



Advancing public health with digital regulatory compliance

Virginia Chan

Head of Digital Transformation, APAC

Siemens Digital Industries Software



Siemens at a glance



Operating Companies



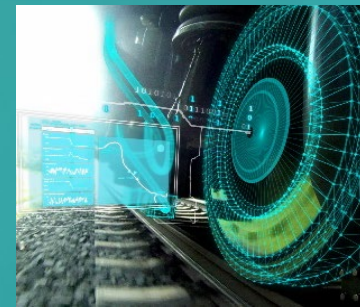
Gas and Power



Smart Infrastructure



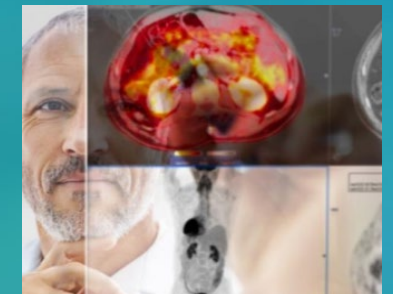
Digital Industries



Mobility



SIEMENS Gamesa
RENEWABLE ENERGY



SIEMENS Healthineers

Service Companies

Financial Services

Global Business Services

Real Estate Services

Global Public Health Challenges call for Safe, Effective use of Software & Digitalization

Global Demographics

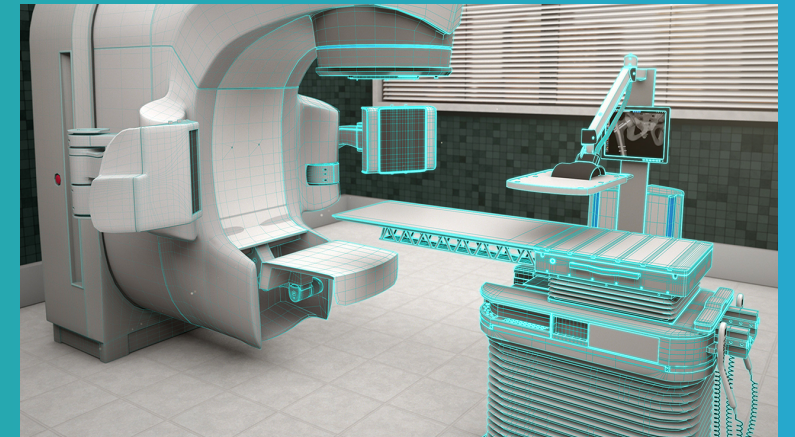
Highest population growth
in regions with least ability to pay
Insufficient HCPs
Familiar chronic disease patterns

Value-based Healthcare

Volume procurement
Reimbursement tied to total
“episode of care”
and patient outcomes

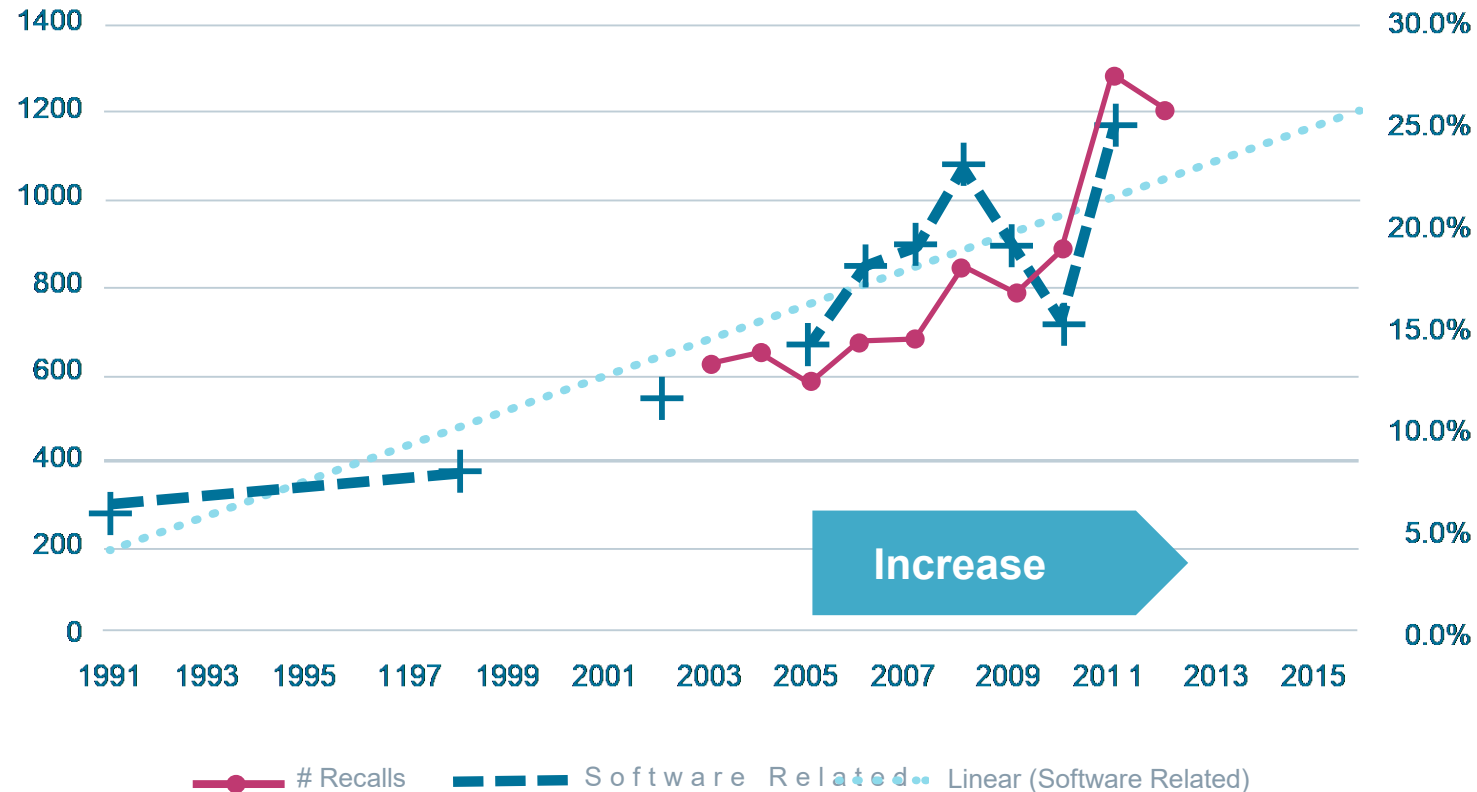
Complexity vs. Maturity

Faster product turns for
differentiation & margin retention
Software-based innovation
Precision medicine
Global Regulatory Variation



Industry performance

Total FDA Recall Events with Software Contribution



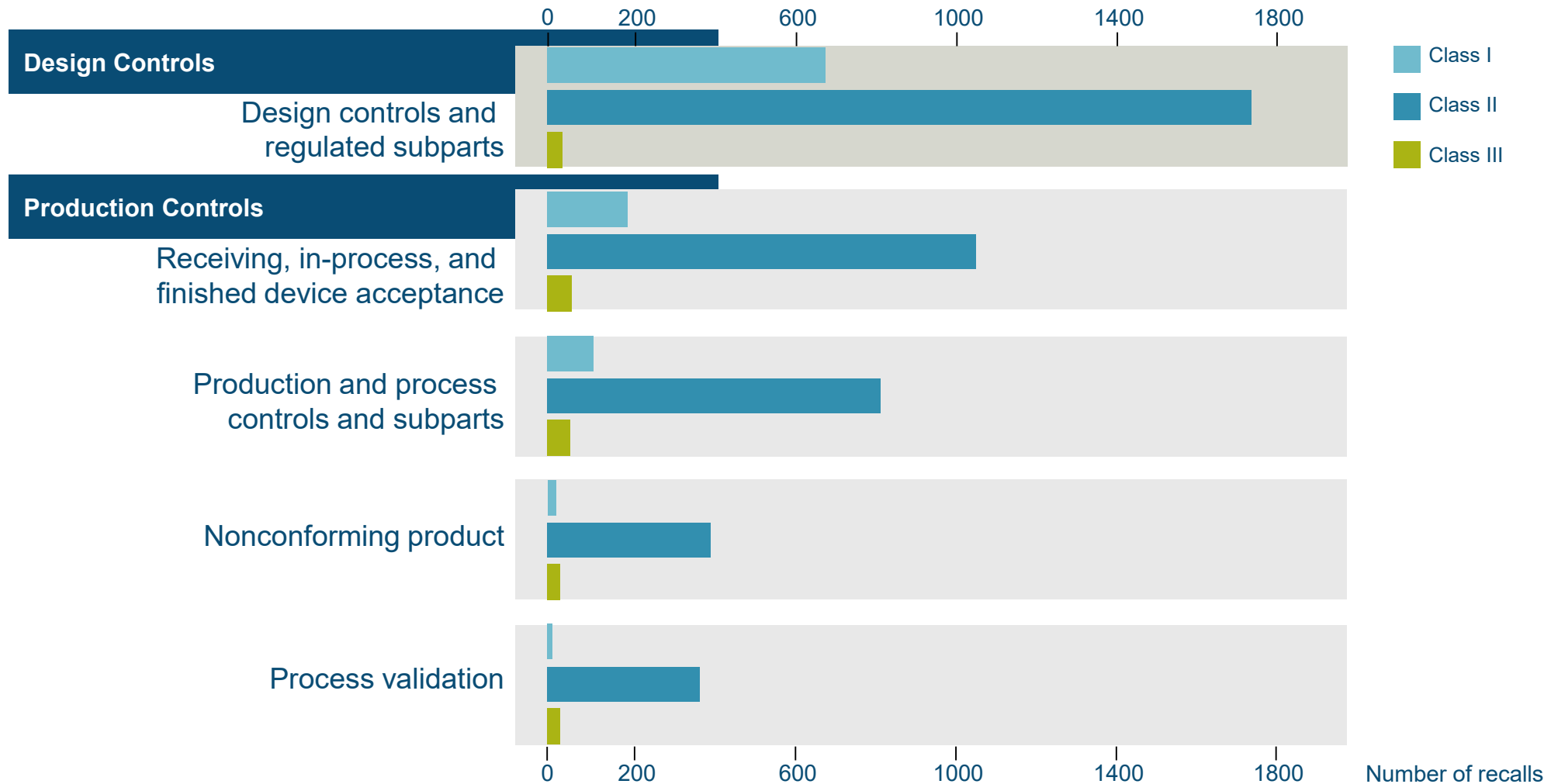
3X
Increase in adverse events

50%
Increase in recall events

120%
Increase in software related recall

Source: Software-Related Recalls: An Analysis of Records
by: Lisa K Simone, Software Engineer with the Center for Devices and Radiological Health at the US FDA

Recall causes by regulation



US FDA's Collaborative Relationship with Industry Ecosystem Stakeholders



Case for Quality

Move from compliance to quality

Digital Evidence

Promote Modeling & Simulation

Digital Regulatory Review

Re-use Existing Digitalization Assets

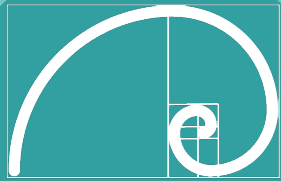
 **Siemens collaborates with FDA to define R&D + Manufacturing best-practice**

2021

**USD136
BILLION**

IoT

Making sense of data is essential...



**GENERATIVE
DESIGN**



**ADDITIVE
MANUFACTURING**



**IIoT
IoT/ EDGE**



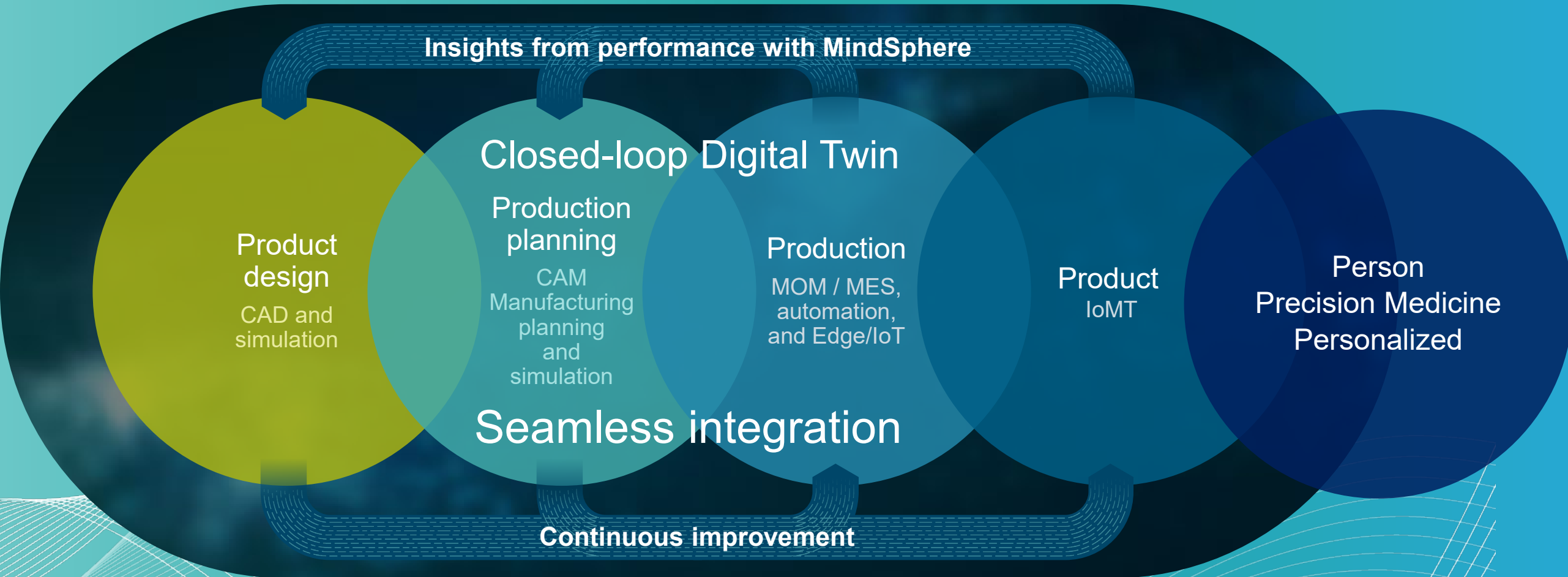
AI



ANALYTICS

...to manage and thrive in complexity.

Healthcare 4.0 – Harness the power of data with digitalization



Medical Device digitalization “blueprint” aligned with Regulatory Requirements

Value Drivers

SIEMENS
Ingenuity for Life

Mindsphere

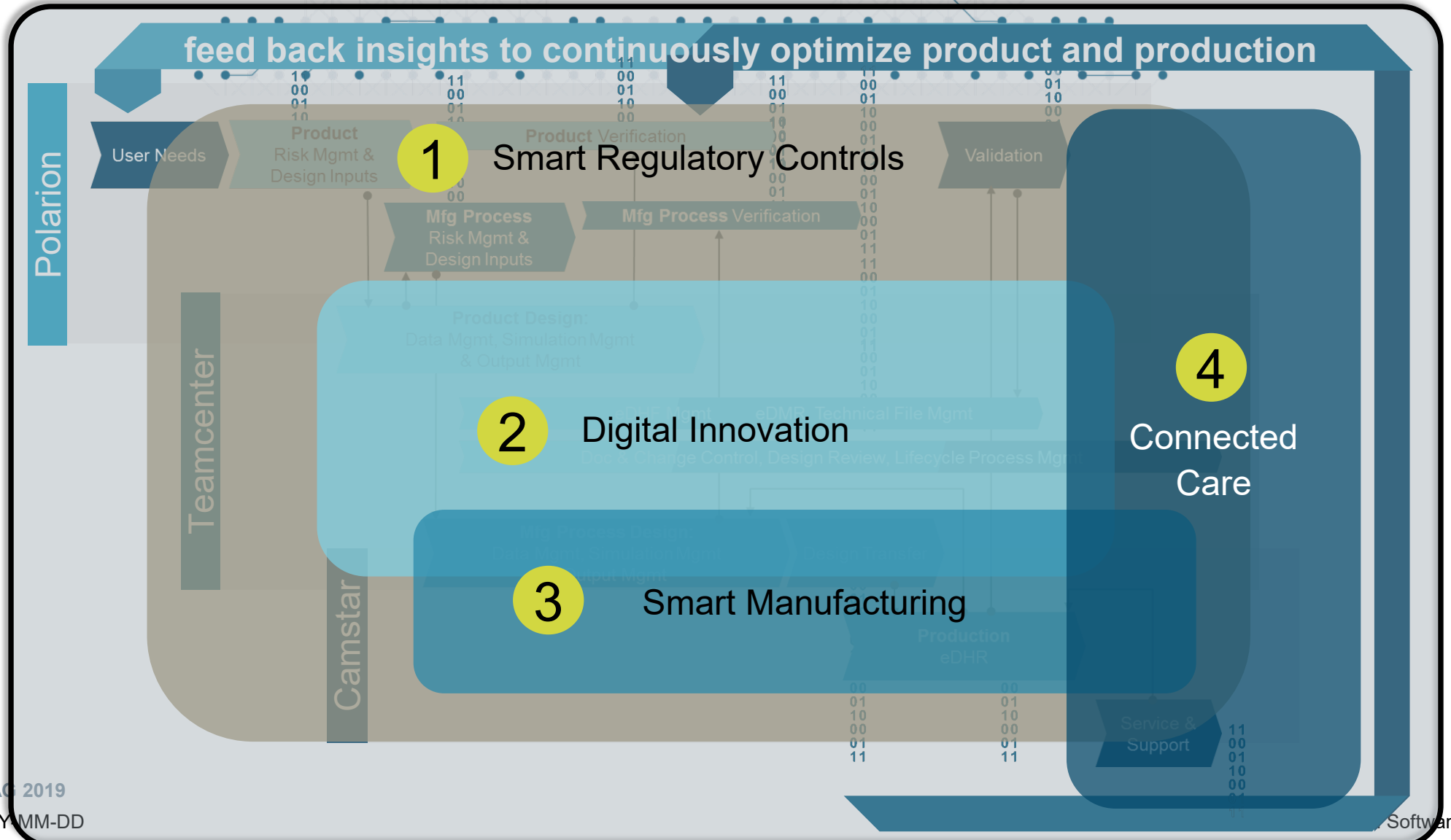
Unique Differentiated Solution

Integrated ALM, PLM, MOM Platform

Industry Catalysts

Multi-disciplinary Engineering Apps

IoT Platform & Integrated Apps



Digitalization

Data-driven, model-based controls for Requirements, Risk, Product Definition, and V&V traceability

Results

Accuracy, predictability, and faster time to market clearance

1 Smart Regulatory Compliance with “Intelligent” Design Control



Stop / Start

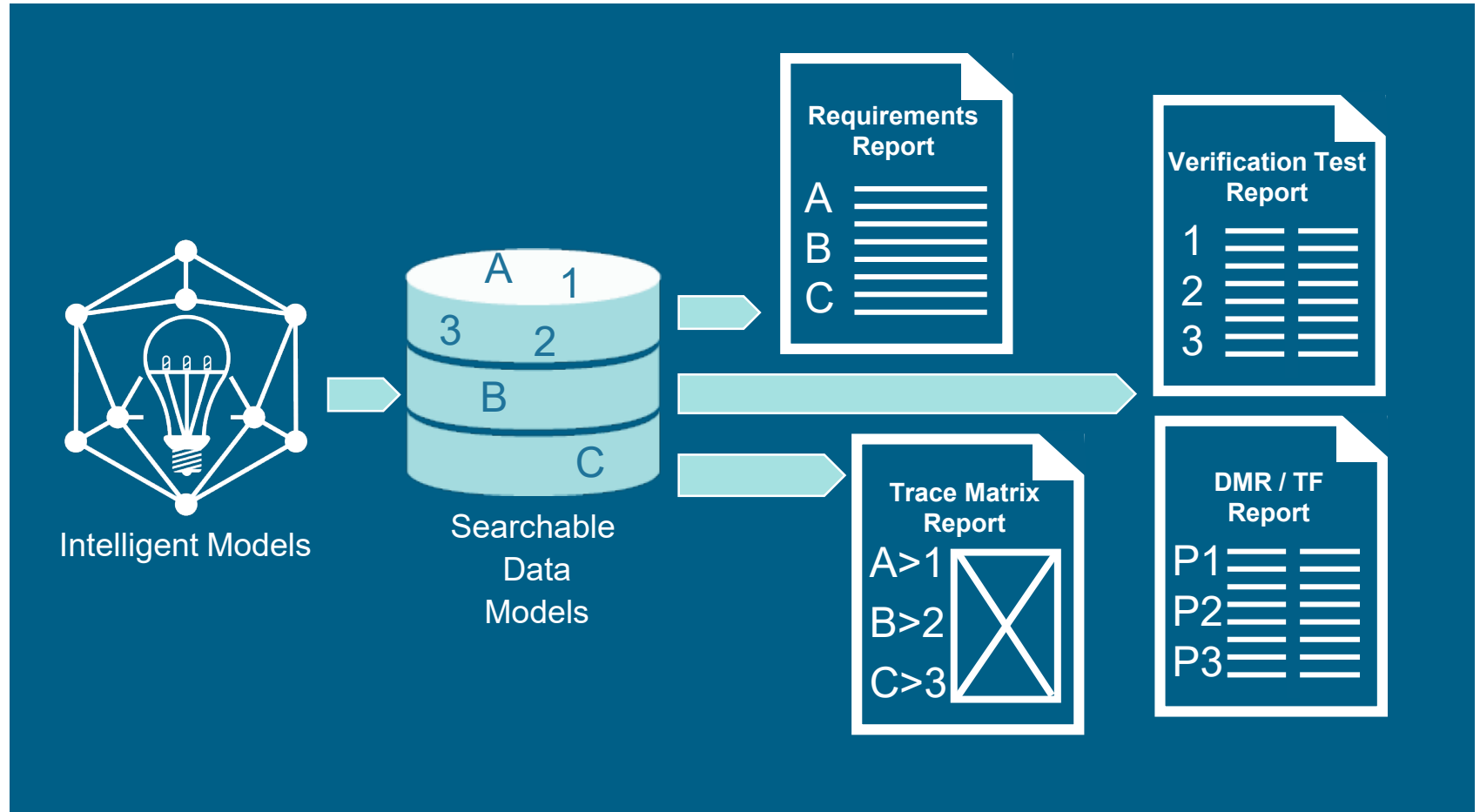
Select

PCA dose

Focus on Design elements – Intelligent Design Control

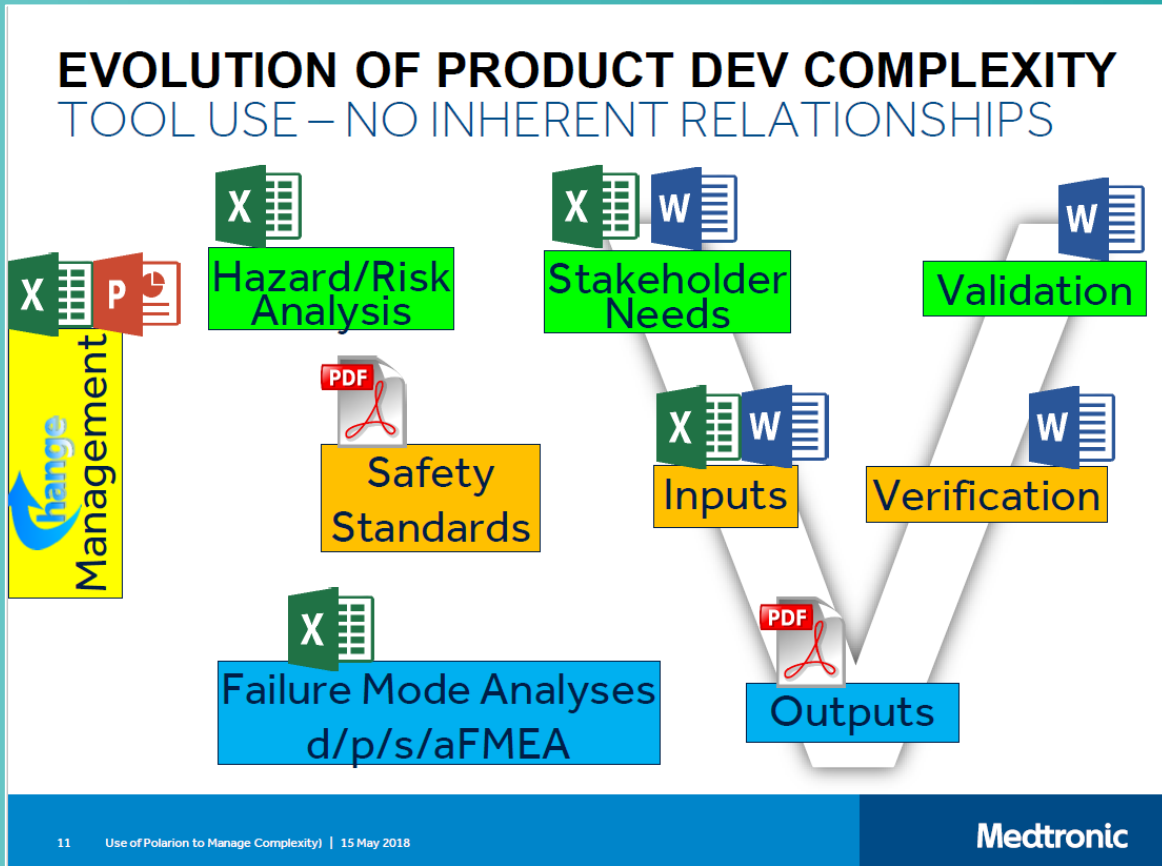
Intelligent Design Control

- Reduces copy mistakes
- Maintains data integrity
- Enables extensive search, re-use, analysis
- Links design elements, e.g., hazard situations to requirements to test cases
- Creates trace reports

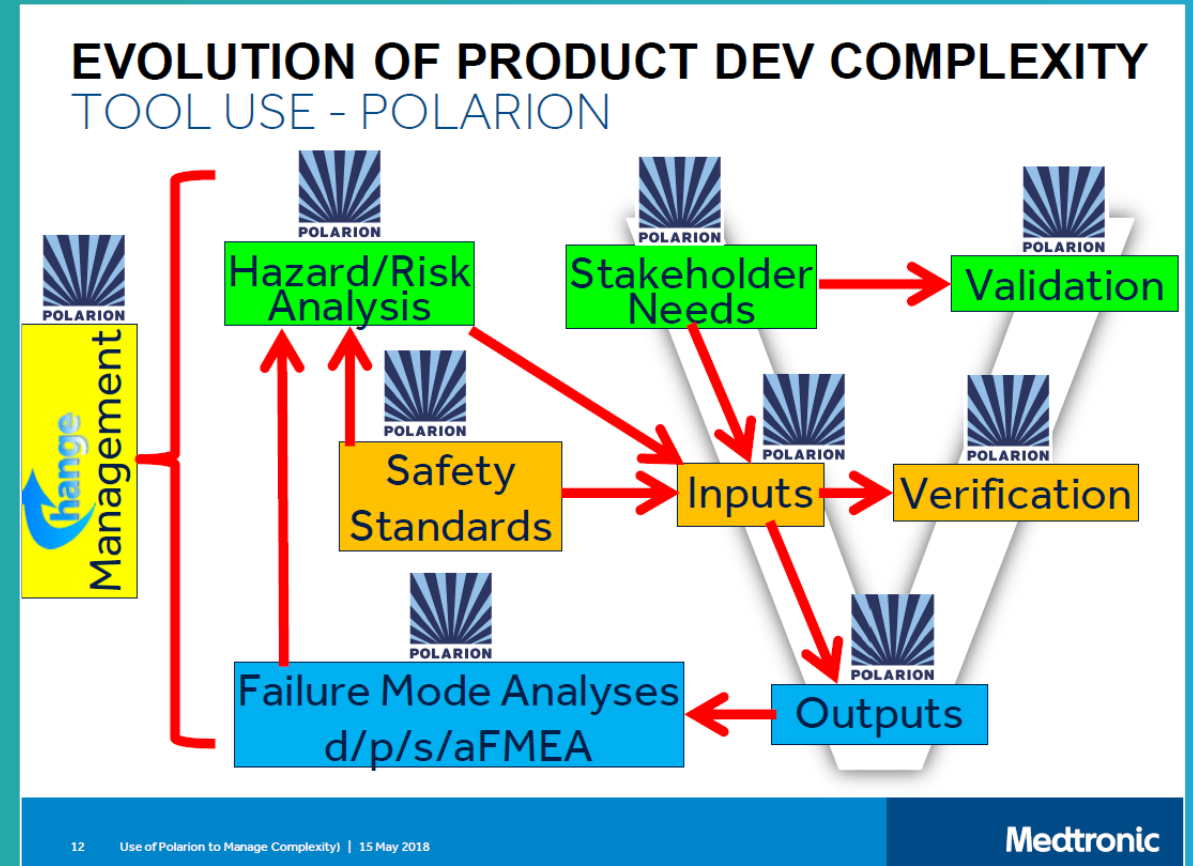


Re-organize design elements for presentation to different stakeholders

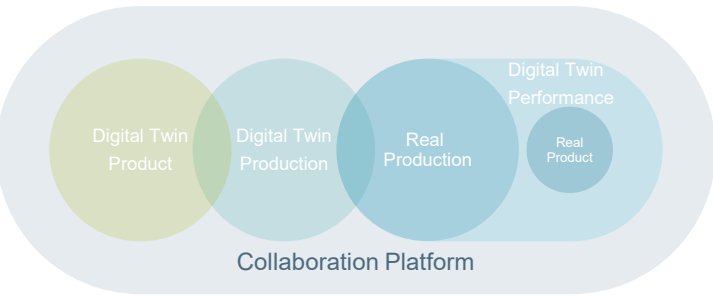
Intelligent Design Control: Integrated Risk Management



Before



After



Requirements Management

Ensure new requirements have appropriate V&V test plans

DFMEA Chart

DESIGN FUNCTION	EFFECT	ROOT CAUSE(S) and RISK CONTROLS	PRE-MITIGATION			
			SEV	Occurrence	RISK INDEX	OCCURRENCE RATIONAL
DMDI-4809 - The device will withstand clinical environment	HS DMDI-6632 - Appropriate power is not available	+	Unanalyzed	Unanalyzed		
	HS DMDI-6637 - System overheats	+	Unanalyzed	Unanalyzed		
DMDI-5876 - The disposable device will be sterile	HS DMDI-6591 - Device corrodes in humid environment	+	4 - Critical	4 - Probable	A	
	RC DMDI-6692 - Metal surfaces are not plated or plating is damaged	+				
	RC DMDI-6693 - Should only be used in low humidity environments	+				
DMDI-6735 - The intended use is for evaluation of red blood cells (at a trace level)		+				
DMDI-6736 - The intended use is for evaluation of glucose (36-820 mg/dL)		+				
DMDI-6739 - The intended user of the device is a trained lab technician		+				
DMDI-6740 - Product will be offered with a throughput of up to 240 samples an hour	HS DMDI-8106 - Throughput slows over time	+	2 - Moderate	4 - Probable	C	
		+				
DMDI-6741 - The use environment will be a clean clinical lab - environment is intended to be...		+				
DMDI-6760 - The intended use is for evaluation of urobilinogen (0.24-5.24 mg/dL)	HS DMDI-8041 - Bubbles in sample	+	4 - Critical	5 - Frequent	A	
	RC DMDI-8042 - Vibration of system causes fluid and gas to mix	+				
	RC DMDI-8043 - Rapid introduction of fluid causes gas mixing	+				
	RC DMDI-8044 - Mixing tip geometry causes gas mixing	+				
	RC DMDI-8047 - The mechanical system will vibrate at a level under 60dB	+				
	RC DMDI-8034 - Software will control speed of fluid introduction	+				
	RC DMDI-8035 - The mechanical system will employ fluid introduction geometry designed to minimi...	+				
	RC DMDI-8045 - The mechanical system will employ a tip that minimizes fluid/air mixture	+				

Digitalization

Multi-disciplinary design collaboration, combined with multi-physics simulations

Results

Optimized performance of competitively differentiated, premium-value devices

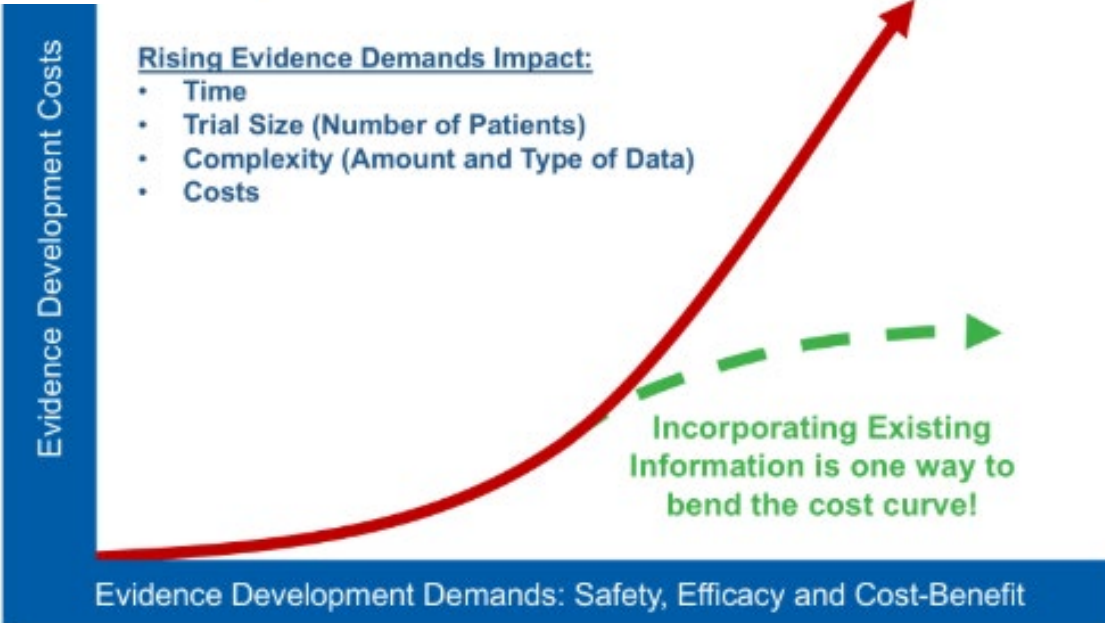
2

Digital Evidence
“4D” Design Excellence

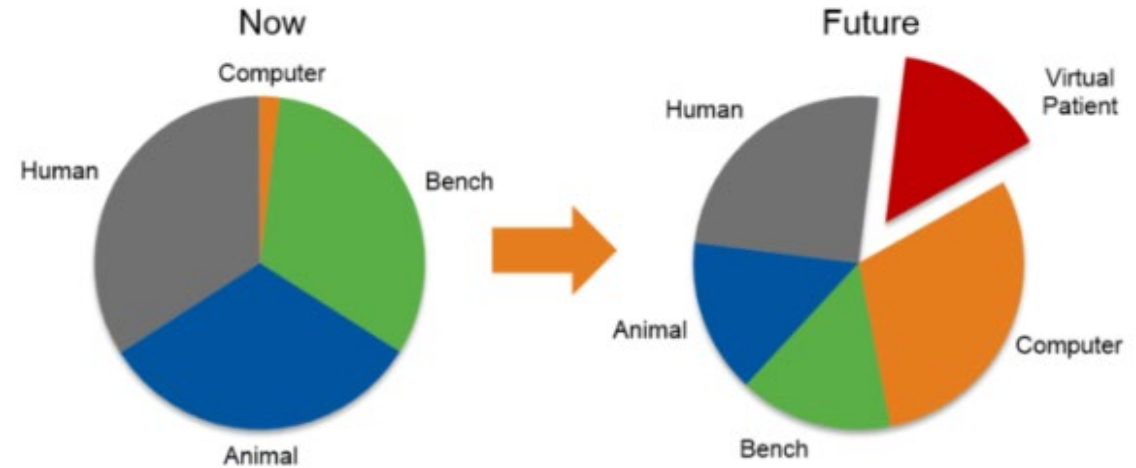
“Digital Evidence” → Use Modeling & Simulation to augment Clinical Trials & Traditional Testing Methods



Current Clinical Data Acquisition Techniques

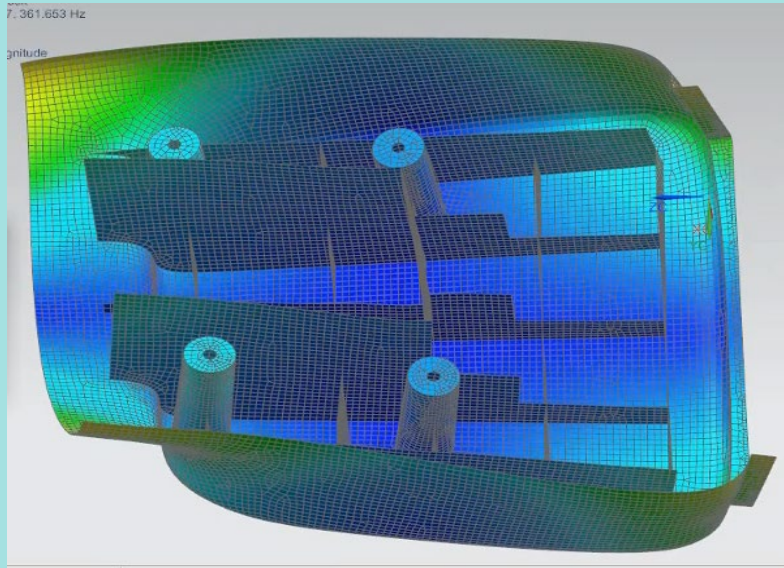


Sources of Evidence

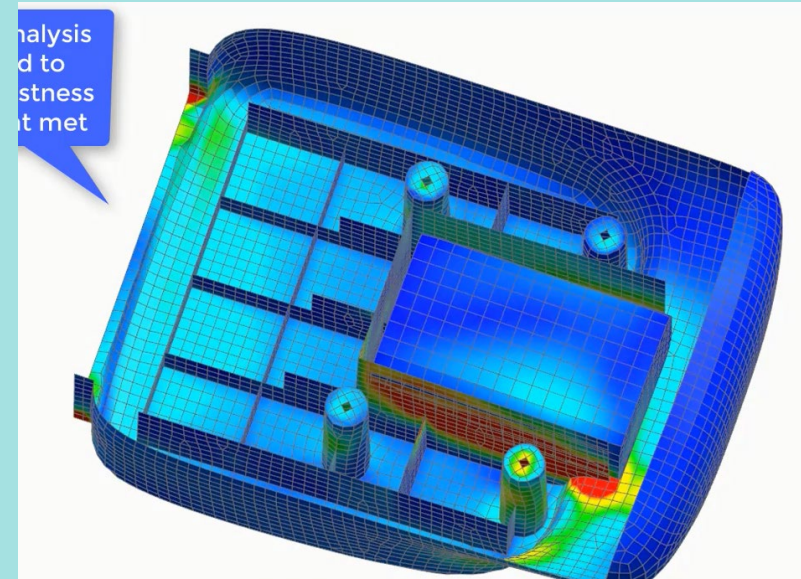


“Classic” Mechanical Modeling & Simulation

Work out Quality Problems early in the Product Lifecycle



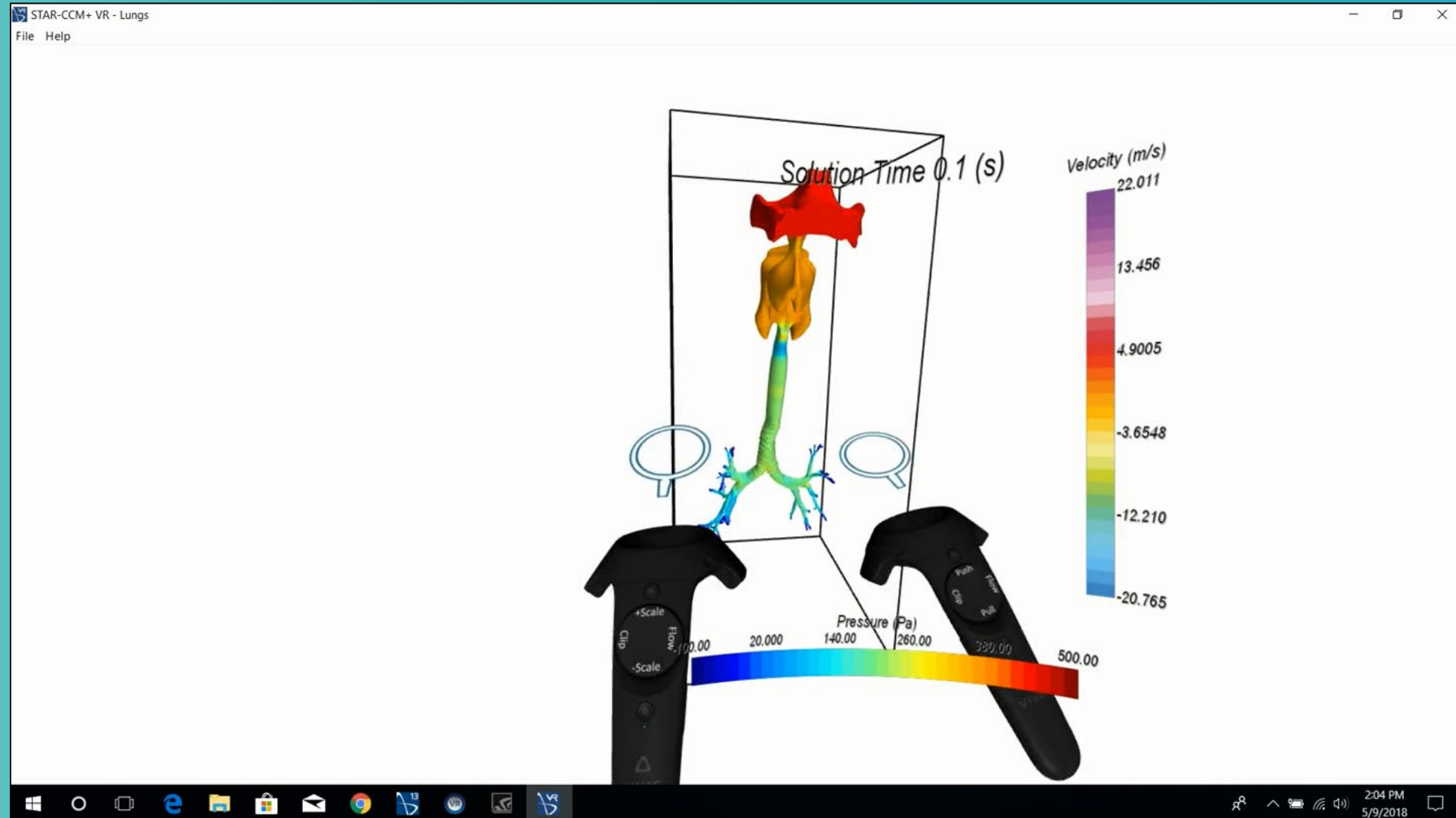
3D Modal Analysis



3D Impact Analysis

Computational Fluid Dynamics (CFD)

VR walkthrough of respiratory anatomy to see predicted physiological behaviors



Digitalization

Use manufacturing models to schedule and execute production, enforcing routes, inspections, and rework

Results

High quality, efficient, and regulatory compliant production & eDHR

3

“Case for Quality” with Smart Manufacturing



Stop / Start

Select

PCA dose

Tasks

mL

Opcenter Execution MD&D (Camstar)

Best-in-class for Medical Device & Diagnostic manufacturers

Main functionalities
and benefits



Camstar Medical Device Suite



Paperless manufacturing
(eDHR)



Identify, analyze and
prevent errors



Advanced planning
and scheduling



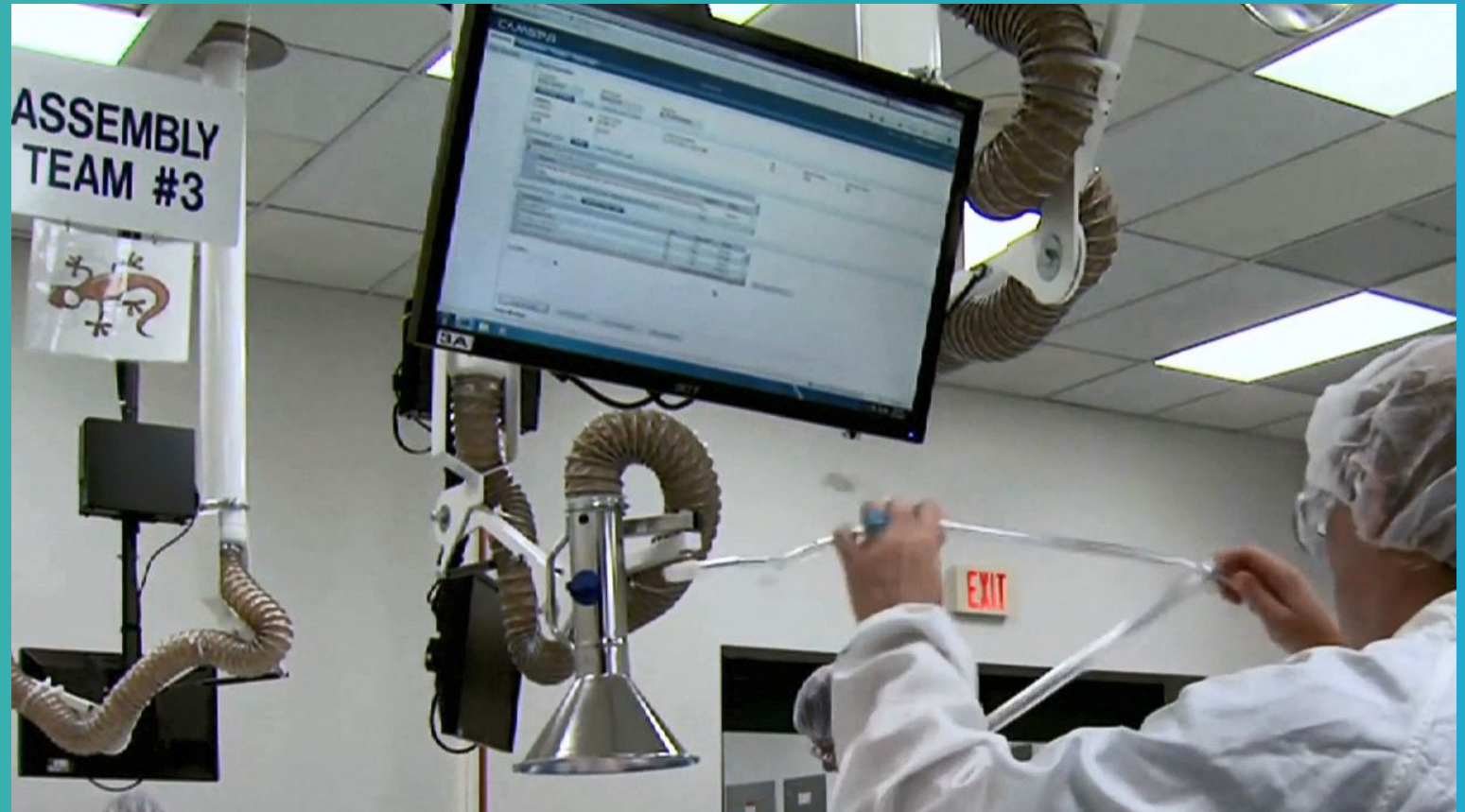
Manufacturing enforcement
and quality (5M)



Closed-Loop Manufacturing
& change enforcement



Single as-built track & trace
record



Digitalization

Labeling fully integrated with product development and manufacturing operations

Results

Error-proofed, efficiently constructed labeling, configured for all countries and regions

4

“End to End”
Labeling & Submissions

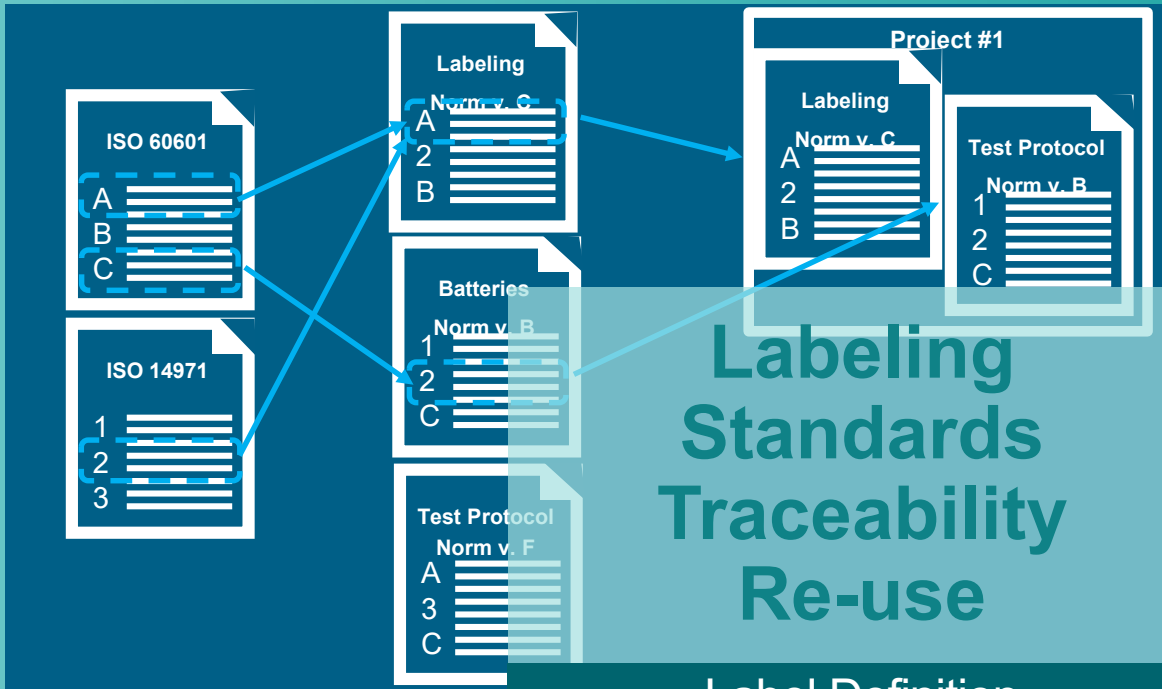


mL
Tasks

Stop / Start

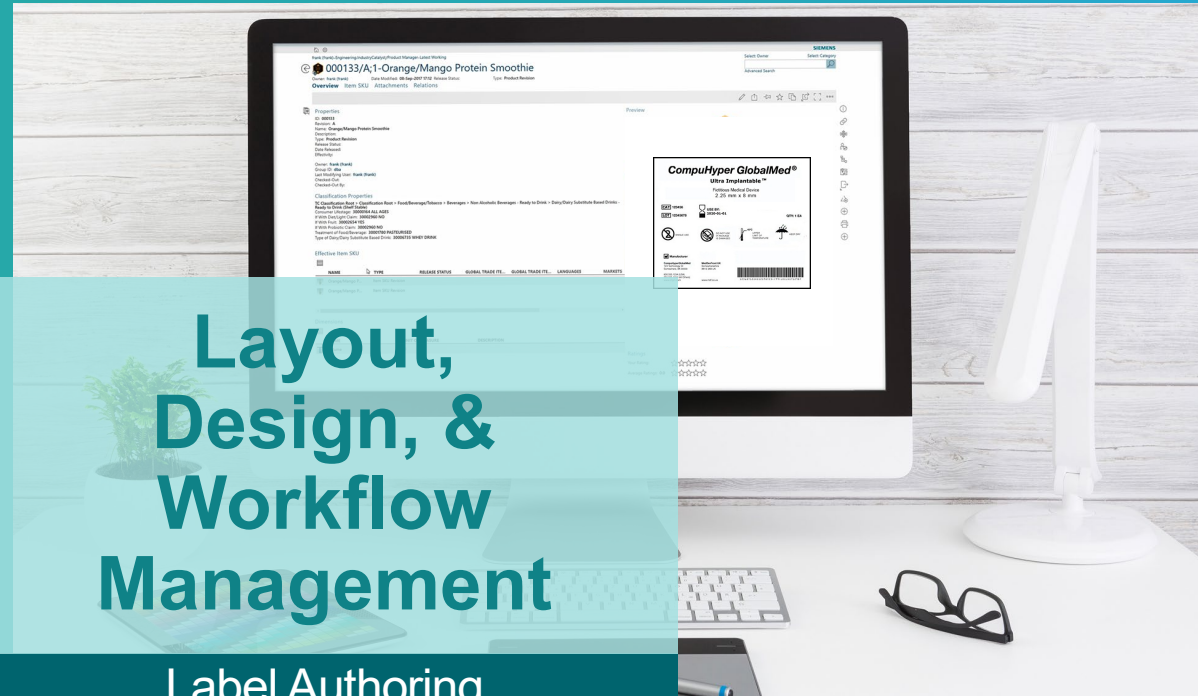
Select

PCA dose



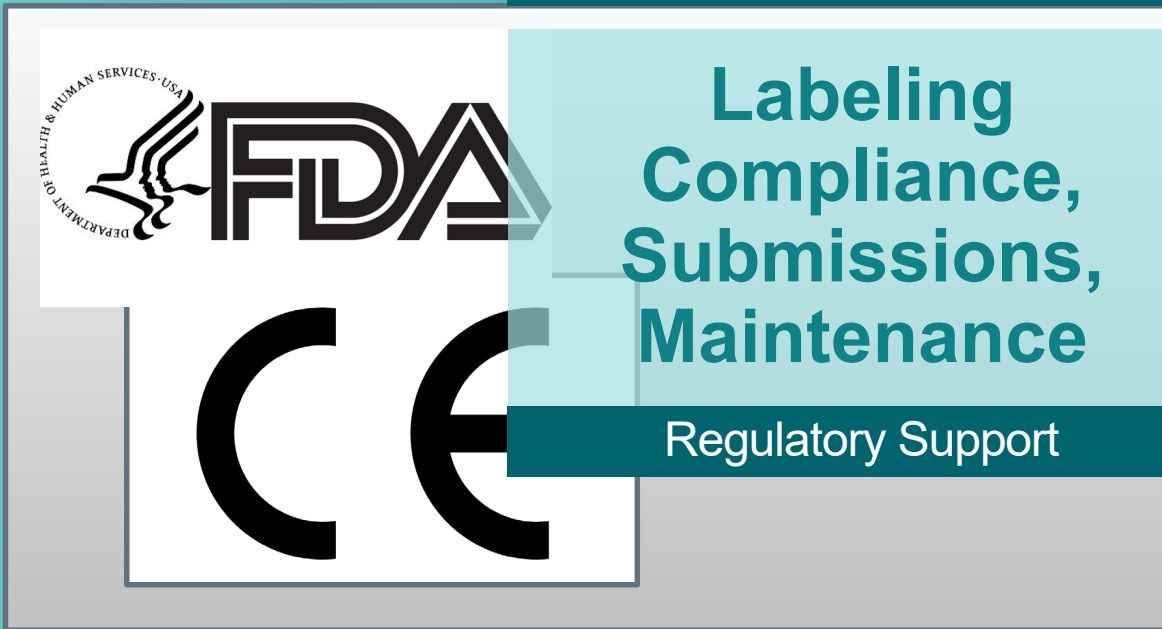
Labeling Standards
Traceability
Re-use

Label Definition



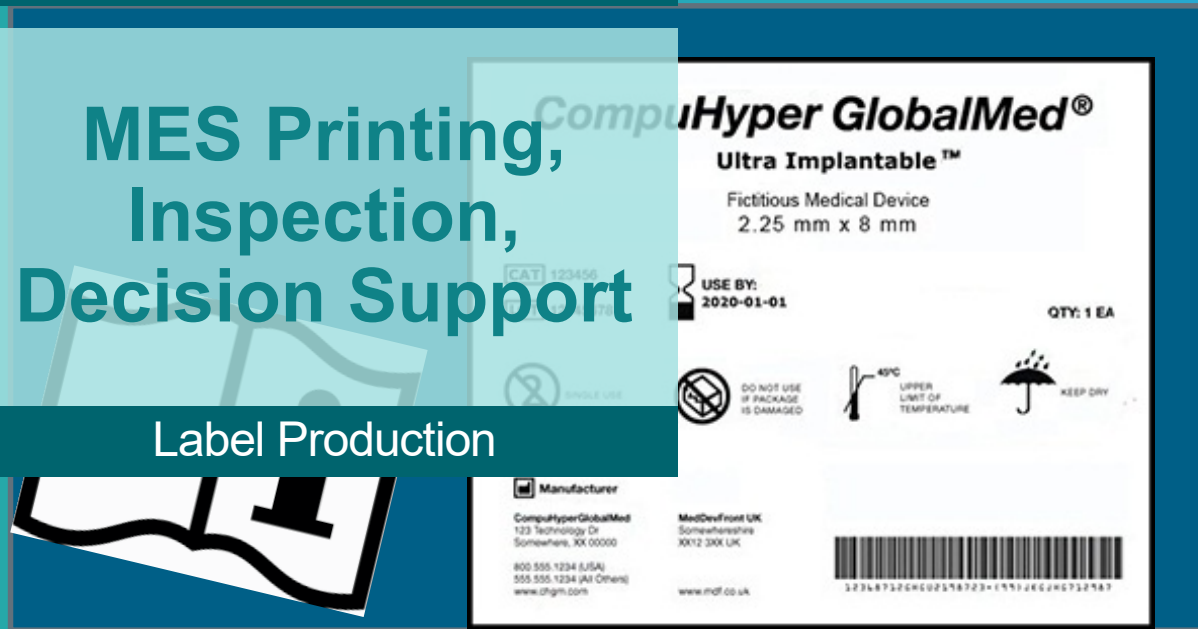
Layout,
Design, &
Workflow
Management

Label Authoring



Labeling
Compliance,
Submissions,
Maintenance

Regulatory Support



MES Printing,
Inspection,
Decision Support

Label Production

Digitalization

Big data analytics
and AI,
to track and predict KPI's

Results

Proactively monitor
and respond to
performance issues,
concerns & complaints

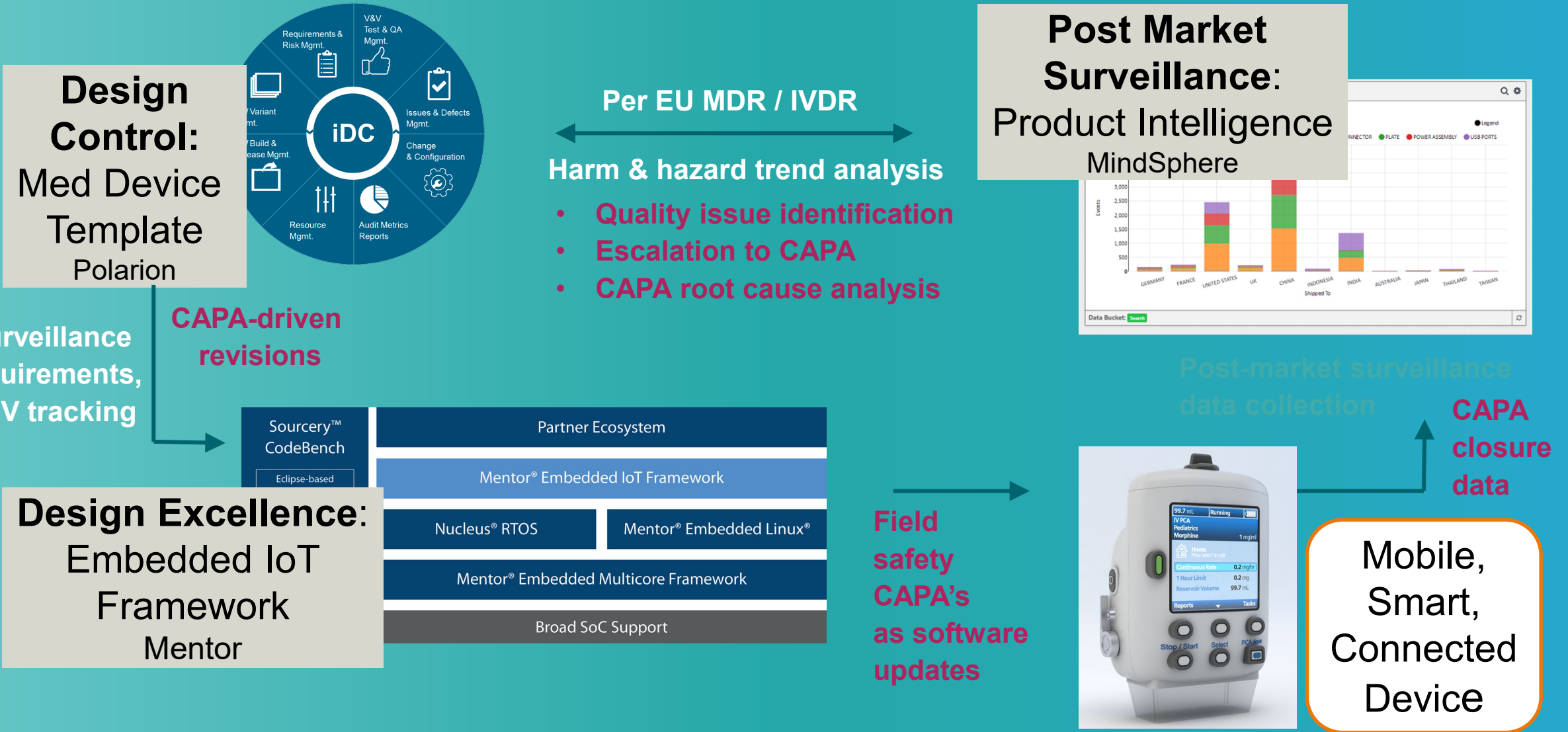
5

“Closed-loop, Predictive”
Post Market Surveillance



Solution: Post Market Surveillance

Closing the loop with Internet of Medical Things (IoMT)



Smart Regulatory Review Process From document to data model process

Challenges of Regulators on Regulatory Review Process



60-70% of regulatory submission in poor quality

Time and capacity wasted in administration

Delays in product introduction

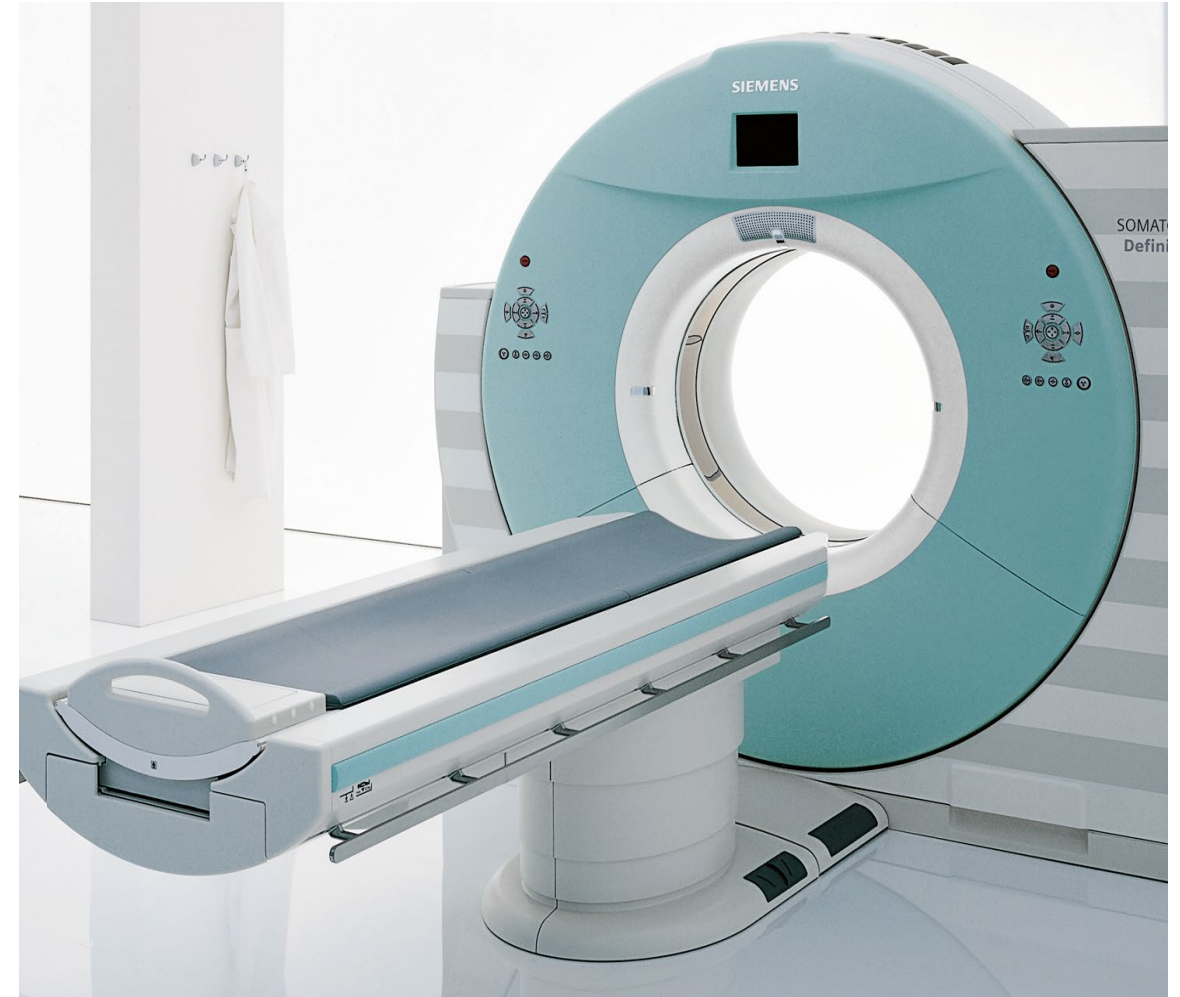
Review Process

Time & Capacity spent on review precedent cases manually

Post Market Surveillance

Design control does not sufficiently address issue
eDHR is inaccurate or incomplete

PMS report is not timely



Digitalization of Regulatory Review Process for faster, better, improved traceability and transparency

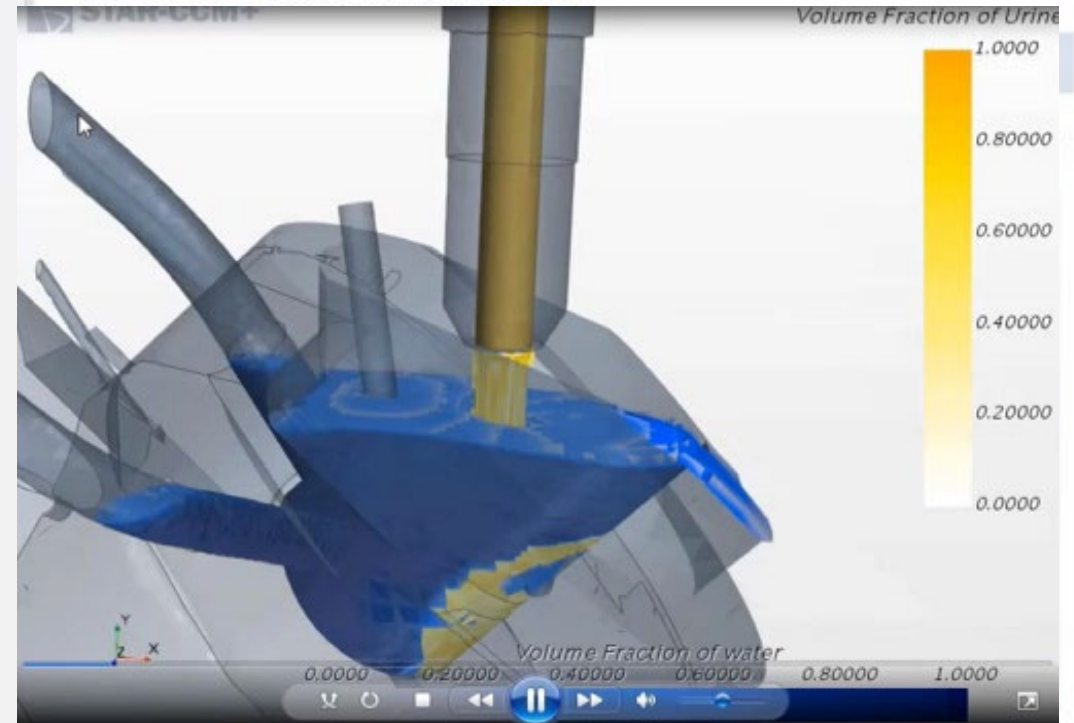


DMDII

Search

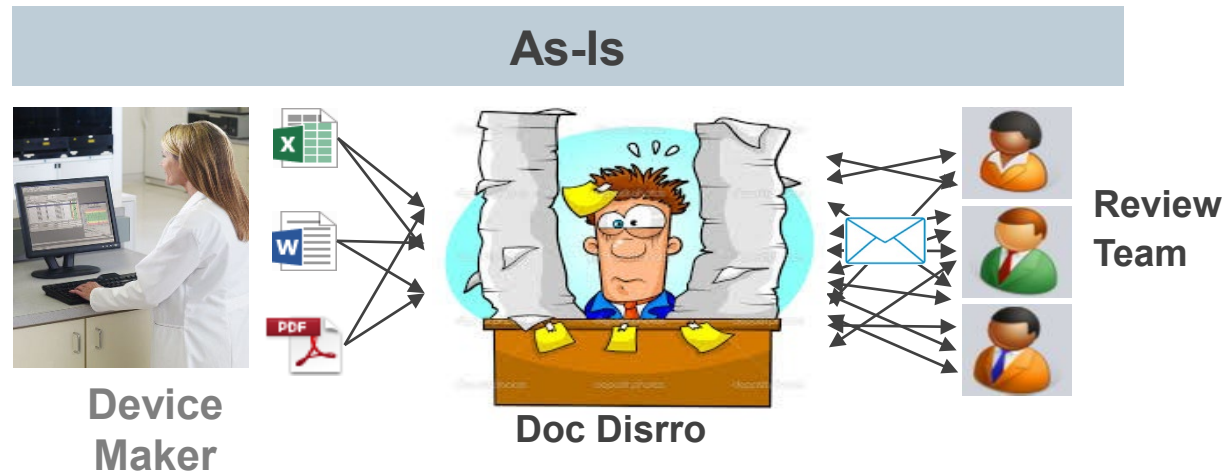
Larry Sampson
My Polarion

- Glossary
- IEC 60601-1-2012
- Images
- Standards
- Template Instructions
- Test Fields
- Sources
- Inputs
- Outputs
- Risk Management File
- Testing
 - Index
 - IFU Test Protocol
 - IFU Test Report
 - Product Test Protocol
 - Product Test Report**
 - Simple Test Run Results
 - Simulation Test Protocol
 - Simulation Test Report
 - Software Test Case
 - test report
 - VandV Test Plan
- Polarion

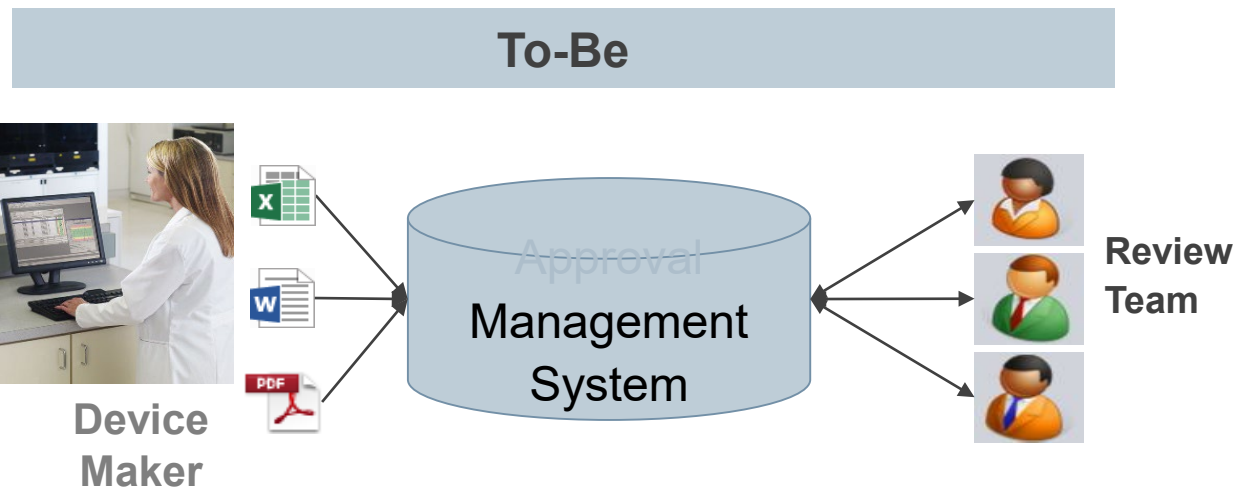


#	Result	Step	Expected Results	Actual Results	
Test Case Id	Result	Test Title	Comment	Execution Date	Executed By
DMDI-6579	Passed	Package vibration testing	Vibration testing complete - preliminary result shows compliance with 60dB levels	Fri Jun 29 22:22:47 UTC 2018	Larry Sampson

Digital Document Submission ≠ Digital Process

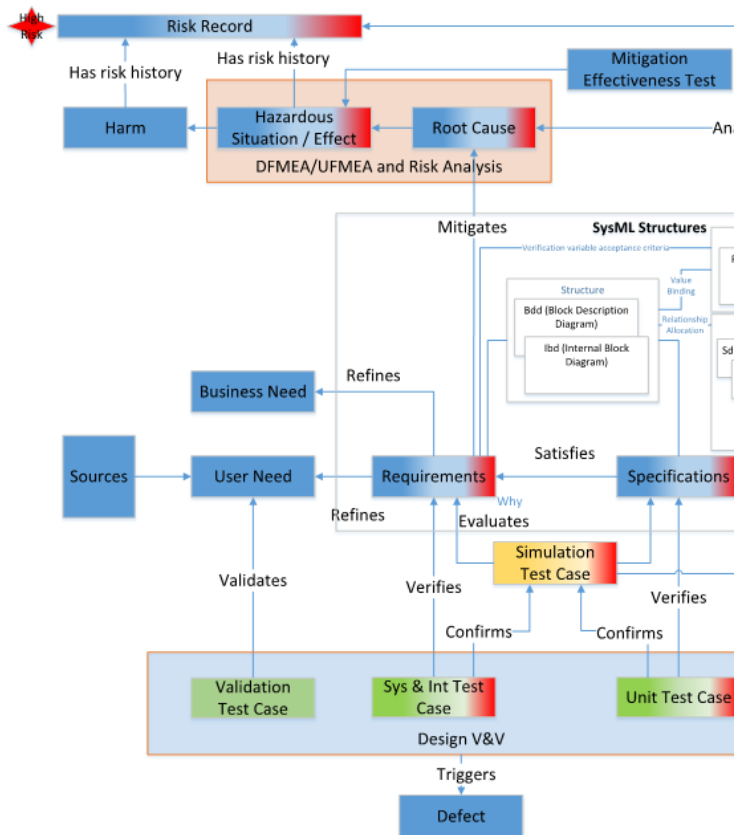


- ▶ Manual Import, Classification, Compare
- ▶ Document (paper) based
- ▶ Request/Monitor by e-mail and phone
- ▶ Manual change history tracking



- ▶ Automatic Import, classification, compare
- ▶ System based with workflow
- ▶ Real time visibility
- ▶ Change history tracking

Automatically Organize Data In The Regulated Format



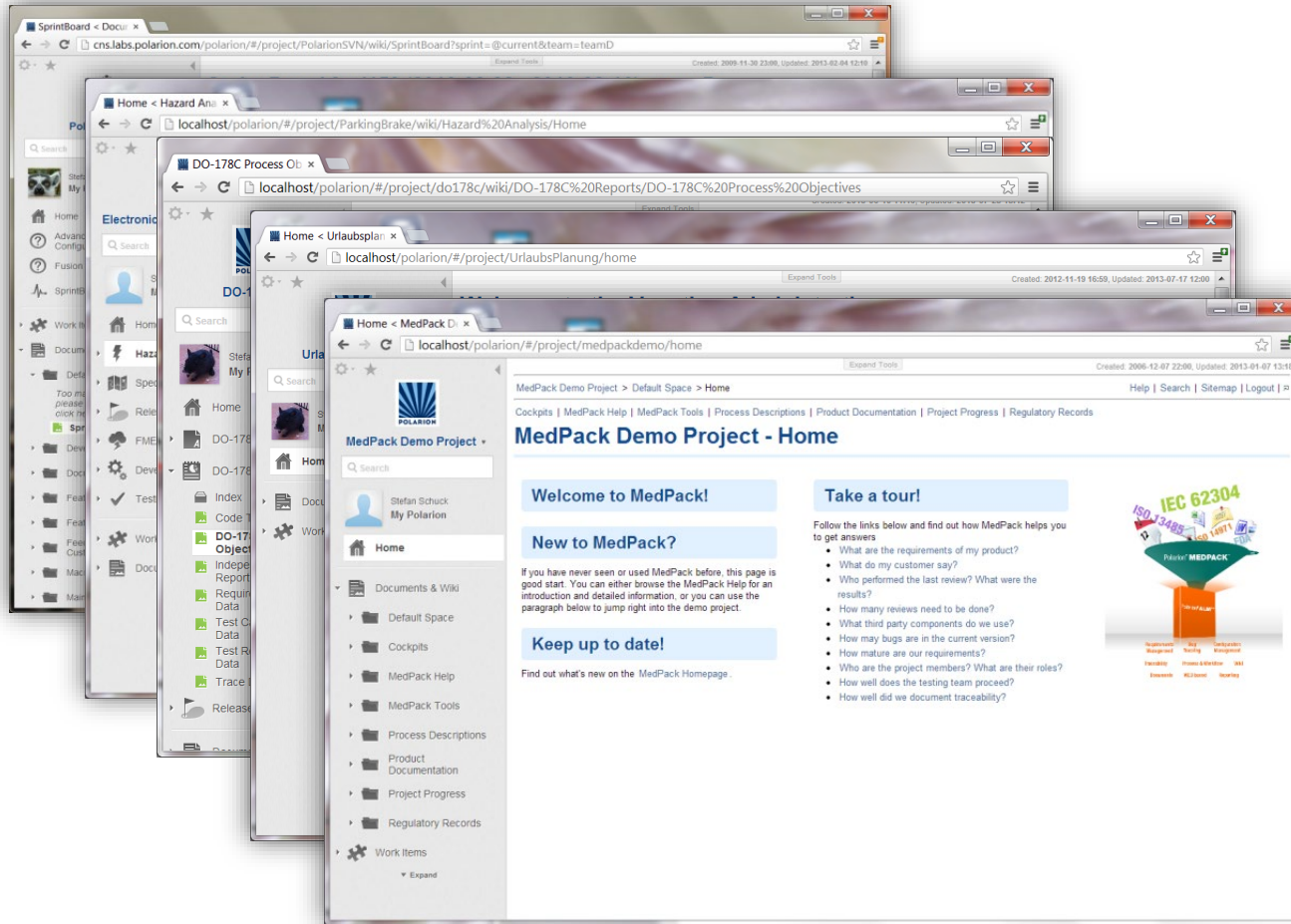
Data Model & Digital Process that Sorts, Organizes, Links, and Classifies All Data

- ▶ Product Sources
- ▶ User Needs
- ▶ Product Requirements
- ▶ Test Cases
- ▶ Risk Analysis (Harm & Hazardous Situations)
- ▶ Post Market Feedback
- ▶ Outputs
- ▶ And more...

eDHR (BOP)

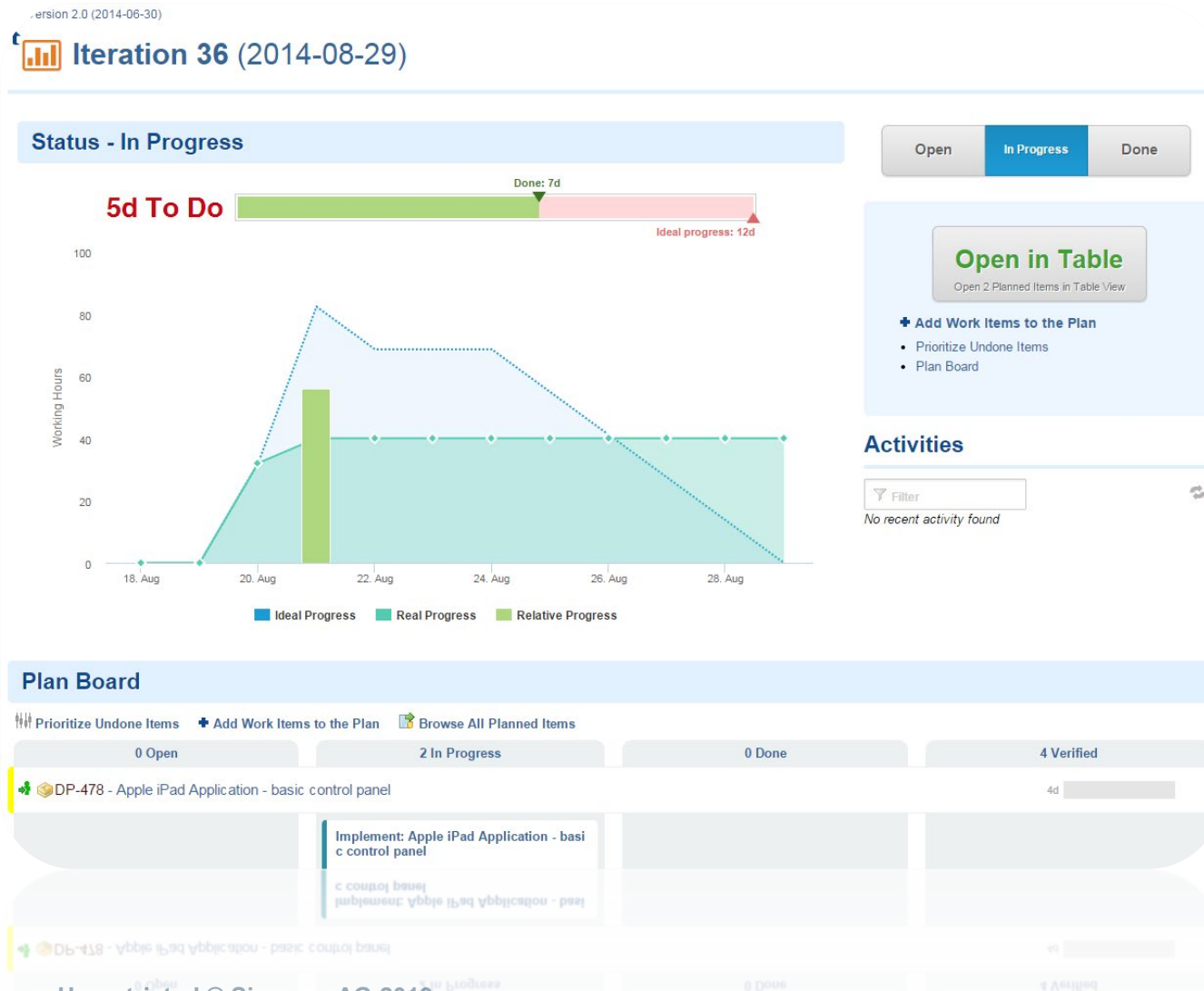
Standardized Regulatory Workflows Governing the Process

SIEMENS
Ingenuity for life



- ▶ Processes for device classes:
 - ▶ II/III/IV
- ▶ In –VITRO Diagnostics
- ▶ Local Manufacturers Application
- ▶ General Medical Devices
- ▶ Adverse Incident Report
- ▶ etc

Visibility & Reporting, Dashboard



Clearly Display, Share and Collaborate

Open and closed items

Verified and completed items

Estimated complete date(s)

Assignee & owner

Automatically calculate and estimate a release date

Reporting Project Status – Approximate approval release

Dashboard

Hydraulic Hybrid Vehicle

Sam Silverans (Admin)
My Polaron

Home
Dashboard
Assets
ISO 26262
Requirements
Development
Testing
Work Items
Documents & Pages

My Triggers
Info: List of my triggers, ordered by status and priority.

ID	Title	Status	Priority	Assignee(s)
0 items found				

Work Items without Parents
Info: List of all work items currently lacking a parent.

ID	Title	Type	Status	Severity
EN-1145	The controller must be stimulated by a Driver_Inputs_Layer to simulate the input	Requirement	Approved	Must Have
EN-1143	During virtual testing, the controller must interact with a Plant_Layer to simul.	Requirement	Approved	Must Have

2 items found

My Open User Stories
Info: List of all my Work Packages that are not part of a sprint.

ID	Title	Linked Work Items
----	-------	-------------------

My Contribution Group Effort

Project Activity (60 days)
Info: Daily trend of all created and updated Work Items.

Updated Work Items (orange line), Created Work Items (green line)

almdemo.polarion.com

Release Report

Release Item: EL-196 - Release 1.0
Release ID: EL-196
Release Plan: Version 1.0 (2017-03-31)

Release QA: Mark Test
Release PM: Robert Project
Status: Feature Frozen

Feature Freeze Date: 2017-01-31
Code Freeze Date: 2017-02-27
Public Launch: 2017-03-31

Build ID:

QA Assessment

Definition of Done

- 25% Epics Done and Meet Acceptance Criteria**
All targeted Epics are Verified or Rejected.
4 Epics targeted for this Release
3 not Verified or Rejected
- 34% User Stories Done and Meet Acceptance Criteria**
All planned User Stories are Verified or Rejected.
18 User Stories planned in the Release Plan
12 not Verified or Rejected
- 17% Issues Done and Meet Acceptance Criteria**
All targeted Issues are Verified or Rejected.
6 Issues targeted for this Release
5 not Verified or Rejected
- Release Verification and Validation Done**

E-Library

Jiri Walek
My Polaron

- Specification
 - Index
 - Administration Specification
 - Catalog Specification
 - Epic Statistics
 - Product Specification
 - Requirement Approval Status
 - Requirement Statistics
 - Requirement User Story Coverage
 - User Story Statistics
- Planning
 - Index
 - Release Report
 - Releases
 - Unplanned User Stories
- Development
 - Index
 - Development

Document Workflows & Signatures

The screenshot shows a document management interface for 'Drive Pilot System Requirements Specification'. The document is in 'Draft' status, version 4.1, created by David Merrill on 2013-04-30. The interface includes a sidebar with navigation options like 'Home', 'Concept', and 'Requirements'. A 'Signatures' panel on the right shows a list of users and their actions: 'Reviewed' (Status Change Not Available) signed by Andy Holton and David Merrill, 'Declined' (none), and 'Invited' (Brian Kennedy). Below the document details, there are sections for 'Approved Versions', 'Reviewed Versions', and 'Document Signatures'. The 'Reviewed Versions' section lists three versions: 10821 (2015-04-14 11:31), 1.0 (2015-04-15 10:34), and 2.1 (2015-04-24 13:03). The 'Document Signatures' section shows a signature by Jean François Thibeault on 2015-04-14 11:31.

The workflow diagram below the screenshot illustrates the document lifecycle. It starts with 'Draft' (pink box). From 'Draft', users can 'Send for review' to 'In Review' (pink box), 'Route for obsolete' to 'Routing for Obsolete' (yellow box), or 'Back to Draft'. From 'In Review', users can 'Route for approval' to 'Routing for Pre-Approval' (pink box) or 'Back to In Review'. From 'Routing for Pre-Approval', users can 'Pre-Approve' to 'Pre-Approved' (blue box), 'Reject' to 'Rejected' (red box), or 'Back to routing for approval'. From 'Pre-Approved', users can 'Approve' to 'Post-Approved' (blue box). From 'Rejected', users can 'Back to Draft'. From 'Routing for Obsolete', users can 'Make obsolete' to 'Obsolete' (yellow box) or 'Back to Draft'. From 'Obsolete', users can 'Create new draft'. From 'Post-Approved', users can 'Create new draft'.

Document lifecycle control

Linked and bound together with workflows

Workflow change signatures

Multiple stakeholders for status change control

Electronic signatures conform to FDA CFR 21 Part 11

Flexible, configurable, and customizable

► Application → System Requirements → Design Inputs → Test Results → Recalls

► Ensure complete coverage and adherence to processes

► Consistent and predictable

► Clearly define “complete”

Polarsion Software
http://www.polarsion.com Drive Pilot (AP) System Requirements (rev. 1.000)

System Requirements Specification

3 Requirements

3.1 General Operations

WI-010 - DrivePilot shall easily engage operations while the vehicle is at rest. [✓] Approved, Version 1.0]

WI-014 - DrivePilot may not be engaged while the vehicle is under manual control.

- provide voice authentication
- provide handbrake access
- provide manual backup
- can only be activated by driver

[✓] Approved, Version 1.0]

WI-016 - DrivePilot shall be easy to operate without extensive training. [✓] Draft, Version 1.0]

WI-016 - Before any user may engage DrivePilot on public roads, that user must successfully complete a tutorial and test DrivePilot operation. [✓] Draft, Version 1.0]

WI-017 - DrivePilot will disengage with audible, visual notifications if the following occur:

- Gear change apparatus is manually actuated
- Brake is manually engaged
- User disengages DrivePilot
- Accelerator pedal is manually engaged
- Turn signal is activated

[✓] Draft, Version 1.0]

WI-020 - DrivePilot is NOT compatible with any vehicle that has "auto parking" capability. Some models of vehicles come equipped with capability. Not all models are so equipped, only when correctly optioned out.

Manufacturer	Model
Toyota/Lexus	Plus, LX200
Volkswagen	Tiguan, PassatCC, Golf

[✓] Draft, Version 1.0]

WI-026 - DrivePilot shall operate with input power of 12 Volts, not to exceed 18 Amps with a +/- variance tolerance of 10%. [✓] Draft, Version 1.0]

3.2 User Console

WI-023 - The DrivePilot user console shall have common views in the built-in displays, and alternative console applications. [✓] Draft, Version 1.0]

WI-024 - The DrivePilot user console will operate in the following platforms [✓] Draft, Version 1.0]

WI-026 - Embedded, wired native Console [✓] Draft, Version 1.0]

WI-027 - Apple iPad Application (Bluetooth) [✓] Draft, Version 2.0]

WI-028 - Android Application (Bluetooth) [✓] Draft, Version 2.0]

1 | Page Polarsion ALM 2012 2013-01-28 14:01

Polarsion Software
http://www.polarsion.com Drive Pilot (AP) Software Design Specification (rev. 1.013)

Software Design Specification

1 Introduction

1.1 Purpose

This document describes the design of a DrivePilot software application. Software components described in this document have been identified as needed to implement requirements from System Requirements Specification. Together, it provides the design specification needed to implement the system.

1.2 References

System Requirements

2 Component Design

2.1 User Console

WI-024 - The User Console will resemble a typical dashboard display and include options for system configuration.

2.1.1 DrivePilot iPad Console Application

WI-026 - iPad User interface application can be downloadable through AppStore, but requires authentication code from DrivePilot to download and operate.

WI-027 - DrivePilot iPad console shall connect via secure Bluetooth to DrivePilot Controller.

WI-028 - The connection is established through connect command of Bluetooth v2.0 protocol.

The DrivePilot Android console application

WI-026 - Android User interface application can be downloadable through Google Play, but requires authentication code from DrivePilot to download and operate.

WI-027 - DrivePilot Android console shall connect via secure Bluetooth to DrivePilot Controller.

WI-028 - The connection is established through connect command of Bluetooth v2.0 protocol.

3 Requirements Traceability

1 | Page Polarsion ALM 2012 2013-01-28 14:08

Polarsion Software
http://www.polarsion.com Drive Pilot (AP) Software Test Specification (rev. 1.011)

Software Test Specification

1 Introduction

1.1 Purpose

The Software Test Case Specification document collects the test cases that verifies the Software Requirements. Each test case specifies inputs, predicted results, and a set of execution conditions for a test item.

2 Approach Refinement

The approach described in the following test plan should be used to perform the testing:

- Software Verification Test Plan

3 Test Cases

3.1 DrivePilot iPad Console Application

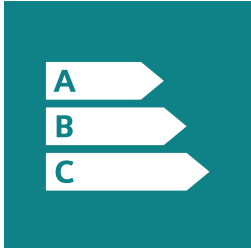
WI-PLT-283 - Check Application requires authentication code

Step	Description	Expected Result
Start Drive Pilot	Connect the DrivePilot to the car	
Connect iPad Console App	Start the application and connect to the DrivePilot	The Application says "Enter Auth Code."
Generate Code	Generate Code using DrivePilot native console	
Enter Code	Enter the generated code to the app	
Submit	Submit the code	The app says: "Connected"

1 | Page Polarsion ALM 2012 2013-01-28 14:05

Smart Regulatory Review Process improve safety, efficacy, security

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Modern Digital Process Governed by a Data Model

- Pre-screen low quality application
- Easy user interface to reduce manual operations and errors
- Always up to date
- Report and analytic for continuous improvement



Secure, Automate, Search to Effectively manage time and resources for review and renewal process

- Workflows, reviews and process control
- Control exactly who sees what information
- Leverage existing data and record more effectively and improve technical and clinical review capabilities



Collaborative, Predictability and transparency

- Track the status of your resources
- Clearly show approval process progress and estimated release dates
- What is: Open, Under Review, Requires Additional Info,
- Verified and Complete
- Predictive new product launch date with progress report
- Enhance collaboration



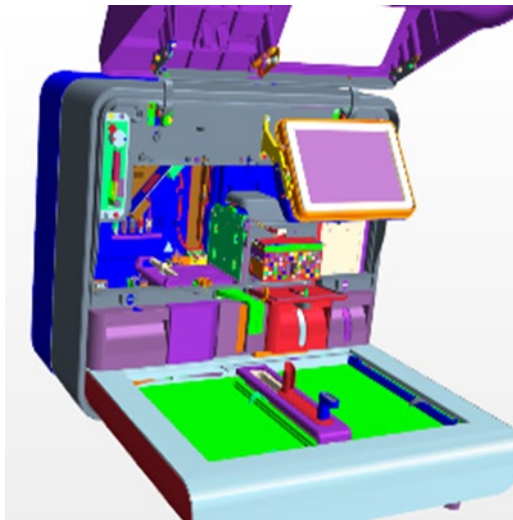
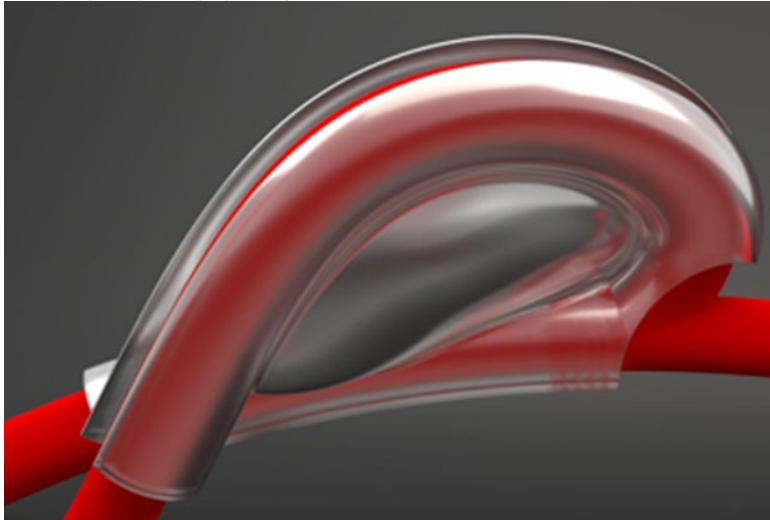
Analyze and monitoring post-market surveillance

- Improved diagnostics and management for continuous optimization of resource and capacity
- Increase efficiency, and reduce costs and improve overall performance
- Augment decision making process
- Enhance safety, efficacy and security to close-loop feedback

Digitalization Strategy for Healthcare Industry 4.0

Innovations for safer, more effective, secure and affordable healthcare

SIEMENS
Ingenuity for life



Smart Regulatory

Intelligent Design Control

Digital Evidence

Digital Twins

Speed up innovation

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