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Engineering the extraordinary

International Conference on Medical Device Safety Risk Management

Capturing Early Phase Development History: Applying Risk Management from Initial Conception

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April 2025

Noel Butterworth, Snr Quality Program Manager





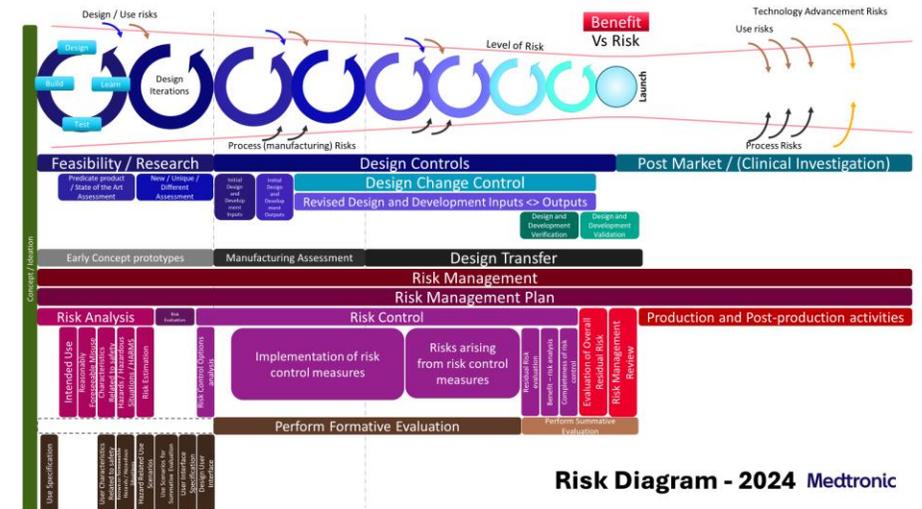
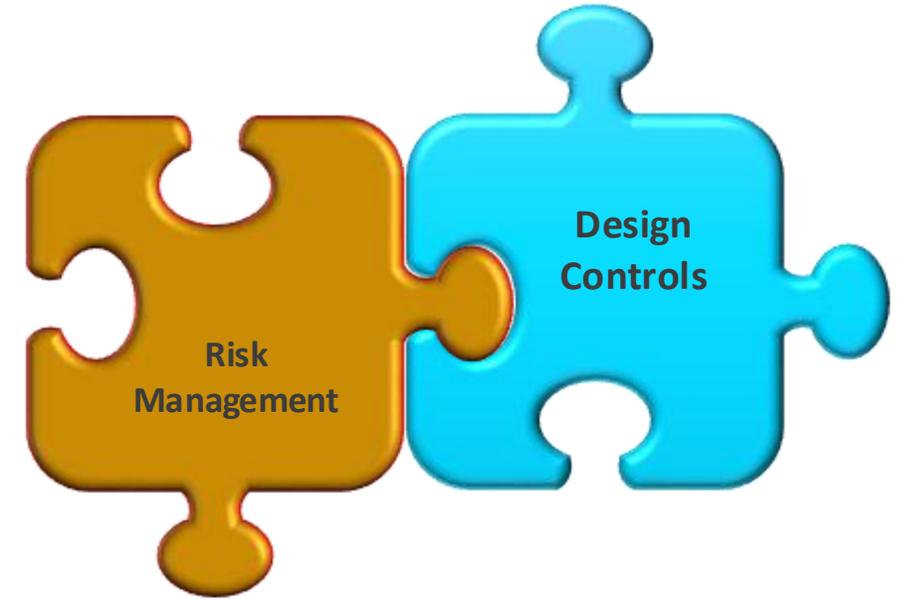
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because King Arthur didn't allow cameras in court at Camelot.

Agenda

“In the next 30 minutes..”

- Identifying & solving risks with design history
- Embedding risk analysis into design conception



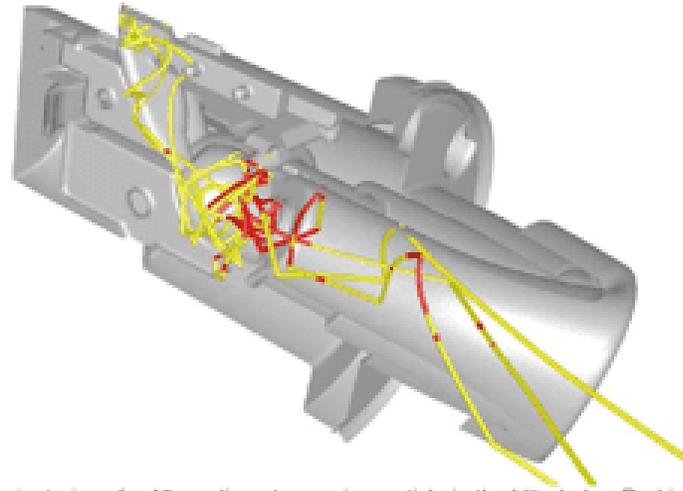
Risk Diagram - 2024 Medtronic

Personal Story

“The Missing Design History”

“We can’t make this [profile]- what is the basis of the design?”

My learning: even in the early days of development it is important to document what has been changed but also why it has been changed



Trajectories of a 48µm-diameter carrier particle in the Ultrahaler. Red indicates

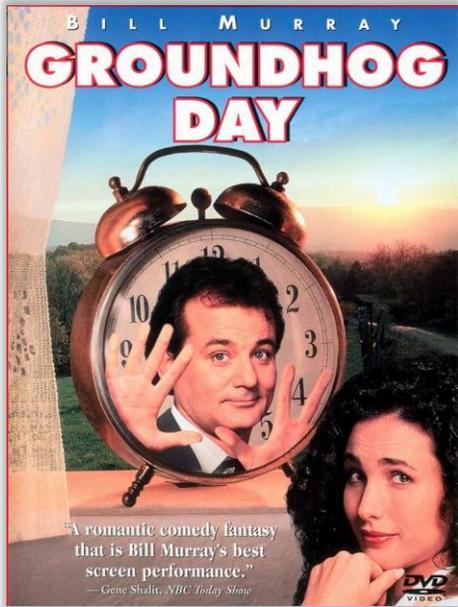
Importance of Wall Collisions for Particle-Particle Detachment in Dry Powder Inhalers, and Advanced Wall Collision Models

- E. Wynn, S. Nichols
- Published 2008



Background- Focus on Risk Management

FDA QMSR



02 February 2024

FDA Releases Final Rule on 21 CFR 820
Harmonisation with ISO 13485:2016

“FDA believes that the more explicit integration of risk management throughout ISO 13485 and incorporated into the QMSR will help best meet the needs of patients....”

-- 21 CFR 820 (2024) Comment 1

“...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.”

-- 21 CFR 820 (2024) Comment 19

“Tendency to silo RM [Risk Management] in design controls, ‘one and done’ ”

-- Erin Keith, FDA Senior Advisor, Presentation to First Risk Management Conference, April 2024

“Safe, effective and high-quality”

This action will continue our efforts to align our regulatory framework with that used by regulatory authorities in other jurisdictions to promote consistency in the regulation of devices and provide timelier introduction of **safe, effective, high-quality** devices for patients.

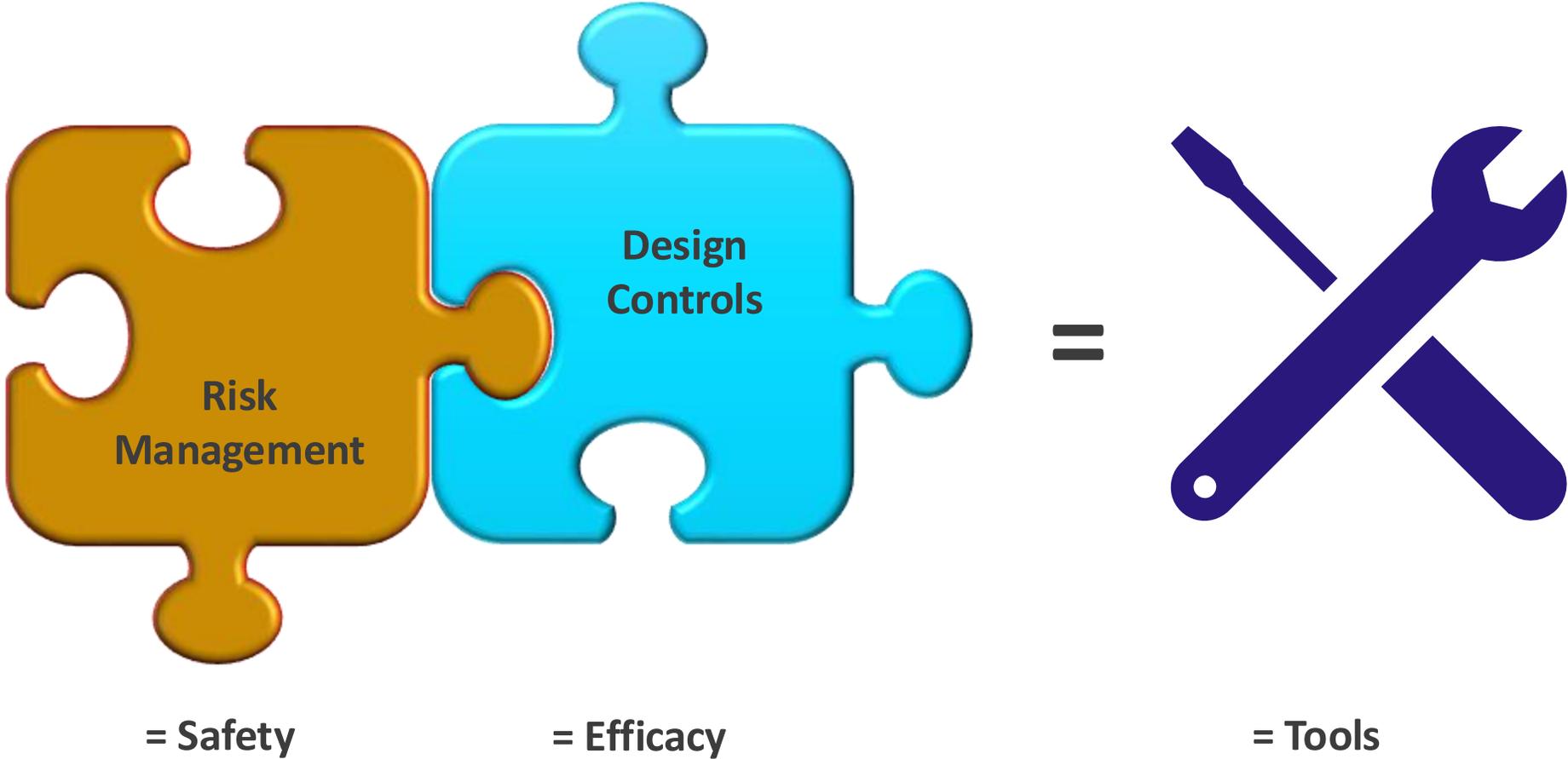
FDA notes that harmonizing the regulation of devices will help provide **safe, effective, and high-quality devices**, contributing to public health through timelier access for patients.

FDA believes the global harmonization of medical device regulation can help provide **safe, effective, and high-quality** devices and contributes to public health through timelier patient access to such devices.

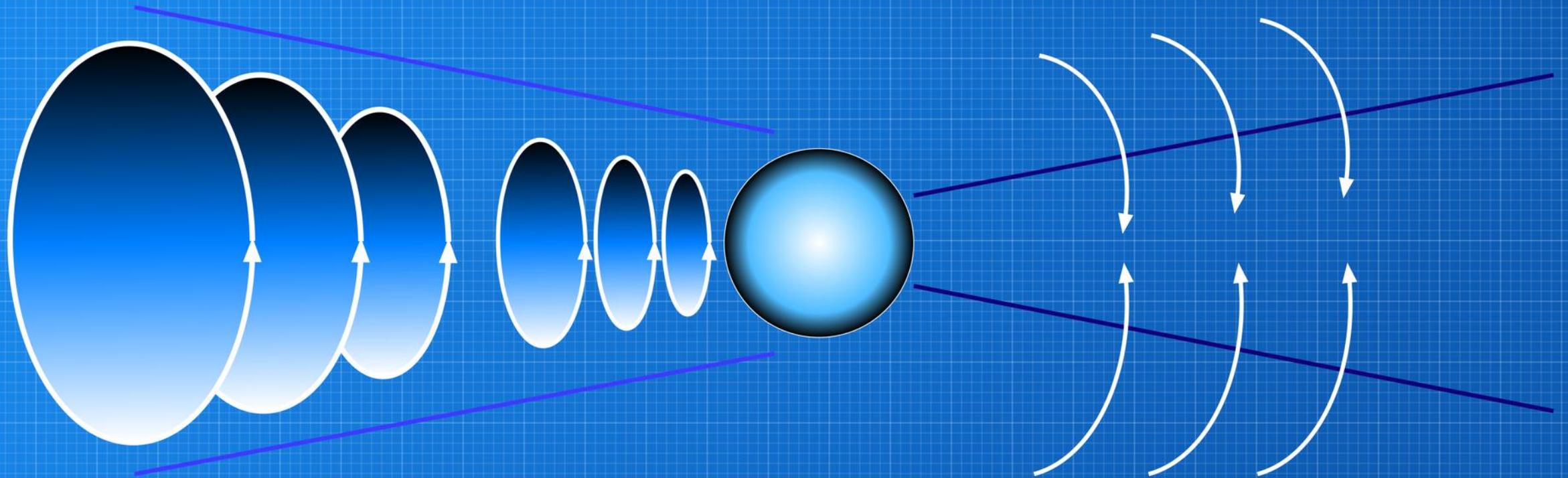
As FDA has explained in the guidance document entitled “The Least Burdensome Provisions: Concept and Principles,” the least burdensome principles should be consistently and widely applied to the regulation of medical devices to help remove or reduce unnecessary burdens so that patients can have earlier and continued access to **high-quality, safe, and effective devices**.

-- FDA 21 CFR 820 Final Rule / QMSR (2024)

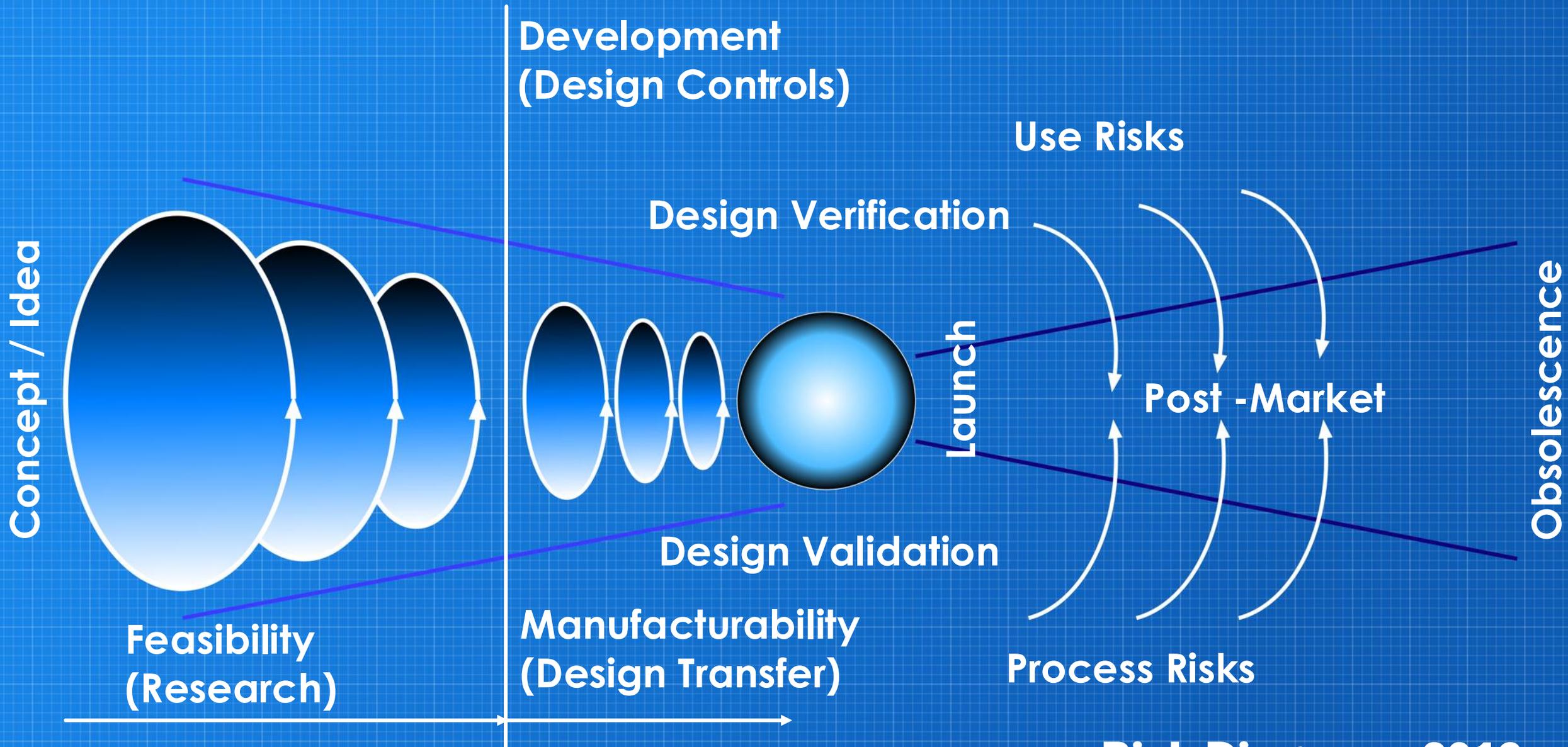
Safe, Effective



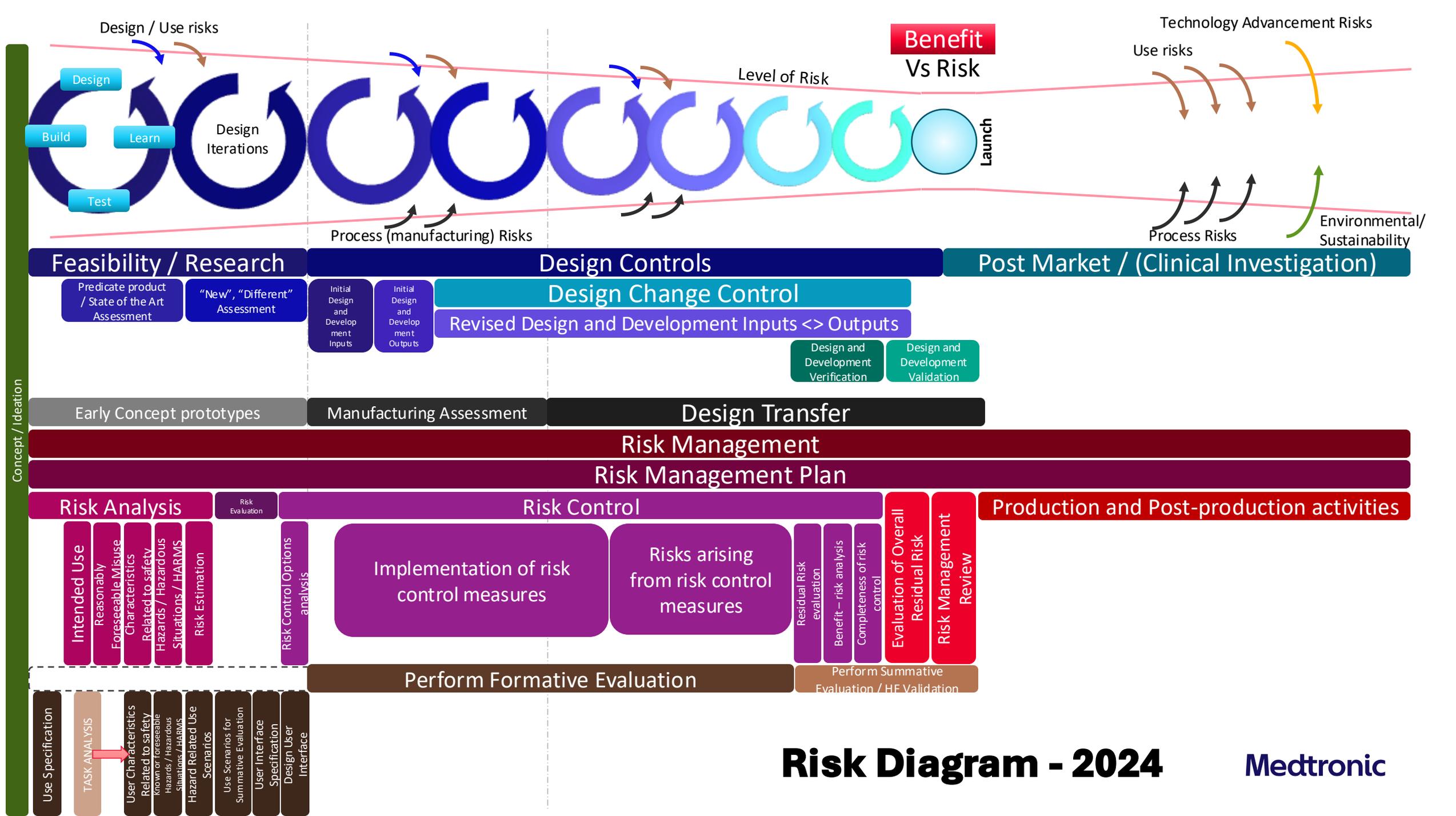
Documentation records being the evidence and *proof* that activity and effort have been successfully conducted for safety and efficacy.



Risk Diagram - 2016



Risk Diagram - 2016



ISO 14971: 2019

3.8

life cycle

series of all phases in the life of a *medical device* (3.10), from the initial conception to final decommissioning and disposal

Risks can be present throughout the *life cycle* of the *medical device*, and *risks* that become apparent at one point in the *life cycle* can be managed by action taken at a completely different point in the *life cycle*. For this reason, the standard needs to be a complete *life cycle* standard. This means that the standard instructs *manufacturers* to apply *risk management* principles to a *medical device* from its initial conception until its ultimate decommissioning and disposal.

ISO 13485: 2016

3.9

life-cycle

all phases in the life of a medical device, from the initial conception to final decommissioning and disposal

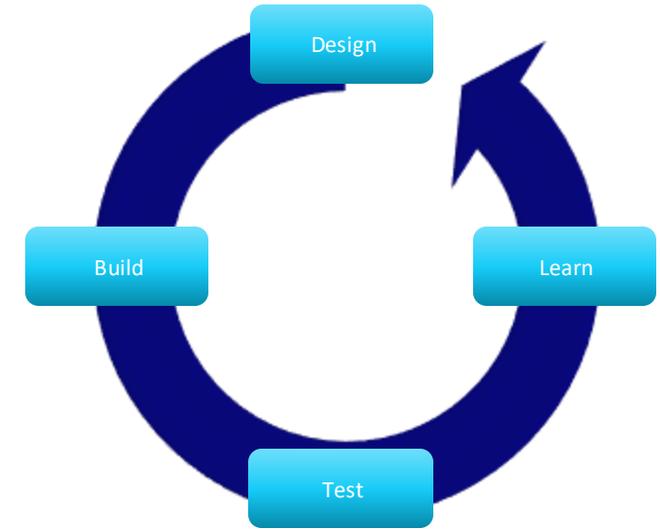
[SOURCE: ISO 14971:2007, 2.7]

>(per '*life cycle*'^{ISO1971:2019} or '*life-cycle*'^{ISO13485:2016} or '*lifecycle*'^{ISO13485:2016 A Practical Guide})

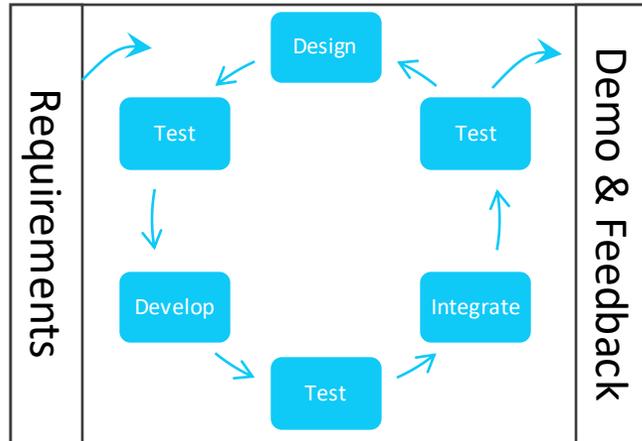
Highest Priority features (core functionality)

Medium Priority features

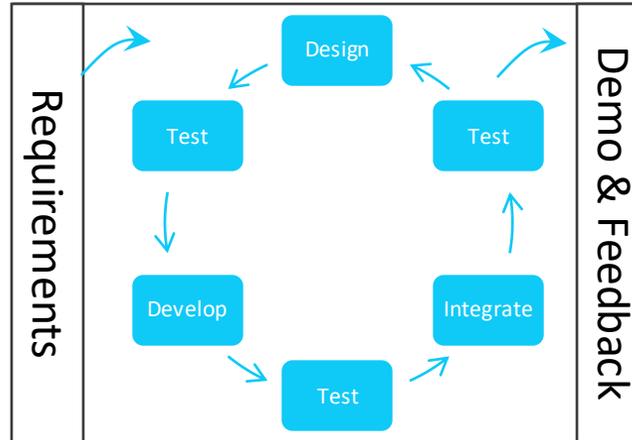
Refinements / Manufacturability



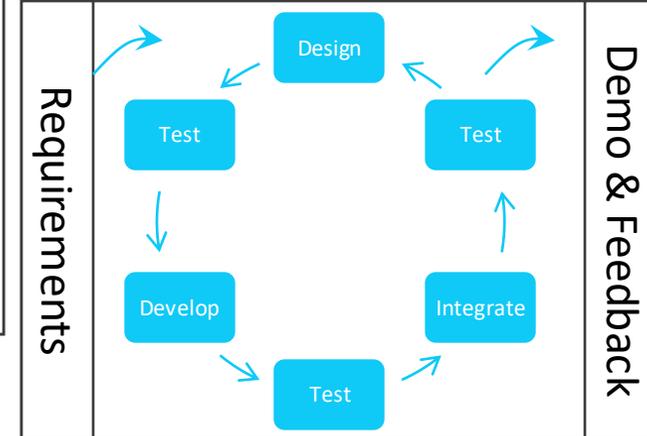
SPRINT 1: Highest Priority Features



SPRINT 2: High Priority Features



SPRINT 3: Medium Priority Features



Agile Project Management**

* Design 'funneling' based on presentation "Insight, Innovation & Design"- PDD Group LTD 2007

** Agile Project Management based on diagram from Agile Project Management for Dummies (Wiley)

- Mark CLayton, Steven J Ostermiller, Dean J Kynaston)

Design Iterations

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Diagrammatic: Design Input / Output iterations need not correspond to specific design iterations

Feasibility / Research

Design Controls



Preamble CFR 820: 63. (1996) “...It is not the intent of FDA to interfere with creativity and innovation, and it is not the intent of FDA to apply the design control requirements to the research phase.manufacturers should document the flow of the design process so that it is clear to the FDA investigator where research is ending and development of the design is beginning. “

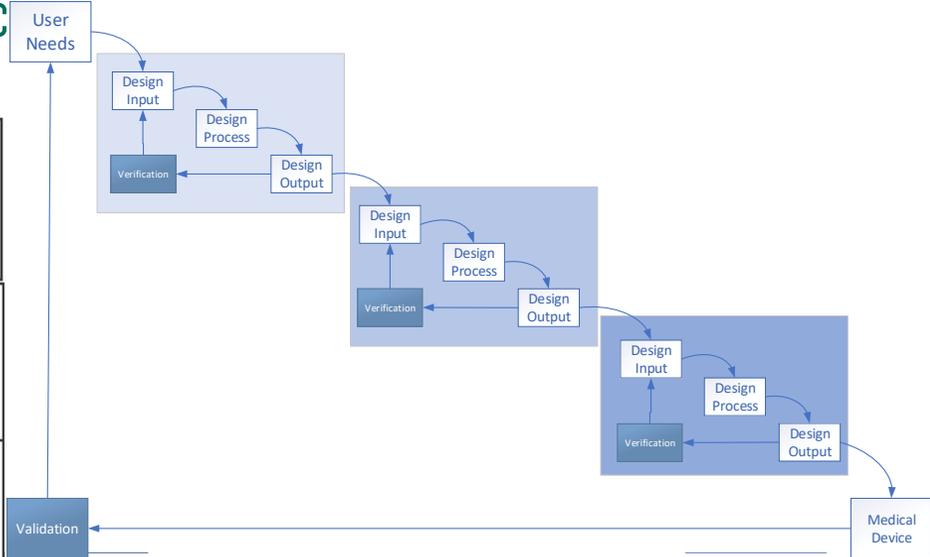
Comments 21 CFR 820: 45 (2024). “...For all devices to which design and development requirements apply, FDA does not expect manufacturers to maintain records of all changes proposed during the very early stages of the design process. However, a successful QMS requires a manufacturer to document design changes made after the initial design inputs have been approved...”

ISO 13485:2016 – A Practical Guide

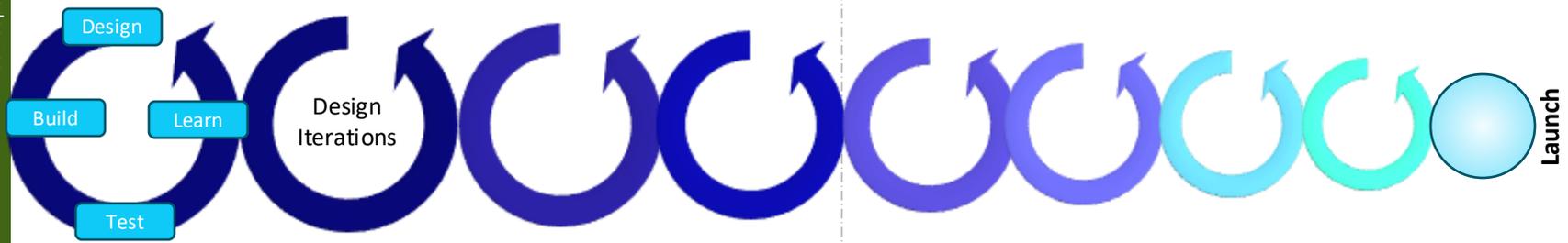
“...an iterative process of translating (those) inputs into a medical device begins ...first step is conversion of the inputs into system or high-level specifications. Thus, these specifications are a design and development output. Upon **verification that the high-level specifications conform to the inputs, they become the design and development input for the next step** in the design and development process...”

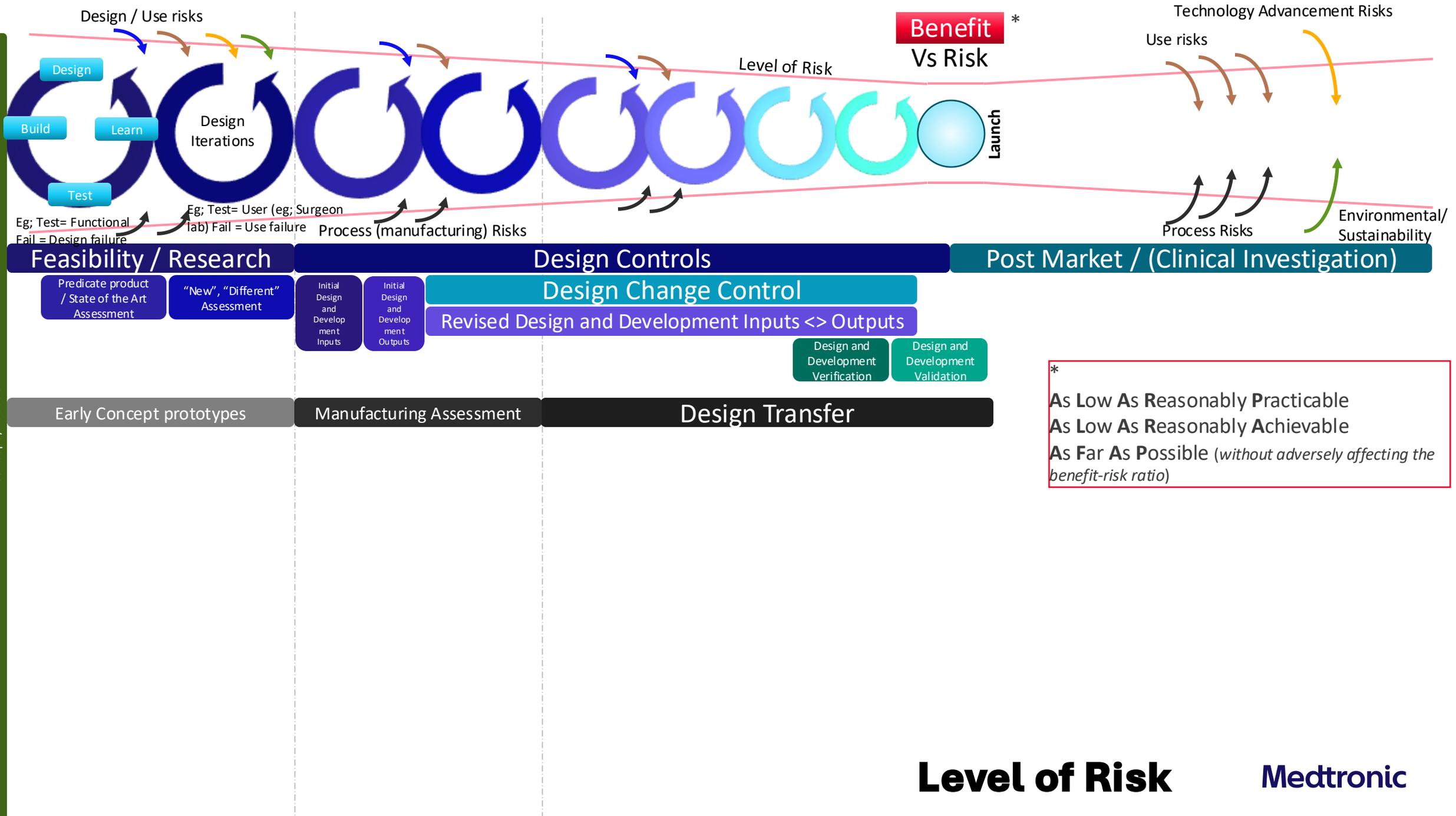
Each input is converted into an output; each output is verified as conforming to its input; and then it becomes the input for another step in the process. In this manner, the inputs are translated into a medical device conforming to the requirements”

Design Control Guidance for Manufacturers (1997): “The design output in one stage is often part of the design input in subsequent stages.”

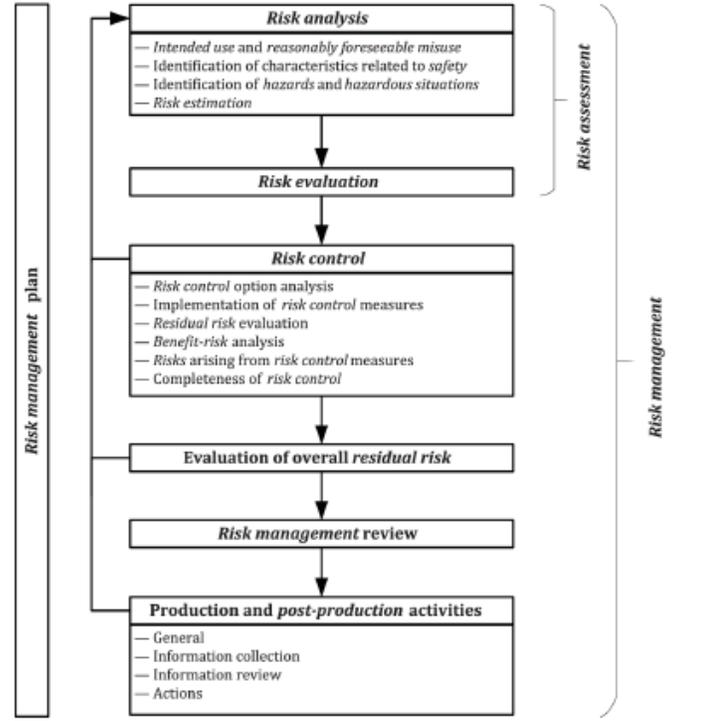
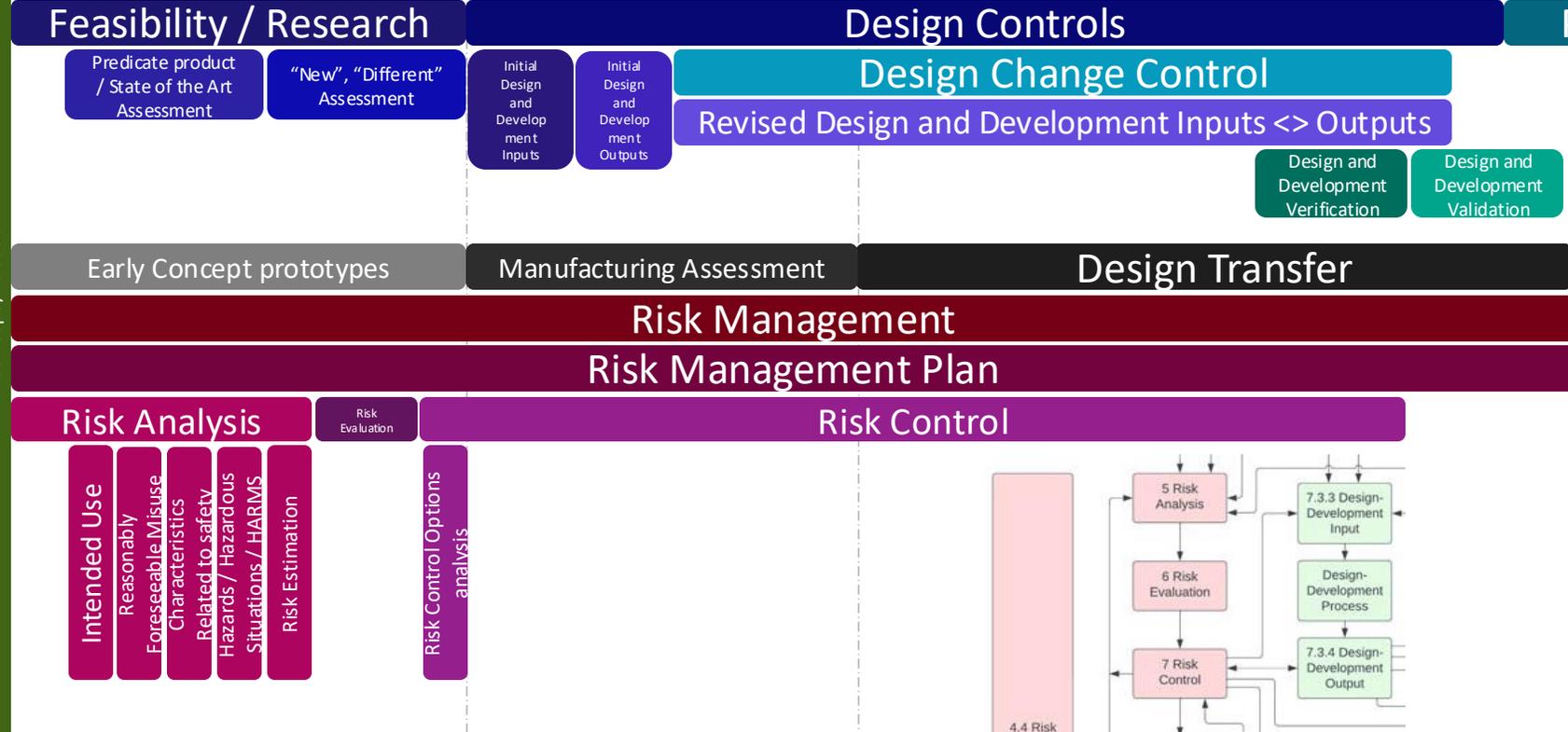
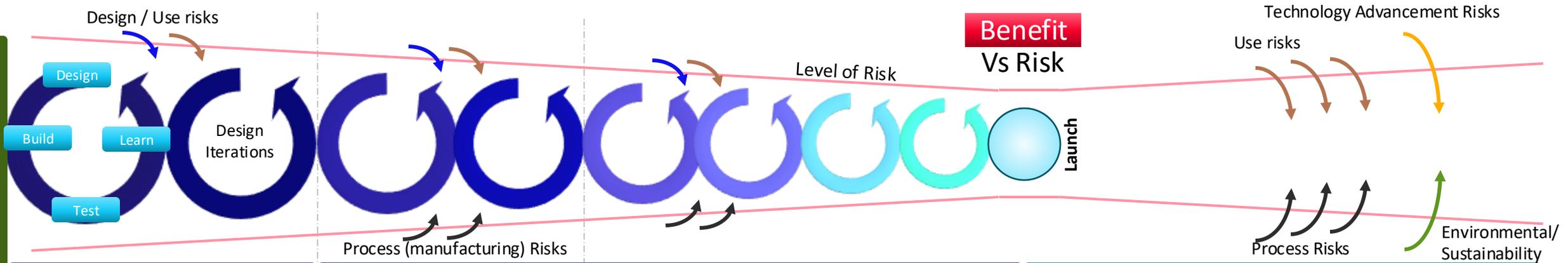


Design Controls Medtronic





*
As Low As Reasonably Practicable
As Low As Reasonably Achievable
As Far As Possible (*without adversely affecting the benefit-risk ratio*)



c) applicable output(s) of risk management;
 ISO 13485:2016 7.3.3 Design and development inputs

Med Device Online: New FDA QMSR Through The Lens Of Risk Management: Requirements And Analysis
 Edwin Bills, Christie Johnson, and Jayet Moon 29 February 2024)

ISO 14971:2019 Medical devices—Application of risk management to medical devices



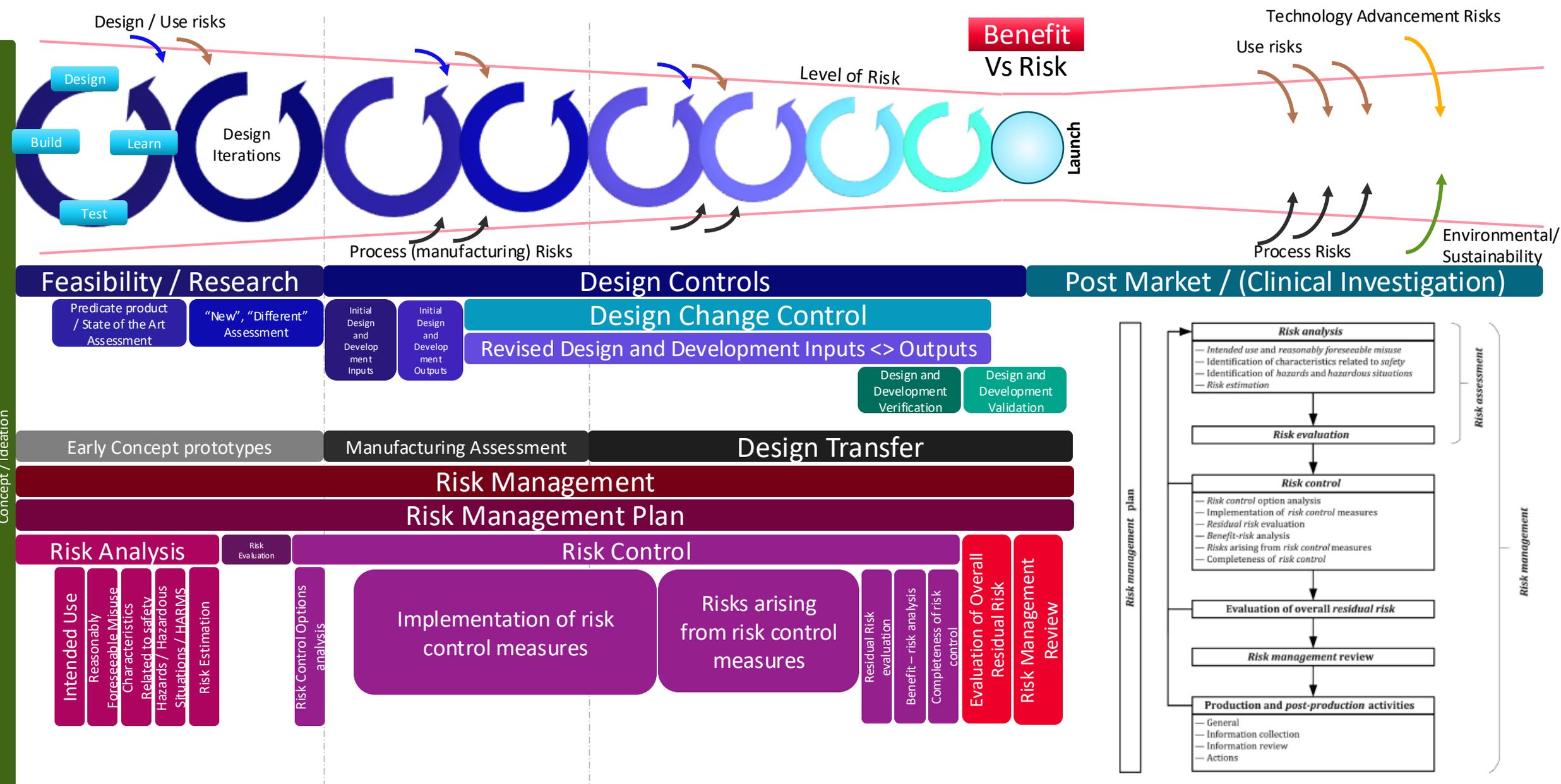
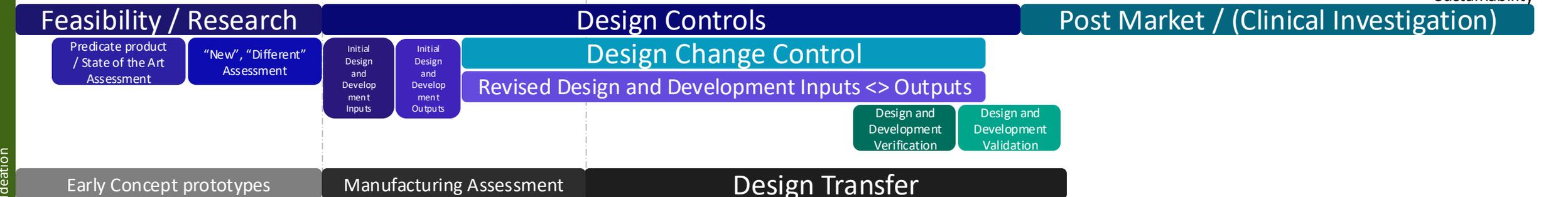
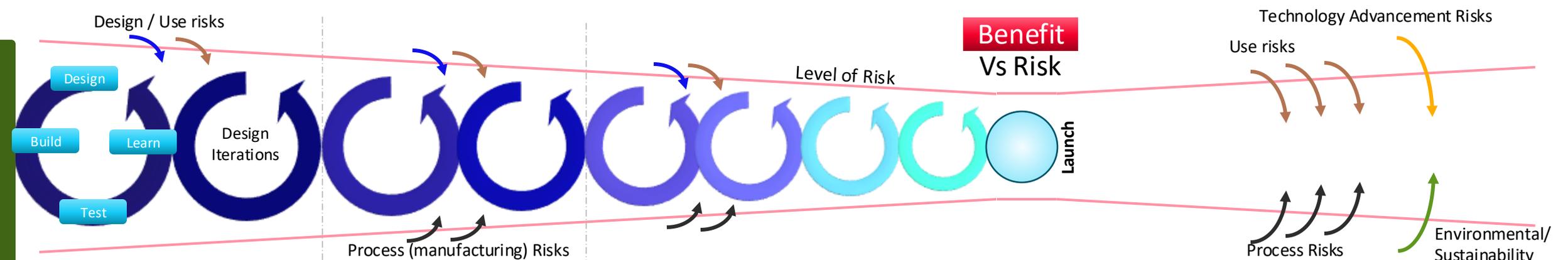
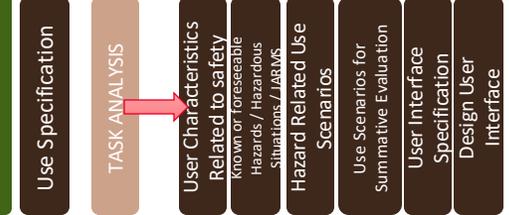
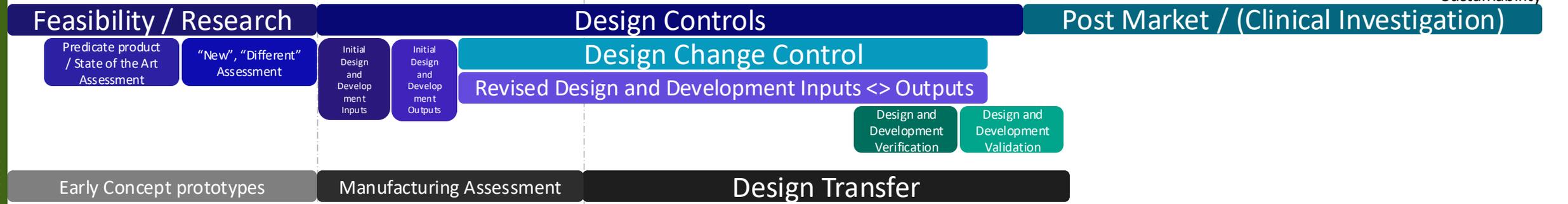
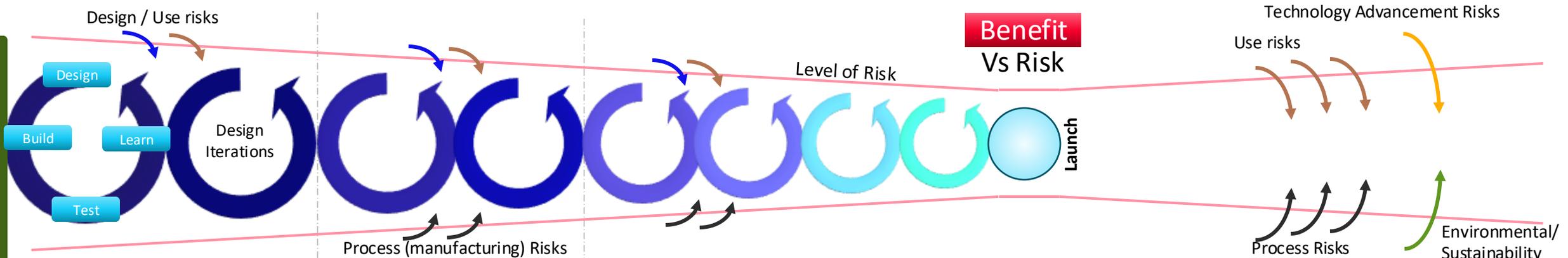


Figure 1 — A schematic representation of the risk management process





Management of Risk through Product Development

RISK: Design History not recorded

Highest Priority features (core functionality)

Medium Priority features

Refinements / Manufacturability



Feasibility / Research

Design Controls

Post Market / (Clinical Investigation)

Risk Management

Design Change Control

Risk Evaluation > Risk Control

Initial Design and Development Inputs

Initial Design and Development Outputs

Revised Design and Development Inputs <> Outputs

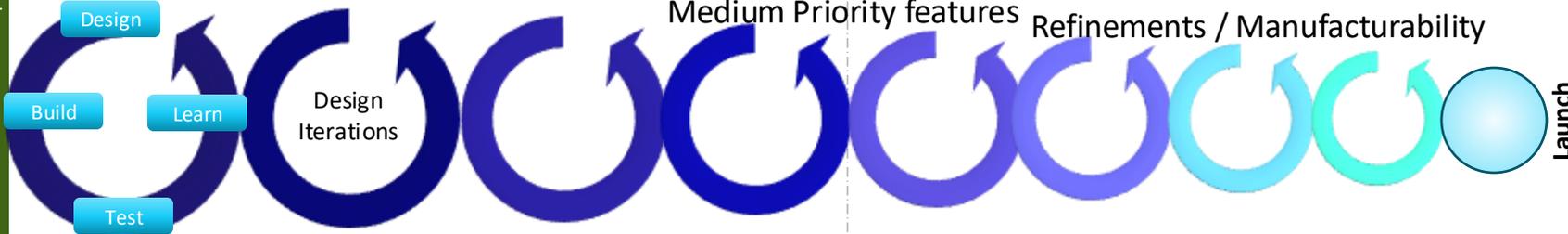
Documentation effort to be commensurate to the risk of the device

RISK: Design History not recorded

Highest Priority features (core functionality)

Medium Priority features

Refinements / Manufacturability



Feasibility / Research

Design Controls

Post Market / (Clinical Investigation)

Risk Management

Design Change Control

Risk Evaluation > Risk Control

Initial Design and Development Inputs

Initial Design and Development Outputs

Revised Design and Development Inputs <> Outputs

Design Controls & Design History

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Concept / Ideation

Summary

- Documentation of development history can be "held-off" during the early phases of a project. However, Risk Management can and should be used to fill the gap- it's required (by definition) from ***initial conception***.
- Managing the highest priority features in the earliest phases will give opportunity to understand some initial risks for those high priority features.
- **Safety** determined from the Risk Management process throughout device Design and Development (including early concept development)
- **Effectiveness** from the design and development history / process, from early concept development through to and including Design and Development Validation.
- Documentation records being the evidence and *proof* that activity and effort have been successfully conducted for safety and efficacy.
- How to record (the information), when to record, who to record and what to record- "TBD", but do not skip **why** to record and **why** the design has changed.



Questions?

("That's a lot of info, folks!")



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