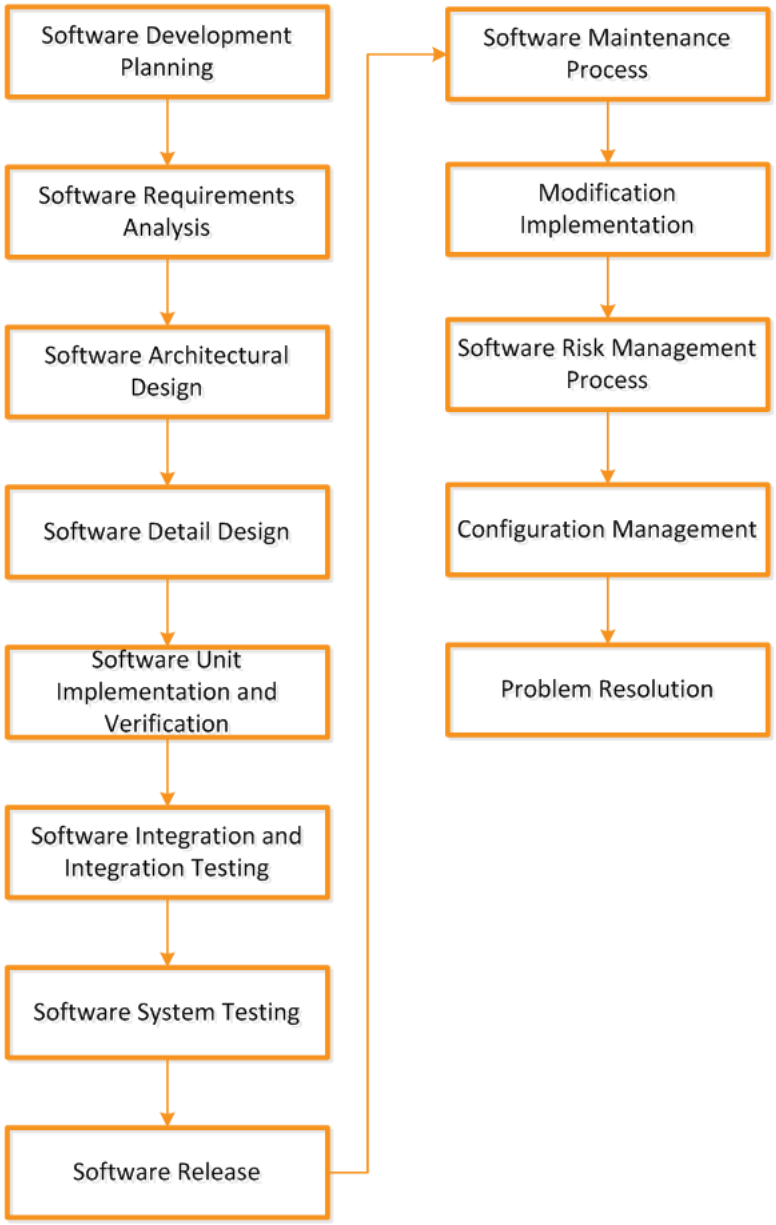
- **Conforming with IEC 62304 requires 2 parts**
  - Processes – Policies & Procedures for your Software Development Life Cycle
  - Evidence that those processes are applied to the medical device software
- **The processes developed and applied to your medical device software depends on its Software Safety Classification**
- **Our Next Steps:**
  - Review Software Safety Classifications
  - High Level Review and Practical Application of Processes
  - Tying Processes to SDLC Evidence for the Test Laboratory

Safety Classifications: IEC 62304 v. FDA Software Level of Concern

IEC 62304 Software Safety Classification	FDA Pre-Market Submission Software Levels of Concern
Class A: No Injury or Damage to Health is Possible	Minor: Failures or latent design flaws are unlikely to cause any injury
Class B: Non-serious Injury is Possible	Moderate: Failure or latent possible design flaw could directly or indirectly result in minor injury
Class C: Death or Serious Injury is Possible	Major: Failure or flaw could directly or indirectly result in death or serious injury

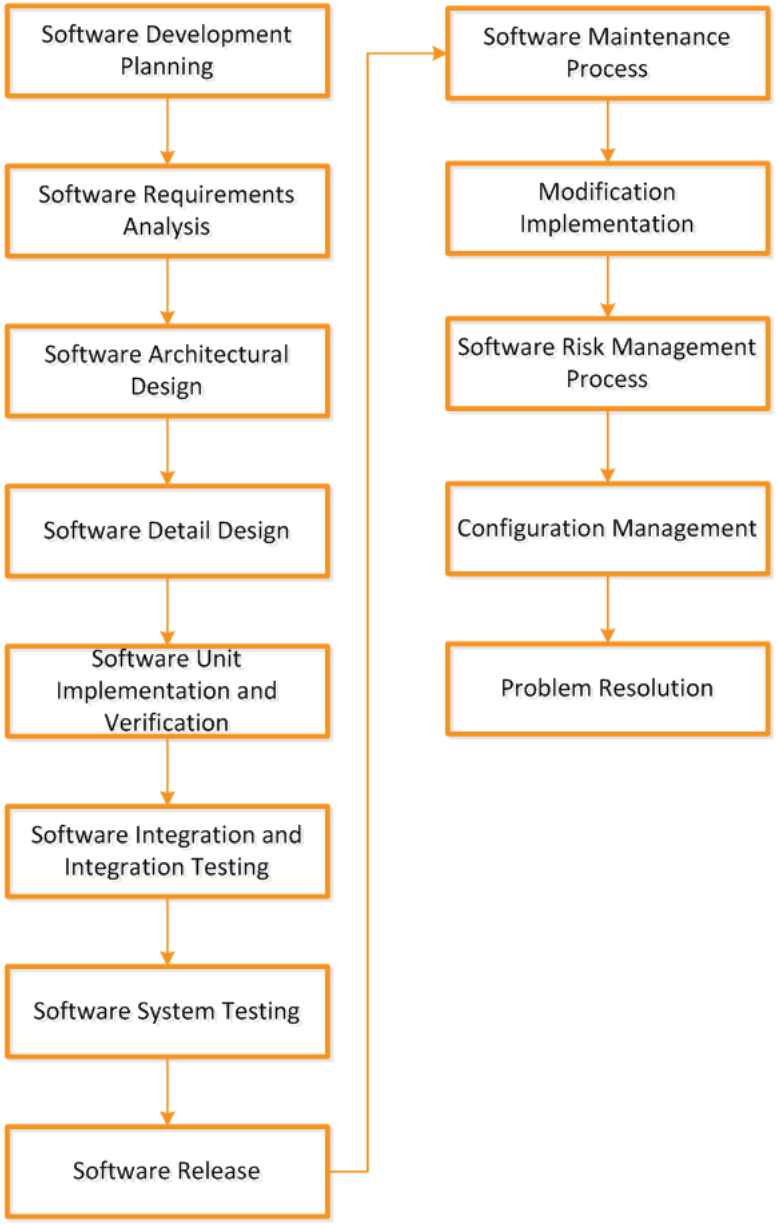
- **Safety Classifications Considerations**
  - The riskier the software, the more rigorous the controls
  - Important Tip: Clear segmentation of software can allow for discreetly classifying parts of the software which may make the documentation and testing easier

Software Development Life Cycle Process



- **IEC 62304 Processes, Tasks and Deliverables must be implemented**
- **Requires a Quality Management System and Risk Management Process compliant with ISO 14971**
- **However, IEC 62304 *does not* prescribe:**
  - An organizational structure
  - A particular methodology
  - A particular document format

IEC 62304 SDLC Deliverables



- Challenge: This has the look and feel of an SDLC known as the Waterfall Model. Is that so?
- NO. What this represents is a set of deliverables for a Test Laboratory or a Regulatory Authority (e.g. the FDA)
- Important: Think in terms of incorporating into your SDLC methodology the creation of these deliverables

IEC 62304 SDLC Deliverables

- IEC 62304 is pretty clear about what deliverables are required
- Test Laboratories have their own check lists you can use as guidance to demonstrate your IEC 62304 compliance
- MethodSense has created an IEC 62304 Action List that identifies the required deliverables and we can share this with you
- Therefore, the IEC 62304 deliverables are well understood and we can focus on practical considerations for implementation

IEC 62304 Implementation for Alternative SDLC Methodologies

- **Waterfall Model:**
  - Generally recognized as impractical and rarely used SDLC model
  - Fails to account for the iterative nature of Software Development
  - As a model accommodates the creation of deliverables (e.g. documents) because it allows minimal change along the way
- **Agile Model:**
  - Generally recognized as a very practical SDLC model
  - Accounts for the iterative nature of software development
  - As a model and depending on its implementation makes it difficult to efficiently create the expected 62304 deliverables (e.g. documents) since requirements may be changing during software development
- **How can you generate IEC 62304 deliverables in an Agile environment?**

- **IEC 62304 Conformance Tips in an Agile Environment**
  - Map onto your Agile SDLC IEC 62304 deliverables
  - Think about segmenting your software to allow the Safety Classifications to apply differently to the different software segments
  - Ensure your automated tools will deliver documents that meet expectations and conformance needs
  - If your deliverables cannot keep up with your method, think about scaling back iterative change in a hybrid approach

IEC 62304 Tips

- **Common software functionality manufacturers fail to recognize as IEC 62304 compliance issues:**
  - **Alarms and Alerts -** often an Essential Performance requirement because they are intended to detect abnormalities
  - **Speed & Position Sensors -** use software to limit range of motion, speed and force which are Basic Safety concerns
  - **Algorithms -** remove the software and the device is no longer able to operate as intended, resulting in the algorithms being part of Essential Performance

- **Pitfalls to Avoid**
  - **Document Your Process Well** – document management is *essential* for meeting compliance goals
  - **Software of Unknown Pedigree (SOUP)** – manage your SOUP appropriately
  - **Document Development** – make certain you are sufficiently resourced to support document development needs
  - **Version Control & Updates –** clearly define what is a software update and further how the software will be maintained in a validated state

- **What if Your Device Software is Developed by a Third Party?**
  - **Supplier Management Process –** confirm that software vendor complies with IEC 62304 and processes are reviewed during vendor audit
  - **Quality Agreement –** confirm that:
    - It defines vendor responsibilities and 62304 Deliverables
    - Vendors procedures used for software development will be provided to you and the test lab for review
  - **Establish your SDLC –** at minimum, your process will define acceptance criteria (i.e. IEC 62304 compliance and deliverables) from your vendor

IEC 62304 Success

- **IEC 62304 File will be reviewed to ensure:**
  - It contains all required documentation including a risk management file
  - Procedures meet the requirements of the standard
  - Each check list item is satisfied
  - A product review is conducted and further a review of the relevant software segments if it has been decided that the software performs Basic Safety or Essential Performance for your device
- **After the review, a Pass or Fail Report is delivered**

Move Commercialization Forward!

MethodSense Thanks You!!!

Confidential

Discussion / Q&A

Thank you.

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