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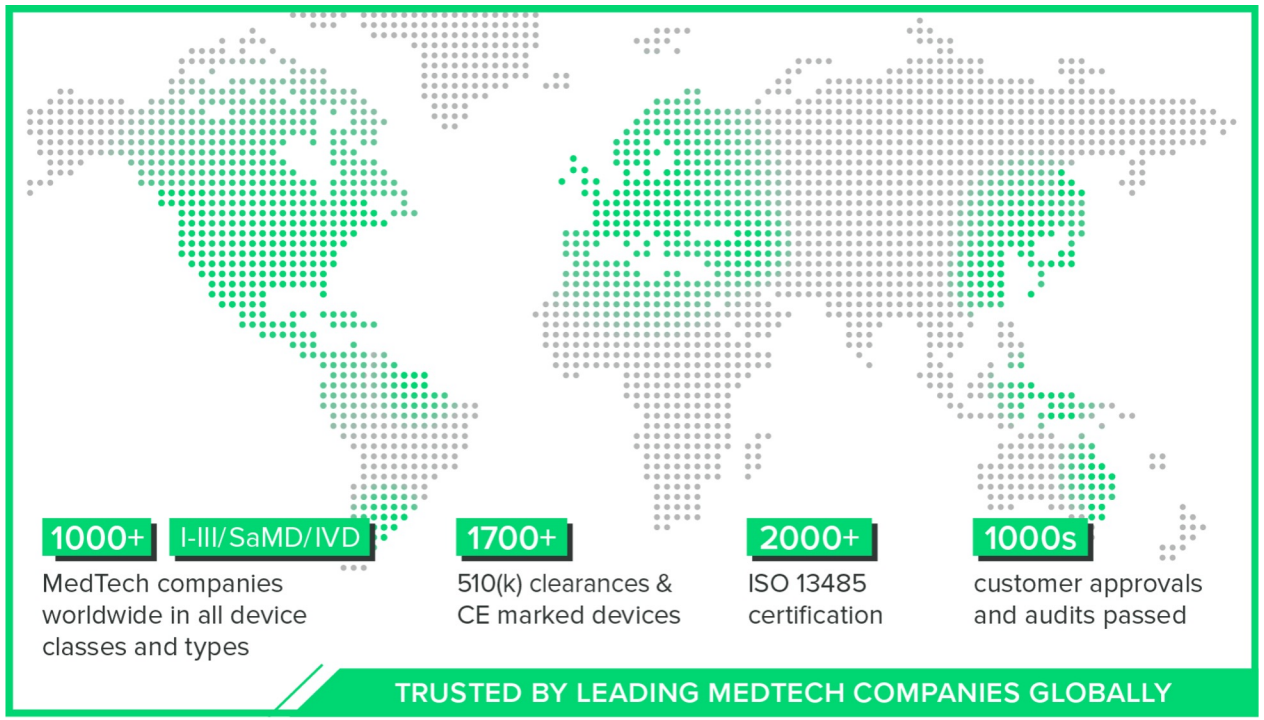

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Developing IEC 62304 Compliant Software: Proven Tips and Best Practices

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IEC 62304: The WHAT

- International standard
- Current revision is ANSI/AAMI/IEC 62304:2006 & A1:2016
- Medical device software – Software life cycle processes
    - Software development to software maintenance
    - Supporting processes - change management, config management, problem report tracking
- Not Prescriptive – the “what”, but not the “how”
- Applicable for SaMD and SiMD

IEC 62304: The WHY

- Promotes Risk-Driven Development
    - Classes A, B, C
    - More risk -> more rigor to ensure safety
    - Flowchart and SWHA to determine classification
- Employs Good Software Engineering Practices

IEC 62304: The WHY

- FDA Recognized Consensus Standard
  - FDA Guidance - Content of Premarket Submissions for Device Software Functions
  - May submit a DOC to specific clauses
  - Satisfies documentation element of Software Development, Configuration Management, and Maintenance Practices
- Harmonized Standard in the EU (2006)
  - Aids with MDR and IVDR compliance / Technical File
  - BSI requests checklist to show 62304 compliance

IEC 62304: The HOW

- Perform a Gap Analysis
- Align with FDA/EU
- Establish Comprehensive Documentation
- Consider Iterative/Evolutionary Software Development Lifecycle Models & Practices
- Promote Awareness and Training

Perform a Gap Analysis

Perform a Gap Analysis

- Start early – start now
- Read and understand IEC 62304 or hire help
- Know your current state
- Identify where your gaps are
- Create a checklist
- Clauses/Requirements
- Procedures, Templates, Project Documentation

Perform a Gap Analysis

Ref	Software Lifecycle Process	Procedures				Templates				Project Evidence
		Document Number	Procedure Name	Section Number	Section Name	Document Number	Template Name	Section Number	Section Name	Document Name and/or Evidence Location
5	SOFTWARE DEVELOPMENT PROCESS	-	-	-	-	-	-	-	-	-
5.1	Software Development Planning	-	-	-	-	-	-	-	-	-
5.1.1	Software Development Plan	-	-	-	-	-	-	-	-	-
5.1.1	The manufacturer shall establish a software development plan (or plans) for conducting the activities of the software development process appropriate to the scope, magnitude, and software safety classifications of the software system to be developed. The software Development Life Cycle Model shall either be fully defined or be referenced in the plan (or plans). The plan shall address the following:									
5.1.1 a)	the processes to be used in the development of the software system (See Note 4);									
5.1.1 b)	the deliverables (including documentation) of the activities and tasks;									
5.1.1 c)	traceability between system requirements, software requirements, software system test, and risk control measures implemented in software;									
5.1.1 d)	software configuration and change management, including SOUP configuration items and software used to support development; and									
5.1.1 e)	software problem resolution for handling problems detected in the medical device software, deliverables and activities at each stage of the life cycle.									

Perform a Gap Analysis

Ref	Software Lifecycle Process	Procedures				Templates				Project Evidence
		Document Number	Procedure Name	Section Number	Section Name	Document Number	Template Name	Section Number	Section Name	Document Name and/or Evidence Location
5	**SOFTWARE DEVELOPMENT PROCESS**	-	-	-	-	-	-	-	-	-
5.1	**Software Development Planning**	-	-	-	-	-	-	-	-	-
5.1.1	**Software Development Plan**	-	-	-	-	-	-	-	-	-
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5.1.1 a)	the processes to be used in the development of the software system (See Note 4);	P-7314	Software Development Procedure	6	Procedure	F-7314	Software Development Plan	6	Software Development Lifecycle	Software Development Plan
5.1.1 b)	the deliverables (including documentation) of the activities and tasks;	P-7314	Software Development Procedure	6.17.1	Deliverables	F-7314	Software Development Plan	6	Software Development Lifecycle	Software Development Plan
5.1.1 c)	traceability between system requirements, software requirements, software system test, and risk control measures implemented in software;	P-7314	Software Development Procedure	6.10.4	Traceability	F-7351	Software Trace Matrix	N/A	N/A	Software Trace Matrix

Perform a Gap Analysis

Ref	Software Lifecycle Process	Procedures				Templates				Project Evidence
		Document Number	Procedure Name	Section Number	Section Name	Document Number	Template Name	Section Number	Section Name	Document Name and/or Evidence Location
5.5.2	**Establish Software Unit Verification Process**	-	-	-	-	-	-	-	-	-
5.5.2	The manufacturer shall establish strategies, methods and procedures for verifying the software units. Where verification is done by testing, the test procedures shall be evaluated for adequacy.	P-7314	Software Development Procedure	6.8.3.2	Software Design and Technical Reviews	F-7341c	Review Meeting Minutes - Implementation	N/A	N/A	Per project SDP, Review Meeting Minutes and/or Pull Request data in BitBucket

No Documented Process?

- Everyone has a process
- Interview and document
- Track which teams said what

Remediation

- Base process
- Add more details as you progress
- Templates as needed
- Reviews, retrospectives, and updates

Align with FDA/EU

Align with FDA / EU – Terminology & Process

- Match terminology
  - SDD and SDS
  - SOUP and OTS/COTS
  - Software unit, item, system and components, modules, sw functions
- Add missing terminology / process elements
  - Design Controls – review, design input, design output, verification, validation
  - Design History File
  - Risk Management File
  - Cybersecurity

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Establish Comprehensive Documentation

Comprehensive Documentation - Process

- Cover all requirements
- May match text word for word but must also include the “how”
- Indicate your evidence
- Explain how the activities of 62304 fit into your SDLC model
- Show/Describe alignment with product development

Comprehensive Documentation - Process

5.2.6	The manufacturer shall verify and document that the software requirements:
5.2.6 a)	implement system requirements including those relating to risk control;
5.2.6 b)	do not contradict one another;
5.2.6 c)	are expressed in terms that avoid ambiguity;
5.2.6 d)	are stated in terms that permit establishment of test criteria and performance of tests;
5.2.6 e)	can be uniquely identified; and
5.2.6 f)	are traceable to system requirements or other source.

Comprehensive Documentation - Project

- Do not wait until the end
- **Evidence of performing activities**
- Keep documentation up to date

Comprehensive Documentation - Project

- Develop and use templates
  - Add text that is similar across projects
  - Provide instructions
  - Optional/required sections / indicate criteria

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Consider Iterative/Evolutionary SDLC Models & Practices

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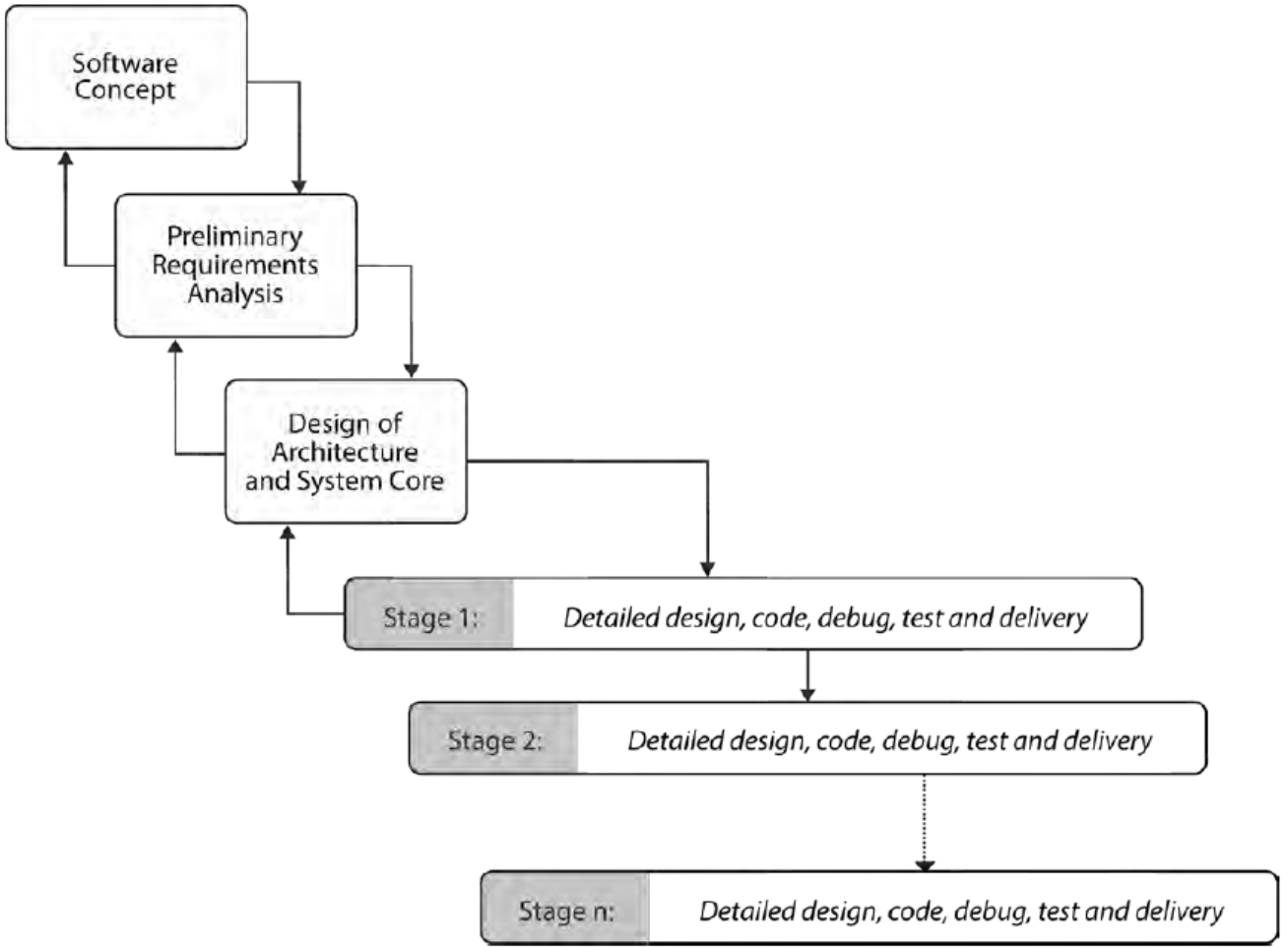
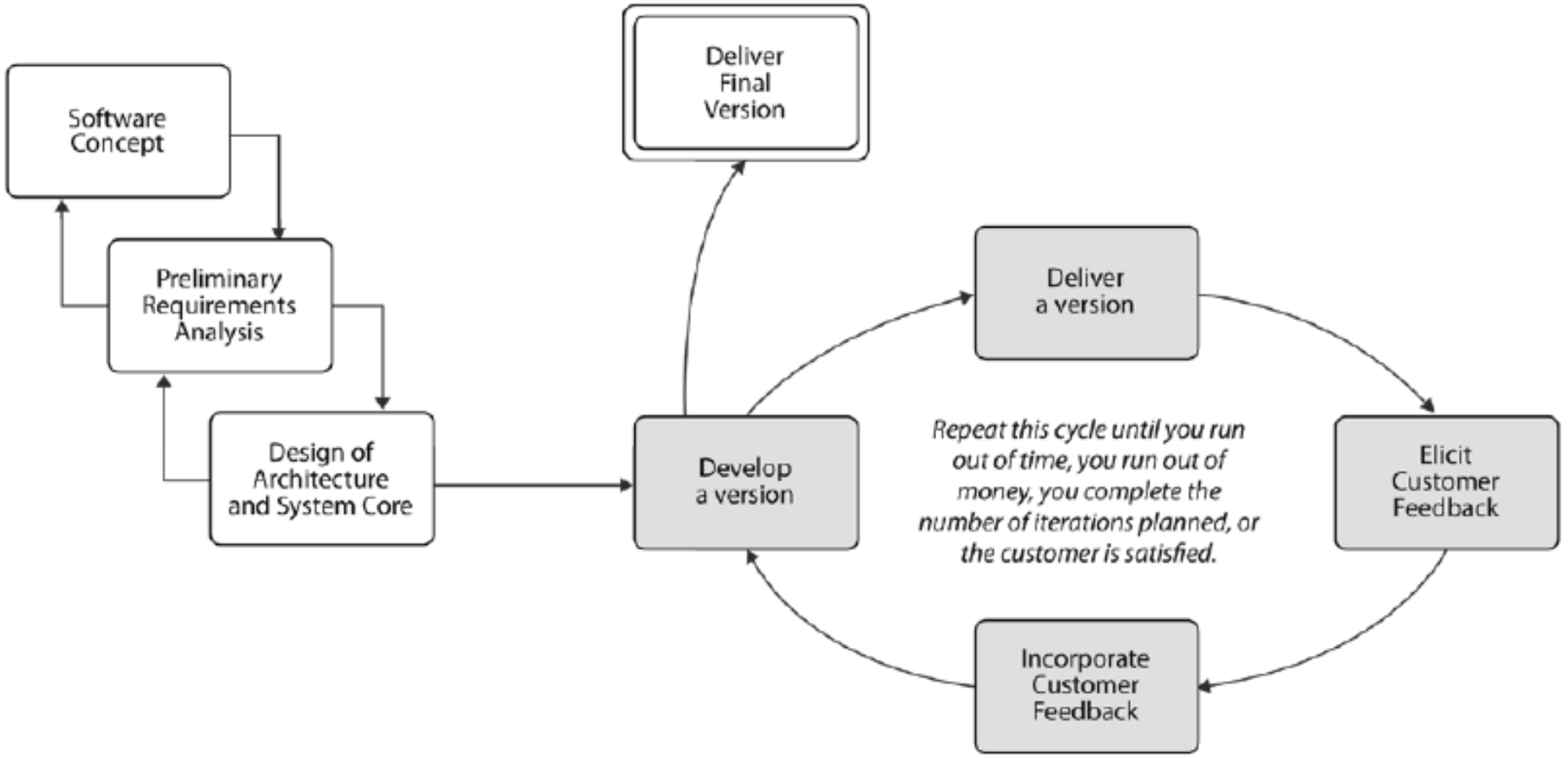
SDLC Models

- IEC 62304 does not prescribe an SDLC model
- May appear waterfall-ish but doesn’t have to be
- Agile - Scrum, Iterative, Incremental, Evolutionary
- Time-boxed iterations versus variable-sized iterations

SDLC Models – Iterative



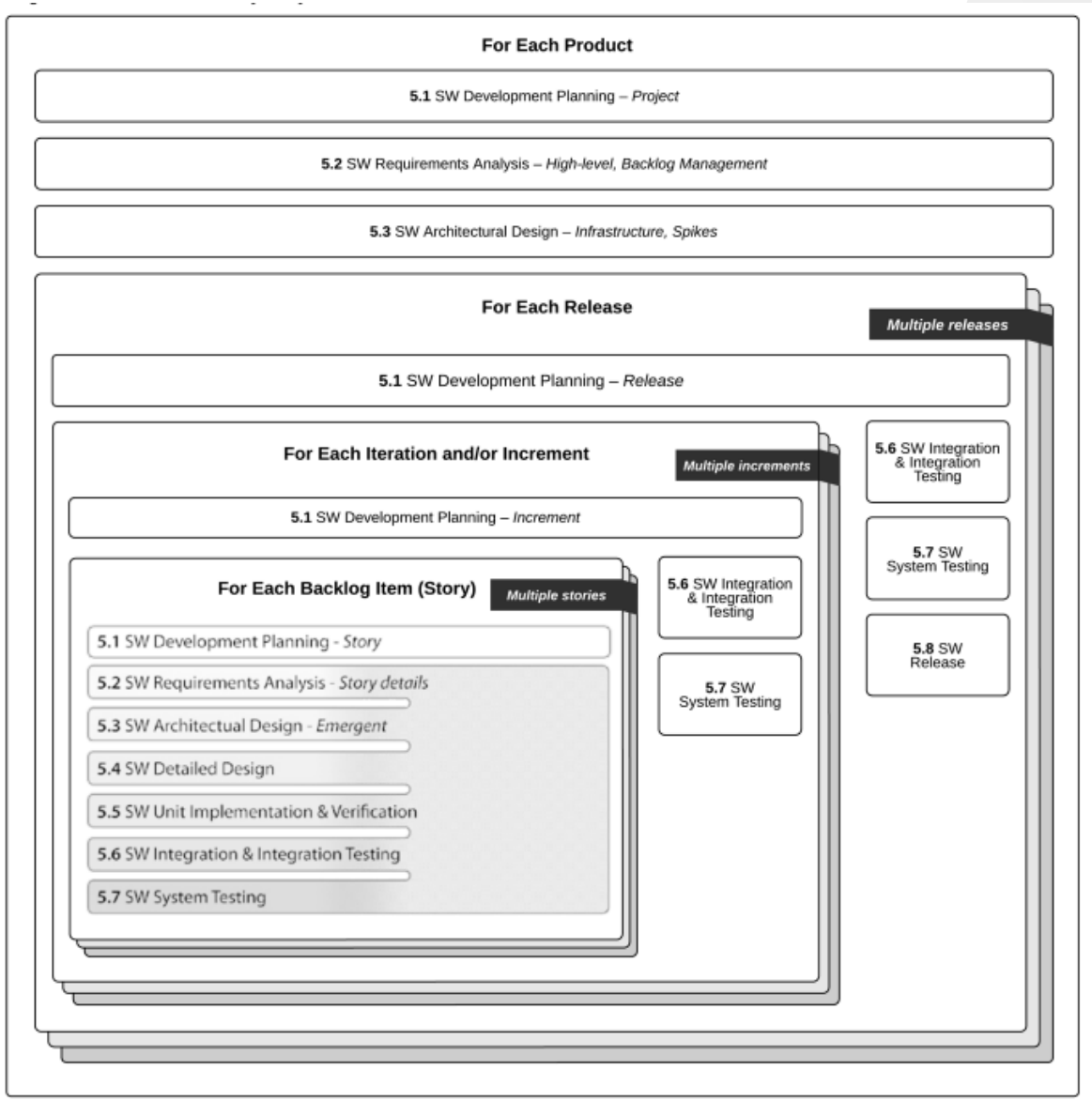
SDLC Models – Evolutionary



Benefits

- Frequent iterations and feedback loops
    - Early detection and resolution of issues (product, process, people, documentation)
- Promotes collaboration – team, client, customers
- Better documentation
    - More refined and details when we know more

Tips – Utilize AAMI's TIR 45



Tips

- Don’t forget testing and verification of individual stories
- Define “done” – implemented, reviewed, tested, etc.
- Include documentation in your story acceptance criteria
- Modify tools to fit your implementation

Tips

- Plan for formal software verification / system testing
- Gate the start of formal verification
- Deliver or demo iteration releases to clients/stakeholders
- Turn user stories into requirements
- Allow fluidity with other activities like requirements, design, test

Tips - fluidity with requirements, design, test

- Document high-level requirements first, adding more details with each sprint/iteration to allow for correct implementation
- Document initial design (architecture/detailed), adding more details as implemented
- Document test case designs

Promote Awareness & Trainin

Promote Awareness and Training

- Educate, not just read and understand
- Explain the why behind process decisions – the driving regulations, standards, and guidances
- Communicate the benefits of the chosen process elements
- Give time to lessons learned, retrospectives, and other process improvement activities

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Recap: How to develop software that is compliant with IEC 62304

Recap

- Start now
- Determine your current state wrt medical device software development
    - Document your process
    - Perform a gap analysis
- Align with FDA/EU
    - Add process based on regulations, other standards, and guidances
    - Align terminology, connect the dots
- Establish comprehensive documentation
    - Explain the “how”
    - Use templates

Recap

- Employ iterative/evolutionary SDLC models and practices
  - Iterations and sprints
  - Demos and delivery of iteration releases
  - Clearly define connection to 62304 activities
  - High-level to detailed, but don’t forget the details
- Promote Awareness and training

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- Software on any operating system – RTOS, Linux, Windows, Cloud
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- Assessments - Quality System, Technical, Design History File, Product Feature/Environment, Risk File (SWHA, Cybersecurity)
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- Software Tool Validation

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Questions?

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