Simplifying Risk Management File Maintenance: Tools, Techniques, and Industry Best Practices

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Speaker

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Founder of Consiliso LLC, Medical Device Business/Quality Systems Consultant

For over 35 years, Mark Rutkiewicz has managed all types of medical device company business processes. He has designed Quality Management Systems for active and non-active implantables, disposables, combo devices, software and capital systems. Mark built and rebuilt online integrated corporate-wide quality/business systems. He has a Bachelor of Electrical Engineering from the University of Minnesota and a Masters of Applied Liberal Studies from Hamline University. He is currently involved with on the MDIC's Safe Space Program. Mark founded Consiliso LLC in 2018, which assists companies in integrating their business systems. Mark is the author of two books on Consiliso, which defines how to implement integrated business processes.

Agenda

1. The Problem
2. The Requirements
3. The Process
4. The New Idea
5. The Questions

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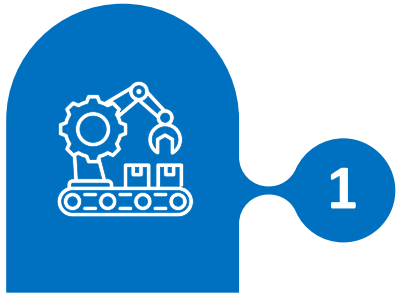
The Problem

1. Maintaining the FMECA created during product development
2. Maintaining Risk files across similar product iterations
3. Manufacturing and complaint data does not align 100% with the FMECA Harms/Interventions and Hazards/Defects

Why are risk management files difficult to maintain?

- ❑ Aligning the hazard, harm, intervention and defect codes
- ❑ Debating values on a scale of 1-10
- ❑ Writing and approving the plan and reports
- ❑ Updating the FMEAs with actual data from complaints and manufacturing
- ❑ Having the experts review the analyses

The Top 5 Risk Management File Difficulties



1. Updating the FMEAs with actual data from complaints and manufacturing

2. Having the experts review the analyses

3. Determining hazard, harm, intervention and defect codes

4. Debating values on a scale of 1-10

5. Writing and approving the plan and reports

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The Requirement

- **ISO 14971:2000 originally said:** The manufacturer shall establish, document and maintain a system to collect and review information about the medical device or similar devices in the production and the post-production phases.

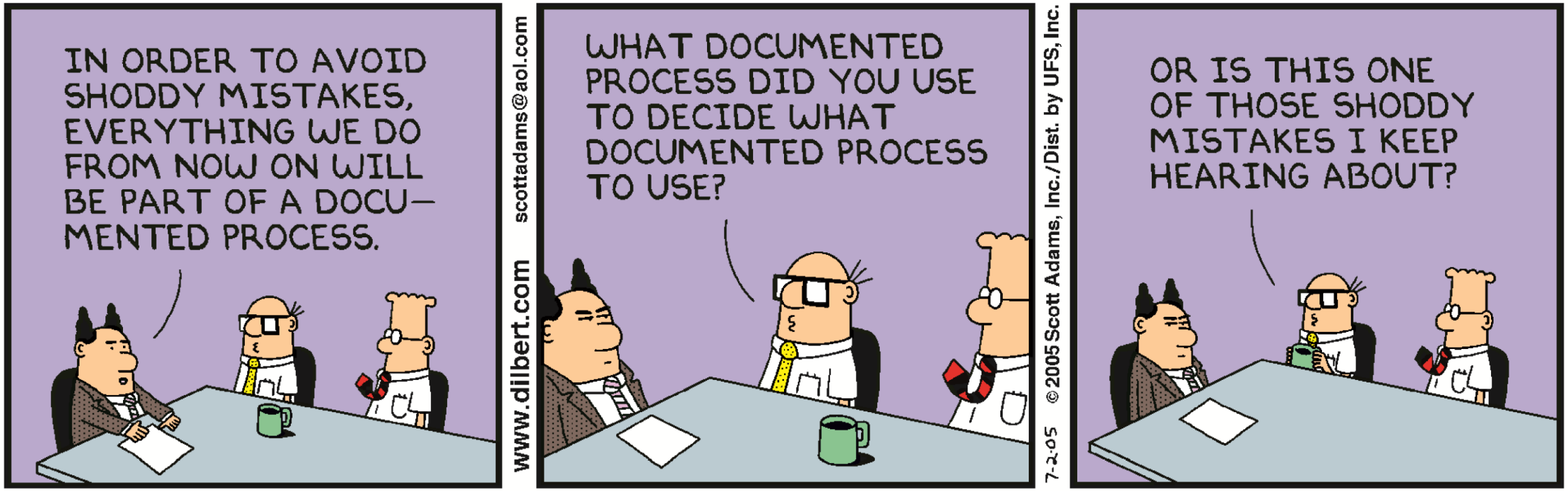
- **ISO 14971:2019 now says:** The manufacturer shall establish, document and maintain a system to actively collect and review information relevant to the medical device in the production and post-production phases. When **establishing this system**, the manufacturer shall consider appropriate methods for the collection and processing of information.

How often should a product's risk management report be updated?

- ❑ When DMR changes occur
- ❑ Monthly
- ❑ Quarterly
- ❑ Annually
- ❑ Every few years

Why So Hard?

- First established 25 years ago
- Manual tools used to establish risk assessments
- Production and post production data not easily available
- No common product lines and risk codes
- Information located in multiple information silos
- Undefined process

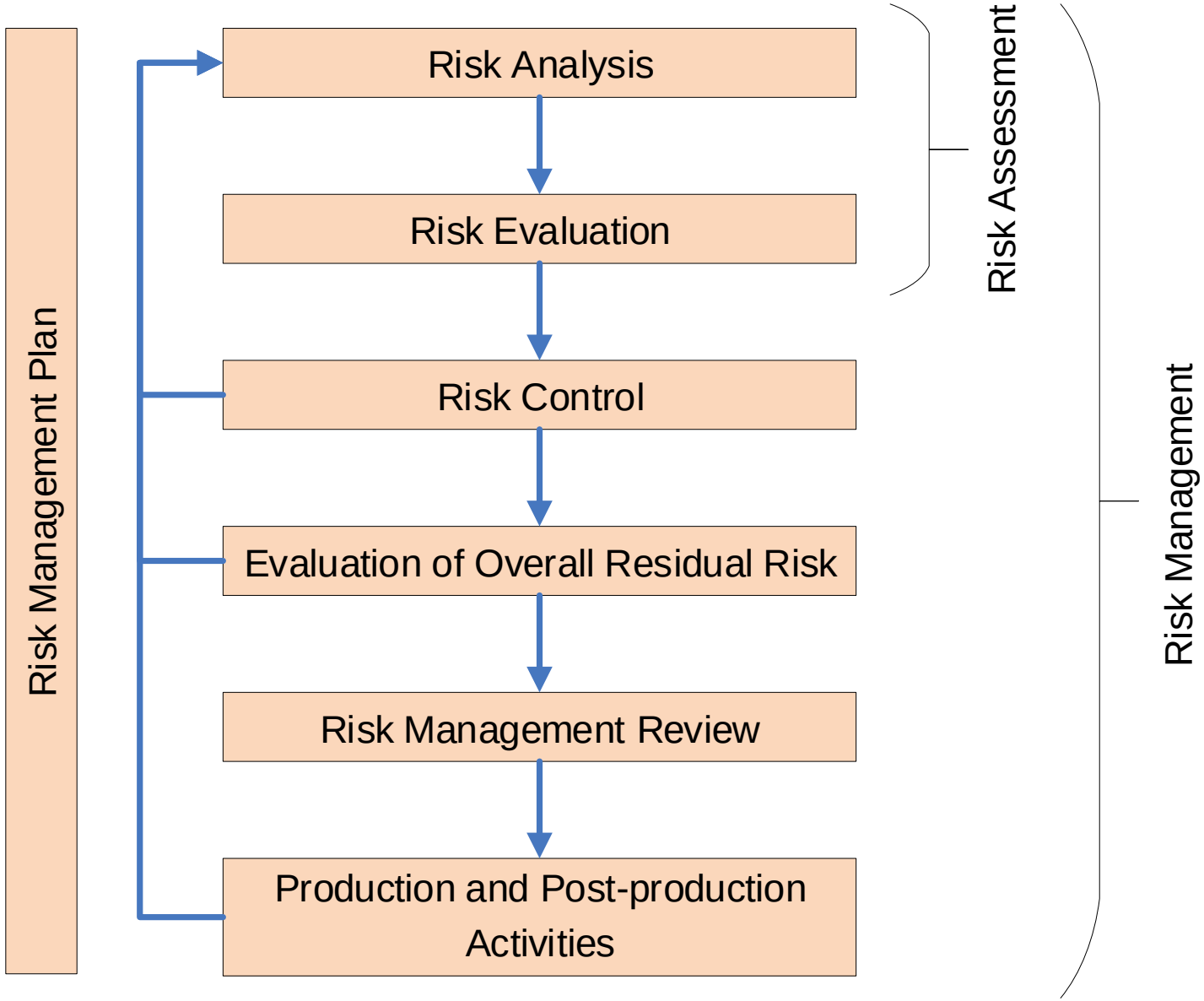


The Process: Plan-Do-Check-Act

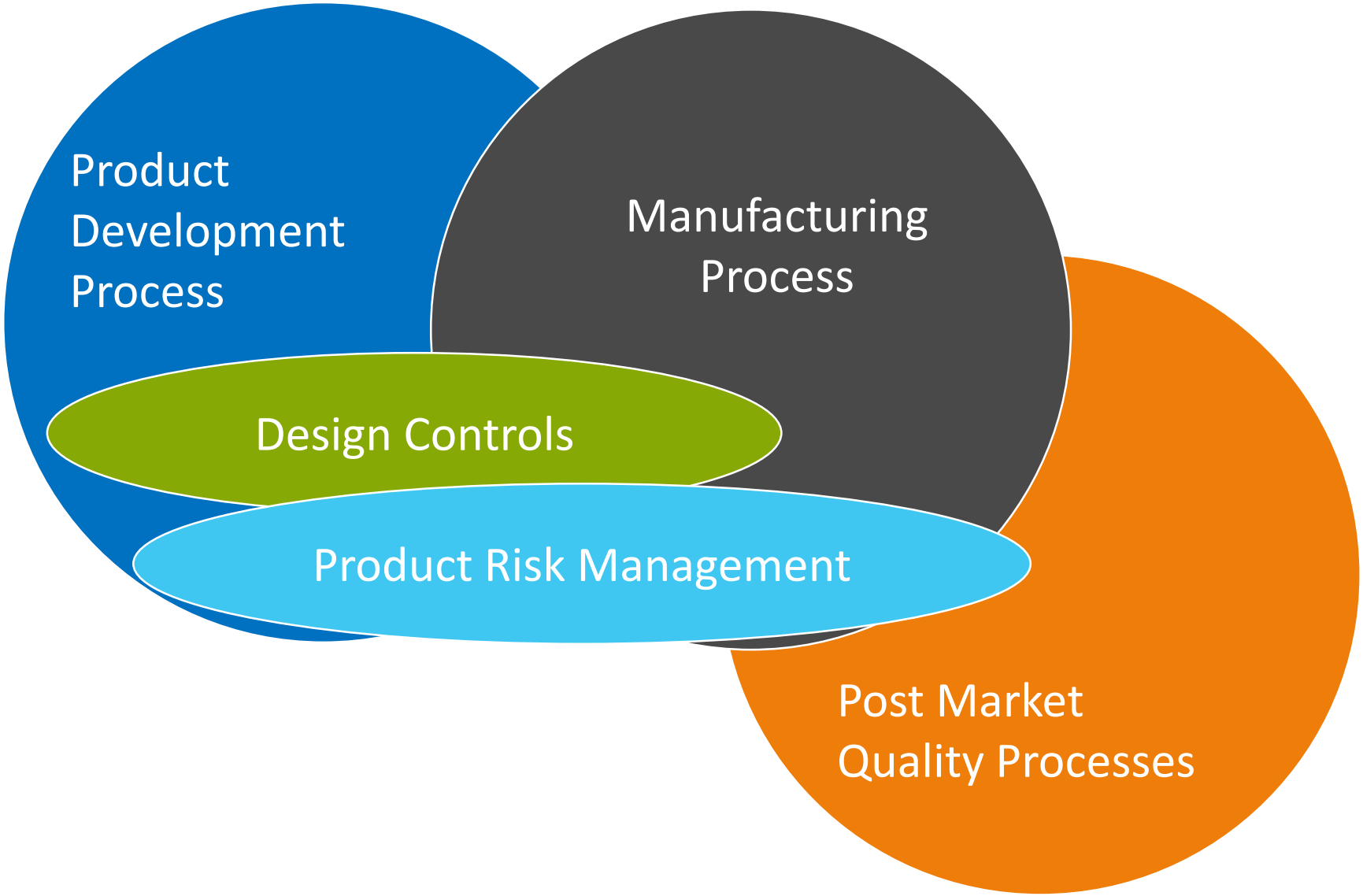
- **Plan** – Define the requirements for a Product Risk Management System (RMS)
- **Do** – Create processes, tools, procedures and operating standards for implementation
- **Check** – Verify the output meets the design and regulatory body requirements
- **Act** – Update the RMS to eliminate non-value added steps and to speed the process

REPEAT

ISO 14971 Risk Management Process - Requirements



Consiliso Product Processes



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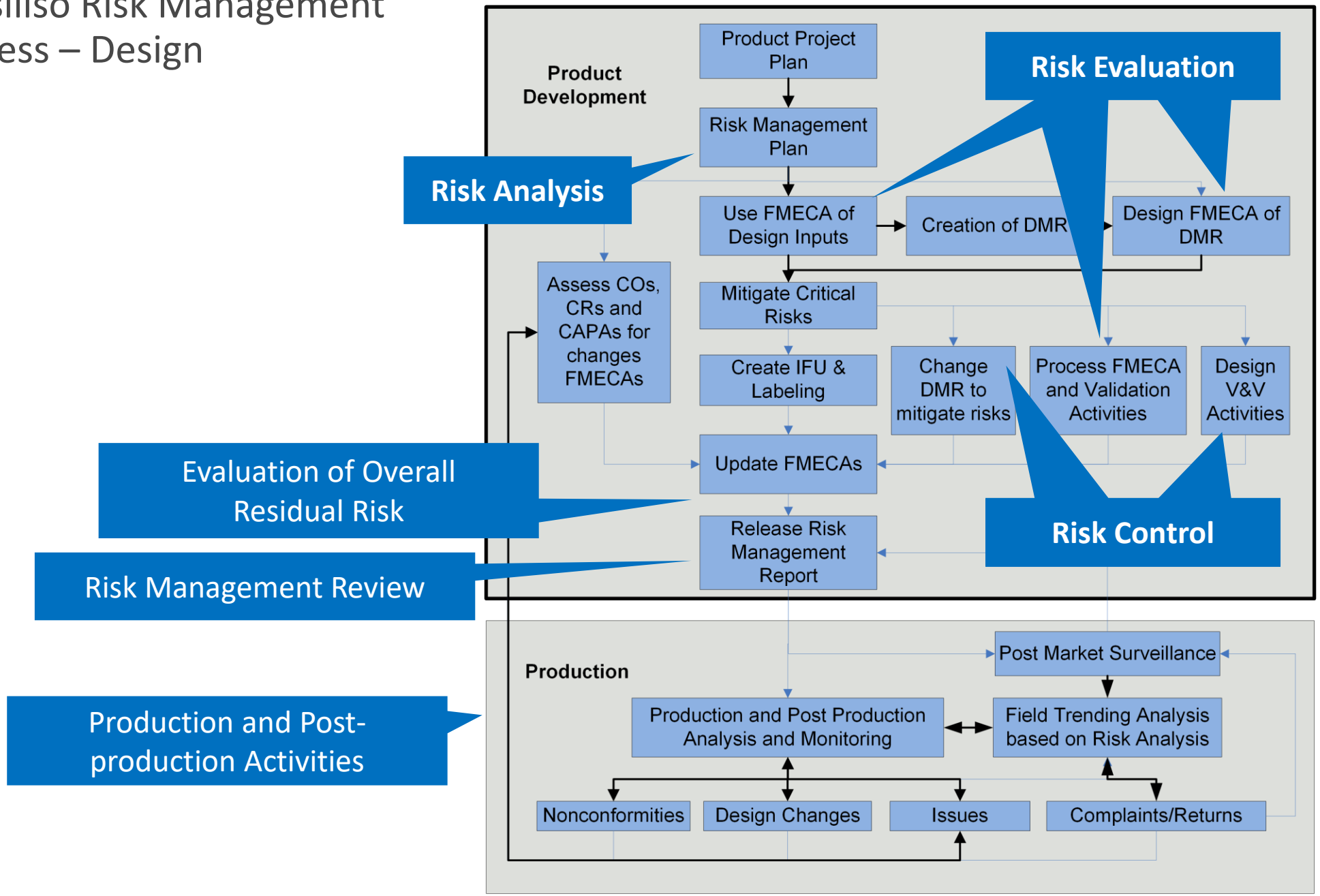
Consiliso Risk Management Process – Design



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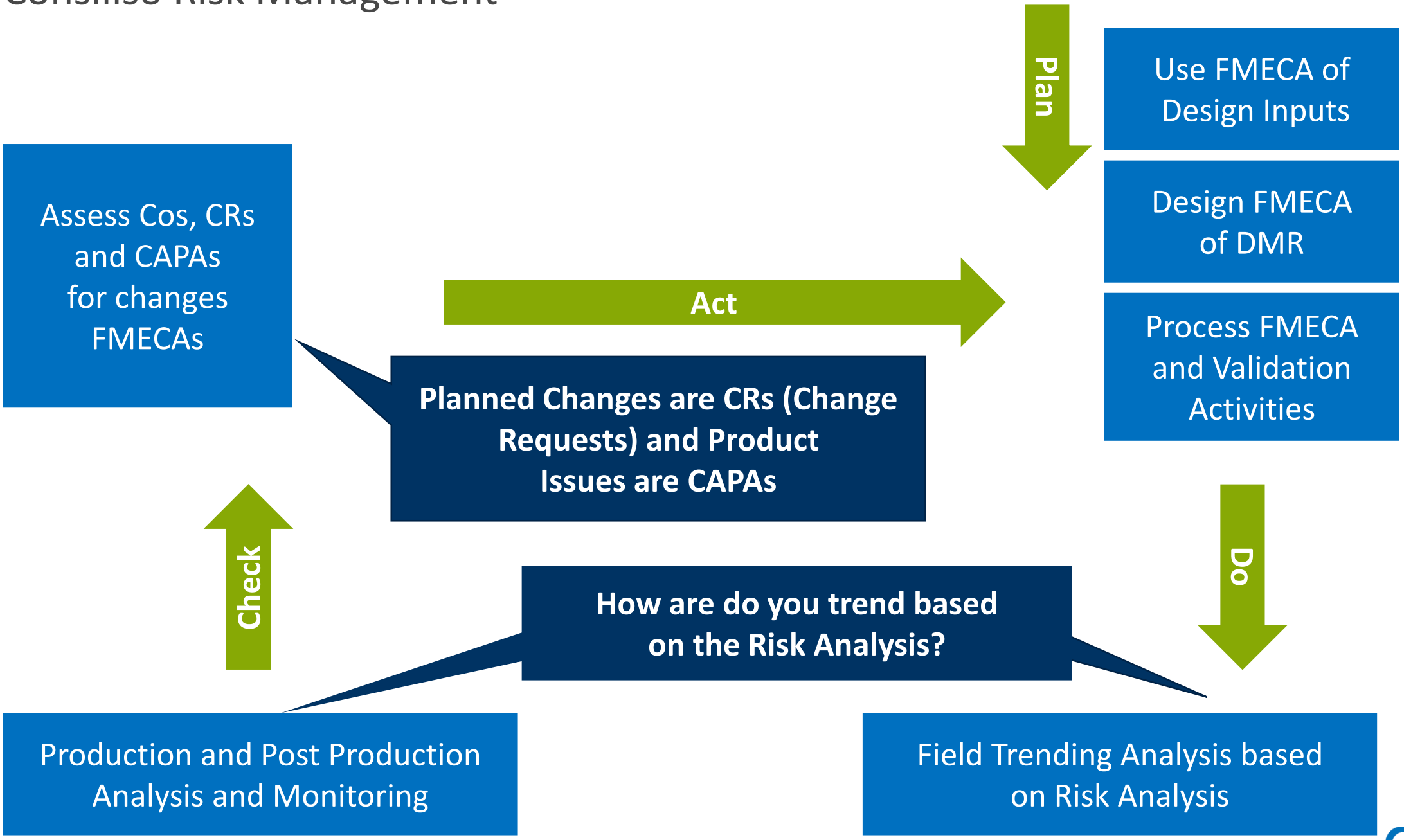
Consiliso Risk Management



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Production and Post Production Analysis and Trending – ISO 14971:2019

- Create a system to actively collect and review

Information Collection:

- Production, users, install and servicing, supply chain, public/ competitive product information and state-of-the-art (e.g. standards, articles)

Information Review:

- New hazards, risk no longer acceptable, state-of-the-art has changed

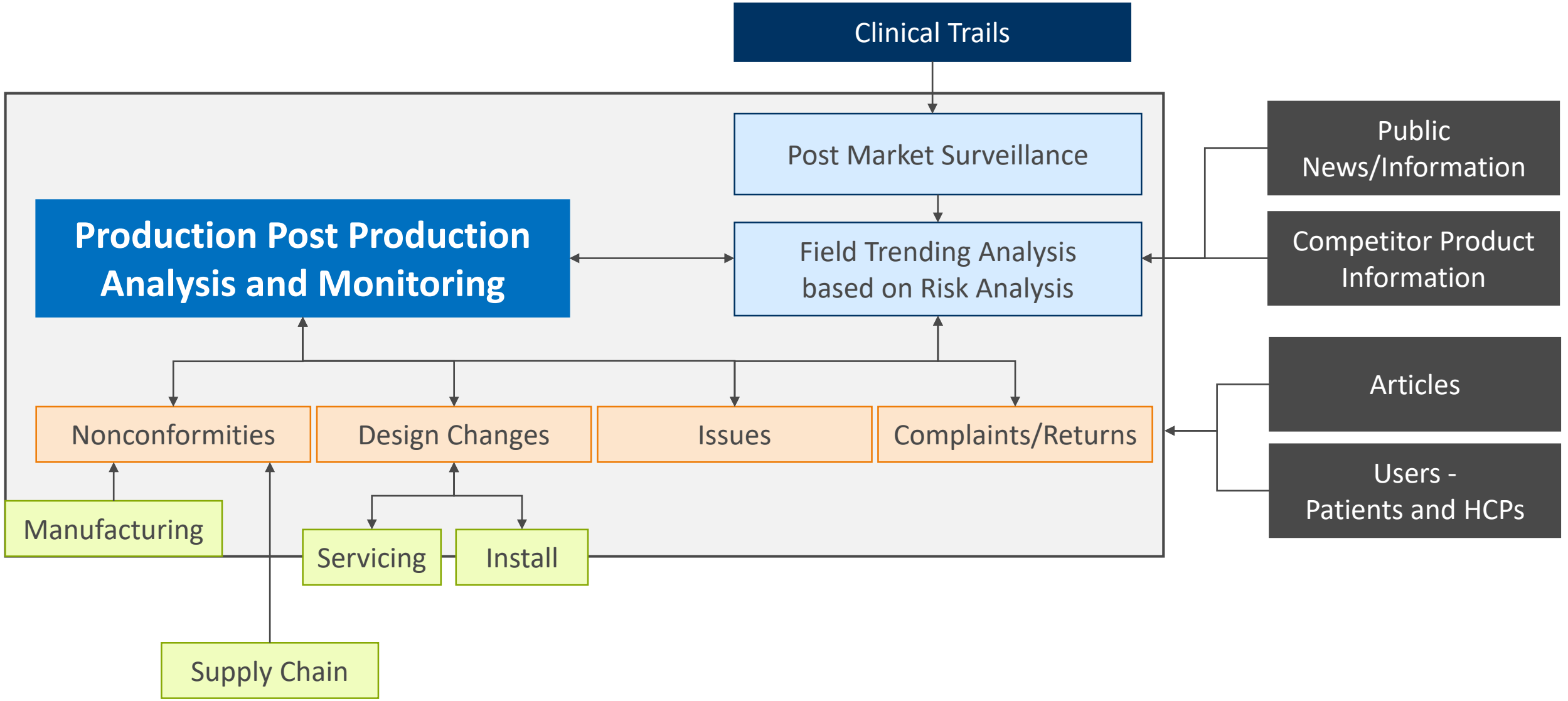
Actions:

- Particular Medical Device-change or field action, update RMF
- Risk Management Process-Evaluate previous risk management activities, update risk management process

What is the best method for Production and Post Production Analysis and Monitoring

- ❑ Updating the Risk Management Reports
- ❑ Customer Surveys
- ❑ Updating the Clinical Evaluation Reports (CER)
- ❑ Publish Product Performance Reports
- ❑ Standards Board Reviews
- ❑ Supplier Scorecards
- ❑ Quality System Management Reviews
- ❑ Monthly Product Trend Reviews
- ❑ Monthly Manufacturing Reviews
- ❑ Clinical Trial Reports

Production and Post Production Analysis and Monitoring



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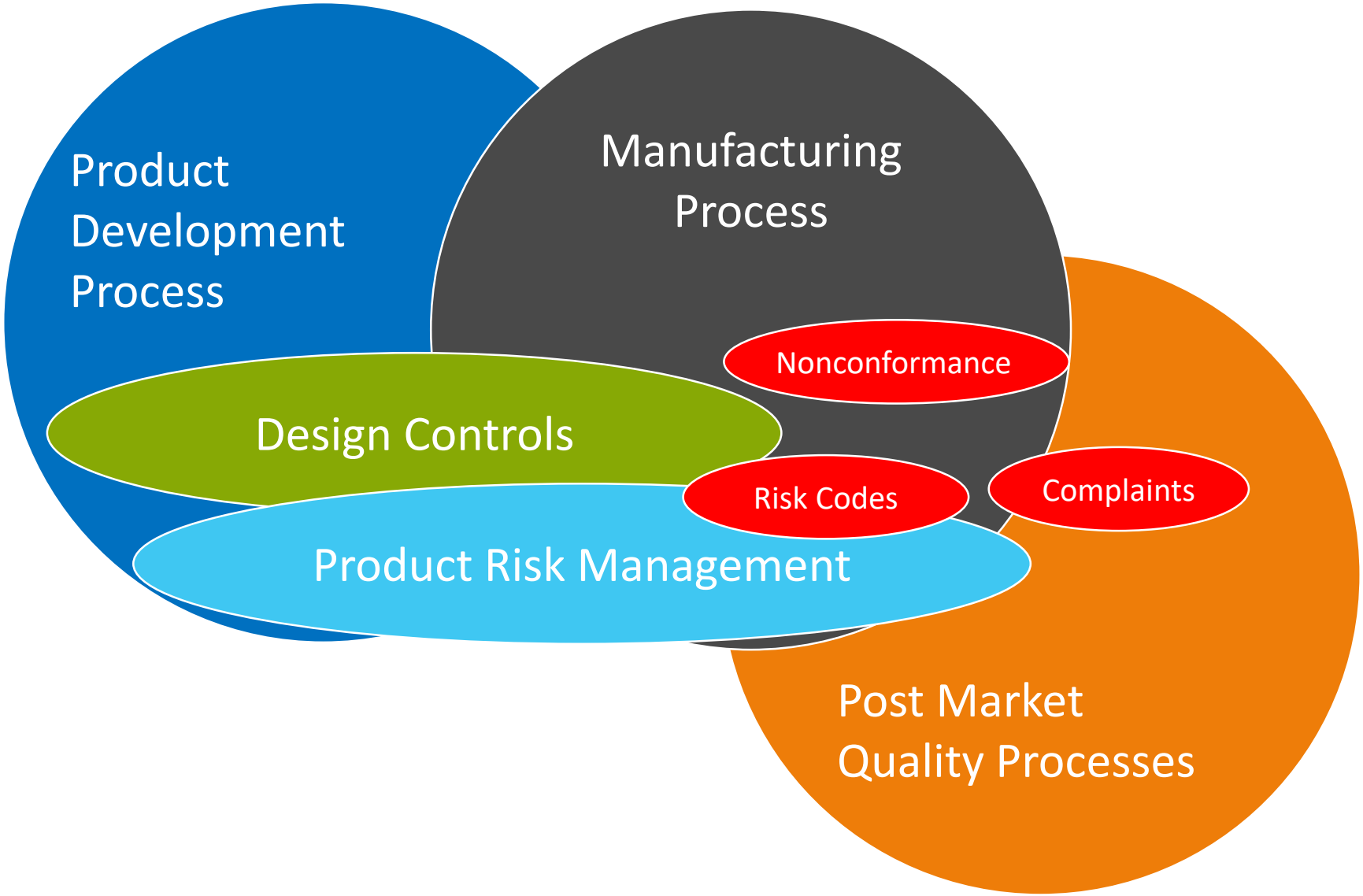
Production and Post Production Analysis and Monitoring – How Do You Do It? Top Ten!

1. Updating the Risk Management Reports
2. Updating the Clinical Evaluation Reports (CER)
3. Publish Product Performance Reports
4. Quality System Management Reviews
5. Monthly Product Trend Reviews
6. Monthly Manufacturing Reviews
7. Clinical Trial Reports
8. Standards Board Reviews
9. Supplier Scorecards
10. Customer Surveys

How to Trend Production Issues to Complaints



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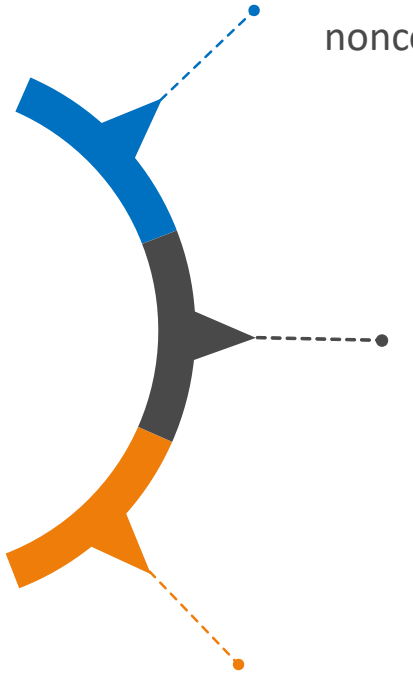
How to Trend Production Issues to Complaints

By FG Part Number, SKU/Model or Product Line

- Group common designed part numbers
- Group SKU/Model number
- Product lines the same in FMECAs, complaints and nonconformances



By Defect Type

- It is obvious, but not defined
- Manufacturing reason codes
- Complaint codes

Rates

- Manufacturing by build quantity
- Field by sales or use quantity

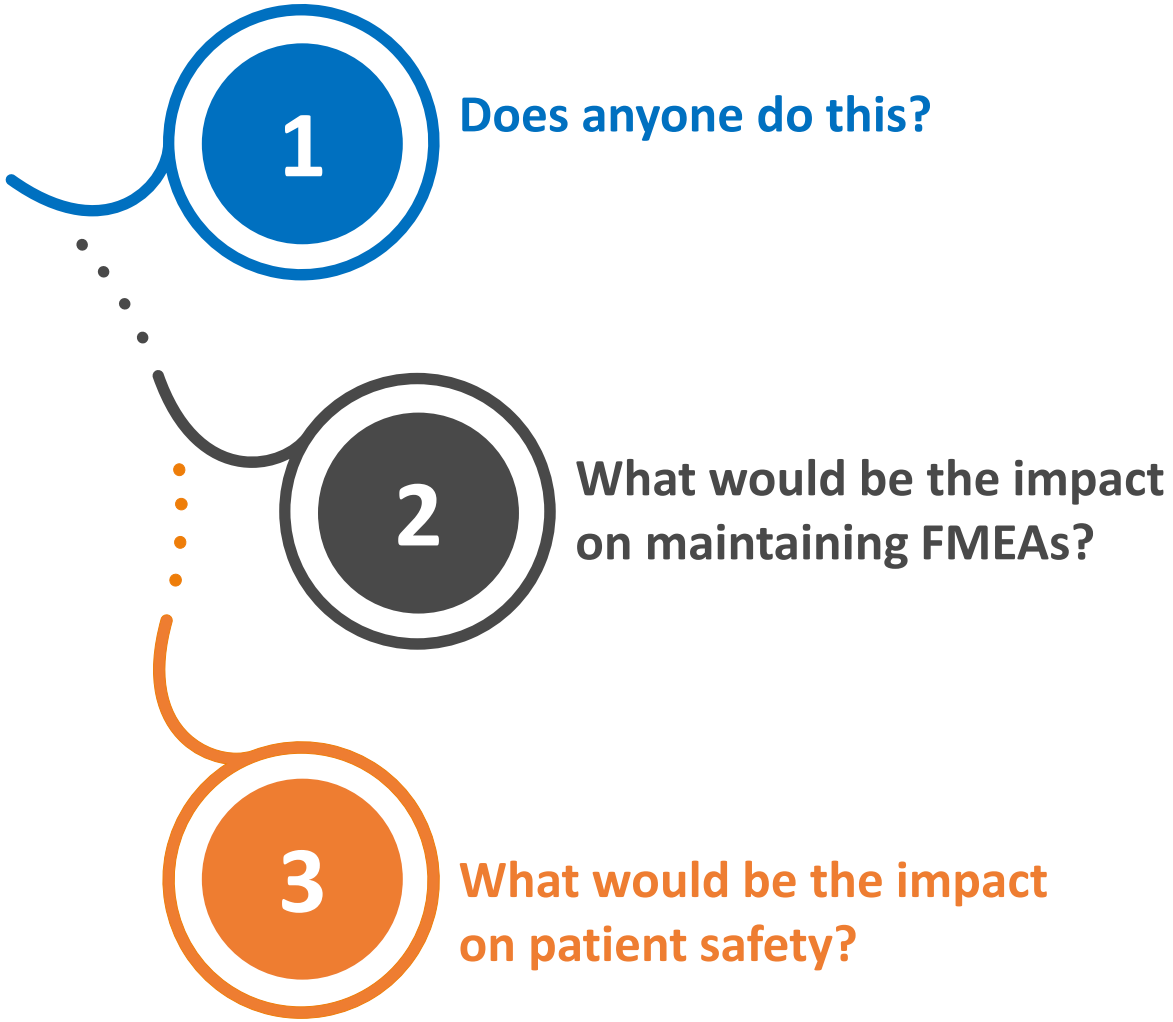
Compare Risk Evaluation to Production Data

FMECA		Complaint
Hazard in product use or possible defects in the design or mfg processes	→	Product Issue observed
Severity-depending on the cause	→	Was there a patient intervention?
Detection-can it be found in manufacturing or in use	→	Did the patient or Healthcare professional see it?

Does Anyone use your Risk Analysis Codes/ID as Nonconformance or Complaint Codes?

The New Idea: What if a Company's Risk Assessment and Complaint and Nonconformance Codes were Identical?

How do I get the complaint group, quality and the design assurance engineers to change their codes?



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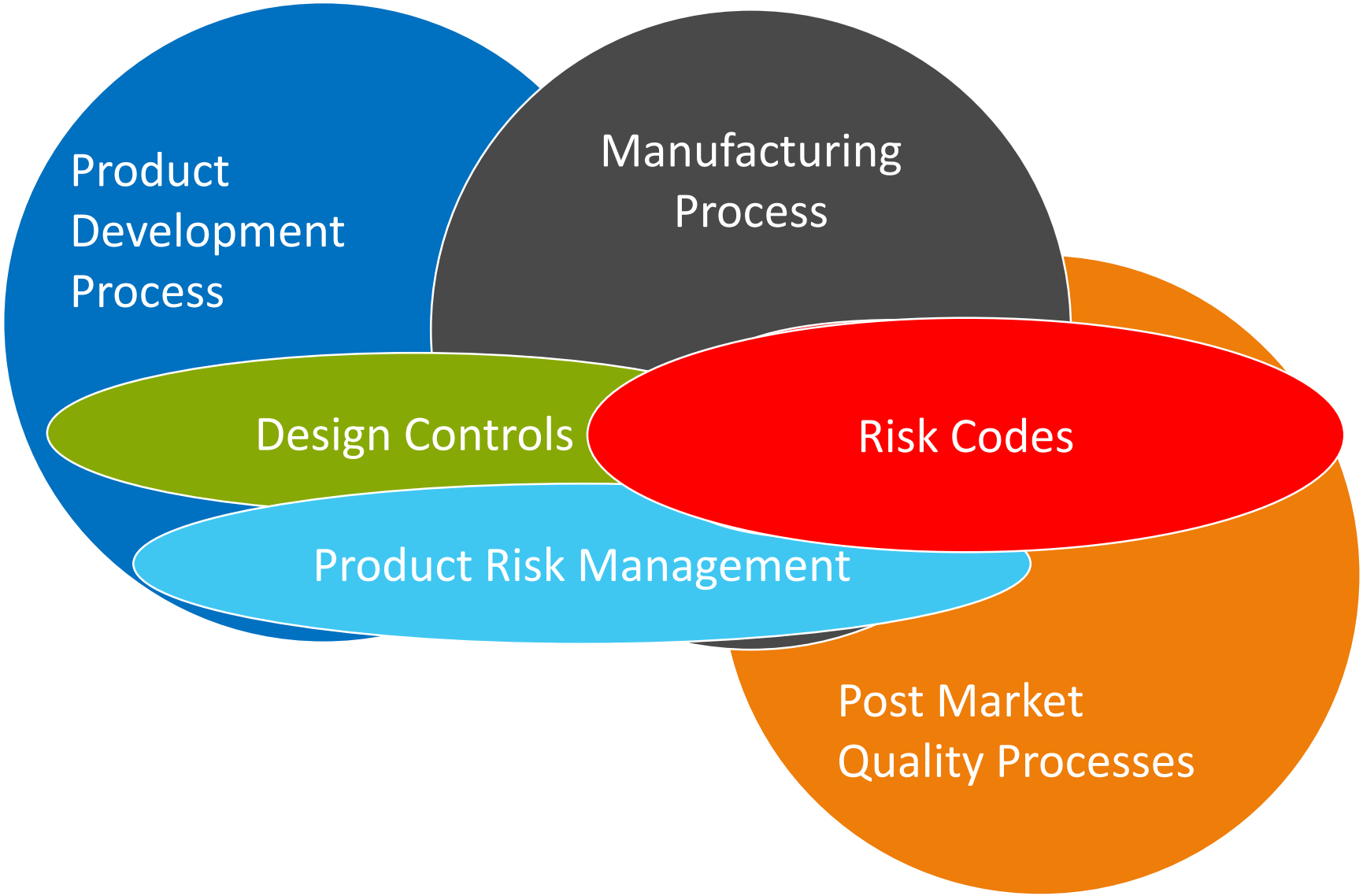
Consiliso Integrated Risk Management



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Information Management Planning is the Key

2. Control the harm, hazard, defect and intervention codes like a part (Use the same part lifecycle statuses)

3. Manage the Risk Management and PDP documents in a Risk Management tool

1. Integrate the complaint process, nonconformance process and part/documentation control systems

4. Define Standard Codes

Standardized Harm and Hazard Codes

Seven sets initially released in 2020 and are being maintained

1. Annex A – Medical Device Problem – 469 Codes
2. Annex B – Cause Investigation-Type of Investigation – 22 Codes
3. Annex C – Cause Investigation-Investigation Findings – 148 Codes
4. Annex D – Cause Investigation-Investigation Conclusion – 35 Codes
5. Annex E – Health Effects-Clinical Signs, Symptoms, Conditions – 797 Codes
6. Annex F – Health Effects-Health Impact – 64 Codes
7. Annex G – Medical Device Component – 294 Codes

The EU and FDA refer to these for regulatory reporting

IMDRF International Medical Device Regulators Forum

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How Do You Create and Maintain Standard Codes?

1. 
   Add into your documentation system
2. 
   Assign lifecycle statuses to each code
3. 
   Assign metadata on type, use and history
4. 
   Use a Standards Board to review and approve
5. 
   Approved codes are only allowed to be use in FMEAs (i.e. Risk Management Tools)
6. 
   New codes may be created from complaints but need to be vetted and then released

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Example Standard Code

H0684

Harm/Hazard • Nervous System - Brain Injury

Rev: Introductory | Effective From: ... to ... | Navigator | Actions

Title Block | Changes | BOM | Events | Relationships | Where Used | Attachments | History

Page Three | IMDRF/FDA Standardization

Number: H0684
Subclass: Harm/Hazard
Description: Nervous System - Brain Injury
Status: Preliminary
Effectivity Date:
Product Line(s): Corp-Quality System
Owning Dept: Quality Post Market
Access: Public
Base Model:

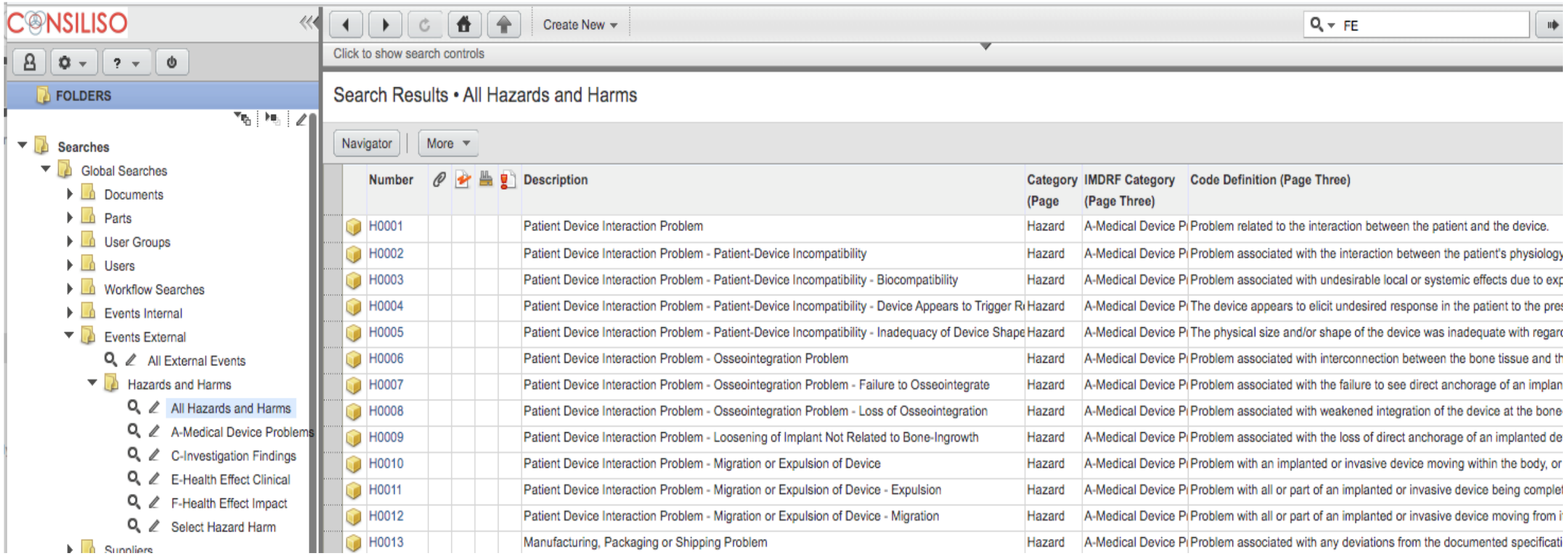
Page Three

Category: Harm
Internal Comments:

IMDRF/FDA Standardization

IMDRF Category: E-Health Effect Clinical
Code Definition: Damage to the brain.
FDA Code: 2219
NCIt Code: C50440
IMDRF code: E0102
IMDRF Version: 1.0

IMDRF codes in PLM system



Number	Description	Category (Page	IMDRF Category (Page Three)	Code Definition (Page Three)
H0001	Patient Device Interaction Problem	Hazard	A-Medical Device P	Problem related to the interaction between the patient and the device.
H0002	Patient Device Interaction Problem - Patient-Device Incompatibility	Hazard	A-Medical Device P	Problem associated with the interaction between the patient's physiology
H0003	Patient Device Interaction Problem - Patient-Device Incompatibility - Biocompatibility	Hazard	A-Medical Device P	Problem associated with undesirable local or systemic effects due to exp
H0004	Patient Device Interaction Problem - Patient-Device Incompatibility - Device Appears to Trigger R	Hazard	A-Medical Device P	The device appears to elicit undesired response in the patient to the pres
H0005	Patient Device Interaction Problem - Patient-Device Incompatibility - Inadequacy of Device Shape	Hazard	A-Medical Device P	The physical size and/or shape of the device was inadequate with regard
H0006	Patient Device Interaction Problem - Osseointegration Problem	Hazard	A-Medical Device P	Problem associated with interconnection between the bone tissue and th
H0007	Patient Device Interaction Problem - Osseointegration Problem - Failure to Osseointegrate	Hazard	A-Medical Device P	Problem associated with the failure to see direct anchorage of an implan
H0008	Patient Device Interaction Problem - Osseointegration Problem - Loss of Osseointegration	Hazard	A-Medical Device P	Problem associated with weakened integration of the device at the bone
H0009	Patient Device Interaction Problem - Loosening of Implant Not Related to Bone-Ingrowth	Hazard	A-Medical Device P	Problem associated with the loss of direct anchorage of an implanted de
H0010	Patient Device Interaction Problem - Migration or Expulsion of Device	Hazard	A-Medical Device P	Problem with an implanted or invasive device moving within the body, or
H0011	Patient Device Interaction Problem - Migration or Expulsion of Device - Expulsion	Hazard	A-Medical Device P	Problem with all or part of an implanted or invasive device being complet
H0012	Patient Device Interaction Problem - Migration or Expulsion of Device - Migration	Hazard	A-Medical Device P	Problem with all or part of an implanted or invasive device moving from i
H0013	Manufacturing, Packaging or Shipping Problem	Hazard	A-Medical Device P	Problem associated with any deviations from the documented specificati

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FE-0001-2

Unassigned

Field Adverse Event Report • Patient XXX111, Cleveland Clinic by Dr John Smith

Comment | Next Status | Navigator | Actions

Cover Page | Affected Items | Related Events | Workflow | Relationships • | Attachments | History

Page Two | Page Three | AE Report Information | Reporting Codes | Field Event Summary Information | Field Event Detail Information | Product Evaluation Information | Product Information | Patient Information

Reporting Codes

Health Effect Clinical code (primary): H0684

Health Effect Impact code (primary): —

Investigation Findings 1 (primary): —

Medical Device Problem code (primary): —

Type of Investigation Code 1 (primary): Testing of Device from Same Lot/Batch Returned from User

Type of Investigation Code 2-6: —

Investigation Conclusion 1 (primary): Cause Traced to Maintenance

Investigation Conclusion 2-6: —

Component code 1 (primary): Electrical and Magnetic - Circuit Board

Component code 2-6: —

Annex E Code

Annex F Code

Annex B Code

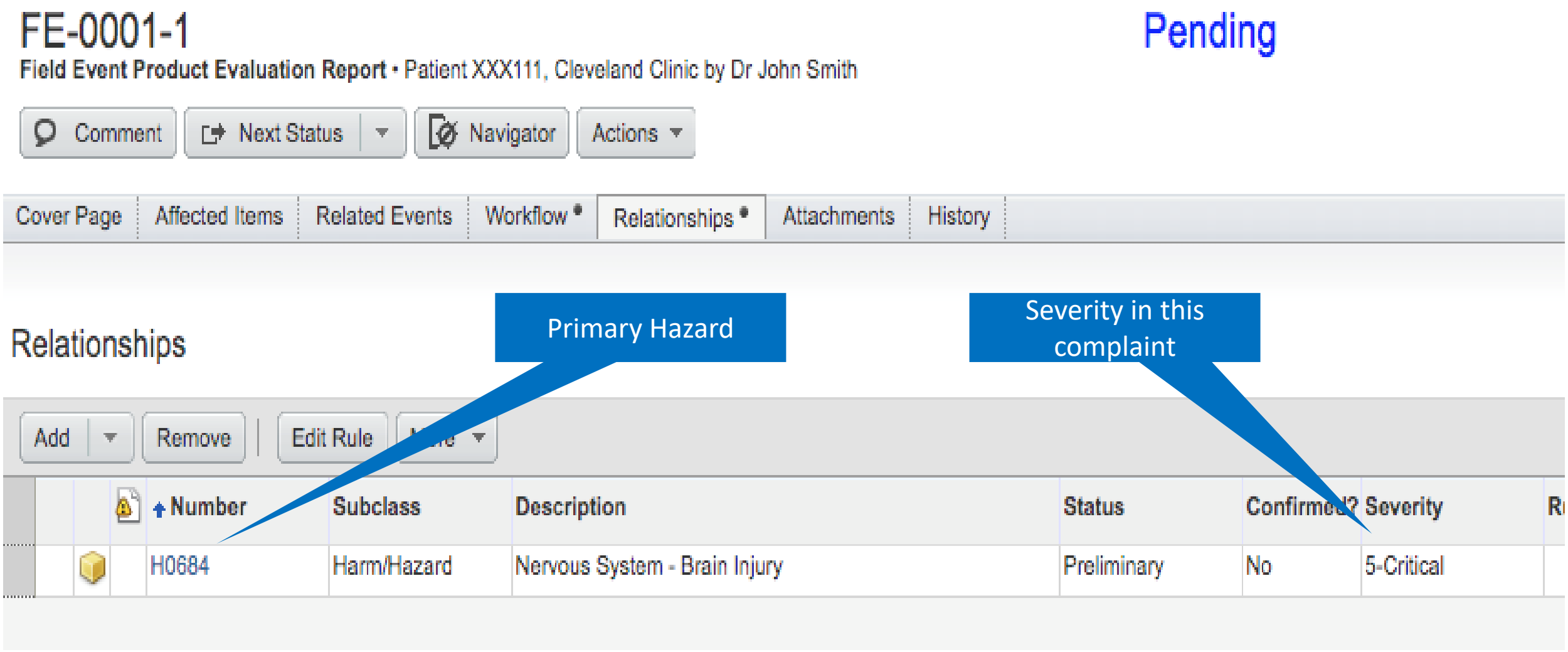
Annex C Code

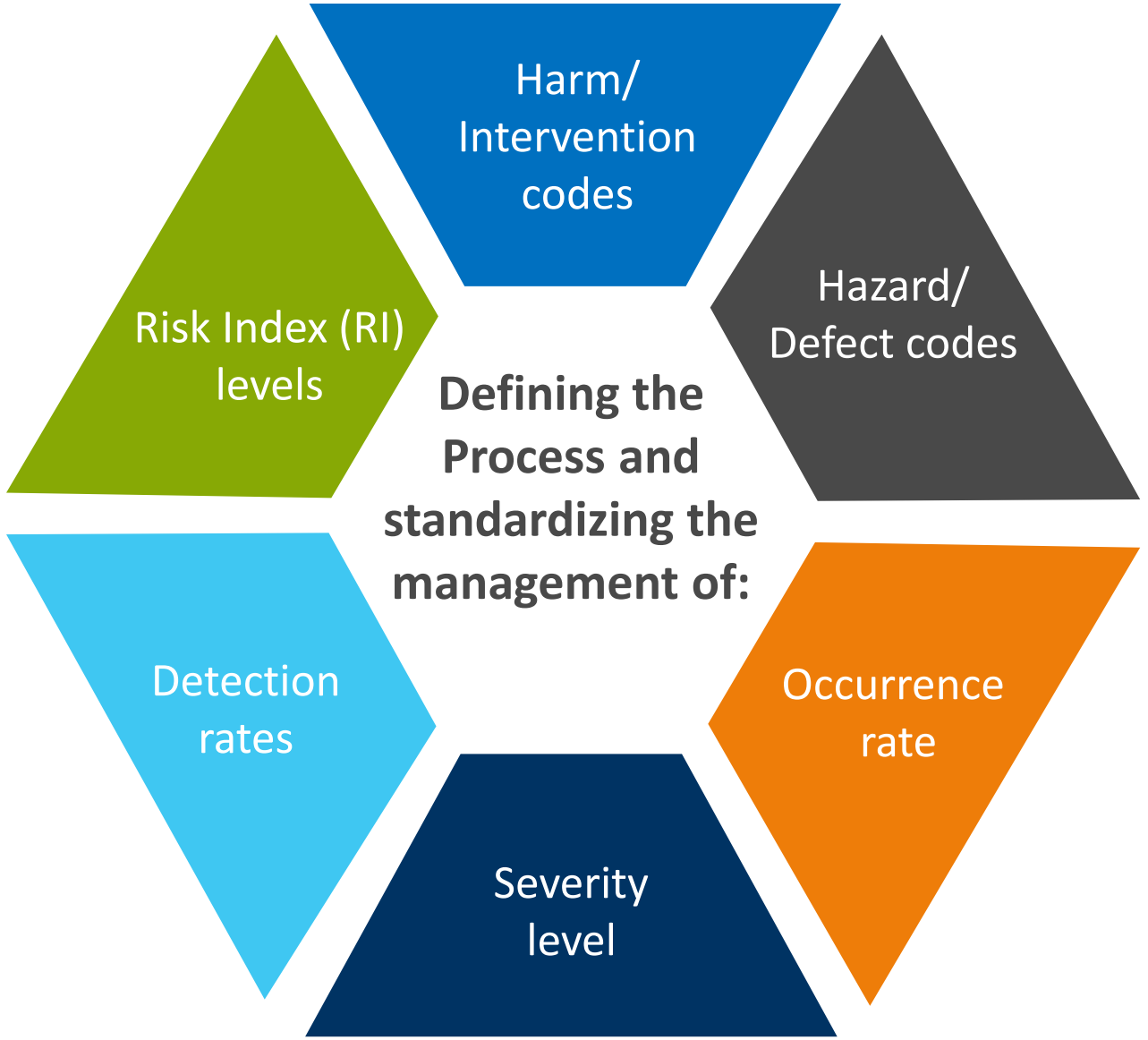
Annex A Code

Annex D Code

Annex G Code

Complaint Analysis link to Harm with Severity





Simplifies your risk assessment process and your ongoing post-production monitoring.

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Future of Industry Standards

- Free common database of risk codes by product type
- Risk Management tools will have links to common codes
- Each Medical Device standard/guidance defines the known Risk Codes
- Suppliers have standard part/process risk codes

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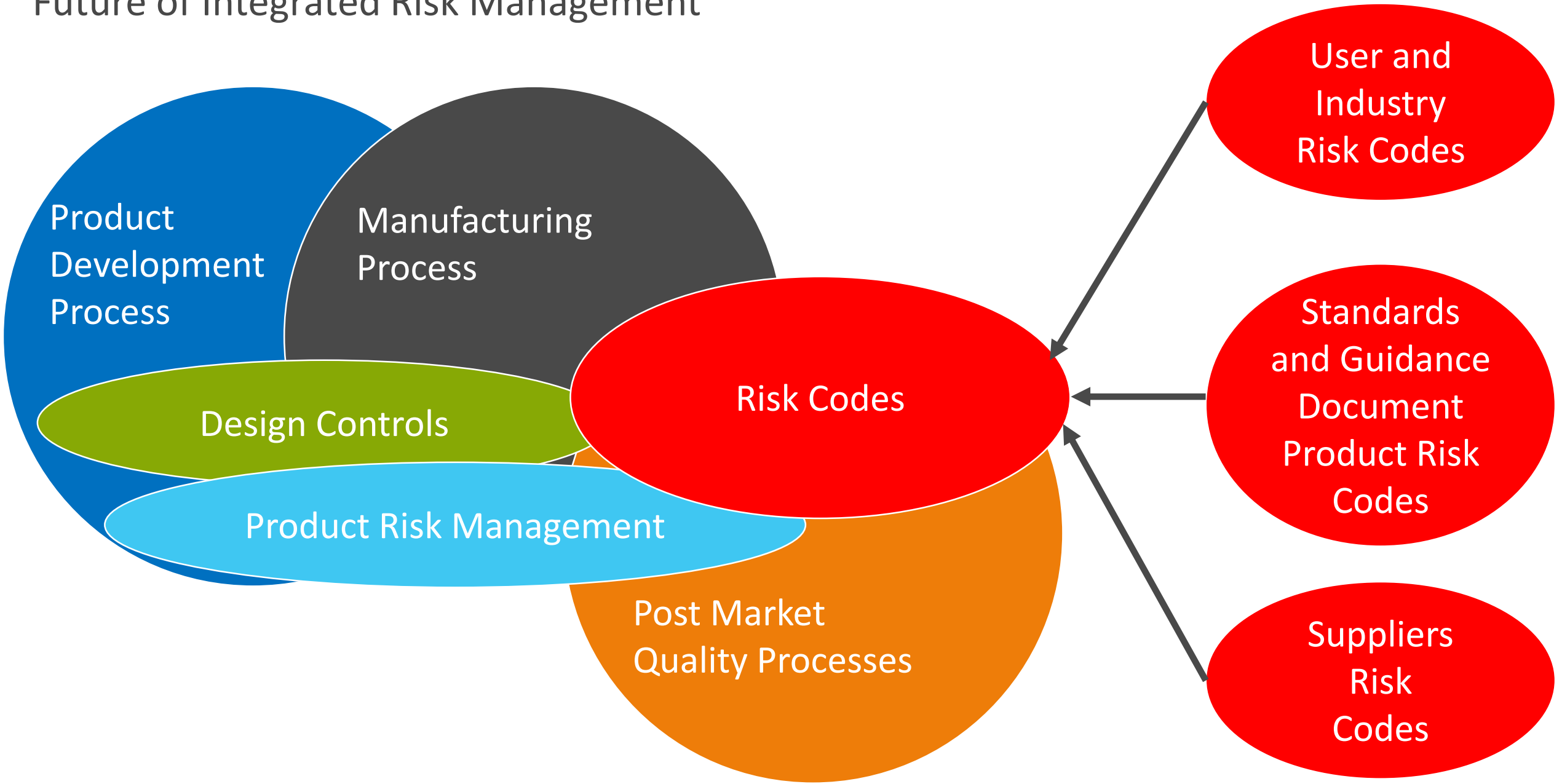
Future of Integrated Risk Management



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Takeaway

*Your manufacturing nonconformances, product complaints and risk assessments should be categorized (i.e. coded) using the **SAME** Harm/Intervention codes and Hazard/Defect codes.*

Summary

- Pre and Post Production Risk Management Activities are varied

- Difficult to link Design Risk Management Analysis to Nonconformances and Complaints

- Need to Architect your Risk Management System

- Best practice is to use Industry standard codes in all areas of the Risk Management Program

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AICPA SOC 2 Formerly SAS 70 Reports

International Organization for Standardization ISO 27001

FedRAMP

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Gartner 2022 QMS Market Guide

Frost & Sullivan 2019 Best Practices Award

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SUMMER 2022
TOP PERFORMER
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INTEGRATIONS

- CRM
- ERP
- HRMS
- LIMS
- LMS
- MES
- MOM
- PLM
- RIMS
- Others

ENGINEERING	CUSTOMER	QUALITY	SUPPLY CHAIN	RISK	DOCUMENT AND KNOWLEDGE MANAGEMENT	SAFETY	ENVIRONMENT
PRODUCT LIFECYCLE MANAGEMENT (PLM)	CUSTOMER QUALITY, COMPLAINTS AND POST MARKET SURVEILLANCE	QUALITY MANAGEMENT AND CONTROL (QMS)	SUPPLIER QUALITY AND RELATIONSHIP MANAGEMENT	RISK AND COMPLIANCE MANAGEMENT	DOCUMENT MANAGEMENT, TRAINING AND CHANGE CONTROL	HEALTH AND SAFETY MANAGEMENT	ENVIRONMENTAL AND SUSTAINABILITY MANAGEMENT

MANAGEMENT REVIEW

CONNECTIVITY

salesforce, CLOUDBYZ, rootstock software, SERVICEMAX, TAVANT, Microsoft, Google, box, MuleSoft, tableau

Embedded & Advanced Analytics | Collaboration (Chatter, MS Teams) | 2-Way Portal | Alerts and Notification | Forms Designer/ Runner | Mobile | Pre-Validated | Ratings | CQ.AI | MyCQ for casual users

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THANK YOU

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