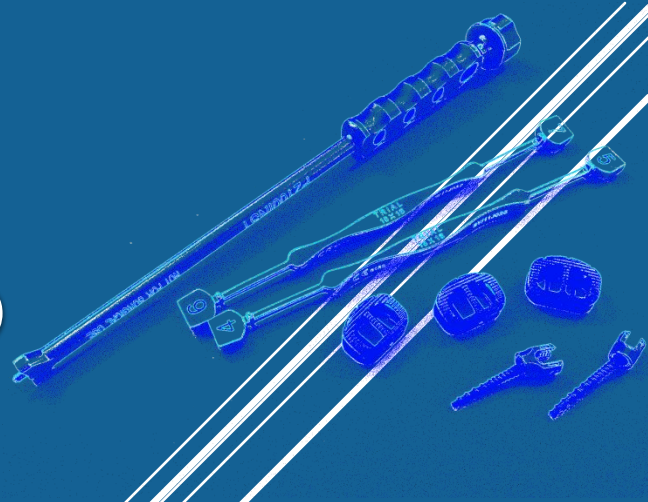
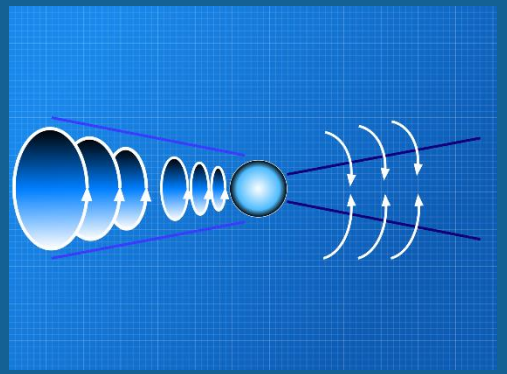
PRACTICAL GUIDANCE TO DESIGN, DEVELOPMENT AND MANUFACTURE OF ORTHOPAEDIC DEVICES



Noel Butterworth

Prin. Design Quality Engineer

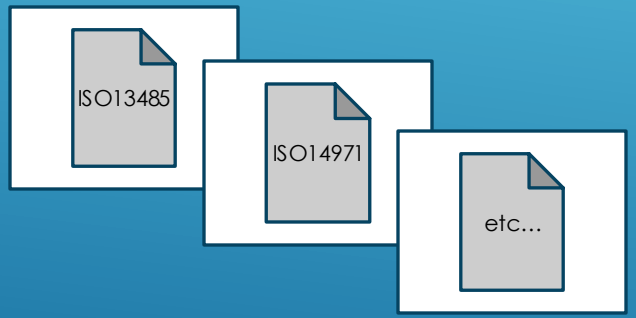
Medtronic Europe Sárl



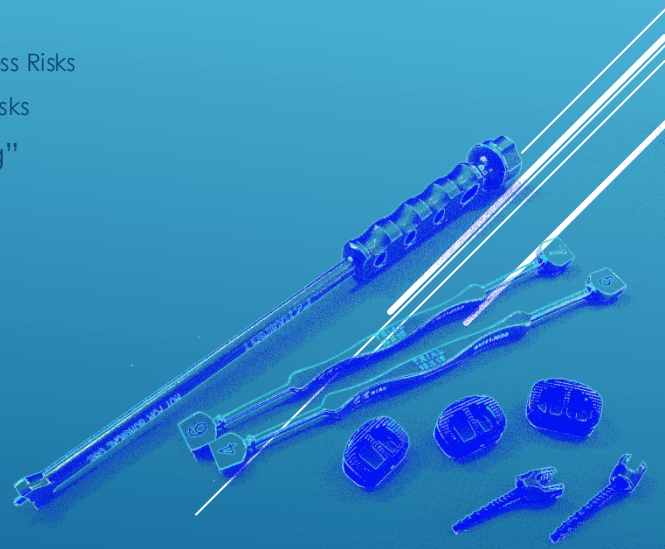
Disclaimer: the opinions expressed within this presentation are solely those of the presenter and are not intended to reflect a company opinion.

OVERVIEW

- Intro: what this **is not**
- Not ‘typical’ Risk Management Presentation



- What **this is**;
- Intro to Risk & Risk/Benefit
- Risk through the Product Life
  - Feasibility
  - Manufacturability
  - Design Verification / Validation
  - Launch
  - Post Market
    - Process Risks
    - Use Risks
- “Tip of the iceberg”



RISK!!!!!

Risks are *everywhere*….

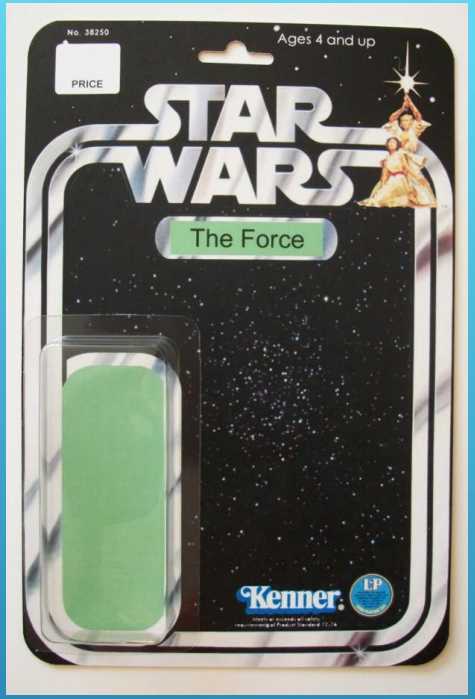
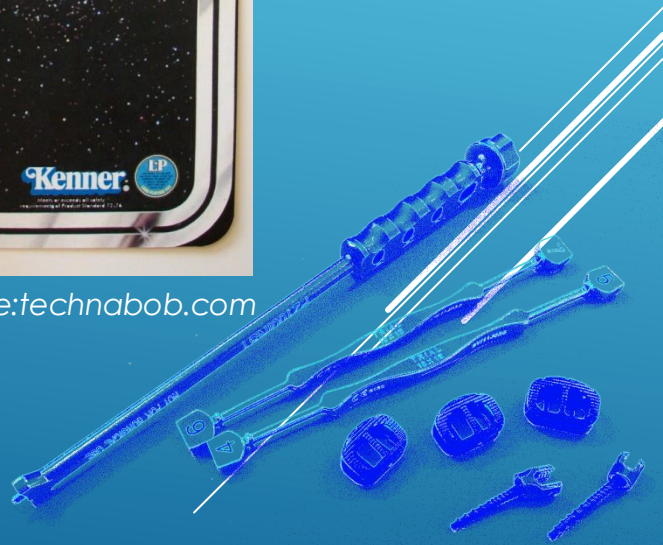


Image source:technabob.com

"They surround us.. (etc)"

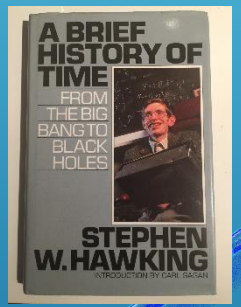
RISKS!



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

- Second Law of Thermodynamics; Entropy increase (or remains the same) in closed system

"The increase of disorder or entropy is what distinguishes the past from the future, giving a direction to time"
--Stephen Hawing, A Brief History of Time



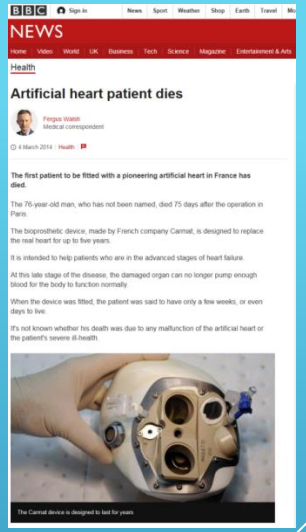
- Medical Devices are not 100% risk free
- **Risk / Management and Risk-Benefit Analysis required**

RISK: ENTROPY

Interlude 1: could you do the Risk/Benefit for this product?

- "***Patient dies after being given [novel new medical device]***"
- "**Artificial heart patient dies**"- BBC News 04 Mar 2014
  - *'The 76-year-old man,….died 75 days after the operation in Paris.'*
  - *'When the device was fitted, the patient was said to have only a few weeks, or even days to live.'*
  - http://www.bbc.com/news/health-26435829
- **"Fourth Patient Treated with Carmat Artificial Heart Dies"** – Qmed 21 Jan 2016
  - http://www.qmed.com/news/fourth-patient-treated-carmat-artificial-heart-dies
  - *,…patient died from "medical complications associated with his critical pre- and postoperative state," '*
  - *'The third patient died of respiratory arrest in December after suffering renal failure. The device played no role in that death.*

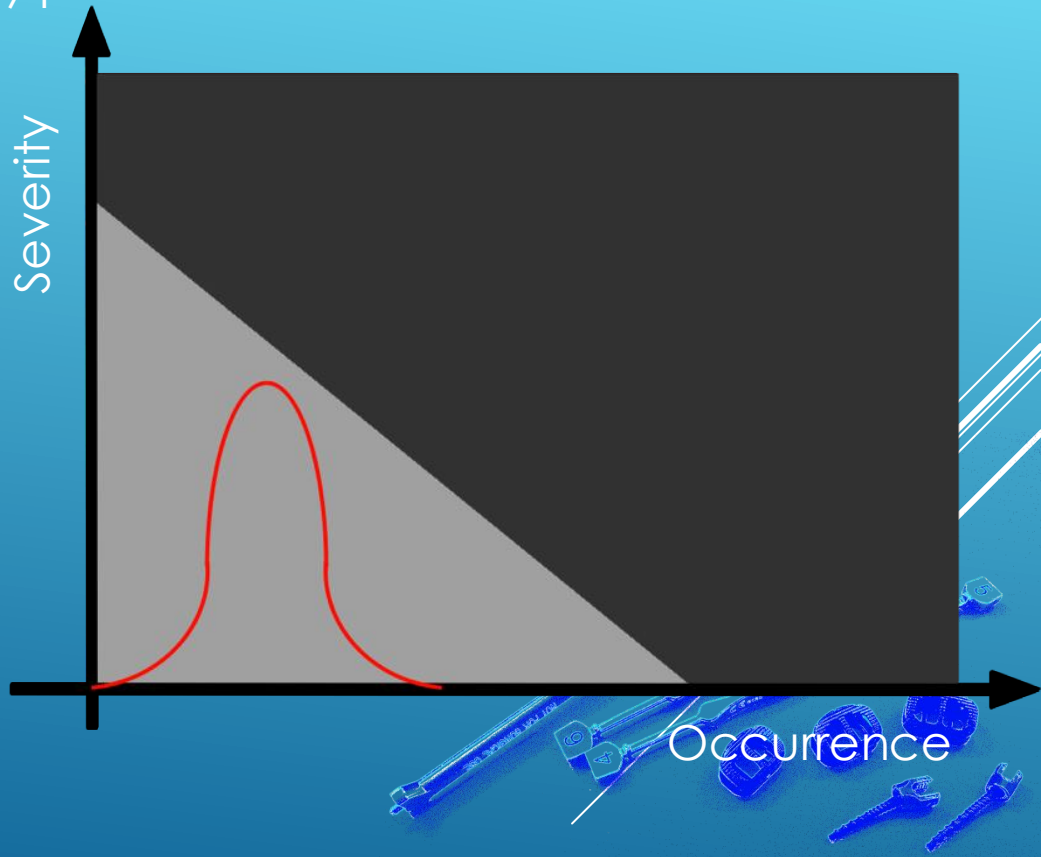
RISK / BENEFIT

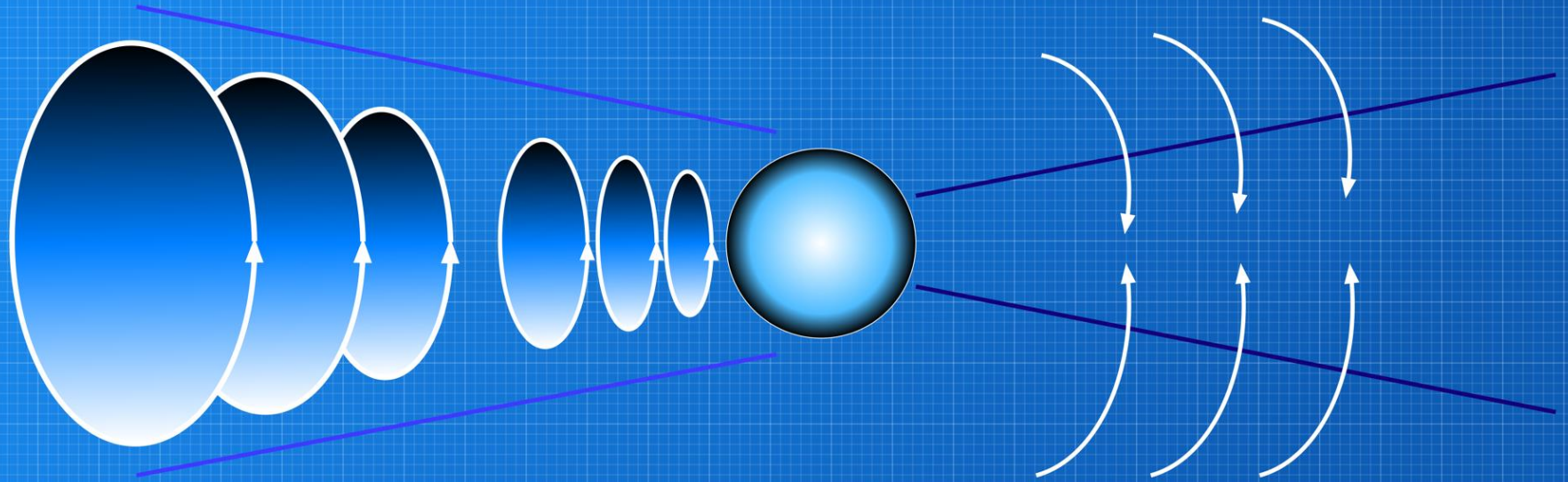


SEVERITY SCALES

Assessing the acceptable "risk level": severity x occurrence (P1 x P2) per ISO 14971

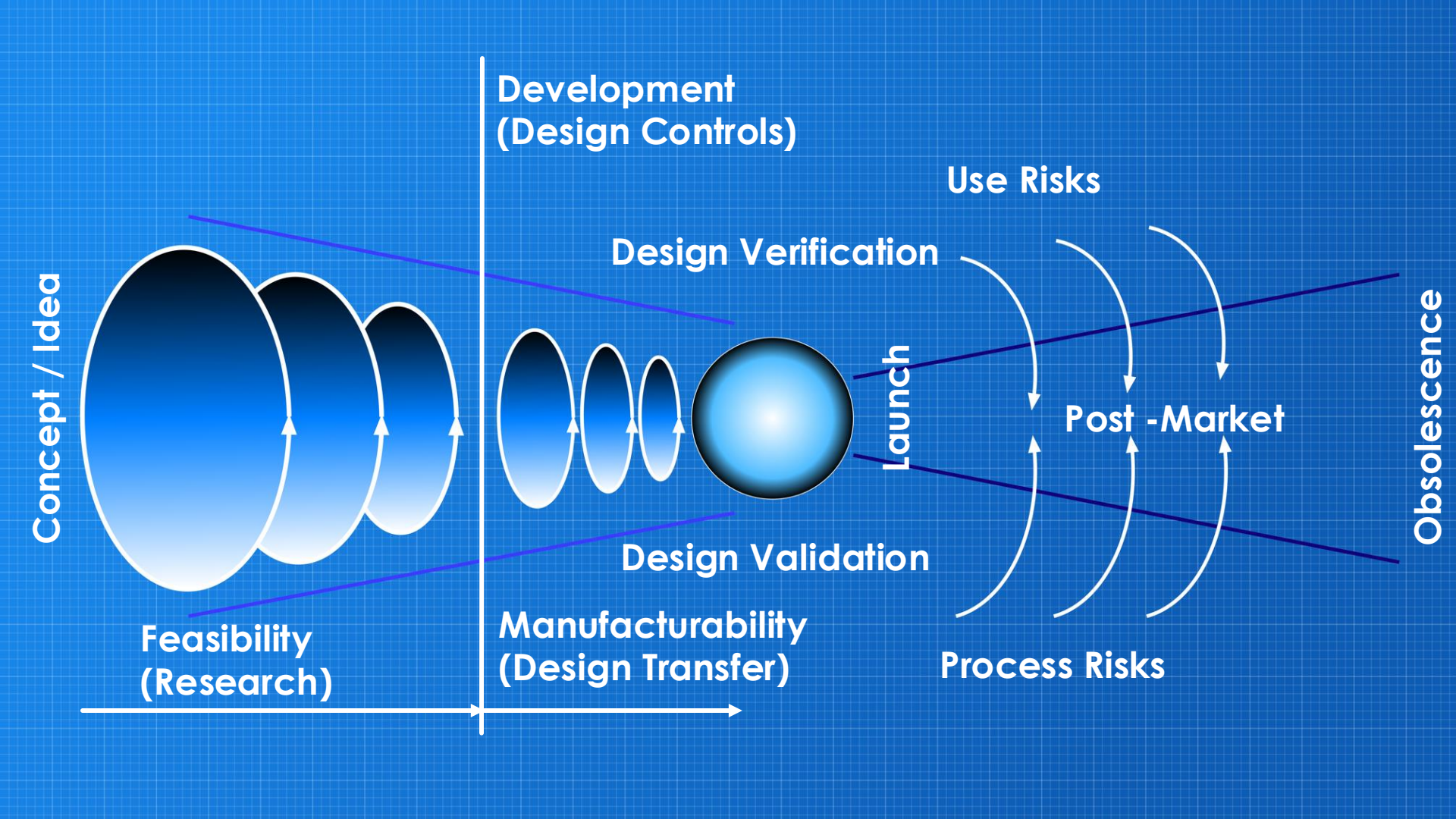
- "As Low As Possible"
- Defined acceptable risk level with the Risk Management Plan – per product
- Severity scoring applicable to product type (Clinical input?)
- Each ***individual*** risk that cannot be reduced further to acceptable level must have risk – benefit analysis





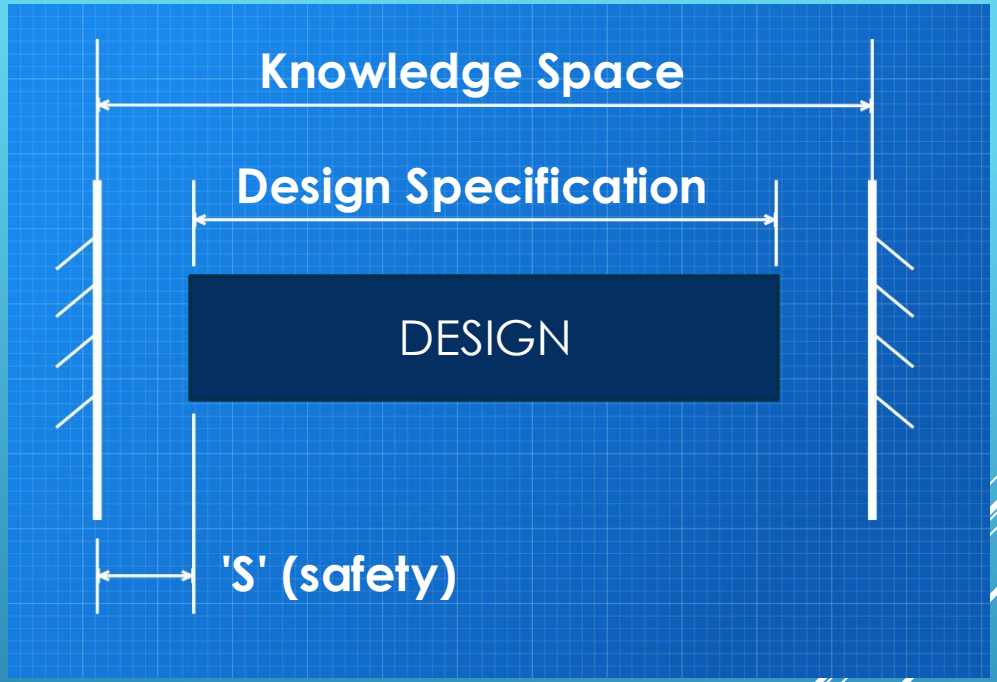
OVERVIEW PRODUCT LIFE

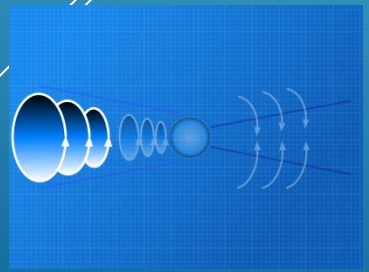
Inspired by :
INSIGHT, INNOVATION & DESIGN
Business value and New Product Development
-PDD Group Limited


Development
(Design Controls)
Use Risks
Design Verification
Concept / Idea
Launch
Post -Market
Obsolescence
Design Validation
Feasibility
(Research)
Manufacturability
(Design Transfer)
Process Risks

FEASIBILITY: KNOWLEDGE SPACE

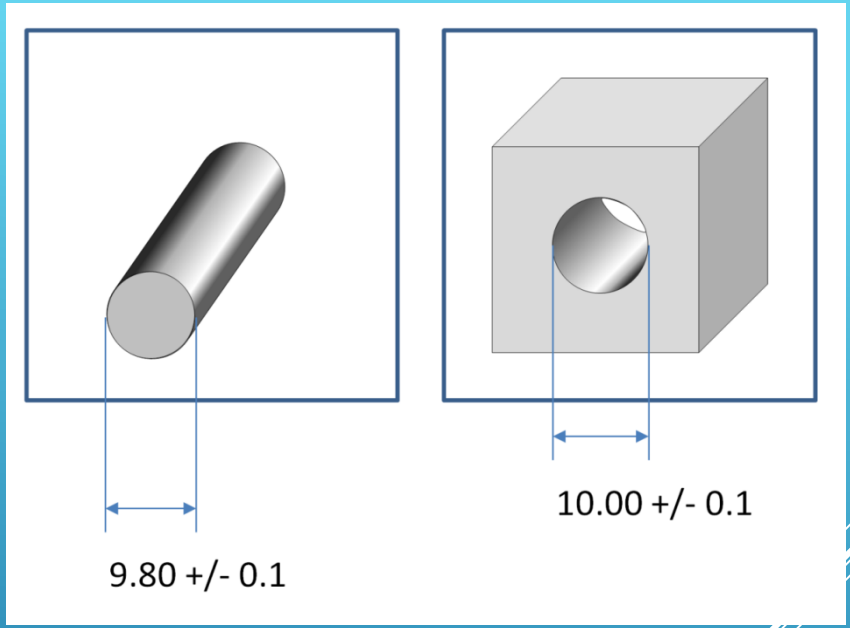
- Feasibility ("early development ") period of significant knowledge gathering of a device
  - Also worst documented
  - Tip: 'shadow' lead engineer
- Specification setting akin to Pharma's "QBD" (Quality by Design)
  - Know the limits; where the device fails

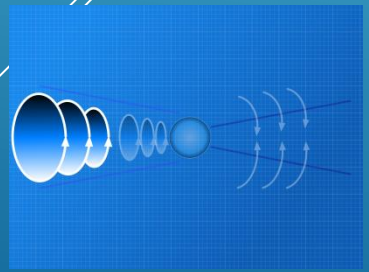




FEASIBILITY : SPECIFICATION SETTINGS

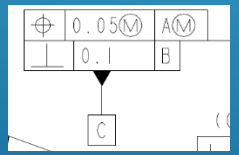
- Example; Engineering drawing specifications
  - Types of specifications
  - Design Engineer's view of the specification vs the Manufacturing Engineer's.





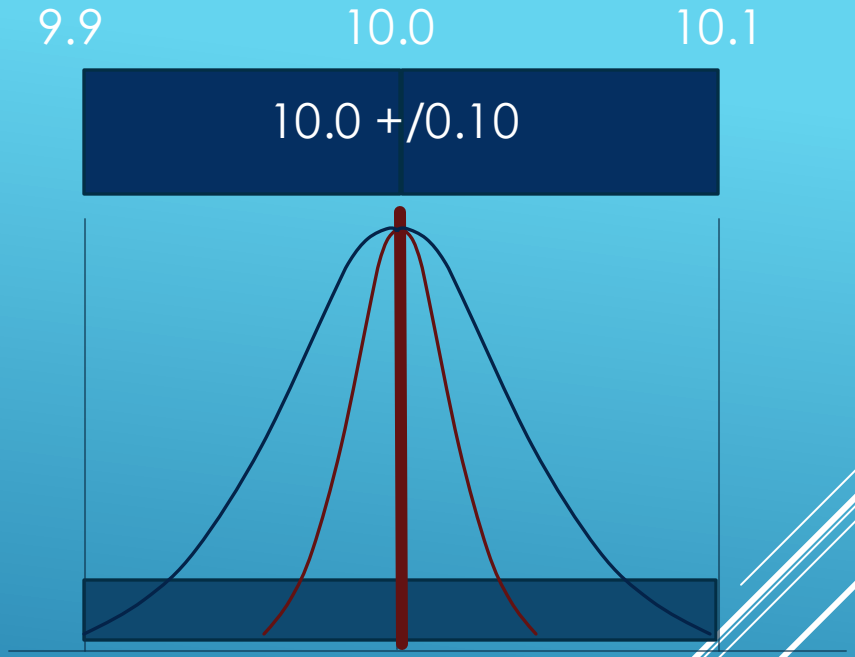
FEASIBILITY : SPECIFICATION SETTINGS

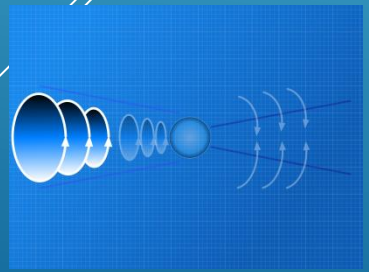
- Nominal value 10.00 +/- 0.1
- **Design Engineer's** View vs **Manufacturing Engineers**
- Skewed nominal;
  - ~~10.0 +0.2 / 0~~ 10.1 +/- 0.1
- R0.1 Min, R0.5 Max
- GDT



"Diameter, with Positional Tolerance 0.05 (on feature position- not shown) at Maximum Material Condition, relative to Datum A (not shown) at Maximum Material Condition, with perpendicularity of 0.1 maximum, relative to Datum B (not shown).

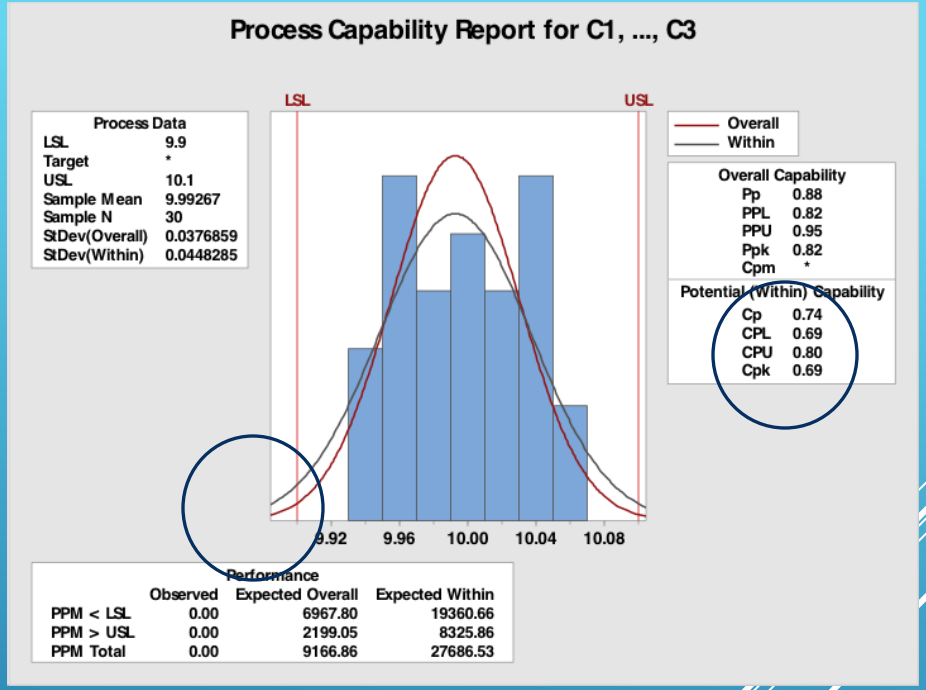
All of which being Datum C"



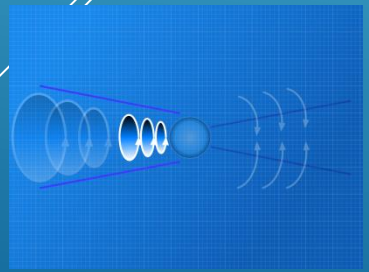


MANUFACTURABILITY: PROCESS CAPABILITY

- Process Performance Index (Ppk) vs Process Capability Index (Cpk)
- *"What is..(Ppk)"* Vs *"What could be..(Cpk)"*
- Which is more powerful / useful?
  - It depends…

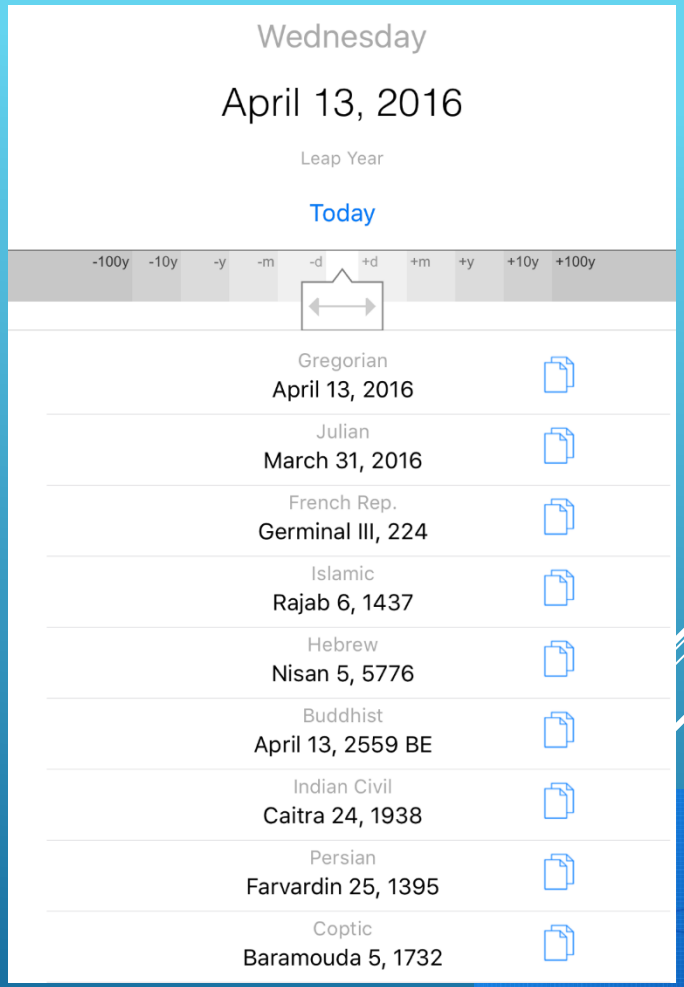


How confident are we that parts at the edge of the specification are 'in spec' or 'out of spec'?



Interlude 2: What time is it?

- What time is it?
  - Who's got the *right* time?
  - Watches , calendars are **measurement systems**, measuring time relative to a datum
- Eg Gregorian Calendar, AD (anno domino) relative to the birth of Christ (which was probably 6 BC)
  - Level of accuracy (consistency)?

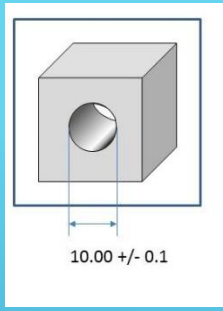


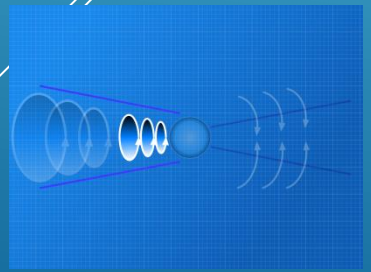
MANUFACTURABILITY: MEASUREMENT

MANUFACTURABILITY: MEASUREMENT

- Measurement values are not "***absolutes***"
  - They are ***relative***
- Hence the importance of "Gauge R&r's" – Reliability and Repeatability studies for measurement systems**.**
- CMM*'s 'notoriously' difficult to have equivalency
  - Calipers?
  - Shadowgraphs/overlays?
  - Pin gauges?

- 1st measure = 9.90
- 2nd measure = 9.89
- 3rd measure = 9.91
- 4th?
- What size is it?
- If the spec is 9.90 (to 10.10) is it in specification?

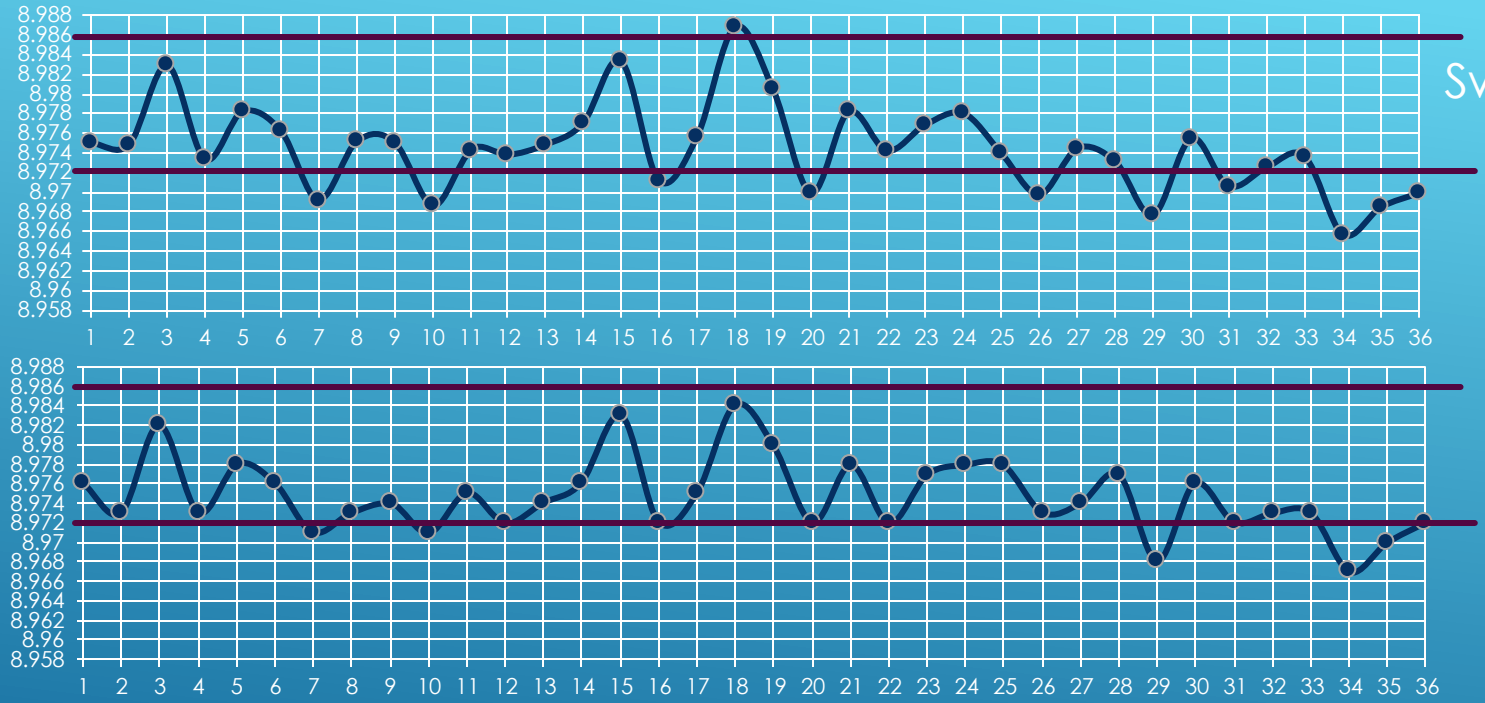




*Coordinate Measurement Machine

Real data

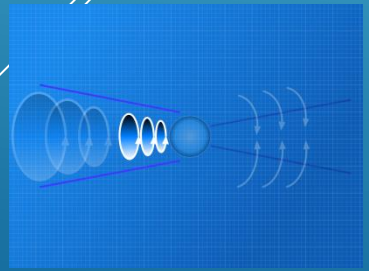
Specification: Ø9 -0.013/-0.028 (f7)



Swiss Precision

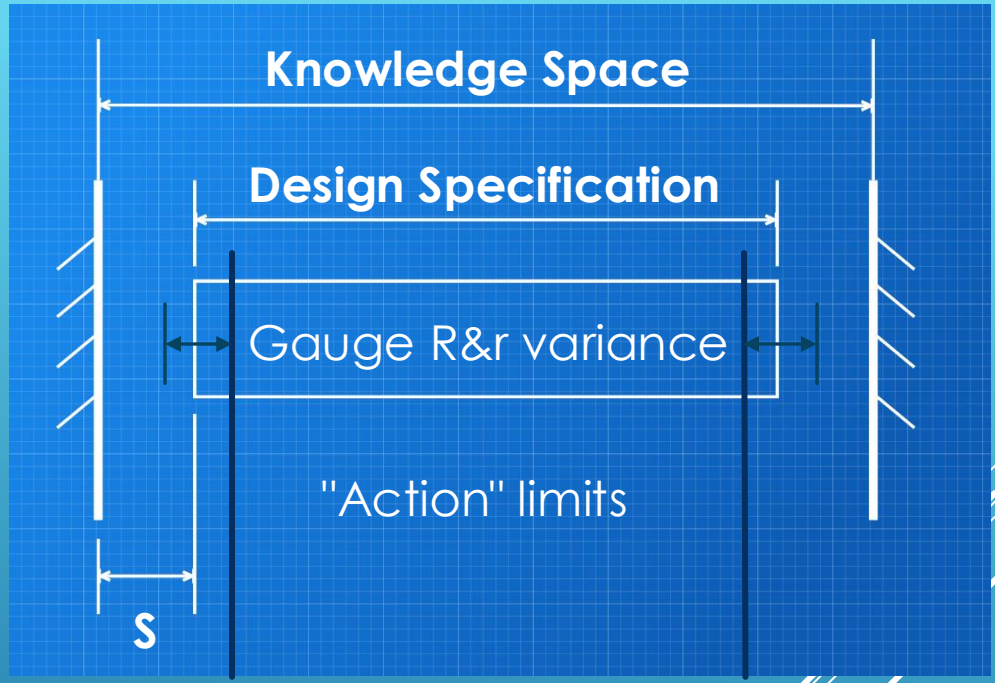
German Engineering

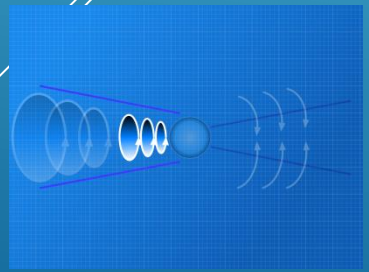
- How many "good parts"?
- Who to believe?



MANUFACTURABILITY: MEASUREMENT

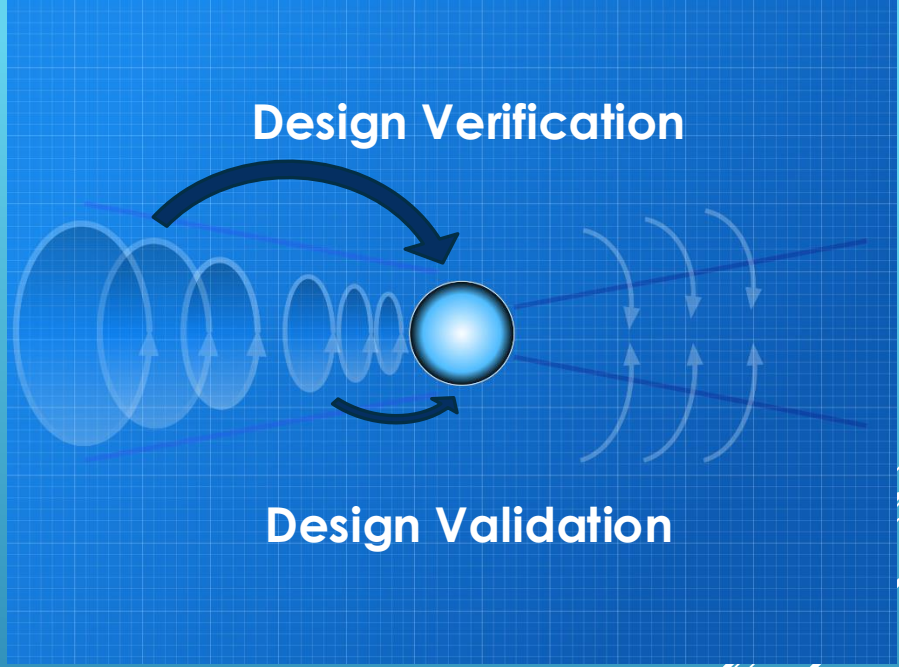
- If parts manufactured from the same process, measured with the same method and have proven to function (eg Verification Validation) with the same values, confidence is high that parts are "good".
- Assess trends of data not absolute values
- Consider process action limits accommodating Gauge R&r variance



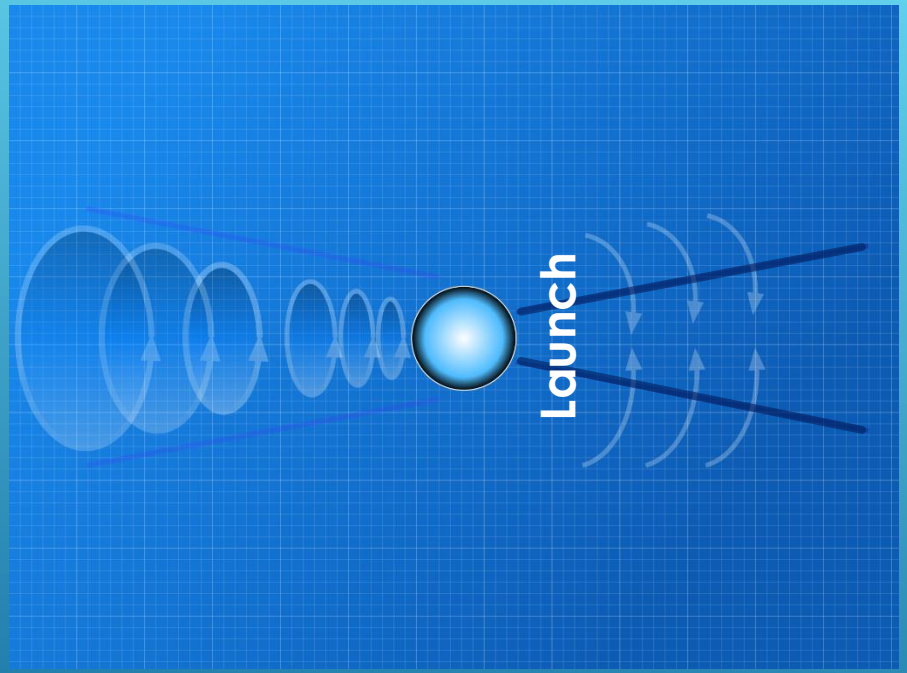


DESIGN VERIFICATION / DESIGN VALIDATION

- Knowledge from Feasibility and Design Control phases should provide confidence to pass Ver / Val
  - "No surprises“
  - Design ‘frozen’
  - Process ‘frozen’



LAUNCH



Interlude 3: Sources of risk

- How often are the ‘root’ causes of issues identified?
- What are the root causes form these ‘7’ examples
- Qmed 27 Jan 2016
  - “7* Medical Device Failures causing Serious Recalls”
  - Things never fail “just by themselves”

*there’s 6

4. Power Switch Problems

A faulty power switch was implicated in the Class I–recall of a Dräger Perseus A500 anesthesia workstation, which could ultimately cause the device to stop working. A similar problem with a power switch was behind the recall of eVent Medical’s LS, 5i, or 7i Inspiration ventilators.

5. Alarm Problems

The notion of alarm fatigue has gotten a lot of attention in recent decades, as clinicians gradually become desensitized to the alarms going off in hospitals. But alarms that don’t sound can be especially risky as well, and this was the reason behind FDA to give Class I status to the Hamilton Recalls G5 Ventilator, which may stop working without sounding an alarm.

In recent months, two other Class I–recalls were announced related to possible device failures that failed to trigger an alarm. For instance, the Bivacardia Freedom Drive was recalled because a specific component of the device’s drive mechanism could fail, causing the device to stop pumping without providing advanced warning.

6. Faulty Batteries

The popular press has scrutinized the potential for some batteries to explode in recent years. Simple power outages though can be just as catastrophic in medical devices, however. The potential for batteries to not work correctly was implicated in recalls of the Dräger Medical, Evita V500 and Babylog VN500 Ventilators last year. As the recall notes explain: “The battery (part of the PS500 Power Supply) that powers the Evita V500 and Babylog VN500 Ventilators does not last as long as expected. The battery indicator light shows a sufficiently charged battery even when the battery is depleted.”

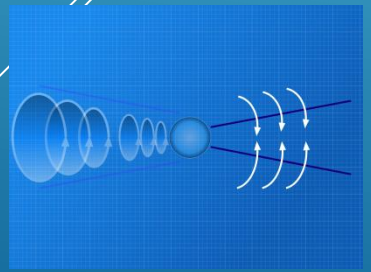
Design / Process(?)

Design / Process(?)

Design / Process(?)

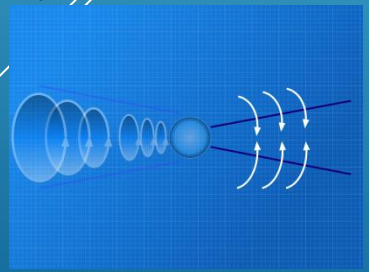
Learn more about cutting-edge medical devices at MD&M West, February 9–11 at the Anaheim Convention Center in Anaheim, CA.

POST LAUNCH: PROCESS CHANGES



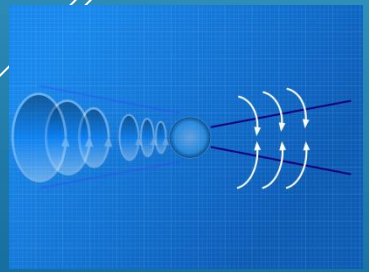
- Sources of risk / "Risk Sauces"

POST LAUNCH: SOURCES OF RISK



- Human Intervention (inappropriate behavior)
- Eg;
  - Fraud
  - Ignoring requirements, regulations, data, feedback
  - Deliberate off-label use
    - (also 'Use risk' by nature)
  - Sabotage
    - Eg; electronic hacking etc.
- Difficult to manage by "Risk Management" activities alone

POST LAUNCH: SOURCES OF RISK



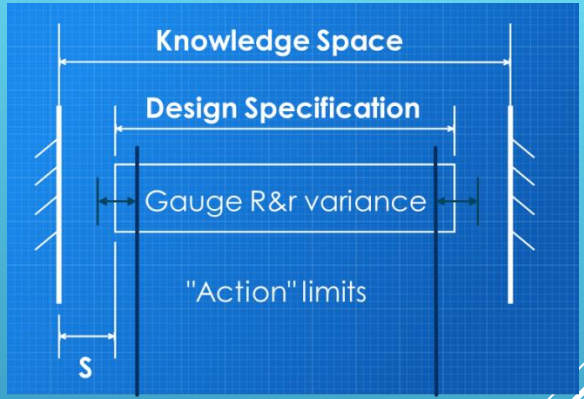
POST LAUNCH: PROCESS RISKS

- **Any and all** process changes need to be thoroughly risk assessed and controlled
- Numerous causes including (not limited too)
- 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


No 2 machines are exactly the same

POST LAUNCH: PROCESS RISKS

- 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
  - "Challenge to the void"- are they really required?
  - Eg: opening of specification (eg. For improved capability)
    - Remember development specification setting et al

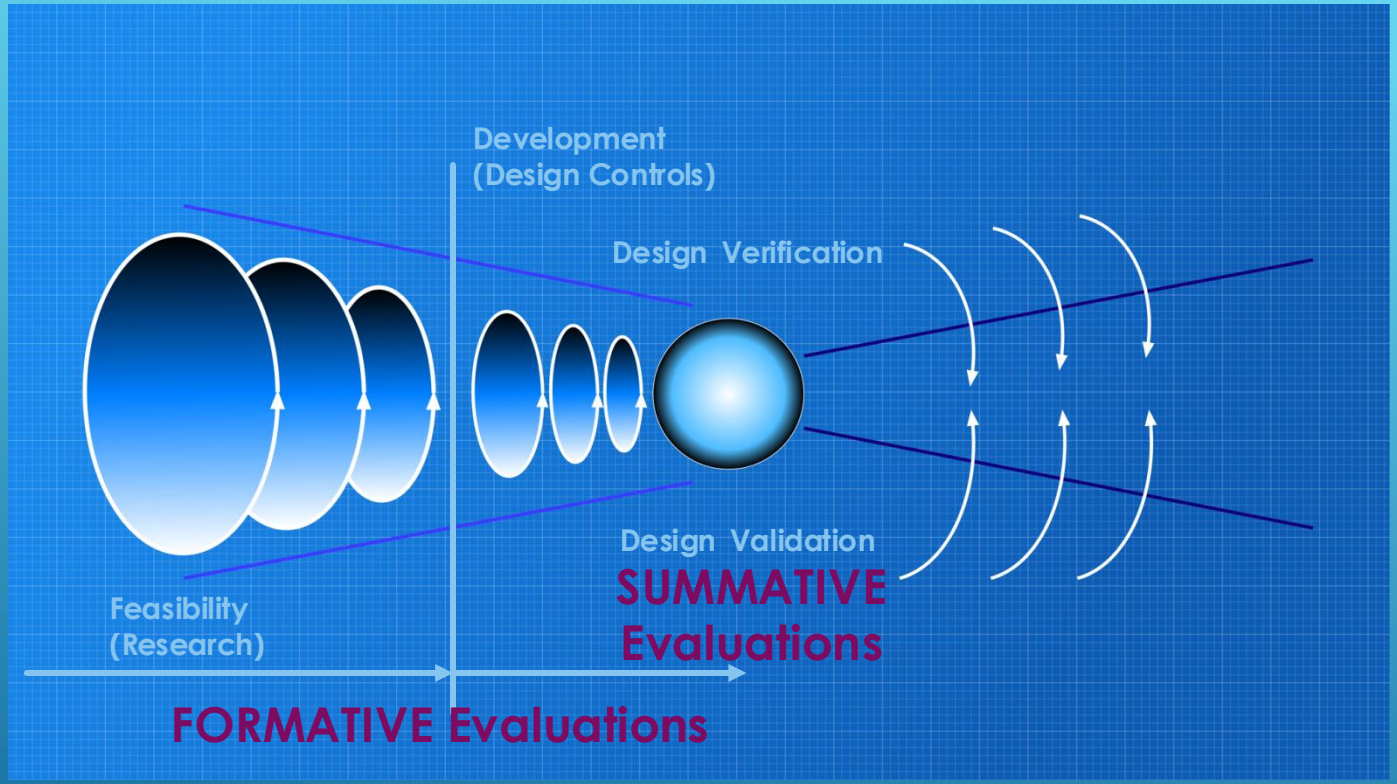


POST LAUNCH: USE

USE!!!!!

- Latest Requirements
- IEC 62366-1:2015 Medical Devices – Part 1: Application of usability engineering to medical devices
- Applying Human Factors and Usability Engineering to Medical Devices
  - Guidance for Industry and Food and Drug Administration Staff
  - "Final" issued Feb 3 2016

- 30s summary:
- During development activities, put your product in people's hands and assess, obtain feedback



POST LAUNCH: USE

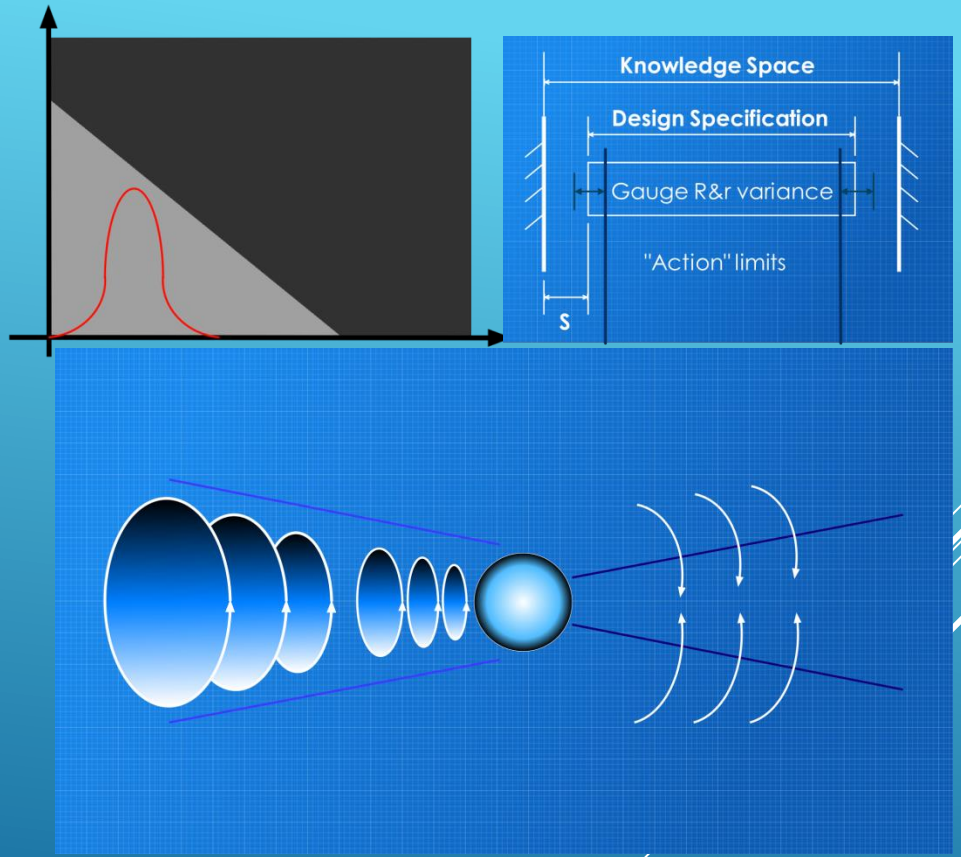
Conduct "Formative evaluation" during development (*subjective* assessment & feedback)

"Summative evaluation" (*subjective* 'validation')at time of Design Verification/Design Validation

"Subjective"= risk= Risk/Benefit likely needed

SUMMARY MESSAGES

- Every device will have a latent "Risk"
  - Everything that is engineered is unique and has a propensity to fail
- Assess until as low as possible or Risk / Benefit needed
- During Research / Feasibility, determine Knowledge Space" and set specifications appropriately
- Use tools eg, Process capability, gauge R&Rs to control manufacture
  - Measurement values are not absolutes caution with dimensions at edge of specification
- Once Design, Process are "Frozen" aim to avoid unnecessary changes
  - Determine root cause
  - Control all Post-market Changes
  - Assess Use risks "early" in development



AND FINALLY

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