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FOCUS ON RISK MANAGEMENT IN QMS CHANGE CONTROL

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opinions of the
presenter and are not
intended to represent the
opinions of Medtronic plc.*



Medtronic
Further, Together

RISK MANAGEMENT & CHANGE CONTROL OVERVIEW

- Risk Management
 - Medical Device: Benefit/Risk
 - In the product Life-Cycle
- Knowledge Management during Feasibility
- Changes during development
- Post-launch design and process changes
- QMS Change Control
- Change Control Software

Types of changes:

Design Changes	CFR820.30 (i) ISO 13485: 2016 Section 7.3.9
Process Changes	CFR820.70 (b) ISO 13485: 2016 Section 4.1.4 / 4.2.4
Document Changes	CFR820.40 (b) ISO 13485: 2016 Section 4.2.4 / 4.2.5

Quality System Changes

*Ref: AAMI TIR102:2019
U.S. FDA 21 CFR mapping
to the applicable regulatory
requirement references in
ISO 13485:2016 Quality
Management Systems*

RISK!!!!!!

Risks are everywhere....

"They surround us.. (etc)"



Image source:technabob.com

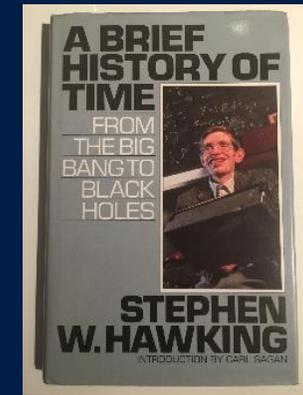
"Everything that is engineered (Design / Manufactured) is unique, and has a propensity to fail"

Second Law of Thermodynamics; Entropy increases (or remains the same) in a closed system

"The increase of disorder or entropy is what distinguishes the past from the future, giving a direction to time"

--Stephen Hawking, A Brief History of Time

- Medical Devices are not 100% risk free
- Risk Management and Benefit-Risk Analysis required



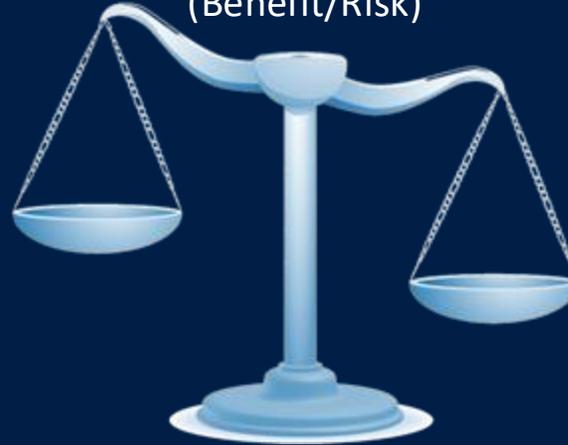
Project Risk



Types of risk:



They are interconnected
(Benefit/Risk)



Product Risk



Successful delivery of a design is the correct balance of product and project risk

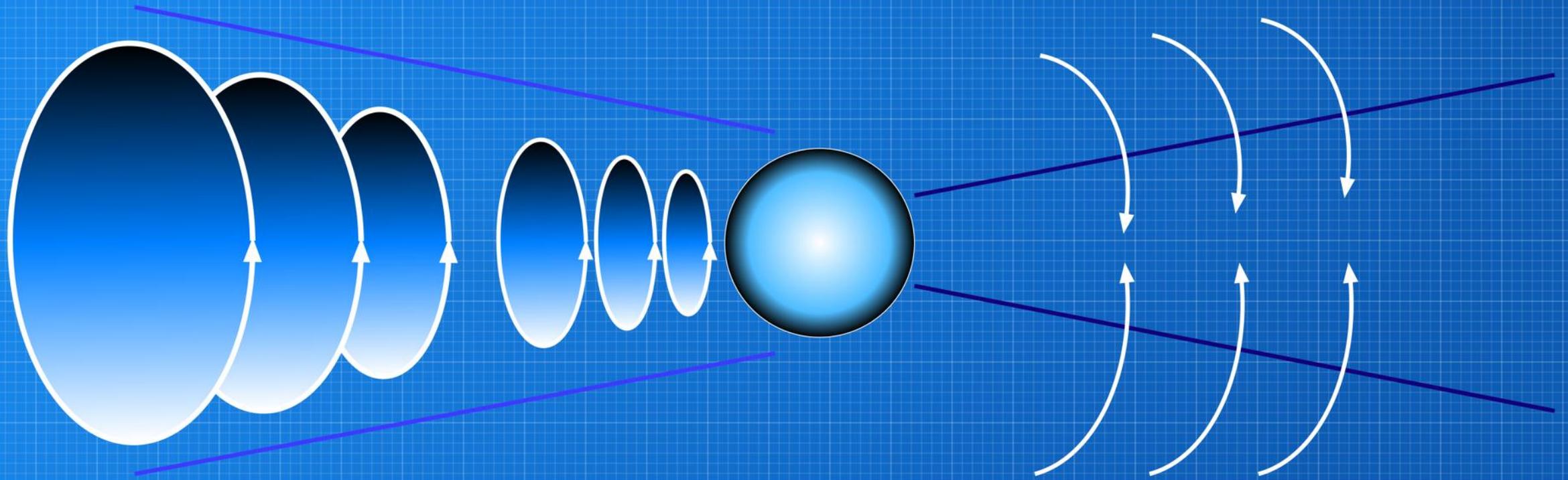
Deliver project earlier

Accept some level of device design risk,
Risk: fail to assess (or ignore) all potential risks, have serious failure issue, recall device (Device / Product risk), bad company image, company shares fall, etc...



Minimise Device design risk Design and test out failure modes

Risk: Extend project time, delay project, fail to deliver project (Project Management risk), no income to company, bad company image, company shares fall, etc...

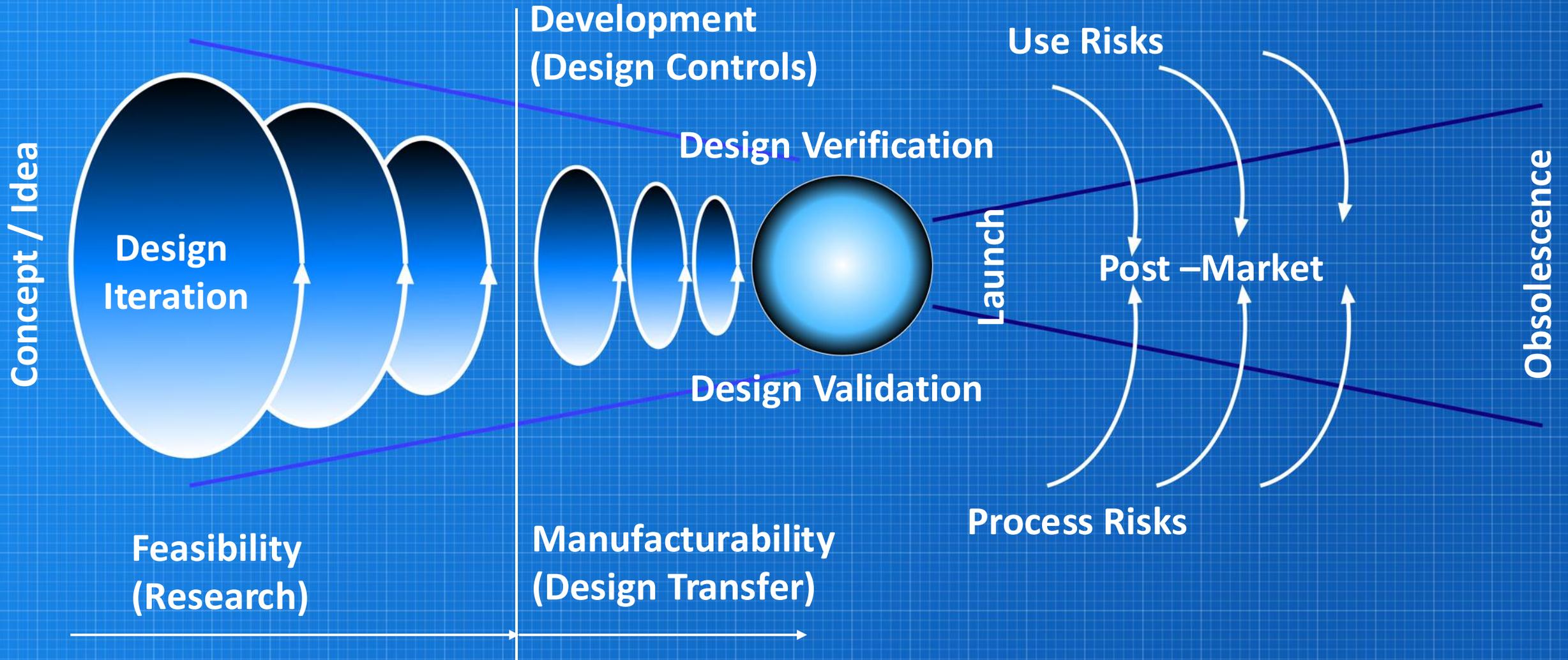


Inspired by :
INSIGHT, INNOVATION & DESIGN
Business value and New Product Development
-PDD Group Limited

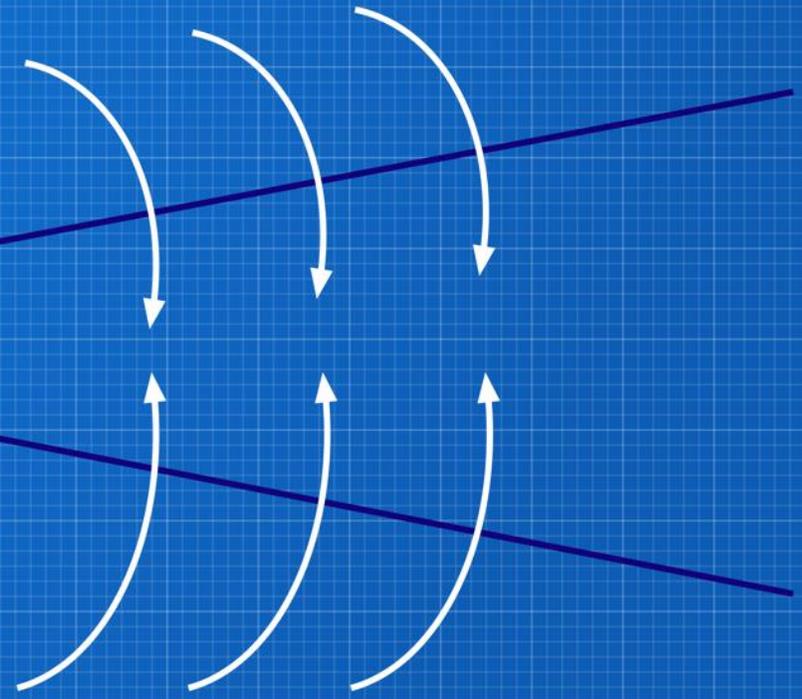
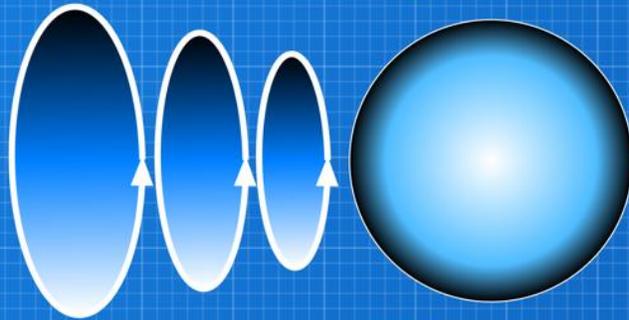
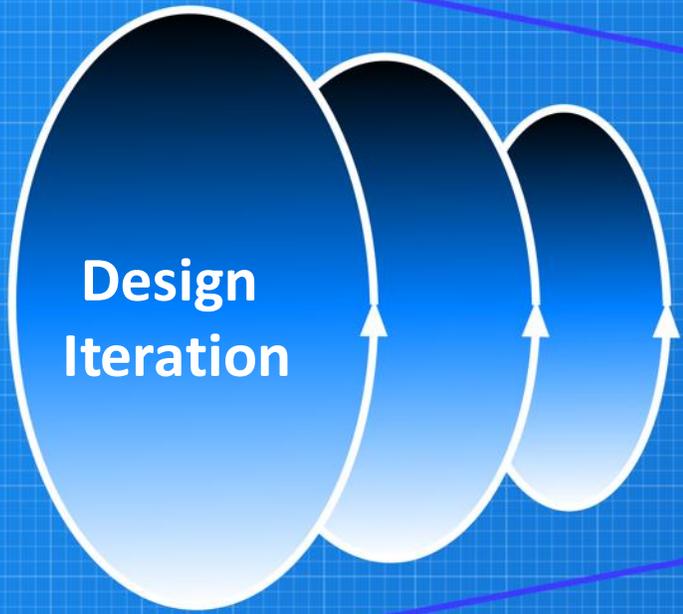
OVERVIEW PRODUCT LIFE CYCLE

Preamble CFR 820: 63. “...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. “

“Life-cycle: all phases in the life of a medical device, from the initial conception...” (ISO 13485:2016, ISO 14971:2012)



Concept / Idea



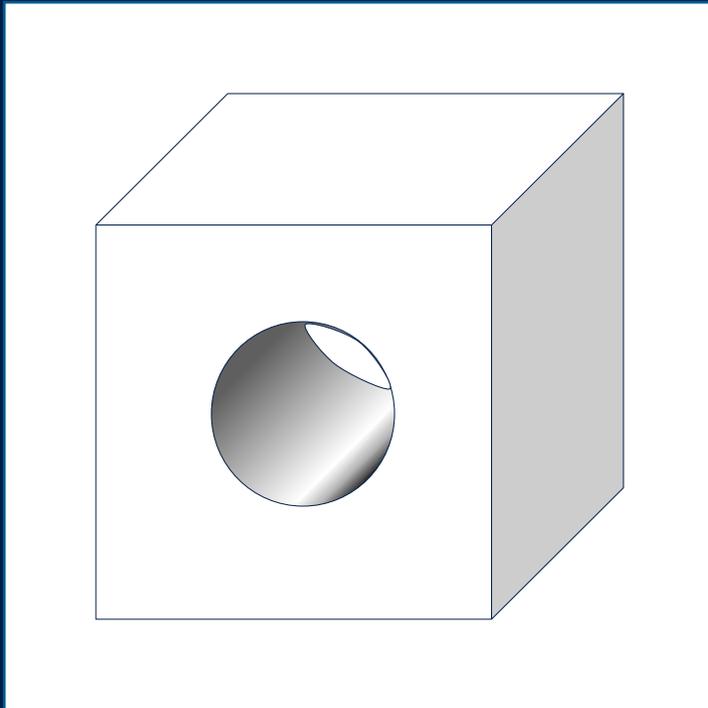
Feasibility
(Research)



Introducing our Medical Device to
be designed

(It's cube with a hole

-Representing any Medical Device with a "specification").



Key Characters of development (Design Controls) Process:



The Customer



The Customer Representative (marketing)



The Design Engineer



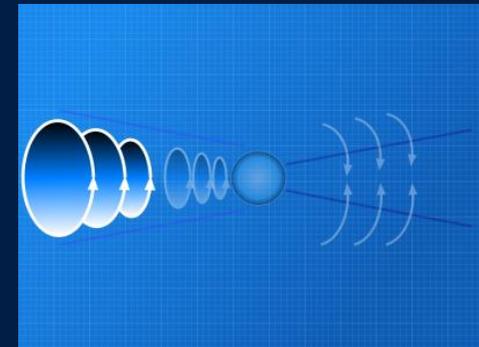
The Manufacturing Engineer



The Quality Engineer

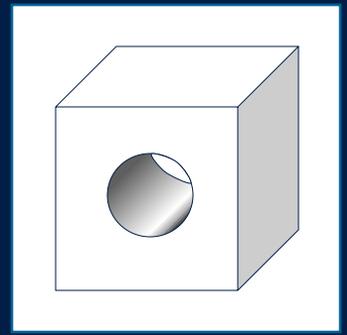
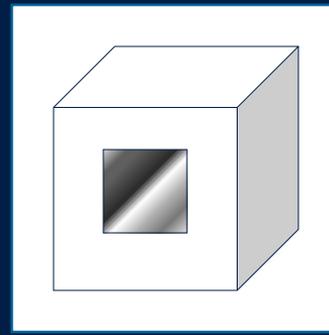


The Independent Reviewer





Prototype development begins..



Look at this new concept I have!

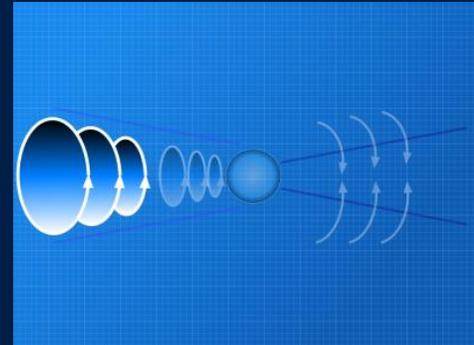


Erm... Ignore this feature here, as I'm changing that on the next prototype version!

Okay..



Why..



I'm changing the design because:

...it might not fit (with another part)..

..not sure we can really make it...

..that's a bit difficult to move...

Risks!

Need to capture and document..!

Design Risk

Design FMEA

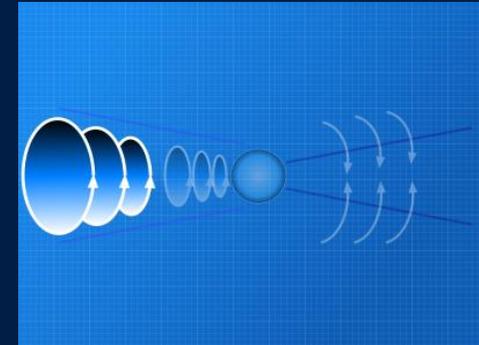
Manufacturing Risk

Process FMEA

Usability Risk

Use FMEA

Knowledge Management

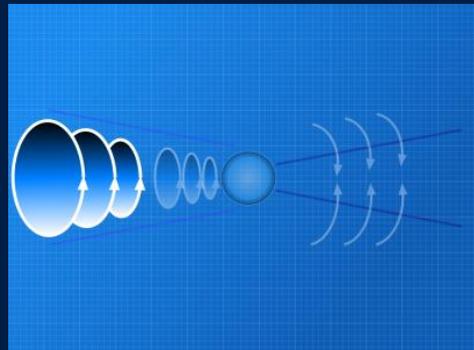
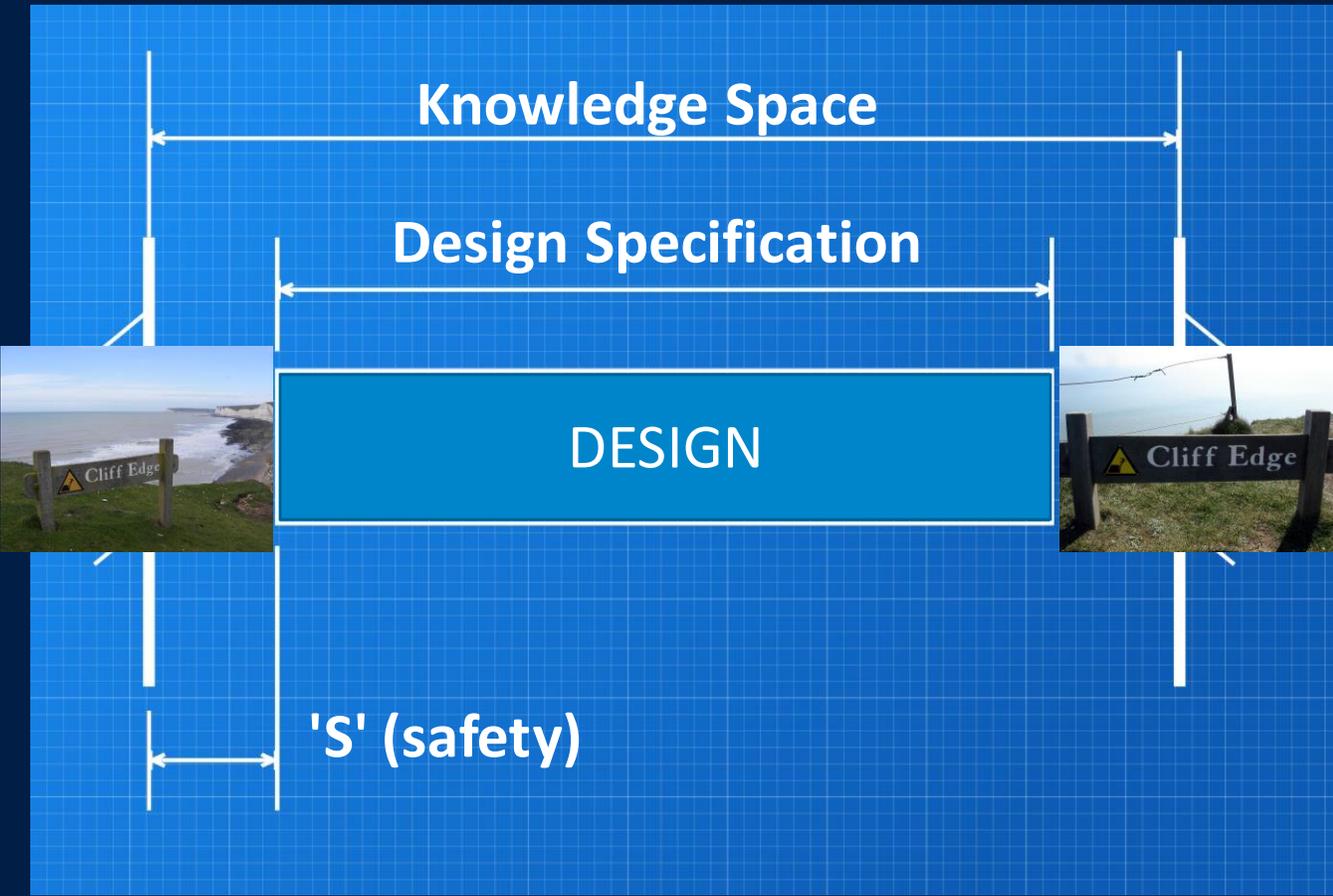


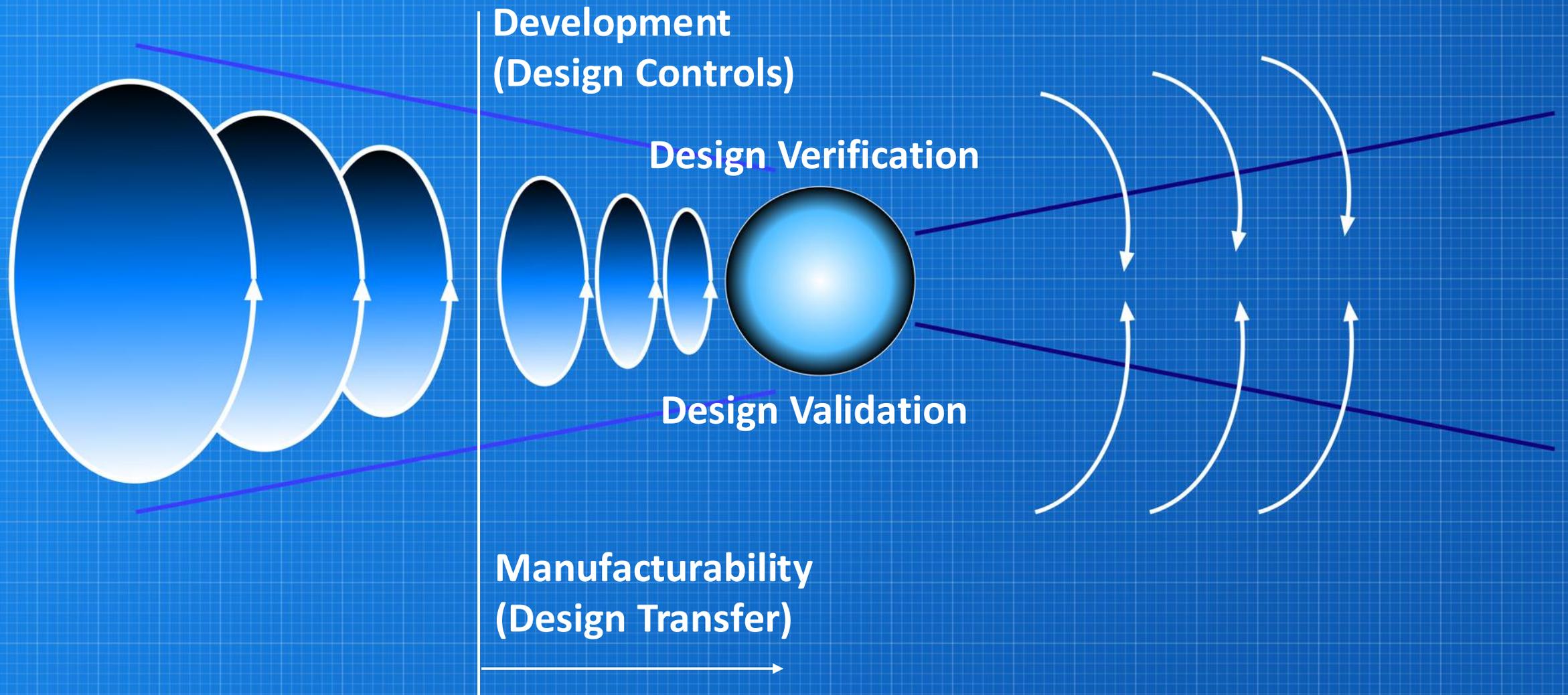
- Foundations for good change control in development (and post launch)= **knowledge management** (in feasibility / development) documented.

- Understand the Knowledge Space of the design
- Specification setting akin to Pharma's "QBD" (Quality by Design)
 - Know the limits; know where the device design fails – the “Cliff Edges of the design”
- From Knowledge Space, Design Engineer sets Design Specification,
 - Significant factor of safety between the Design Specification and the edge of the Knowledge Space

- Feasibility = period of significant knowledge gathering of a device
 - Also worst documented
 - Tip: 'shadow' lead engineer

- Changes need to be well document during feasibility
 - Knowledge management may be used during later stages of development, supporting Design Transfer or to support Post-Launch change requests
 - Change history needs to be ‘what’ and ‘why’ eg; ‘ECNs” (Engineering Change Notes)
 - Story: Change History example



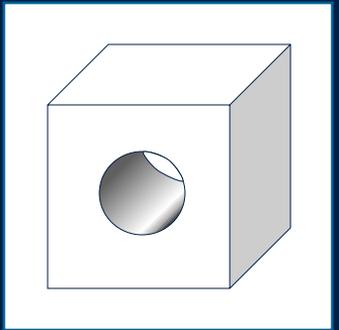


CHANGE CONTROL- DESIGN CHANGES

REQUIREMENTS

- 21 CFR § 820.30(i) Design Changes
 - Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.
- ISO 13485:2016 §7.3.9 Control of design and development changes
 - The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use.
 - Design and development changes shall be identified. Before implementation, the changes shall be:
 - a) reviewed;
 - b) verified;
 - c) validated, as appropriate;
 - d) approved.
 - The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.
 - Records of changes, their review and any necessary actions shall be maintained [...].

CHANGE CONTROL DURING DEVELOPMENT



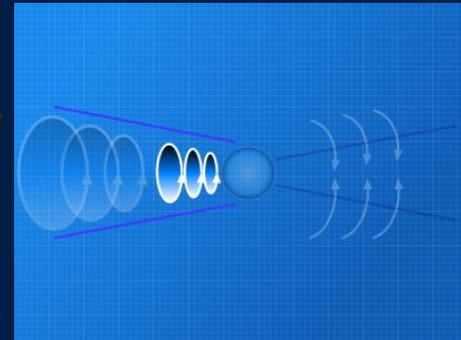
We're changing the design because:

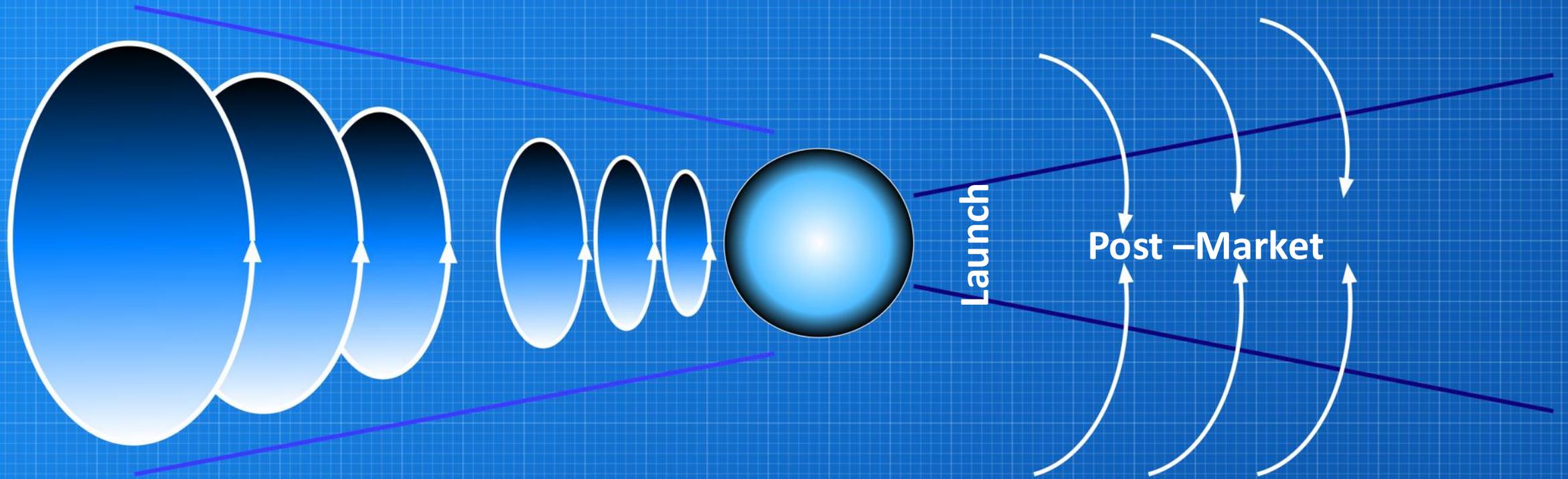


We've identified a risk in our Risk Analysis, it's here, documented, in our Change Request form.....

The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.

Have you risk assessed and documented the potential effect of the change?



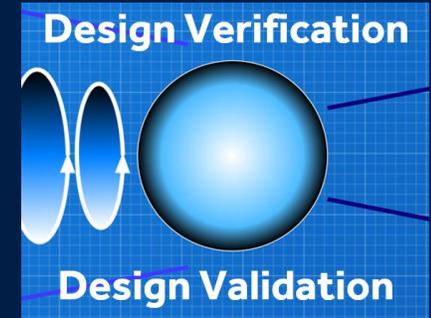


CHANGE CONTROL- POST LAUNCH CHANGES (SCENARIOS)

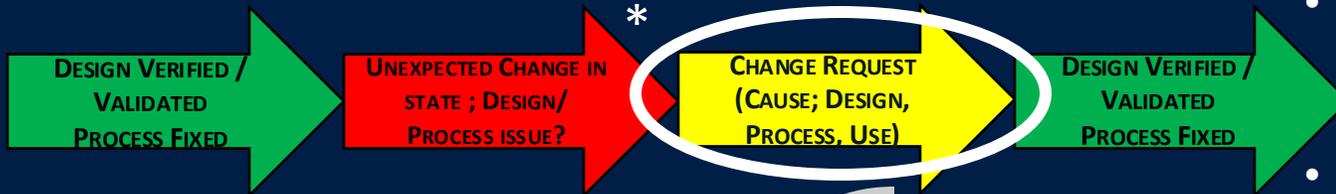
Change of state - Ideal



Changes made versus a baseline of stability, returning to stability



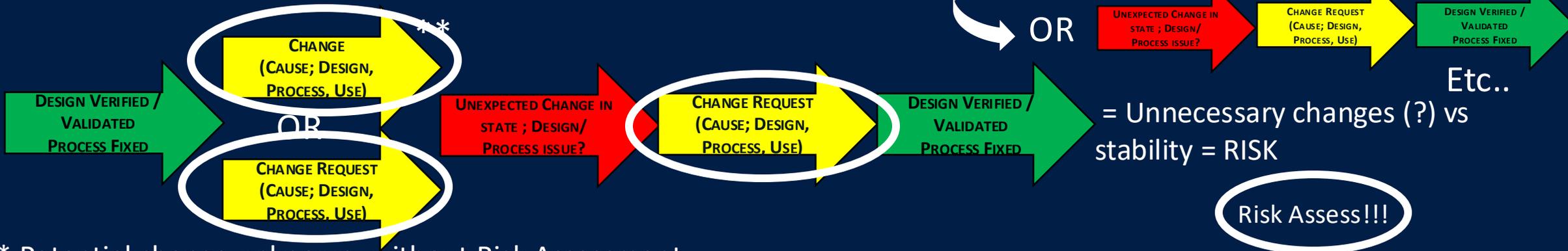
Change of state - Reality



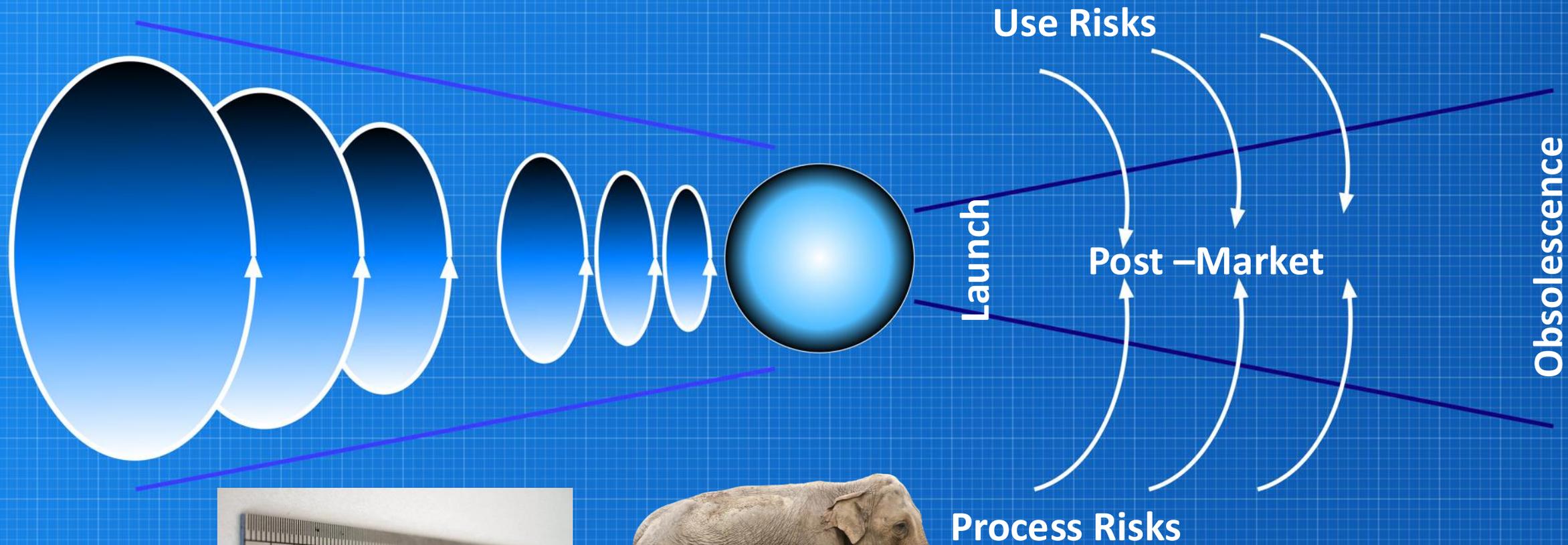
* = baseline not stable- 'inherent issue'

- Design Verification / Validation deficient
 - Eg; specification setting incorrect,
 - Use conditions not thoroughly assessed etc.
- Design Transfer for the process deficient

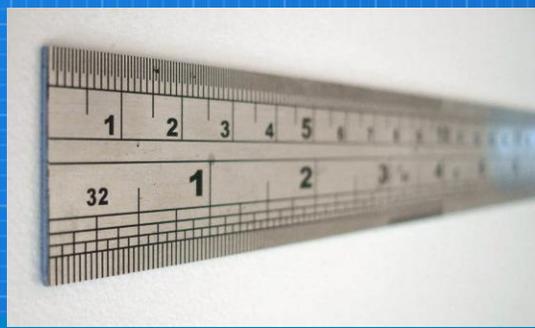
Change of state – “One to watch”



** Potential change unknown, without Risk Assessment



■ Interlude:



MEASURING IN ELEPHANTS

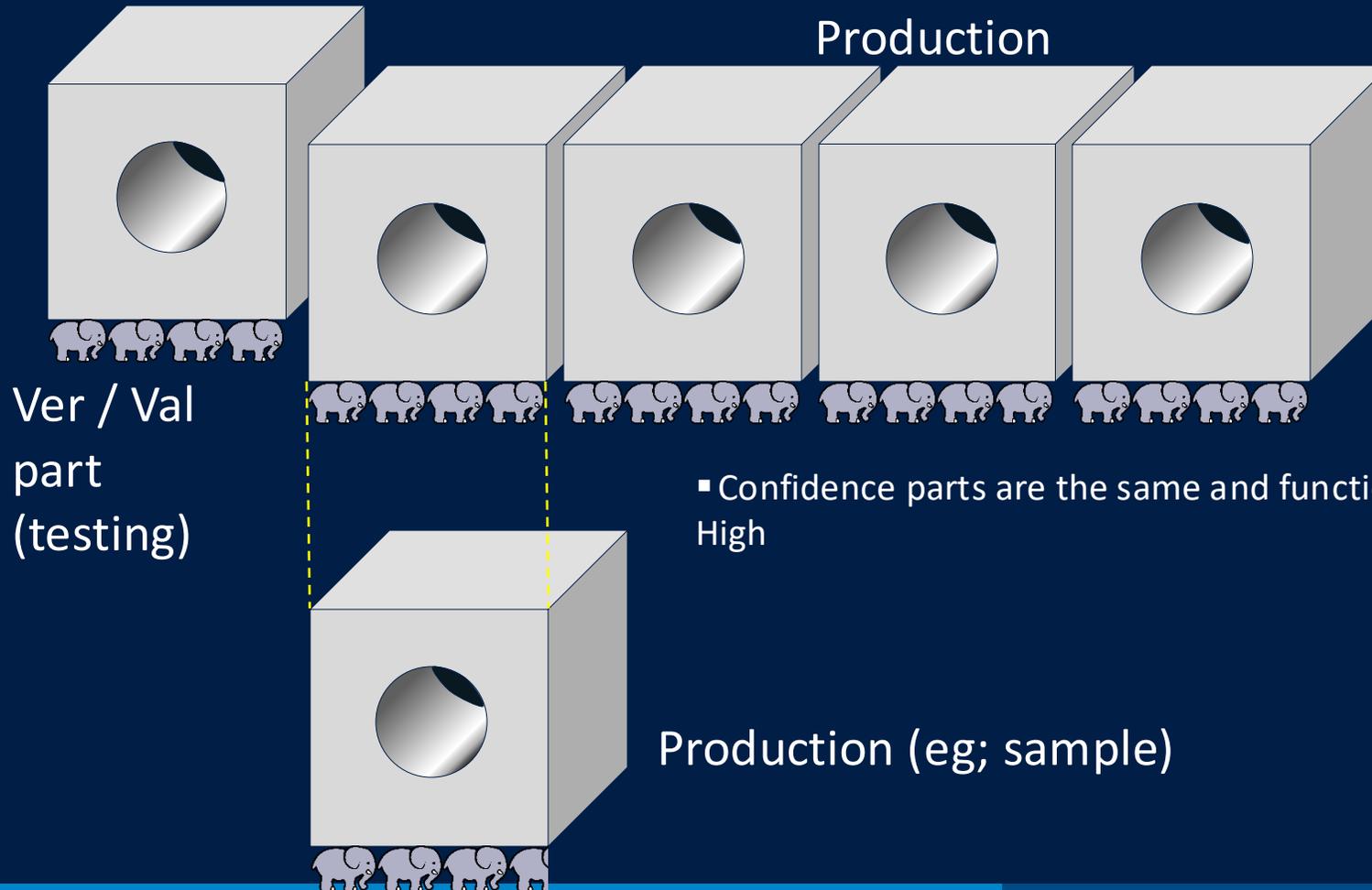
- “A CMM (Coordinate Measuring Machine) Measures in Elephants” --very important and well paid design consultant from Cambridge, UK Circa 1990s



Factory A



Factory B



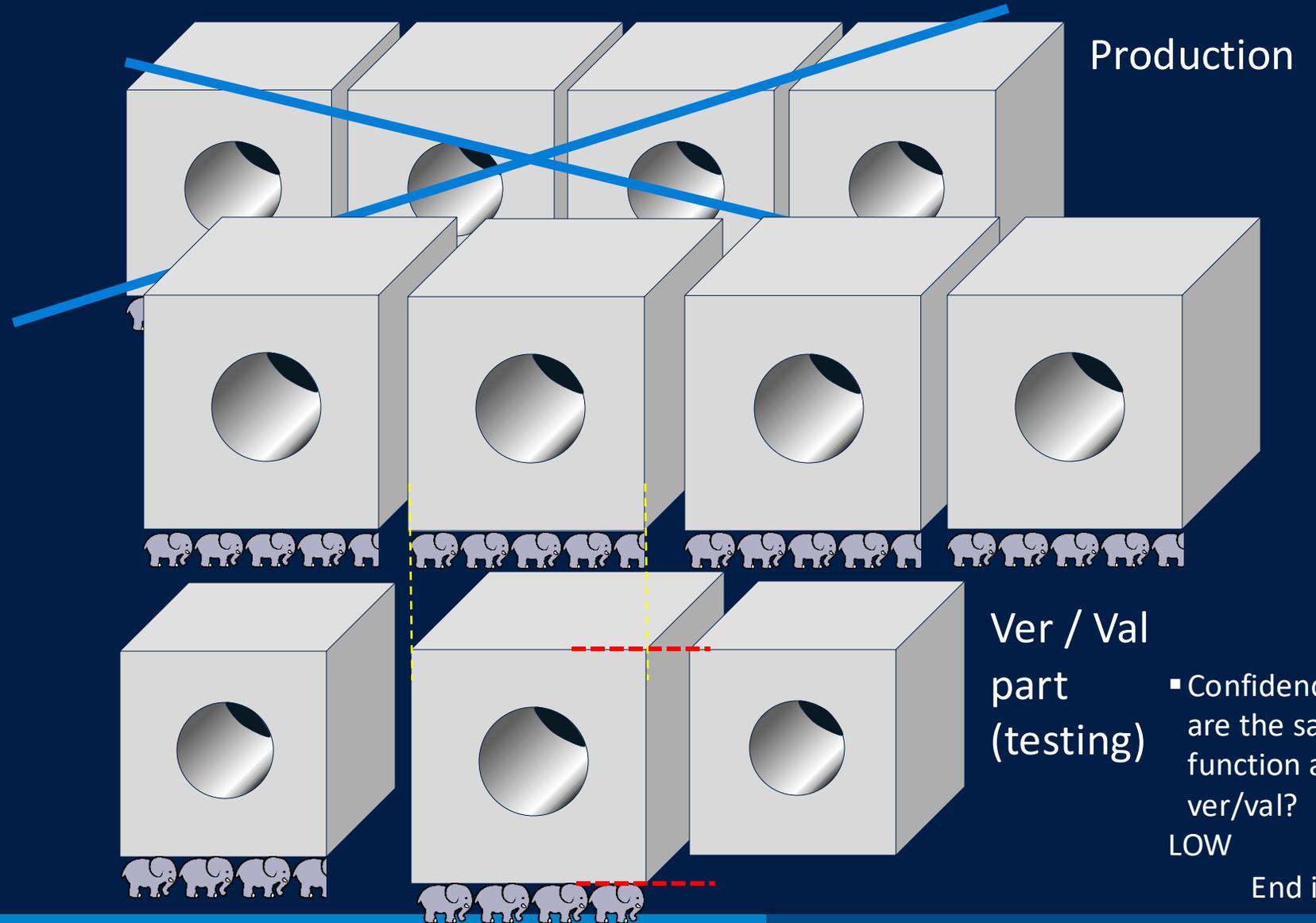
MEASURING IN ELEPHANTS

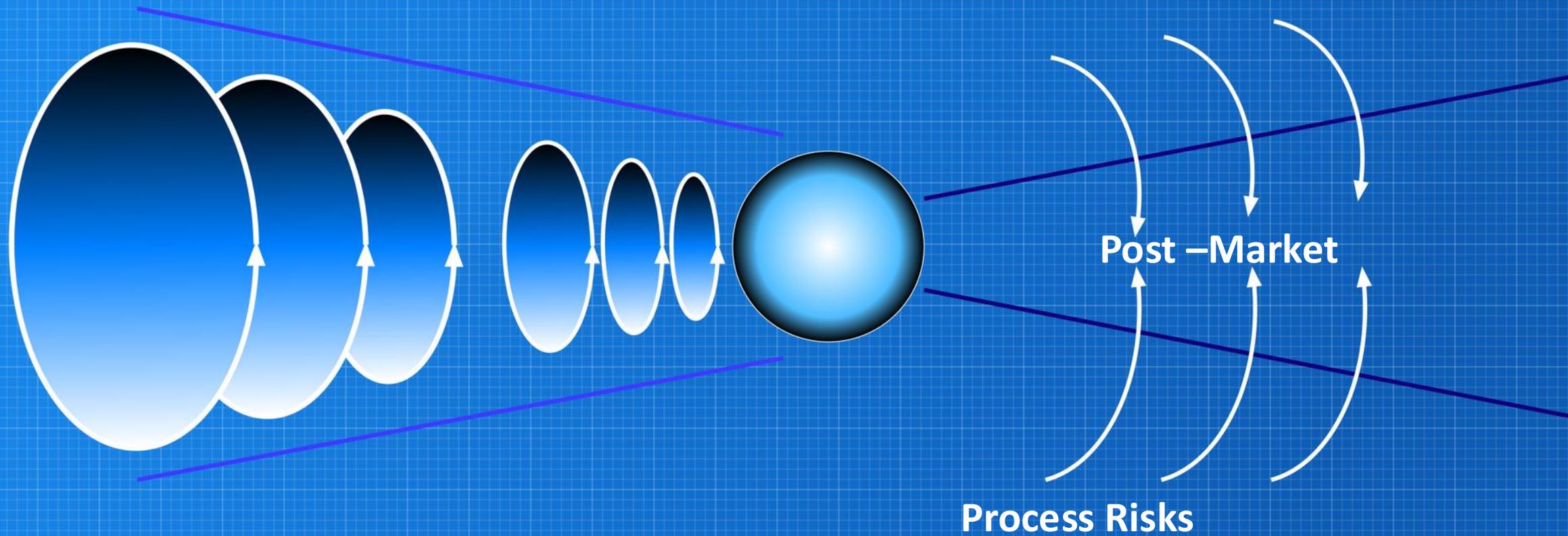


Factory A

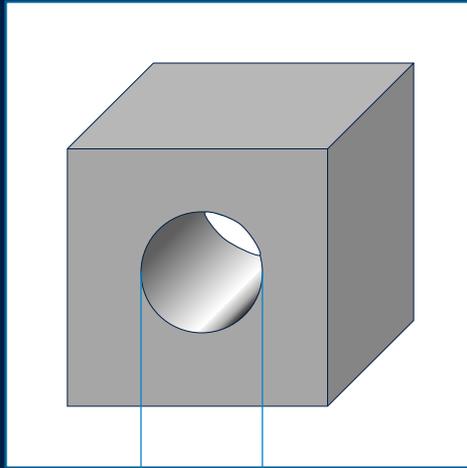


Factory B





First Production

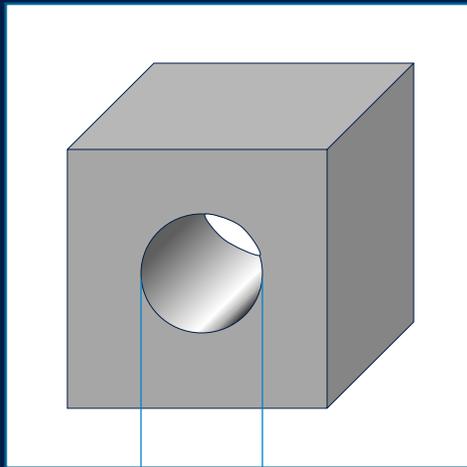


10.05 mm

Machine	Measurement method	Measuring Person
A	A	A

(Functionally tested, confirmed ok)

Second Production

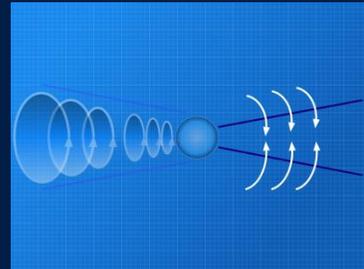


10.05 mm

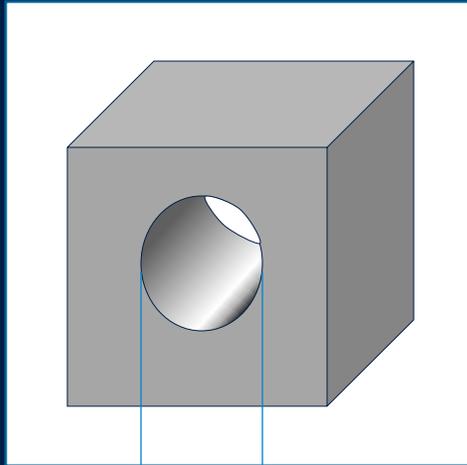
Machine	Measurement method	Measuring Person
A	A	A

Confidence level part is equivalent to “First production” ?

High



Third Production



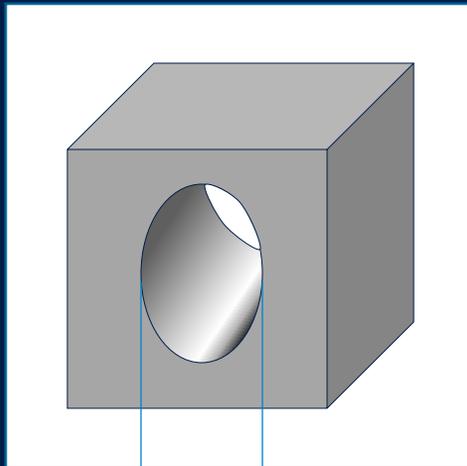
10.05 mm

Machine	Measurement method	Measuring Person
A	A	B

Operator absent, another operator used
Confidence level part is equivalent to “First production” ?

-Depends upon Repeatability & Reliability (gage R&R) of measurement method

Fourth Production

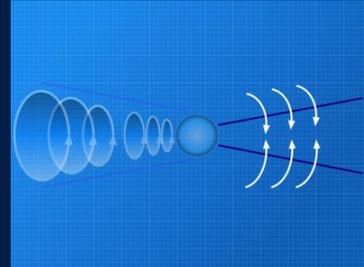


10.05 mm

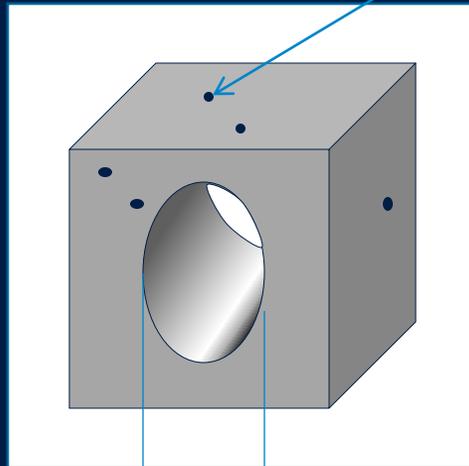
Machine	Measurement method	Measuring Person
A	B	B

Measurement machine on maintenance, calipers used
Confidence level part is equivalent to “First production” ?

-Depends upon Repeatability & Reliability (gage R&R) of measurement method and equivalency to original method



Fifth Production



Surface defects

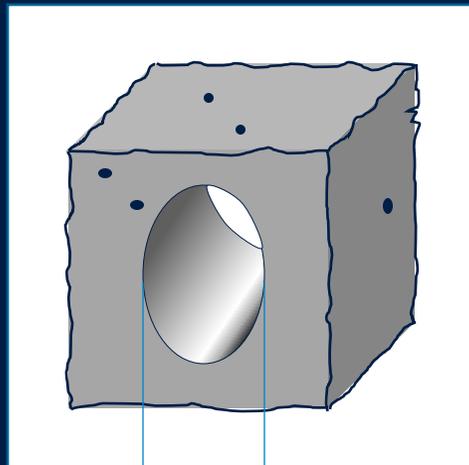
10.05 mm

Machine	Measurement method	Measuring Person
B	A	B

New machine bought, same manufacturer, newer model
Confidence level part is equivalent to “First production” ?

-Depends upon many things, not least qualification and validation of new machine

Sixth Production



10.05 mm

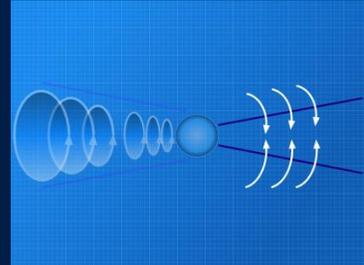
Machine	Measurement method	Measuring Person
C	B	B

Cost saving, alternative “equivalent” machine used

Confidence level part is equivalent to “First production” ?

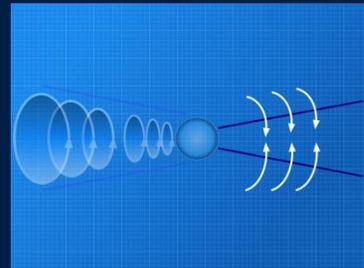
-???????

Critical (control dimension) is still in specification..!



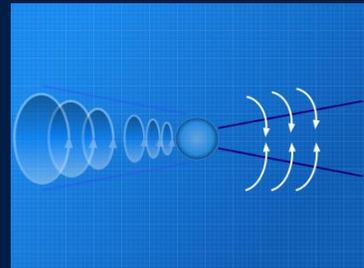
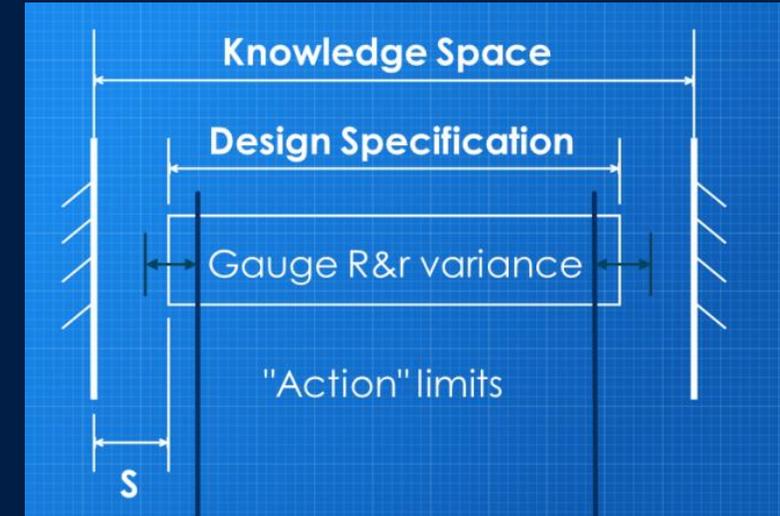
POST LAUNCH: PROCESS CHANGES

- **Any and all** process changes need to be thoroughly risk assessed and controlled
- Numerous causes including (not limited to):
 - Change in operator
 - Skilled engineer
 - “knows the process” “knows how to get good measurement”
 - Is off sick/on vacation/retires
 - Training? Transfer of skills?
 - (Equipment & Process Qualification, gauge R&Rs)
 - Change in equipment
 - Volume ‘ramp-up’, facility change etc
 - Remember; **"Everything that is engineered (Design / Manufactured) is unique, and has a propensity to fail"**
 - Includes manufacturing equipment; no 2 machines are exactly the same
 - Hence need for qualification of equipment and processes to prove equivalency



POST LAUNCH: PROCESS CHANGES

- Design Changes resulting from process changes
 - Caution!
 - **Any and all** *process* changes need to be thoroughly risk assessed and controlled
 - **Any and all** *design* changes need to be thoroughly risk assessed and controlled
 - Are they really required?
 - Eg: opening of specification (eg. For improved capability)
 - Remember development specification setting et al
- Making changes has consequences
- Many Post market field actions come from design or process changes not made correctly



QMS CHANGE CONTROL – ANALOGY TO SOFTWARE CHANGES

- QMS = “Operating System”



Operating System X-100



Operating System X-101 beta 'A'



Operating System X-101 beta 'B'



Operating System X-101 Public Beta

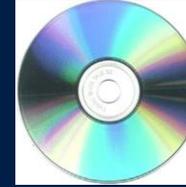


Operating System X-101

Assess the impact of change;

- User interfaces impacted? (Software menus, document templates)
- Functionality- can end goal still be achieved?
- Training- are changes intuitive or support needed?

CHANGE CONTROL SOFTWARE



- Software = solution to everything
 - “removes your risk”
- Caution: software *moves* risk, normally to within the software itself
 - (Use, stability etc)
 - Story 1: Software seller
- Caution: Do not rely on the software alone for managing changes, be pragmatic
 - Story 2: Due Diligence example;



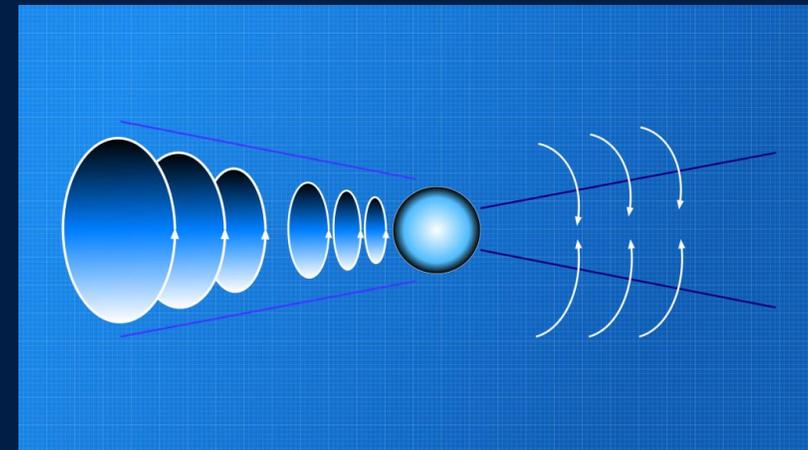
Test 1	Activity	Test 2	Activity	Test 3	Activity
Issue 1.1	Design change to fix issue 1.1, 1.2, 1.3	Issue 2.1	Design change to fix issue 2.1-2.4	Resolution Issue 1.1-1.3 & issue 2.1 – 2.4	“Device ready for Verification”
Issue 1.2		Issue 2.2			
Issue 1.3		Issue 2.3			
....		Issue 2.4			
Issue 1.21	--	--	--	--	Issues 1.4 – 1.22?
Issue 1.22	--	--	--	--	

SUMMARY MESSAGES

- Every device will have a latent “Risk”
 - Everything that is engineered is unique and has a propensity to fail
 - Risk management is a balance of Product / Project risk



- Foundations for good change control in development (and post launch)= **knowledge management** (in feasibility / development) documented.

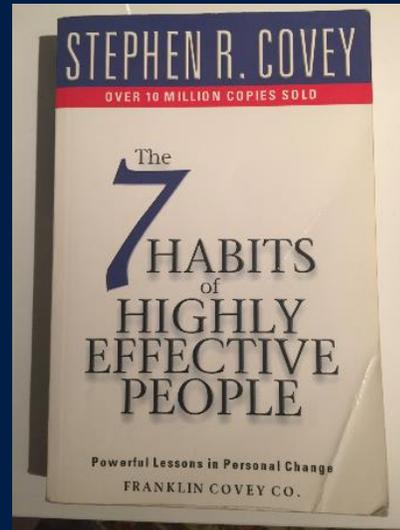


- For any changes, consider a baseline state of stability (Design frozen, Process fixed) an risk assess change including potential net effect



AND FINALLY

- “I personally struggle with much I have shared in this book”,
 - -Stephen R. Covey, The 7 Habits of Highly Effective People



Thank you. Questions?