

Implementing quality with risk management: Aligning with design control for all design phases

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



“RISK MANAGEMENT is a MINDSET”



“Everything that *is* **ENGINEERED** *is* **UNIQUE** ..
...and has a PROPENSITY to **FAIL**”

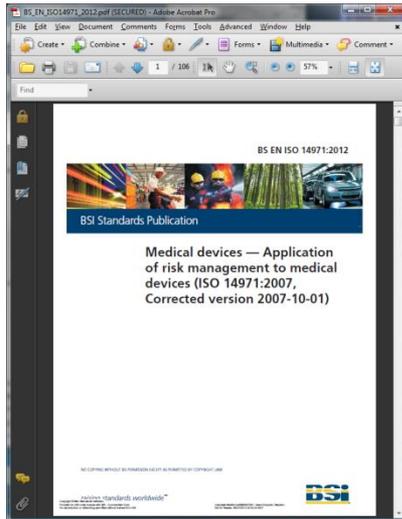


>> To KNOW your DESIGN is to CONTROL your DESIGN >>

<< DESIGN your KNOW to is DESIGN your CONTROL To <<

What is RISK MANAGEMENT?

ISO 14971?



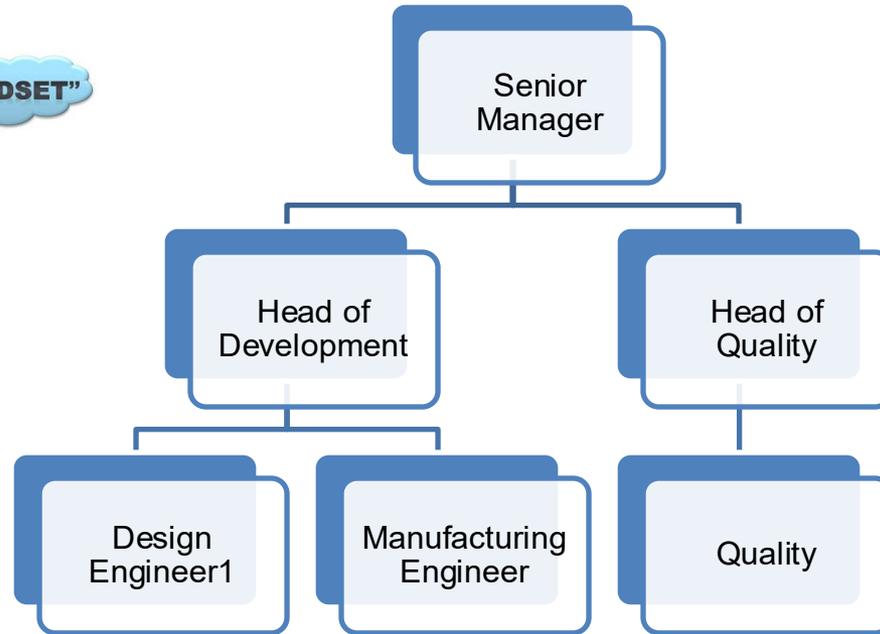
Application of “Risk Management for Medical Devices and IVDs”?



“**RISK MANAGEMENT** is a **MINDSET**”

Following the ISO etc does not “magically” enable risk managed devices

“RISK MANAGEMENT is a **MINDSET**”



Risk management *needs* to be a mindset throughout an organisation, to be successful.

From senior management to all involved in the project including development and manufacturing engineers

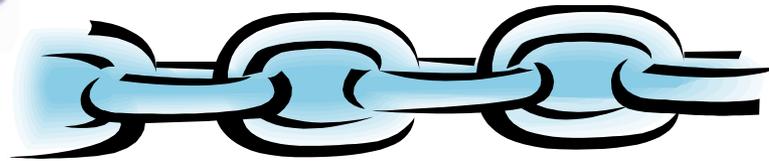
"RISK MANAGEMENT is a **MINDSET**"

Types of risk:

Product Risk



Project Risk



They are interconnected
(risk / benefit)

Scenario:

During development, the design engineers have determined that they need more time than originally planned to successfully launch the product

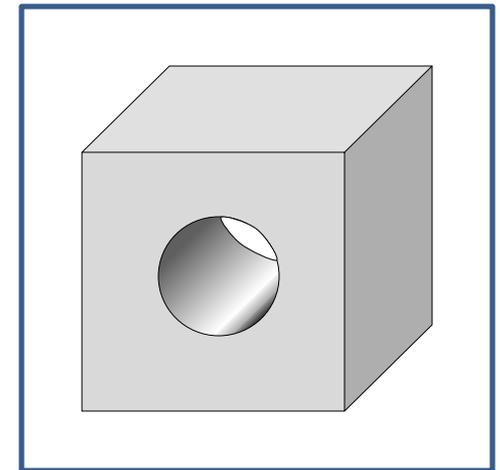
>>At the same time....

The senior management have learnt that a competitor will launch a product similar to Boxy one year before the original estimated launch date.

>>What is the compromise?

- Accelerating the project = risk of poor product delivery
- OR
- Delaying the project= risk of product having limited commercial value when launched

Introducing Part "Boxy"
(It's cube with a hole
-Representing any Medical Device with a "specification").



“Anyone can deliver rubbish on time *”

“RISK MANAGEMENT is a **MINDSET**”



Project Product

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...

* *some fail to deliver rubbish on time..*

What are we trying to achieve with Risk Management?



The perfect product with no risks and therefore no failures on the market and in use?



“Everything that *is* **ENGINEERED** *is* **UNIQUE** ..
...and has a PROPENSITY to FAIL”



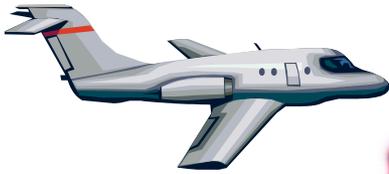
Nothing engineered (designed manufactured) is ever 100% failure free

Engineering rule; Second Law of Thermodynamics – “entropy increases”

Drop a fragile object, it breaks and will never recover it's original form



What are the best engineered products existing in 2012?



Do the very best designs work 100% successfully?

Who tests a pen when they pick up a new one?

theguardian

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Steve Jobs solves iPhone 4 reception problems: 'don't hold it that way'

Antenna design on new iPhone is acknowledged as source of poor connectivity - but Apple says problem is inevitable and advises different grip. Or you could try duct tape...

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You're holding it wrong (again!): Apple pulls out same old excuse to users who complain about purple haze on iPhone 5

- Apple's customer support says 'purple haze' in images is 'normal behaviour'
- User told he to stop pointing his camera at light sources - reminiscent of Steve Jobs telling a user to 'stop holding his phone the wrong way'

By EDDIE WRENIN

PUBLISHED: 13:13 GMT, 3 October 2012 | UPDATED: 20:16 GMT, 3 October 2012

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Two years ago, iPhone users were frustrated after finding themselves with poor signals on their phone.

Steve Jobs's infamously terse reply to 'Antennagate' was, in a direct email to a user, that he was holding his phone wrong.

Now, users of the iPhone 5 are complaining fr

Photo: Steve Jobs' Antennagate

Thu, Jun 28, 2010 at 4:20 PM

Subject: Re: Your new antenna system doesn't like my hand :(

Just avoid holding it in that way.



"Everything that is ENGINEERED is UNIQUE ..
...and has a PROPENSITY to FAIL"



If everything that is engineered can fail, why in Medical Devices is there an expectation from some people that the product will be 100% fault free?

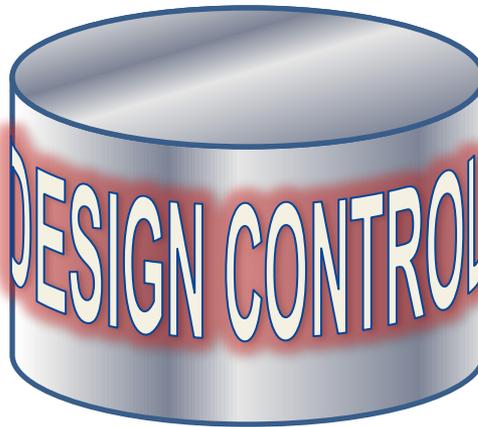
Good Risk Management is actually about knowing how and when your device can and will FAIL

When should we learn the limitations of our device design?

Early Development

After Launch

How do we learn the limitations of our design?



“does what it says on the can / tin”



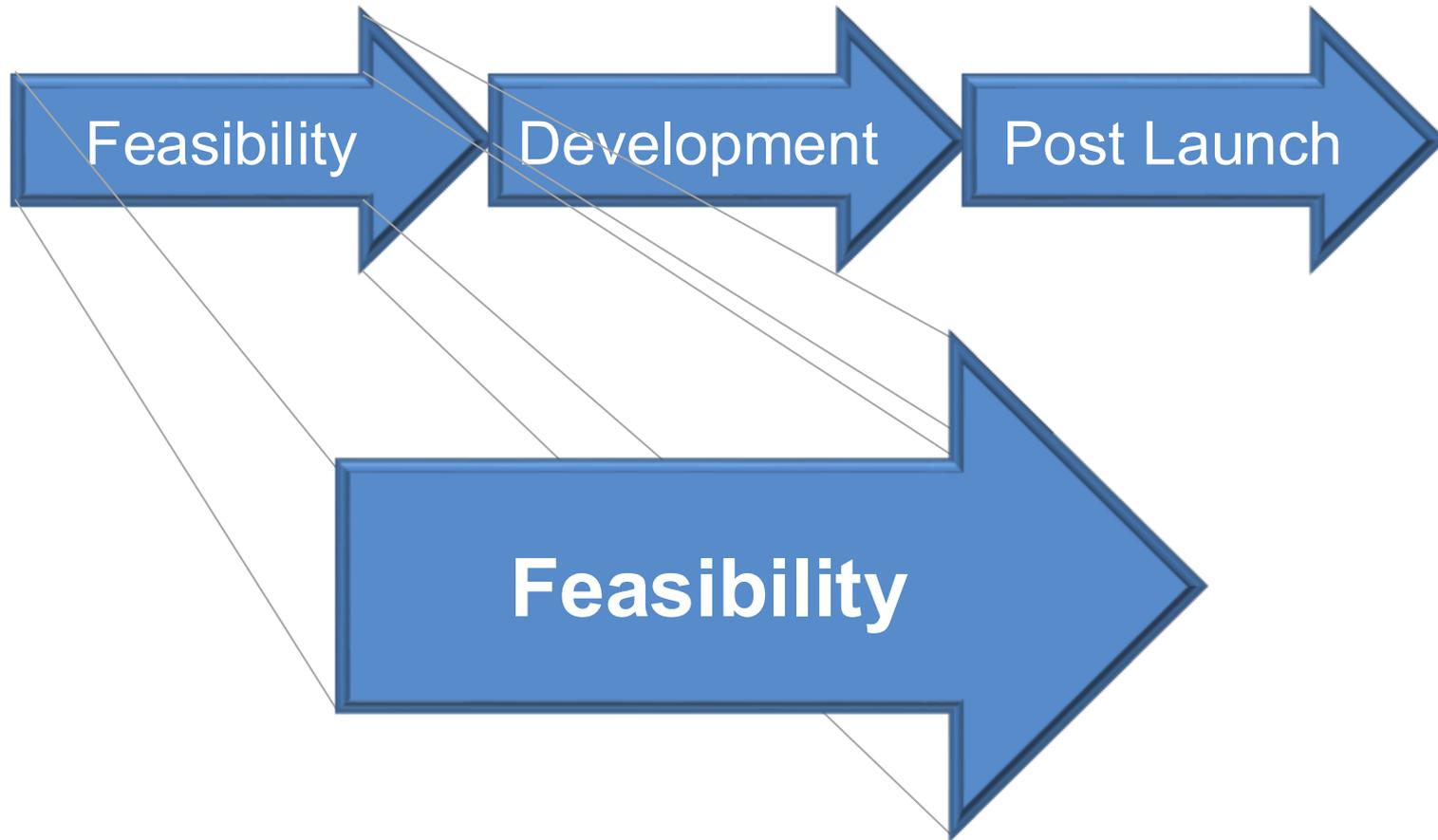
FDA (21 CFR 820.30)

ISO 13485:2003 section 7



Design Control is primarily about defining and documenting correctly the development history of the device – the knowledge of the device design

Product Development “Path”

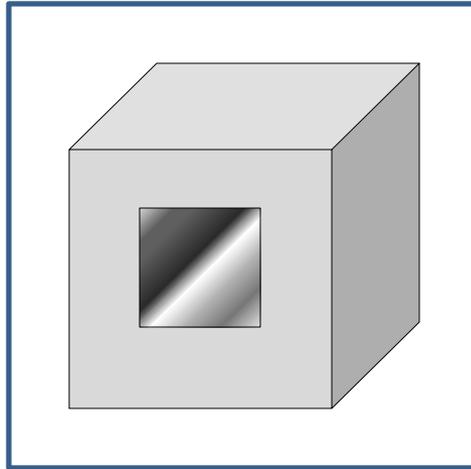


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This is the phase where most design knowledge and (most risks) are generated

Feasibility

Prototype development begins..



Look at this great design!

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

Okay..

Why..

I'm changing the design because:

Risks!

Need to capture and document..!

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

Design Risk

Design FMEA

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

Manufacturing Risk

Process FMEA

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

Usability Risk

Human Factors

Related to Hazards / Harms (ISO14971)

•Drug Product Related Hazards*

ISO 14971 „Hazards“

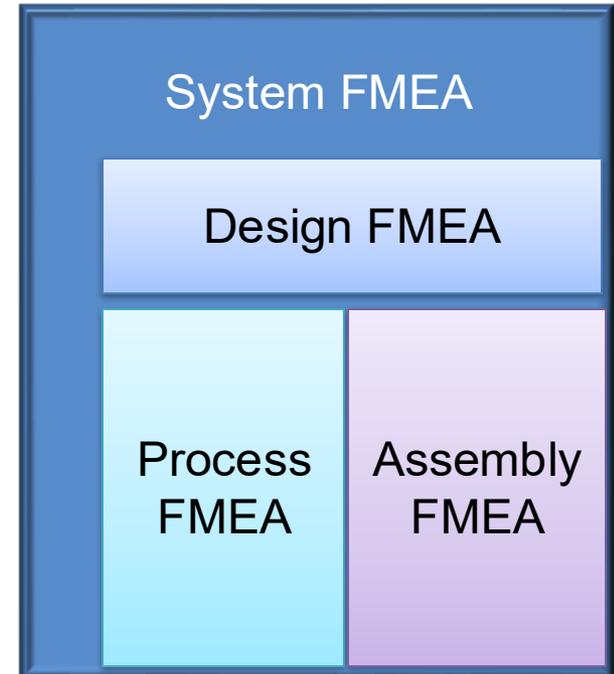
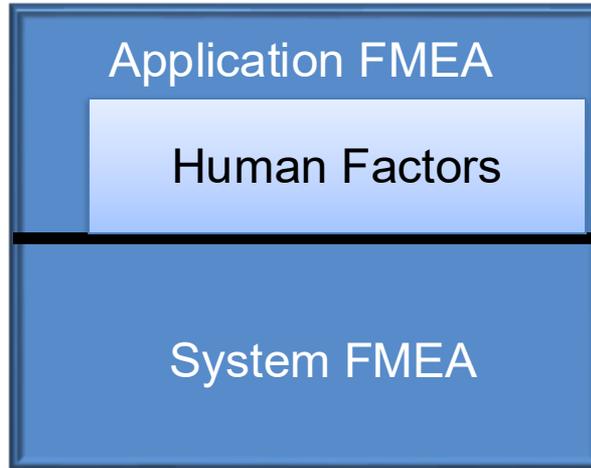
- Administration of drug and device use hazards
- Biologic and non-biologic contamination
- Environmental hazards
- Device misuse (reasonable and foreseeable)
- Energy, electrical or mechanical hazards

Hazard Analysis

Risk Assessment Cascade

Example

(Drug delivery system)



CONTROL your DESIGN >>
DESIGN your CONTROL <<

Risk Assessment Cascade

Example

(Drug delivery system)

- Hazard: No dose
- Severity of Harm: Death or serious injury

Hazard Analysis

Application FMEA

Human Factors

- Patient unable to actuate device
(High torque required > target population's capability)

System FMEA

- Device mechanism fails to function correctly on actuation

System FMEA

Design FMEA

- High torque to actuate device - high friction in mechanism
- Component interaction within mechanism fails – insufficient friction

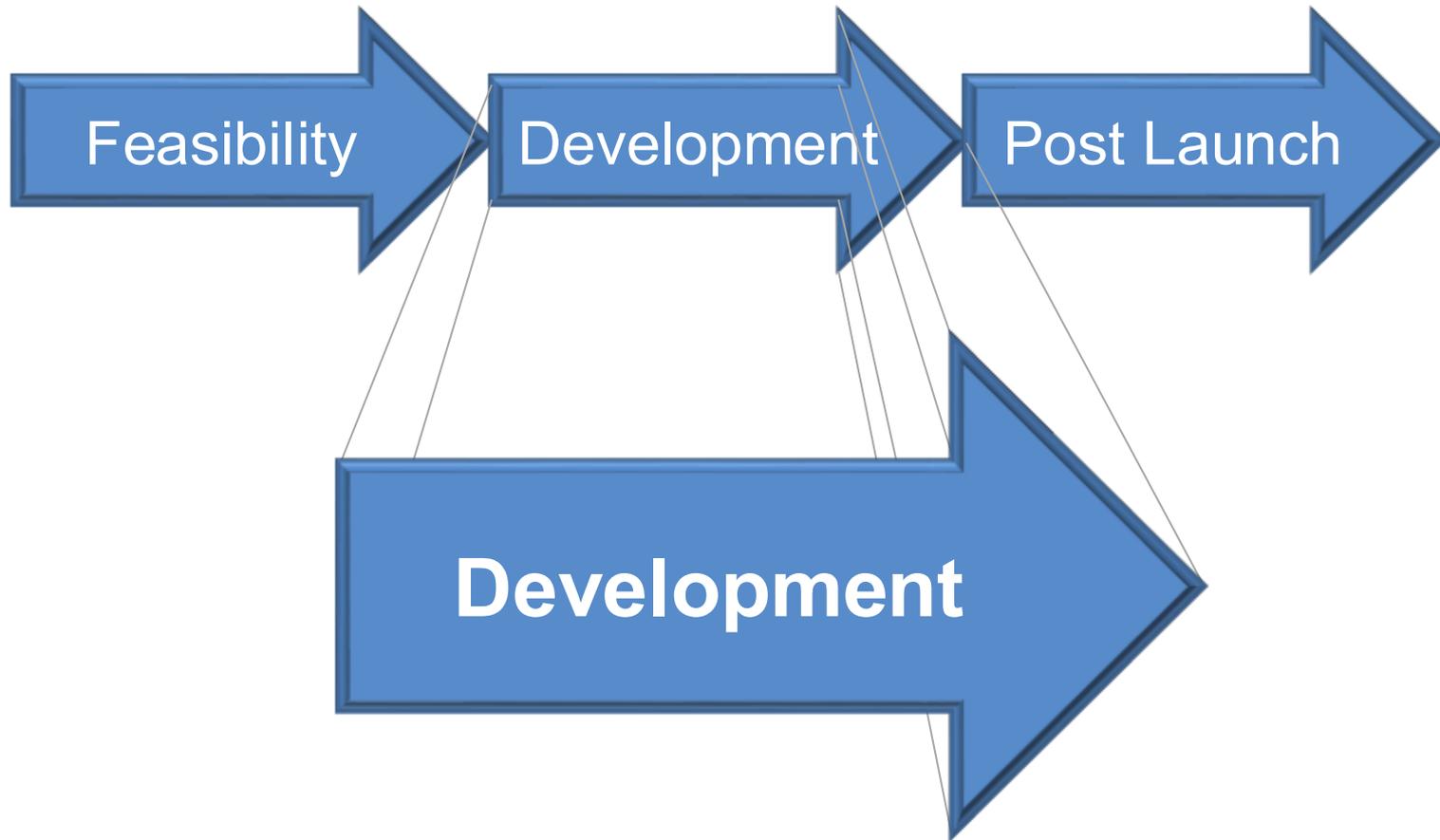
Process FMEA

- Components poorly moulded (short shot) causing mechanism failure

Assembly FMEA

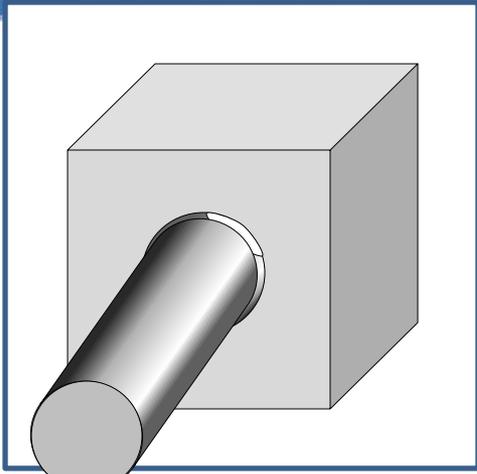
- Components incorrectly assembled causing mechanism failure

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As the design progresses, focus shifts from concept to designing a manufacturable product that will launch

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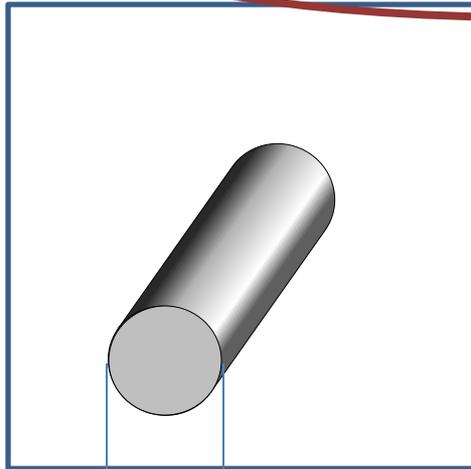
“Boxy” now has a mating part;

Design assessment, Rod is smaller than the hole;
Rod fits and is ok.

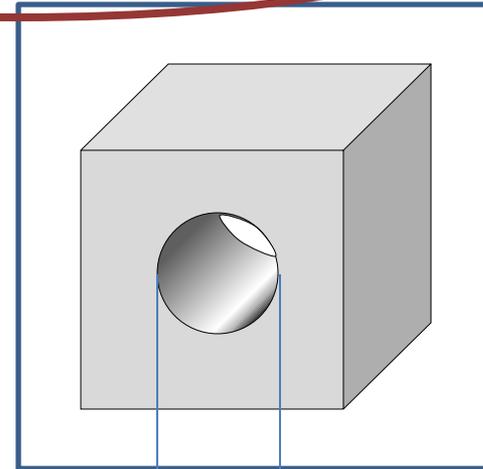
Nominal size difference $10.0 - 9.8 = 0.2$ clearance

Max size 9.90

Min size 9.90

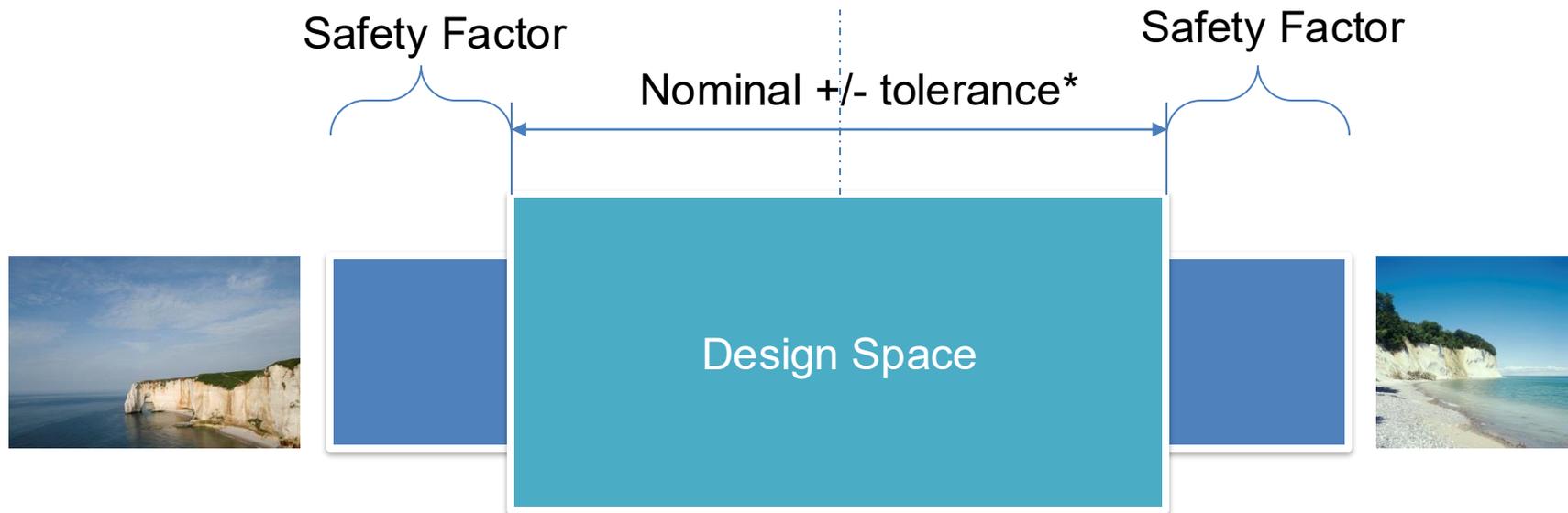


9.80 +/- 0.1



10.00 +/- 0.1

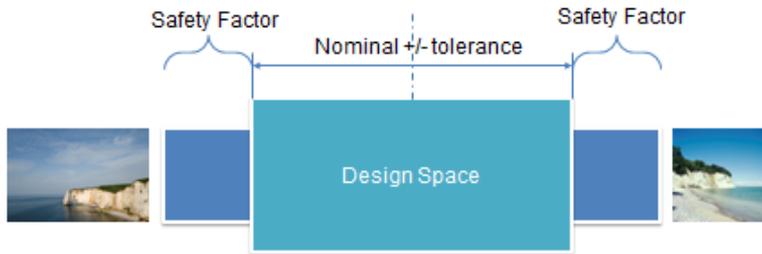
Interlude: Knowledge space, Design space



1. Determine the limits of the design; the “cliff edges”
 1. The point where the design is known to fail
2. Design specification is set within the Knowledge space with an acceptable safety factor between the limits of the Knowledge space and Design space

*mm, m, inches, N, Nm, ml, cc etc..

Note: Having a good knowledge of the Design de-risks the likelihood of failure of Design Verification



Design Verification ◆

Design Validation ◆

End of Interlude

Timings of Design Verification and Validation will vary depending upon each project complexity and associated project / product risks

Manufacturing Assessment

We're looking to manufacture this part:

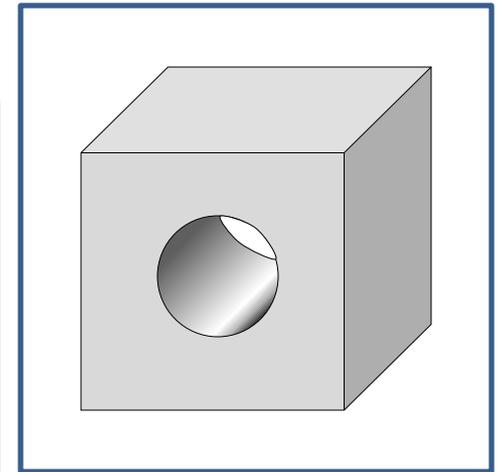
What size is the tolerance on that hole?

± 0.1

We'll not hold that in manufacture.

Think think think

Can we open the tolerance??



<< DESIGN YOUR KNOWLEDGE TO DESIGN YOUR CONTROL TO >>

“CAN WE OPEN THE TOLERANCE”

No the design
is FROZEN

(how can it be frozen?)

It'll cost you...

(Ouch!)

Yes, what
tolerance
would you like

(Never happens like this)

+/-1.0

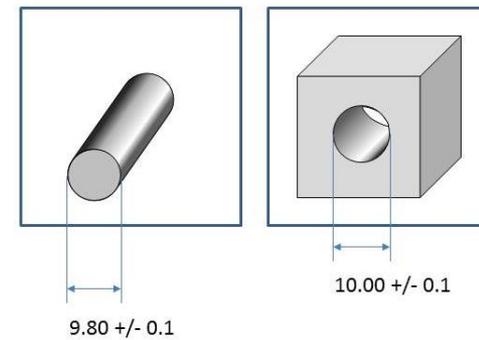
(Why?)

What does a specification REALLY mean ??

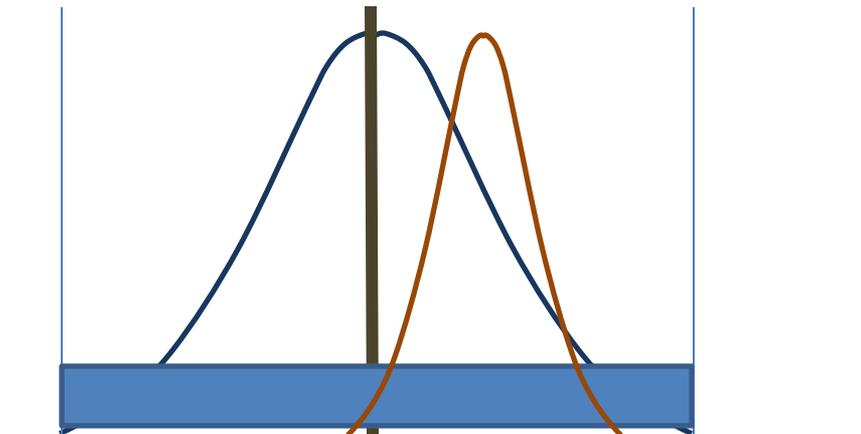
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What does a manufacturing specification of 10 ± 0.1 mean?

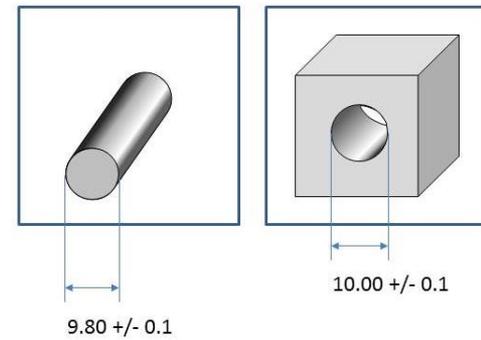
- part can be fabricated in the sizes from 9.9 to 10.1, targeted at 10.0
- Values can be:
 - mm, m, inches, etc..
- What do design engineers believe they will get?
 - Nominal distribution around nominal
 - On nominal ?
- What do Manufacturers believe they can make?
- Reality?



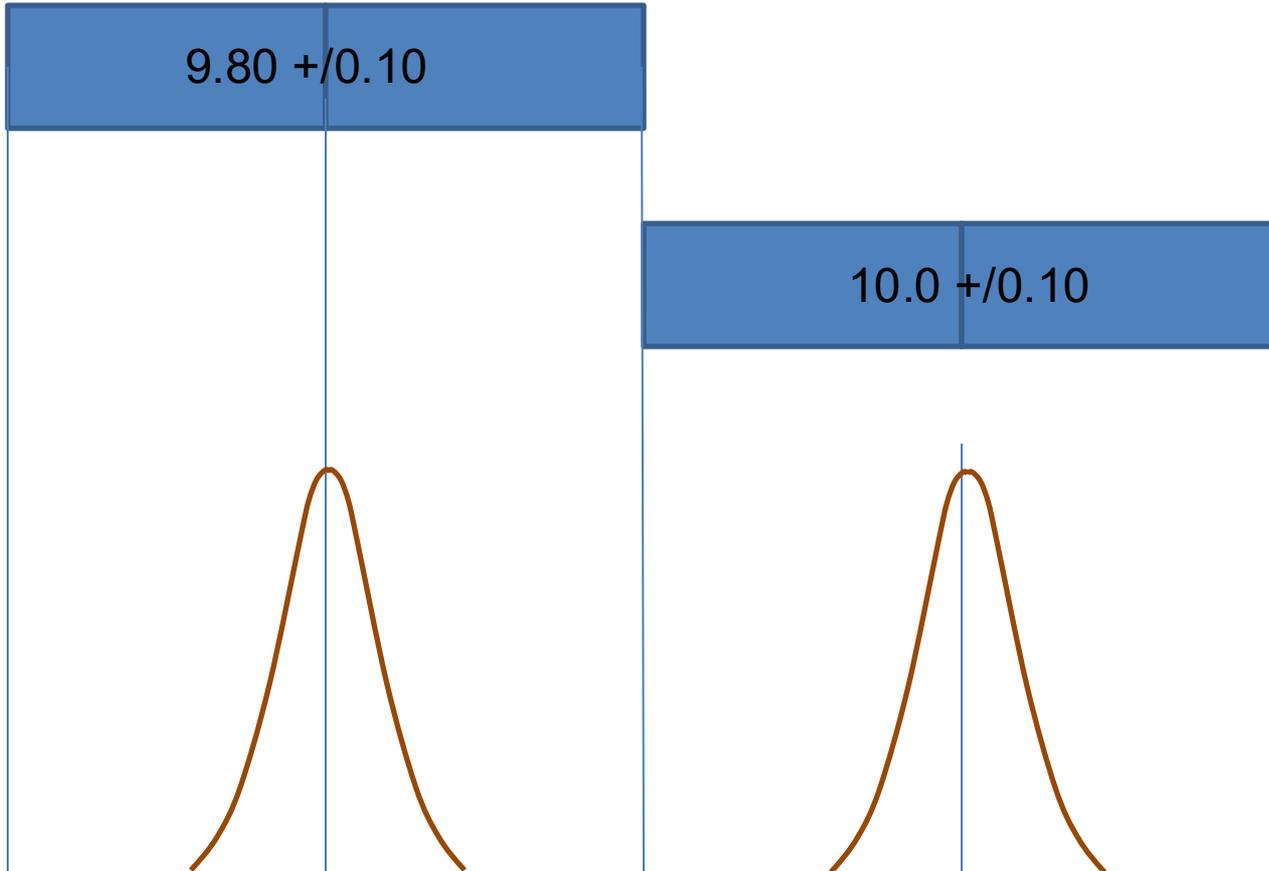
9.9 10.0 10.1



For our two parts ideal production would be...



9.7 9.8 9.9 10.0 10.1



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What happens if...

Qty required: 100

9.80 +/-0.10

Options:

1. Supplier manufactures 100 completely in spec

2. Supplier manufactures >100, sorts and supplies 100 within specification

Sorted and rejected

3. Supplier manufactures 100, has sampling plan (eg: AQL) and controls 5 from 100, all 5 in specification

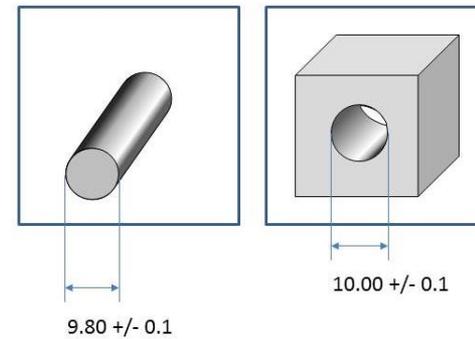
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9.7

9.8

9.9

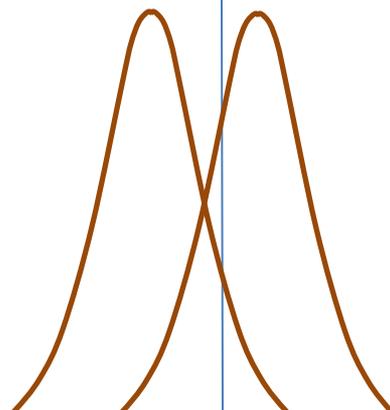
What happens if...



9.7 9.8 9.9 10.0 10.1

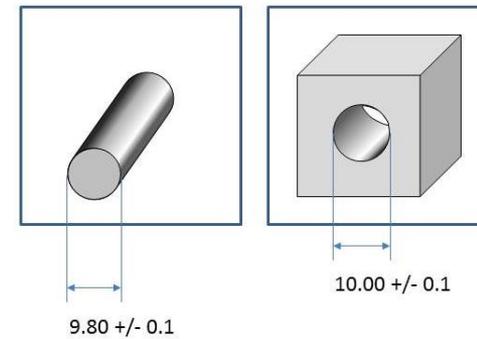
9.80 +/- 0.10

10.0 +/- 0.10

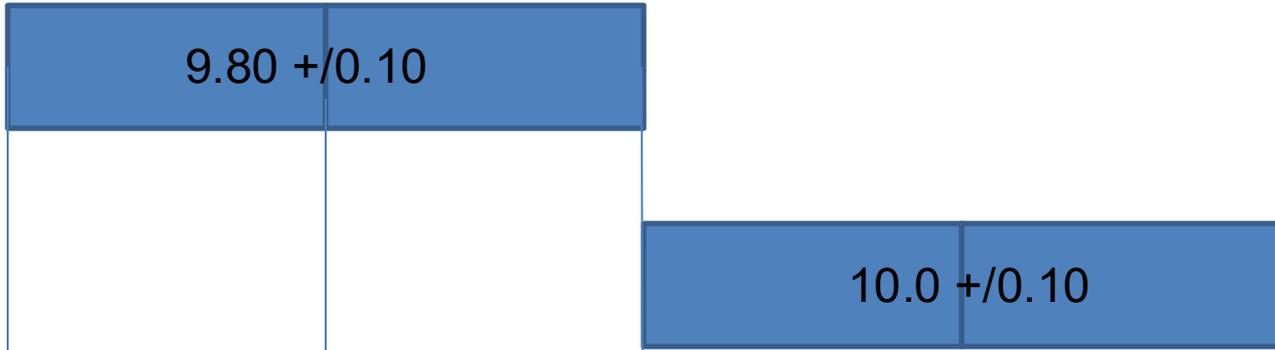


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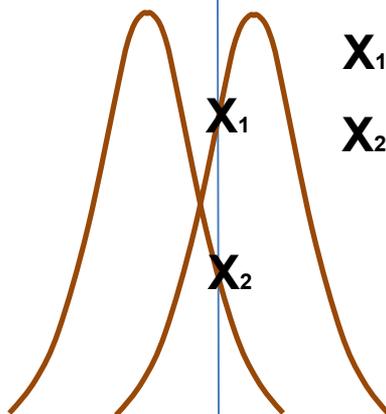
What happens if...



9.7 9.8 9.9 10.0 10.1



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$X_1 = 9.91$
 $X_2 = 9.88$

Actually, X_1 part measured 3 times:
1st = 9.89
2nd = 9.91
3rd = 9.93
Mean = 9.91

Is the part *really* in specification?



Manufacture for 3 batches

Controlling manufacture of a part is the ability to make and measure a part that is EQUIVALENT to the part you have confirmed works.

- This is Design Transfer:
 - Process Control (Process Capability)
 - Gage R&R (Repeatability and Reproducibility)
- In reality the actual “value” of the part does not matter, as long as the measurement system is the same and the corresponding value is the same.
- (I was once told a CMM measures in elephants)



Our engineer has:

- Determined a feasible concept
- Risk assessed the design
- Worked with the manufacturer to ensure the design can be made
- Conducted Design Transfer with supporting Process FMEAs, Capability Analysis and Gage R&R to support it can be made
- Verified the product has been designed right

What's missing...?

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USABILITY

>> To KNOW your DESIGN is to CONTROL your DESIGN >>
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Scenario; Design Validation, devices are taken to a target user and asked for usability feedback



Is Design Validation really the point to obtain feedback on the Usability of the design?



Feasibility

Development

Post Launch

Design Validation



Can you use
this device?

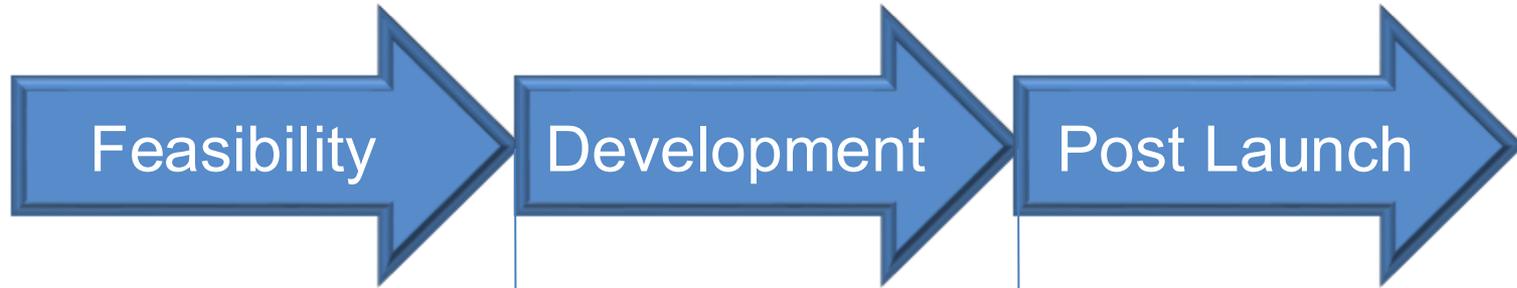
No.

How far back in
development
do you need to
go to fix?

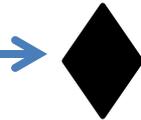


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How about...



User assessment



Design Validation



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Risk Assessments also need to have a good “balance” of characters conducting the risk assessment:

Glass is half full or half empty (characters)

Glass is half empty

Glass is half full

That will never work!!

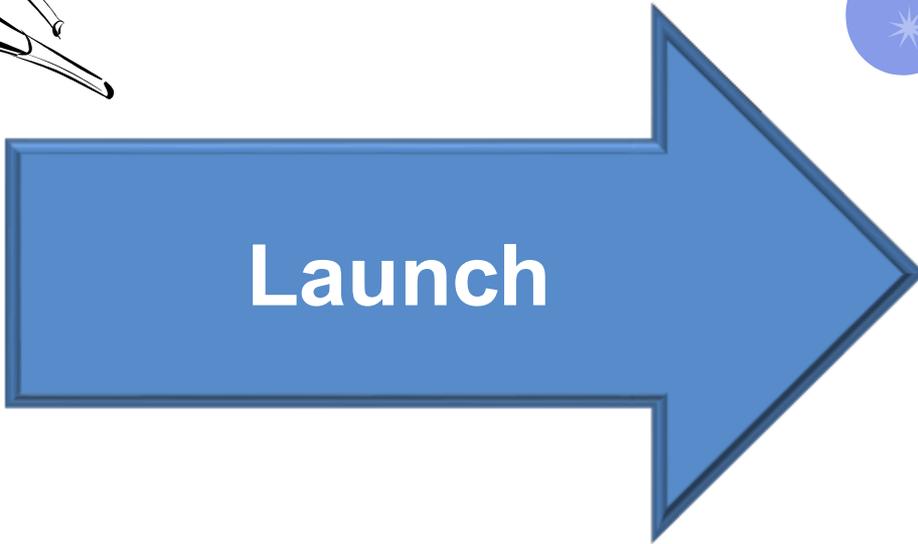
(Typically the overly critical Quality Engineer)



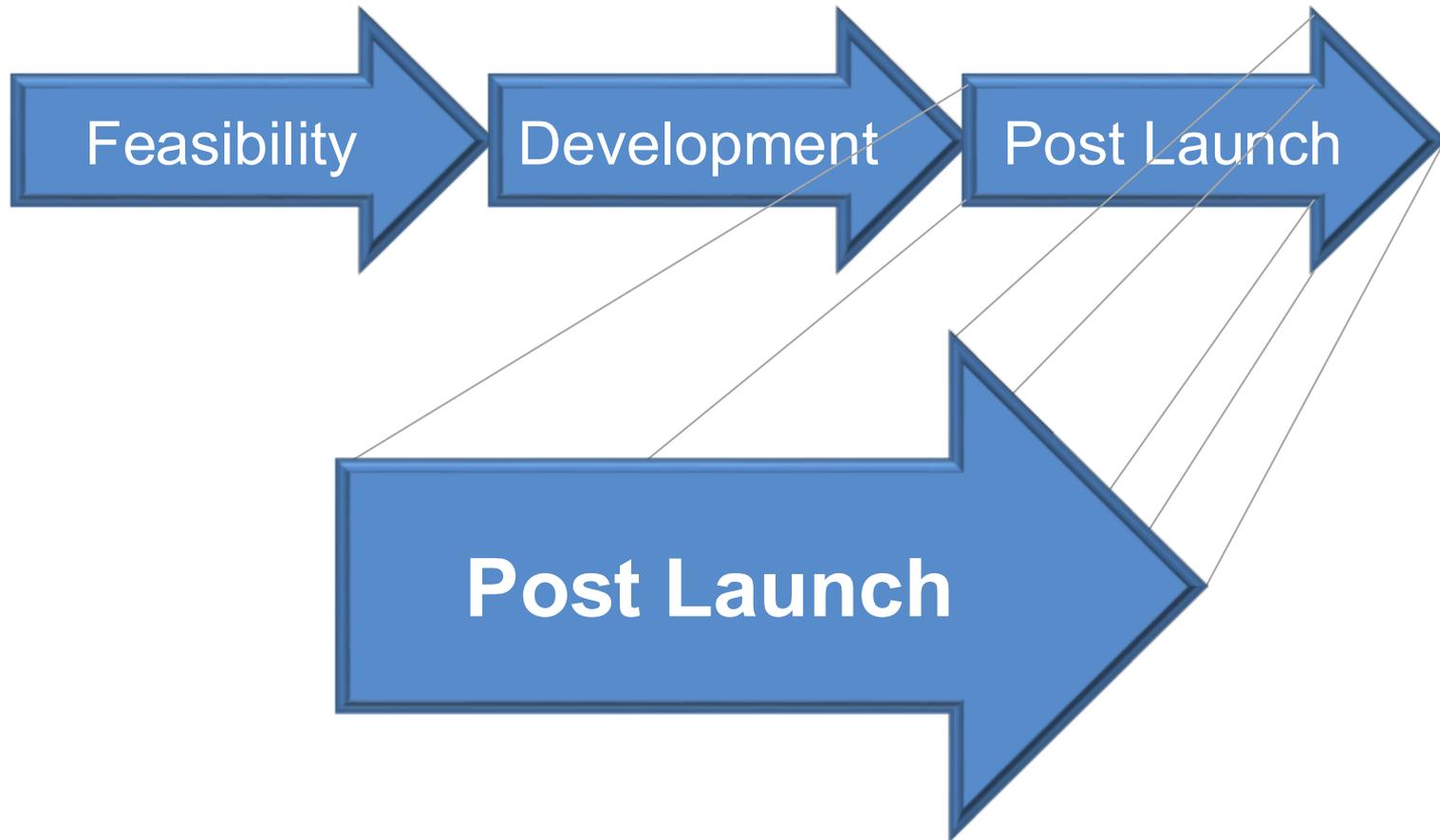
That failure mode is impossible, it will never happen!!

(Typically the proud Design Engineer)

Sometimes realism helps. Sometimes the glass is neither half full nor half empty (It's a wine glass, think about it...)



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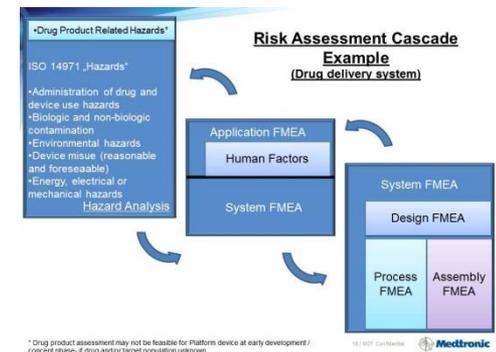


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Post Market Production changes

- Assessment of impact of change on the design (Design Change, Design Transfer)
- Arguably not required if supplier / manufacturer has a Process Control Plan and manages changes via change control to the Control Plan

During Post Market, any changes to the process must be risk assessed by the product development team for potential impact on the design



How is the change assessed relative to the original design?

- **“Can we open a tolerance?”** 
- Why go to the effort of months of Design Development work, put months of work into documentation of Design Transfer, for the supplier / manufacturer to make changes without related design assessment?



Example of Post Market production changes to Boxy

Post Market Production changes

- ***During Post Market, any changes to the process must be risk assessed by the product development team for potential impact on the design, relative to Design Transfer, Design Verification and Design Validation (and original needs / Design Inputs)***

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Summary: Remember the 3

“RISK MANAGEMENT is a MINDSET”



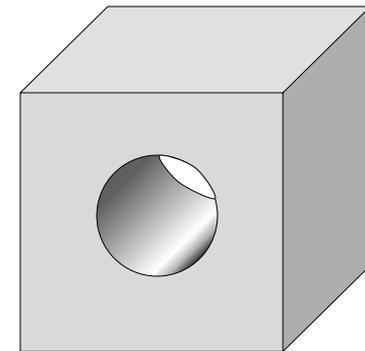
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Thank you! – Your Take Home Messages:

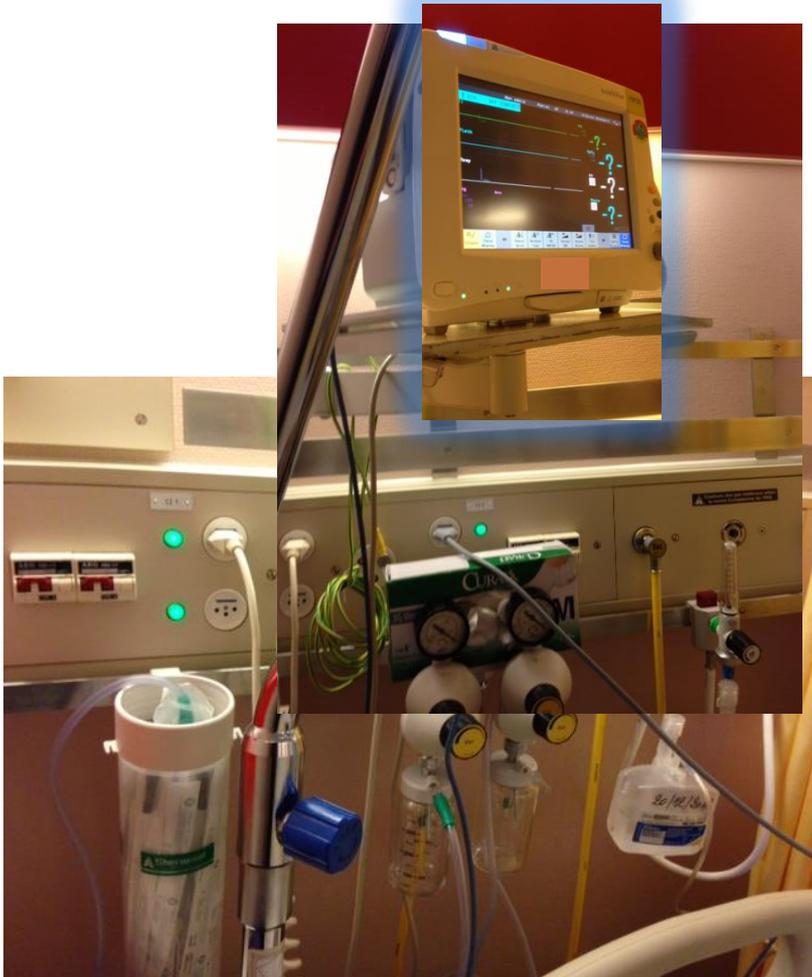


Back up slides:

What are we trying to achieve with Risk Management?

The perfect product with no risks and therefore no failures on the market and in use?

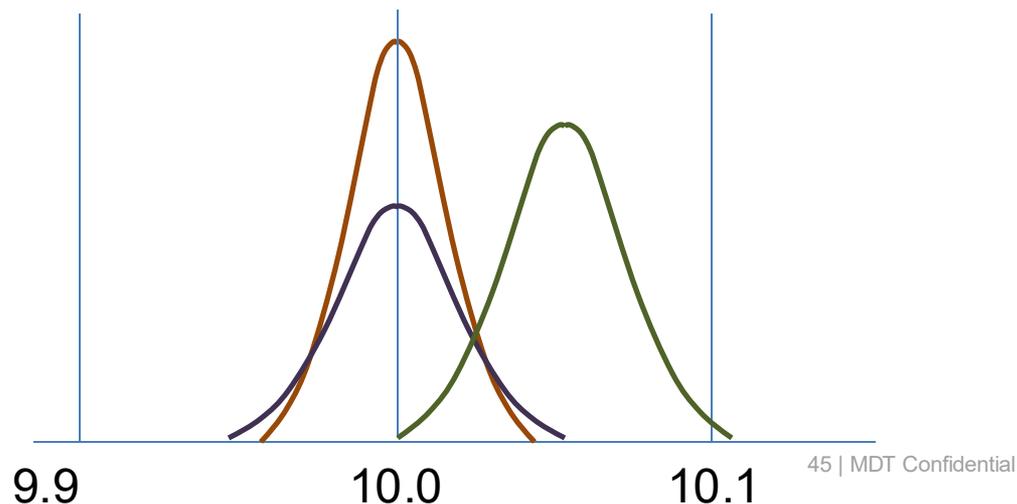
Why? (Because we really want them too)



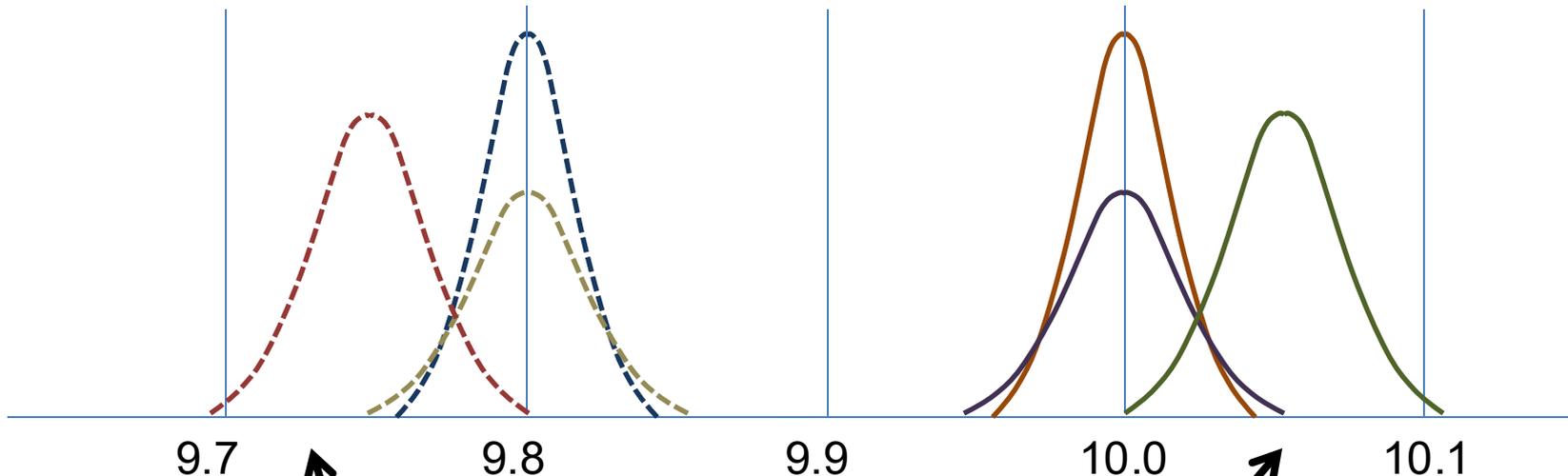
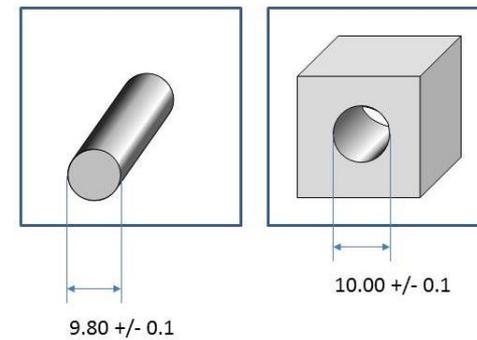
3 batches of Boxy manufactured, 5 parts sampled per batch

Batch 1	Batch 2	Batch 3
10.01	10.03	10.04
10.02	9.97	10.07
9.99	10.01	10.06
9.98	9.99	10.08
9.99	9.98	10.09

Is Batch 2 = Batch 1? Batch 3? (note all are “in specification”)

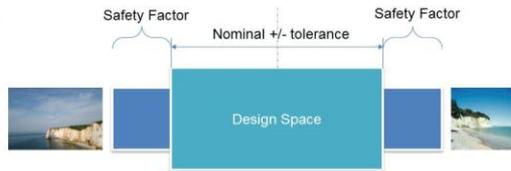


From 3 batches of Boxy and Rod we have similar distribution

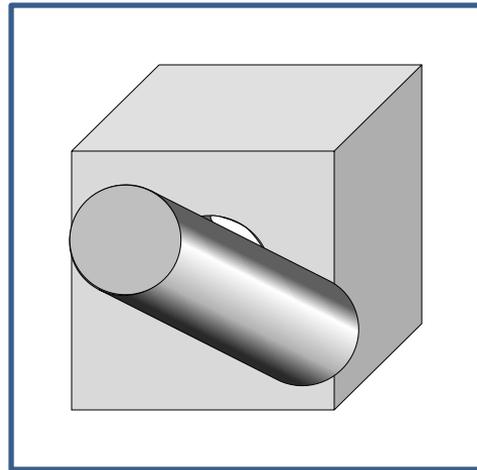
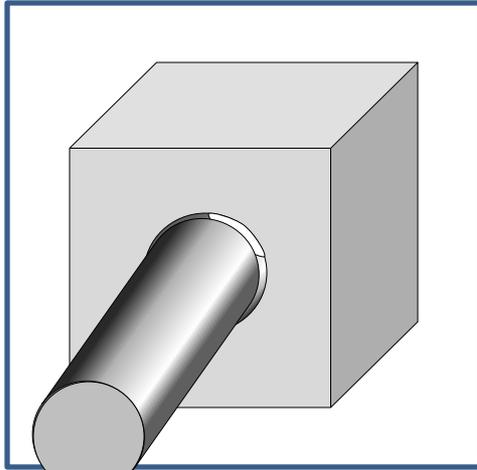


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...but for the 3rd batch the fit between them is notably looser...
Is the loser fit acceptable?



Usability: intuitive that rod should fit in the hole?



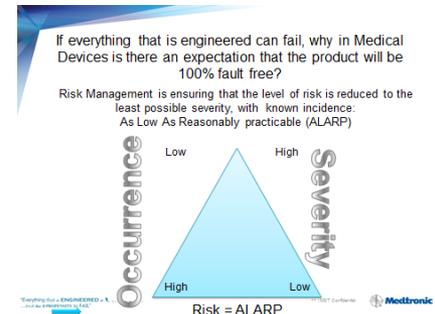
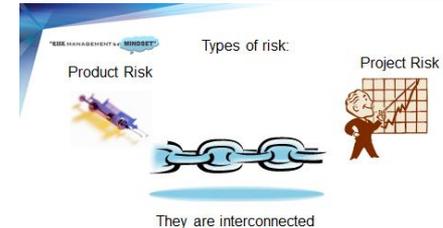
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Or...



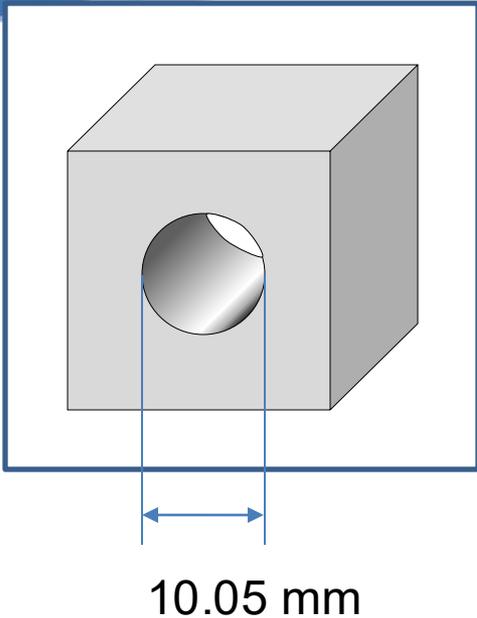
Design Validation



Progress at risk? Product v Project?

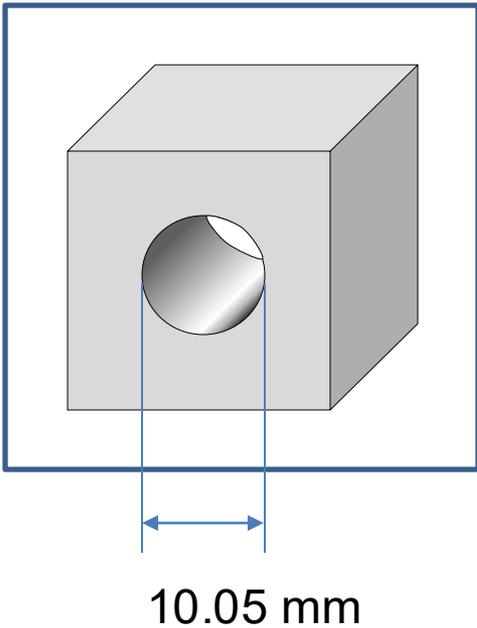
- Depends upon severity / likelihood of Hazard/Harm from the Usability failure

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Machine	Measurement method	Measuring Person
A	A	A

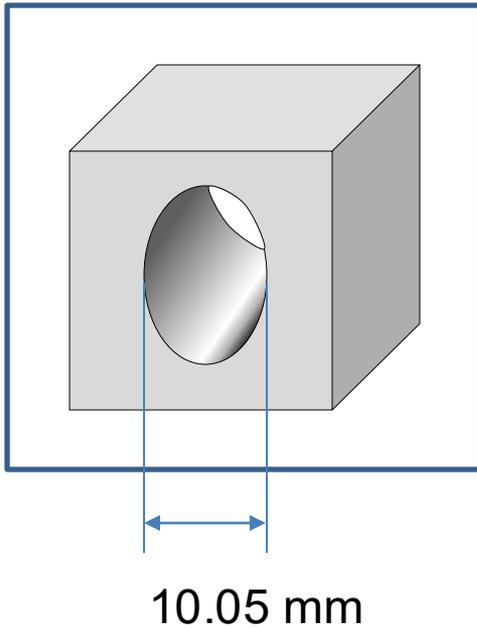
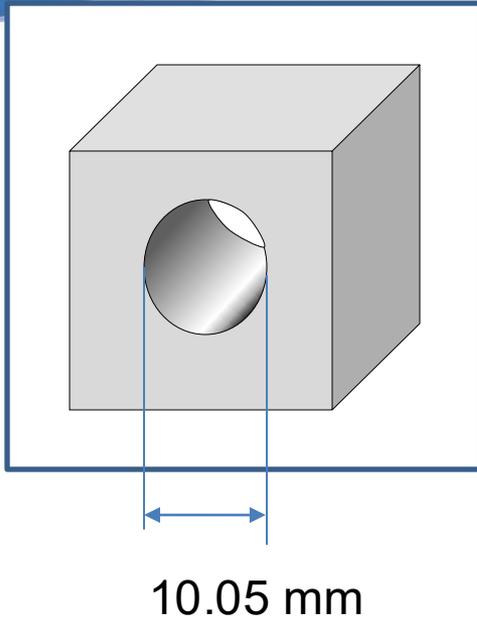
First Production
(Functionally tested, confirmed ok)



Machine	Measurement method	Measuring Person
A	A	A

Second Production
Confidence level part is equivalent to “First production” ?
High

>> TO KNOW your DESIGN is to CONTROL your DESIGN >>
<< DESIGN your KNOW to IS DESIGN your CONTROL TO <<



Machine	Measurement method	Measuring Person
A	A	B

Third Production
Operator on vacation, another operator used

Confidence level part is equivalent to “First production” ?

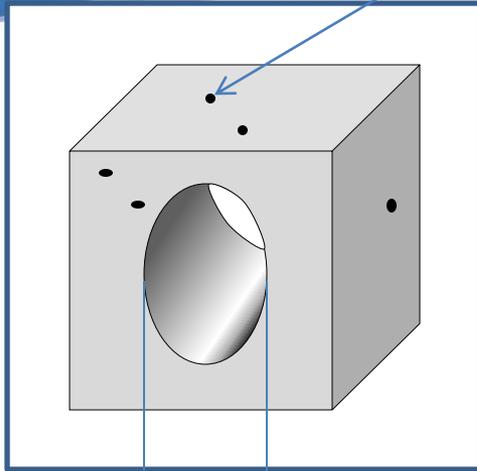
-Depends upon Repeatability & Reliability (gage R&R) of measurement method

Machine	Measurement method	Measuring Person
A	B	B

Fourth Production
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

Surface defects



10.05 mm

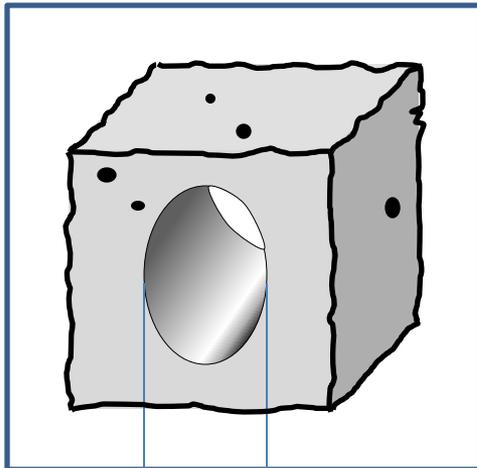
Machine	Measurement method	Measuring Person
B	B	B

Fifth Production

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



10.05 mm

Machine	Measurement method	Measuring Person
C	B	B

Sixth Production

Cost saving, alternative "equivalent" machine used,

Confidence level part is equivalent to "First production" ?

-???????

1
"Everything that is ENGINEERED is UNIQUE ..
...and has a PROPENSITY to FAIL"

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

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