Key Expectations for ISO 14971 Compliance with Implementation of QMSR

Edwin Bills + Christie Johnson

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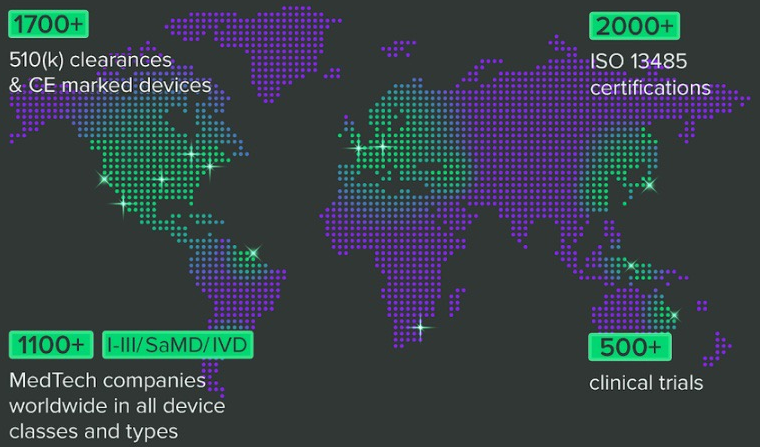


G2 CROWD LEADER QMS SOFTWARE Since Winter 2019

G2 CROWD LEADER MEDICAL QMS SOFTWARE Since Spring 2021

"Best QMS I have ever used..."

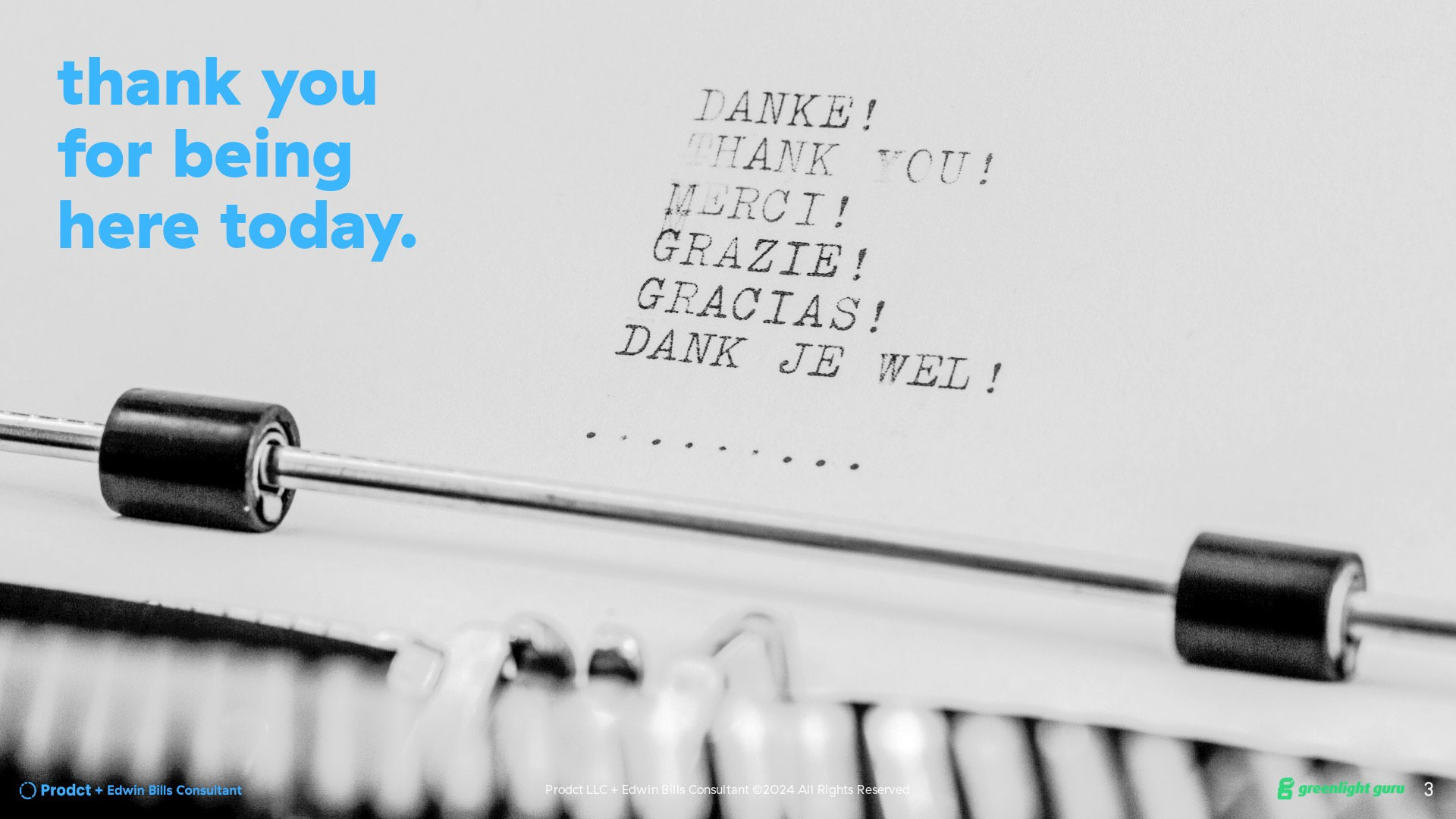
"User-friendly EDC and esponsive support team"

"This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry."

"The whole experience of using Greenlight Guru Clinical is accessible and user-friendly"

"Makes your QMS Simple and Effective"

thank you for being here today.



If you learn anything today, it's this:

You need to practice risk management to comply with QMSR

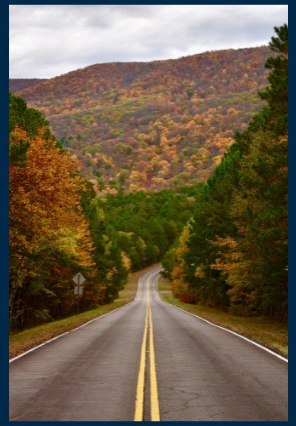
FDA tells us complying with ISO 14971 is a very good idea

Your quality system is more than your SOPs... It's behaviors and attitudes, too

Your risk management processes need to touch the whole lifecycle of your device (FMEA is NOT enough)

You can do it!

agenda



1. Cast of characters
2. Brief introduction to and history of the standards
3. Risk buzz
4. QMSR Comments
5. What lifecycle risk management looks like
6. For the little guys
7. Closing thoughts

Ed Bills + Christie Johnson

Ed

- ☆ 23 years in Medical Device RM +
- ☆ Many more years in Quality
- ☆ Advisor & trainer to medtech in Quality + RM
- ☆ Authored:
  - ☆ Book on RM
  - ☆ Many articles on RM
  - ☆ Guest author for several book chapters
- ☆ Long-time member of ISO technical committee for Medical Device RM

Christie

- ☆ 13 years in Medical Device Risk Management
- ☆ Advisor to startups + emerging entrepreneurs in Quality + RM
- ☆ Authored:
  - ☆ Quality and RM chapter in published NIH pandemic response book
  - ☆ Several articles on RM
- ☆ Tireless champion of startups and small businesses
- ☆ New member to the ISO technical committee for Medical Device RM

The players

21 CFR Part 820 / QMSR

FDA's Quality Management System Regulation

ISO 13485:2016

International Quality Management System Standard

ISO 14971:2019

International Risk Management Standard

oh the times they are a'changin

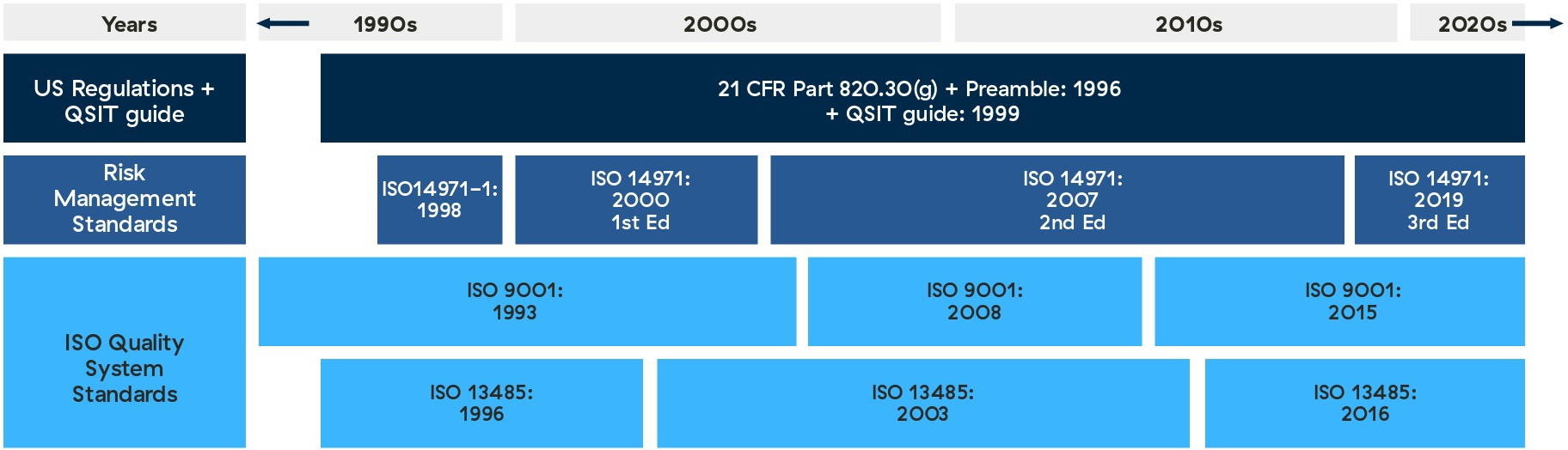
21 CFR Part 820 is harmonizing with ISO 13485:2016 under the new

Quality Management System Regulation (QMSR)

effective February 2026

Access the new QMSR here:
https://www.fda.gov/media/177022/download

A little history lesson with Professor Bills



To comply with QMSR, get familiar with ISO 14971:2019.

QMSR incorporates **ISO 13485:2016** by reference.

ISO 13485:2016 points to **ISO 14971:2019.**

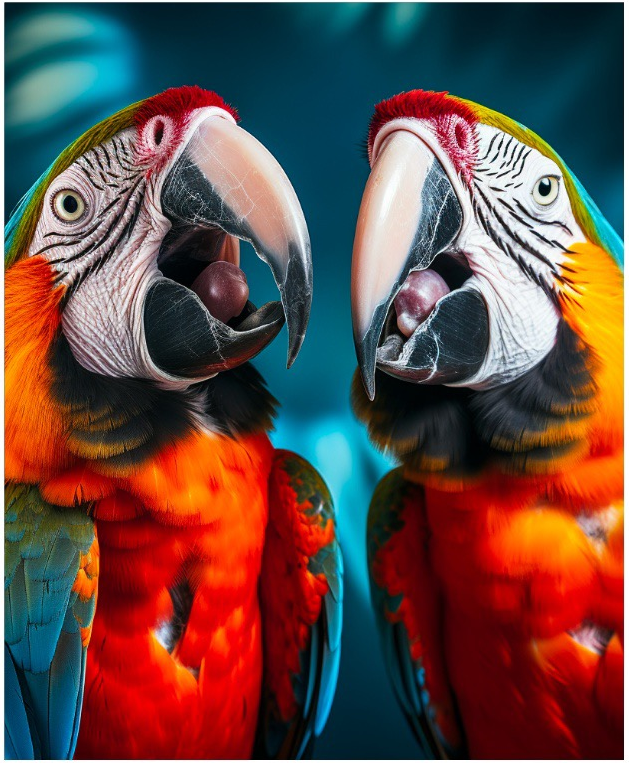
Everybody's talking about risk

FDA is being trained

ON ISO 14971:2019

MEDCON 2023

FOCUSED ON RISK



MORE REFERENCES TO RISK

in recent FDA presentations + warning letters

AAMI NeXus 2024

FDA introduced + discussed new QMSR and Risk

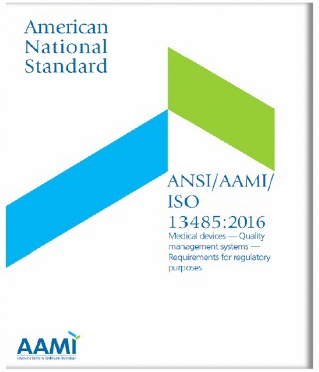
FROM FDA'S PRESENTATION AT MEDCON 2023

Delivered by Keisha Thomas and Karen Masley-Joseph

MEDCON CONFERENCE
COLUMBUS, OH · APRIL 24-27, 2023

Rationale for Utilization of ISO 13485: 2016

- Modernized QMS principles
- Greater integration of risk management activities
- Globally harmonized requirements
  - Standard used by many other Regulatory Authorities
  - Many global manufacturers already comply with ISO 13485
  - Requirements are substantively similar between the current part 820 and ISO 13485:2016



AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

QMSR released with comments

FDA provided answers to public comments

we can learn a lot from their answers

QMSR Comments are stuffed with references to risk

Quality Culture

Comment 27

14971 May be Helpful

Comment 9

Risk Definitions

Comment 31

Total Lifecycle Risk

Comment 19

Quality Culture: Comment 27

"...FDA expects medical device manufacturers, led by individuals with executive responsibilities, to **embrace a culture of quality** as a key component in... safe and effective medical devices..."

"A culture of quality meets regulatory requirements through a set of **behaviors, attitudes, activities, and processes**."

which behaviors and attitudes?

... and what does this have to do with risk management?

QUALITY CULTURE STARTS AT THE TOP

Encourage curiosity + question asking

Collaboration to create quality policy + objectives

Invite Quality and Risk perspectives

Invite patients + users to talk to the team

Provide resources for quality + risk

Lead with empathy

Risk Definitions: Comment 31

‘… we do not believe that a definition for “risk” unique to the QMSR is necessary and are retaining the unmodified definition in ISO 13485.”

Risk Definition from ISO 13485:

Combination of the probability of occurrence of harm and the severity of that harm

ISO 14971 "May Be Helpful": Comment 9

"...Aside from Clause 3 of ISO 9000, FDA does not, in this rulemaking, incorporate ISO 14971 or any other standards referenced by, or listed as a source in, ISO 13485,

but acknowledges that these other standards may be helpful

in understanding application of ISO 13485..."

may be helpful?

There are no other FDA-recognized standards for medical device risk management.

Other things which "may be helpful":
Optional FDA guidance documents, which we all know are NOT optional

Wait. What does ISO 14971 tell me to do?

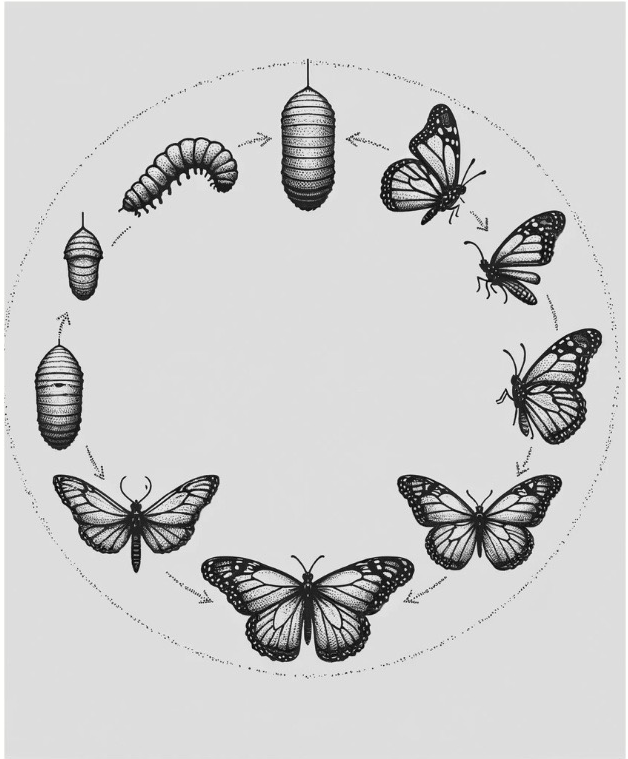
Keep it easy

Total Product Lifecycle Risk: Comment 19

"...Although the integration of risk management principles throughout ISO 13485 does not represent a shift in philosophy,

the explicit integration of risk management throughout the clauses of ISO 13485

more explicitly establishes a requirement for risk management to occur throughout a QMS and...



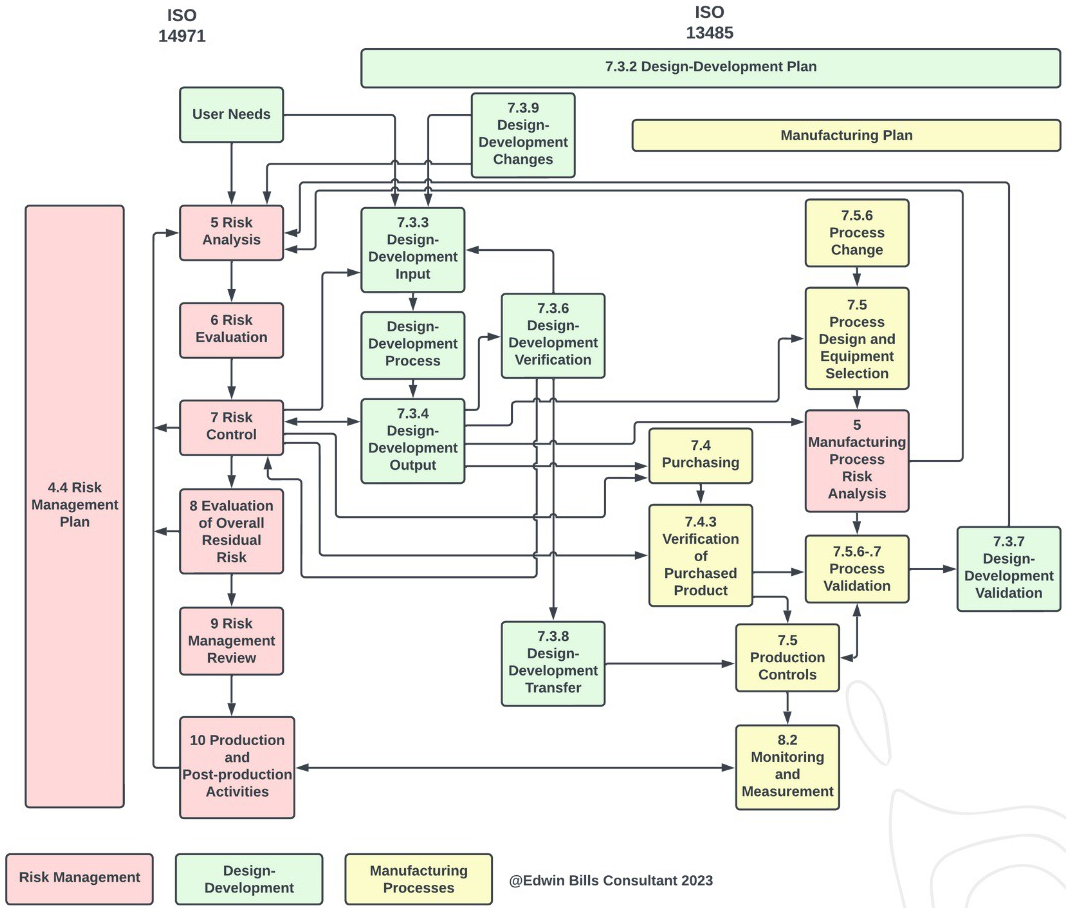
...should help industry develop more effective total product life-cycle risk management systems..."

ISO 13485:2016 is dripping in references to Risk Management

- overall QMS
- purchasing
- product realization
- monitoring + measurement
- human resources

At first glance...

The relationship between ISO 13485 and risk is complicated.



Intersections of ISO 13485:2016 and ISO 14971:2019

Learn more here:

https://www.meddeviceonline.com/doc/the-intersection-of-iso-and-iso-under-the-proposed-fda-qmsr-0001

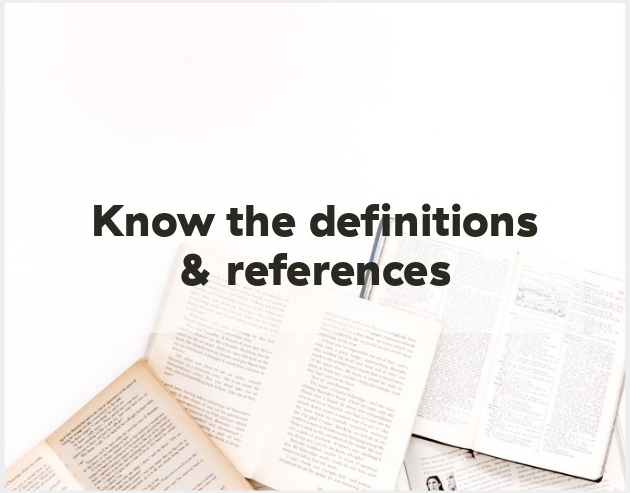
and here:
https://www.meddeviceonline.com/doc/new-fda-qmsr-through-the-lens-of-risk-management-requirements-and-analysis-0001

got that?

Think about Risk Management per ISO 13485:2016 **like chapters in the story of bringing a product to life.**

1. prologue
2. design + development
3. manufacturing
4. post-market

1 | Prologue



1 | Prologue

Know the definitions & references

- 3.17 risk
- 3.18 risk management
- 3.9 life cycle
- 7.1 NOTE

  "further information can be found in ISO 14971"

Design your QMS based on risk

Consider risk in the scope and depth of the QMS

ISO 13485:2016 § 4.1.2 (b)

"... apply a risk based approach to the control of the appropriate processes needed for the quality management system"

... including Risk Management processes

ISO 13485:2016 § 7.1

"the organization shall document one or more processes for risk management in product realization"

Create + maintain records

Quality records need to be kept

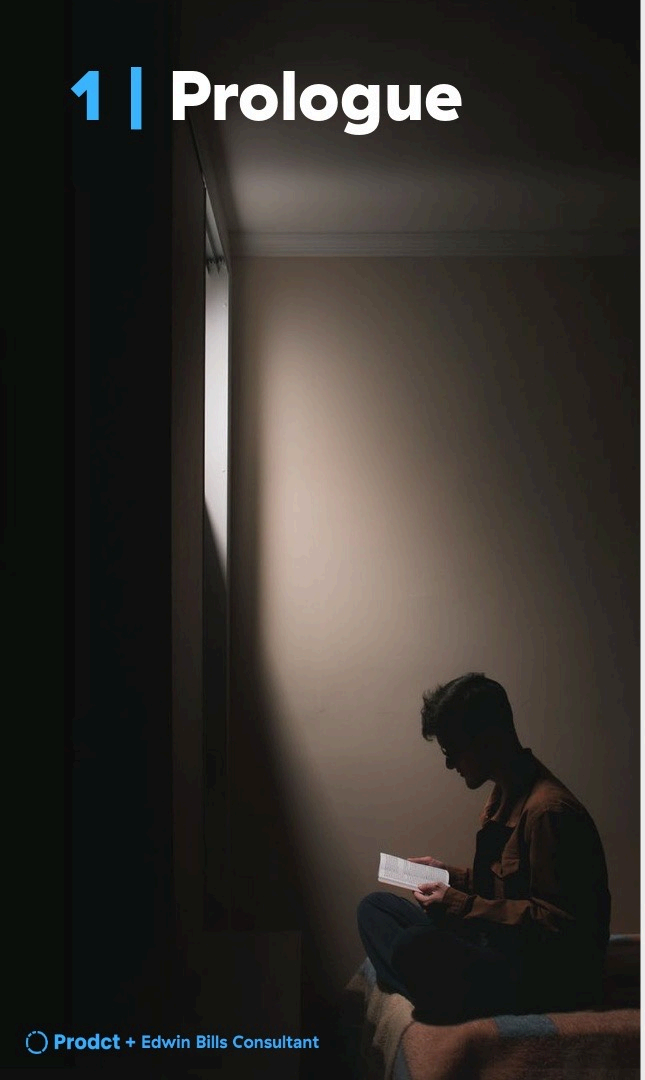
ISO 13485:2016 § 4.2.5

"records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system"

...including Risk Management records which need to be accessible throughout the product lifecycle

ISO 13485:2016 § 7.1

"Records of risk management activities shall be maintained"



Management is ultimately responsible

...to provide resources

ISO 13485:2016 § 5.1

"top management shall provide evidence of its commitment to the development and implementation of the qms and maintenance of its effectiveness by... (e) ensuring availability of resources"

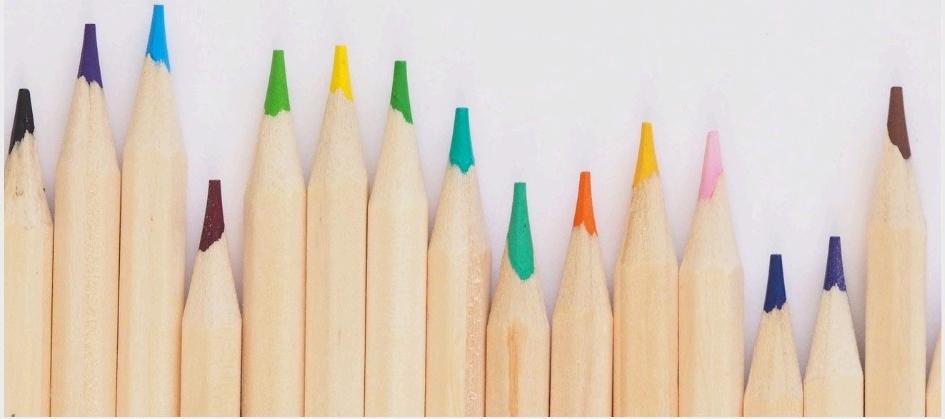
and qualifications + training which provides competent personnel

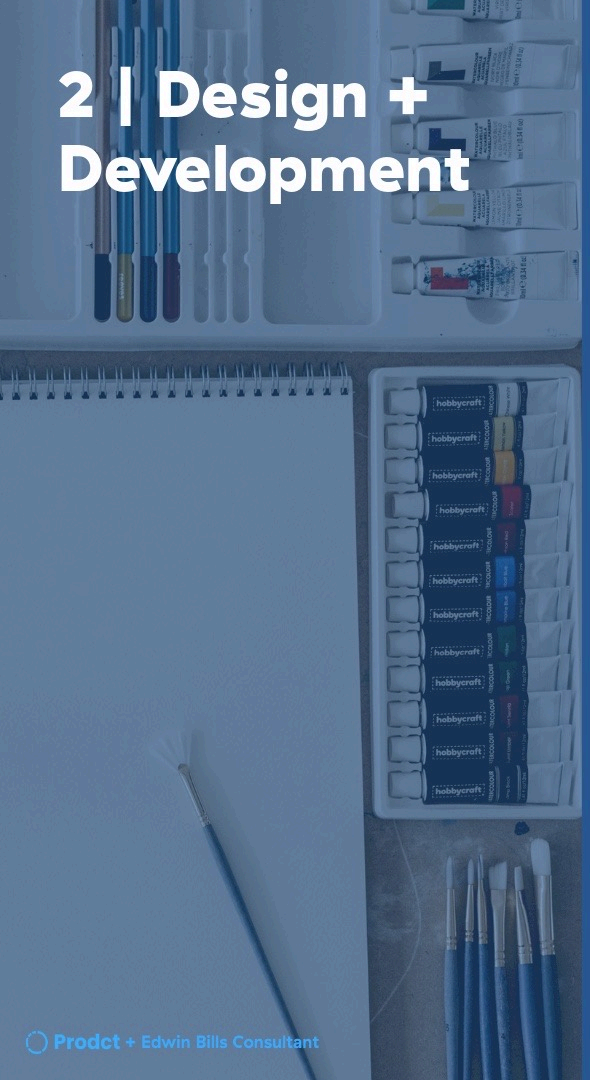
ISO 13485:2016 § 6.2

"*Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience*"

"The methodology used to check effectiveness [of training] is proportionate to the risk associated with the work for which the training or other action is being provided"

2 | Design + Development





2 | Design + Development

Risk Management + Design Requirements feed each other

ISO 13485:2016 § 4.1.2 (b)

"Inputs relating to product requirements shall be determined and records maintained... shall include (c) applicable outputs of risk management;"

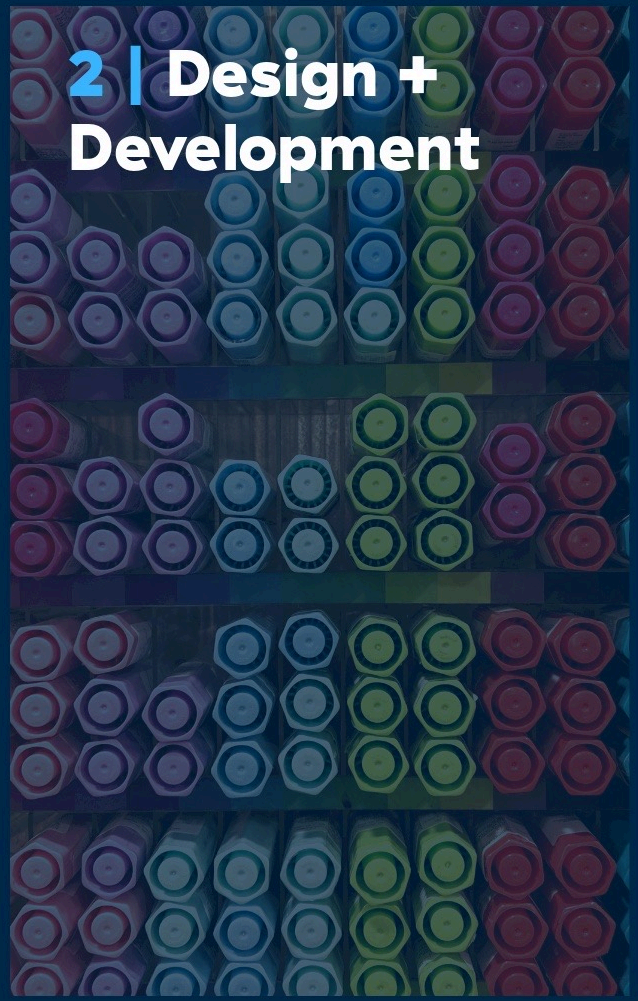
Risk + Requirements inform each other iteratively.

IS MY RISK MANAGEMENT FILE READY?

If your risk management file *only* contains an FMEA, you have work to do.

Inputs to Risk Analysis

iterate, iterate, iterate, iterate, iterate



2 | Design + Development

Evaluate every change's impact to Risk

you can't know until you check.

ISO 13485:2016 § 7.3.9

"The review of design and development changes shall include ... inputs or outputs of risk management ..."

Every change order (ECO, ECN, CO, etc.) should include an evaluation of the change on risk management inputs and outputs (not just a checkbox)

3| Manufacturing

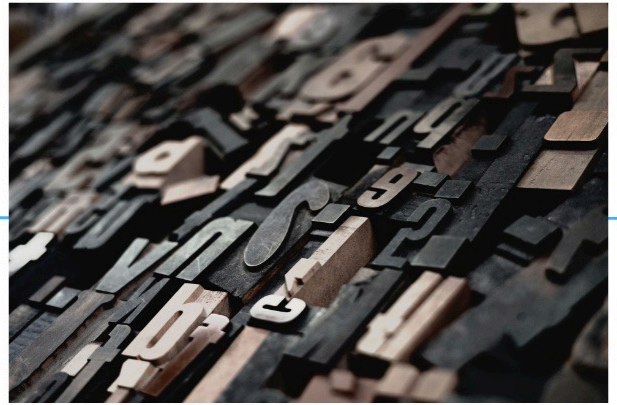
Supplier management, incoming inspection, process + software validation should all be proportionate to the risk of the product

Evaluate every process change's impact to risk

Nonconformities in production should be analyzed for risks

3 | Manufacturing

"...proportionate to the risks"



Criteria for evaluation and selection of suppliers

§ 7.4.1

Non-fulfillment of purchasing requirements (supplier/part nonconformities)

§ 7.4.1

Verification of purchased product (incoming inspection)

§ 7.4.3

Process + software validation

§ 7.5.6

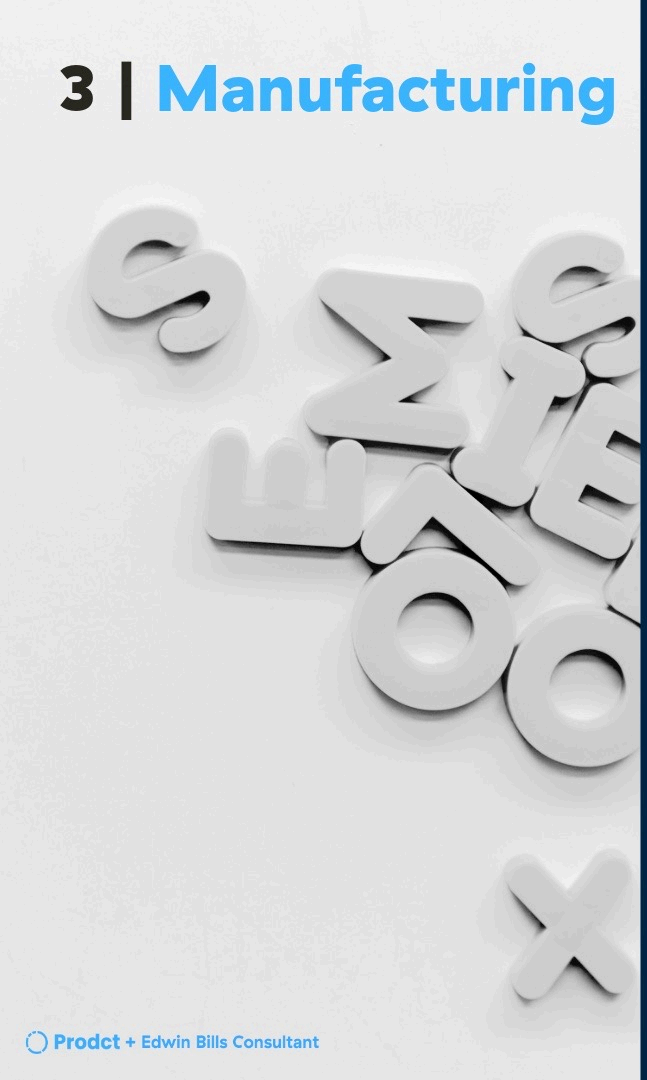
Changes in the manufacturing suite are evaluated for impact to risk, too.

ISO 13485:2016 § 7.3.9

*"The review of design and development changes shall include … inputs or **outputs** of risk management …"*

Reminder – **outputs** of Risk Management include

- ✓ design features
- ✓ manufacturing controls
- ✓ safeguards
- ✓ information for safety



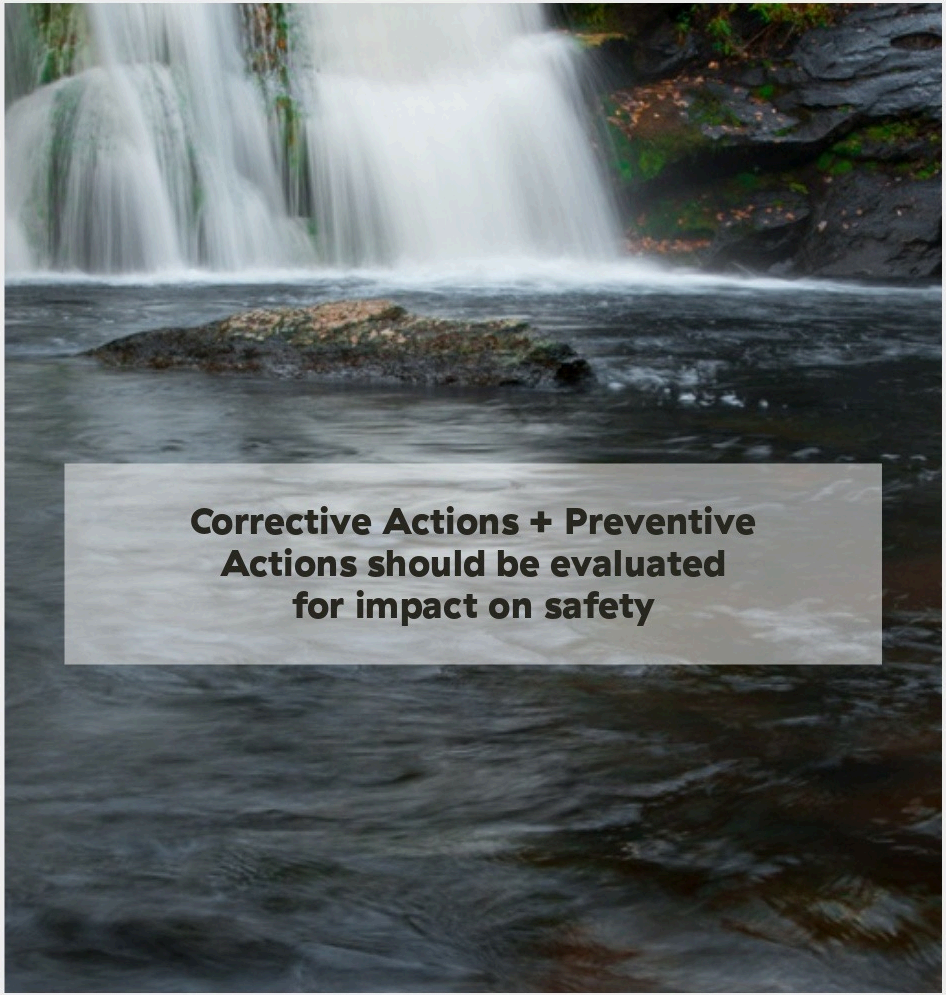
Nonconformities in production should be analyzed for risks

NCMRs should be evaluated and dispositioned based on **risk**

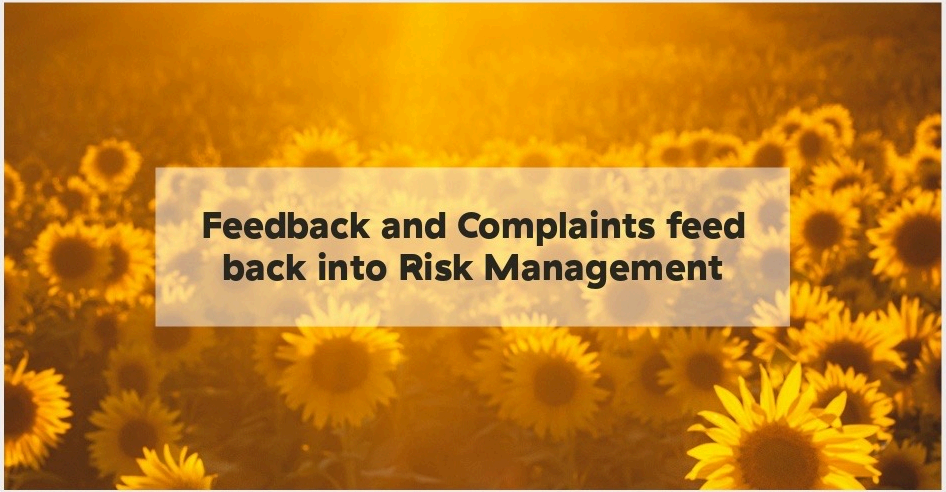
ISO 13485:2016 § 8.3.1

"Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained"

4| Post Market



Corrective Actions + Preventive Actions should be evaluated for impact on safety



Feedback and Complaints feed back into Risk Management

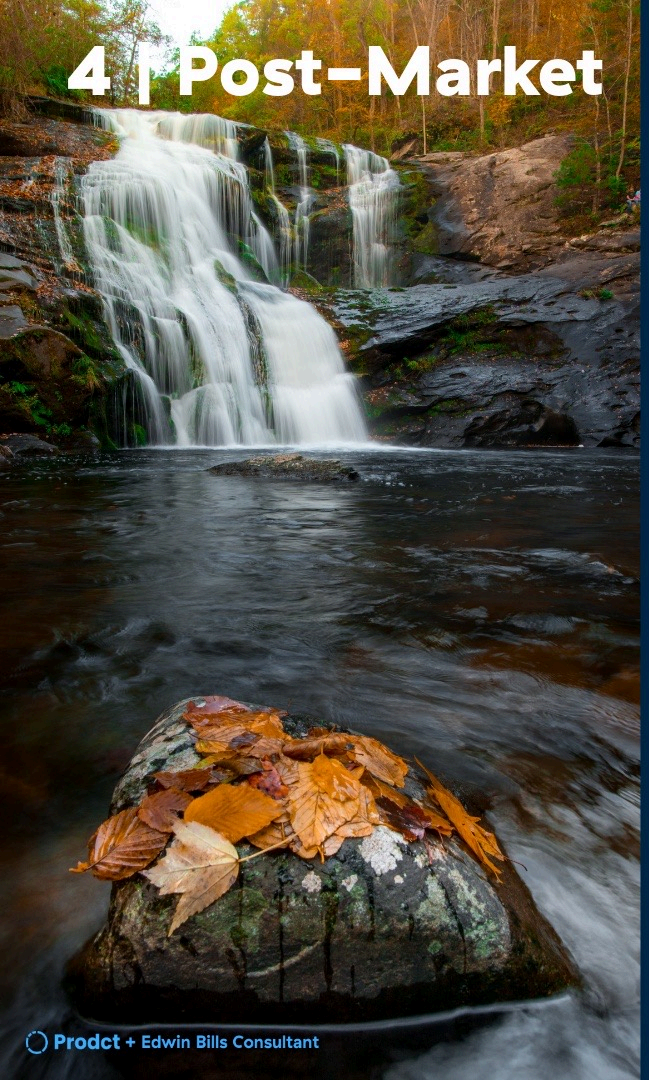
4 | Post-Market

Feedback and Complaints should feed back into Risk Management

Every single complaint should be evaluated for a relevant entry in the Risk Management File

ISO 13485:2016 § 8.2.1

"The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realizaiton or improvement processes"



4 | Post-Market

Corrective Actions and Preventive Actions should be evaluated for impact on Safety

Corrective Actions may impact risk

ISO 13485:2016 § 8.5.2 (e)

"...verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device"

Preventive Actions may also impact risk

ISO 13485:2016 § 8.5.3 (d)

"...verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device"

Where do I start?

Do I have a QMS already?

yes

conduct gap analysis for compliance to ISO 13485:2016 appropriate for your company & product(s)

where risk is referenced in ISO 13485:2016 – make sure your processes pull in ISO 14971:2019

no

give up, you have no chance

Start creating a risk analysis as you build product requirements.

Update these a lot.

As you build each module of your QMS, refer to ISO 13485 and ISO 14971 to build strong processes.

Remember, there's no phase for risk management

We're Better Together

Risk Management belongs to everyone.

Key takeaways

You need to practice risk management to comply with QMSR

FDA tells us complying with ISO 14971 is a very good idea

Your quality system is more than your SOPs... It's behaviors and attitudes, too

Your risk management processes need to touch the whole lifecycle of your device (FMEA is NOT enough)

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