Product Release
a modern mythology?

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Peter

Definitions

Product release:

A documented decision determining the success of each decontamination procedure allowing the device(s) to be released for the next stage or to the patient

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Definitions

Mythology:

A body of myths …

… Supernatural or imaginary persons embodying popular ideas on natural or social phenomena

…Widely held but false notion

Concise Oxford Dictionary

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Definitions

Product release – a modern mythology?

Is it possible to make a proper product release decision or is there an ever-present element of risk in using a re-processed re-usable medical device

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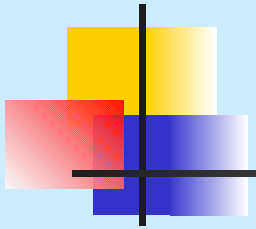

Aims of presentation

To discuss…

…the reason for product release,

…its requirements

…and whether it is achievable

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Product release – why?

Example 1:

"A pack of non-sterile instruments have been sent to theatre. I only just managed to get them back in time"

Discussion during audit

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Product release – why?

Example 2:

"We used a set of non-sterile instruments on a patient last week. What went wrong?"

Telephone call

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Product release – why?

Alternative question:

"Would you use these instruments on yourself?"

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Product release – why?

Example 3:

When asked a practice nurse said:

"If I am having an inspection here I bring my own single-use speculum"

Admission during audit

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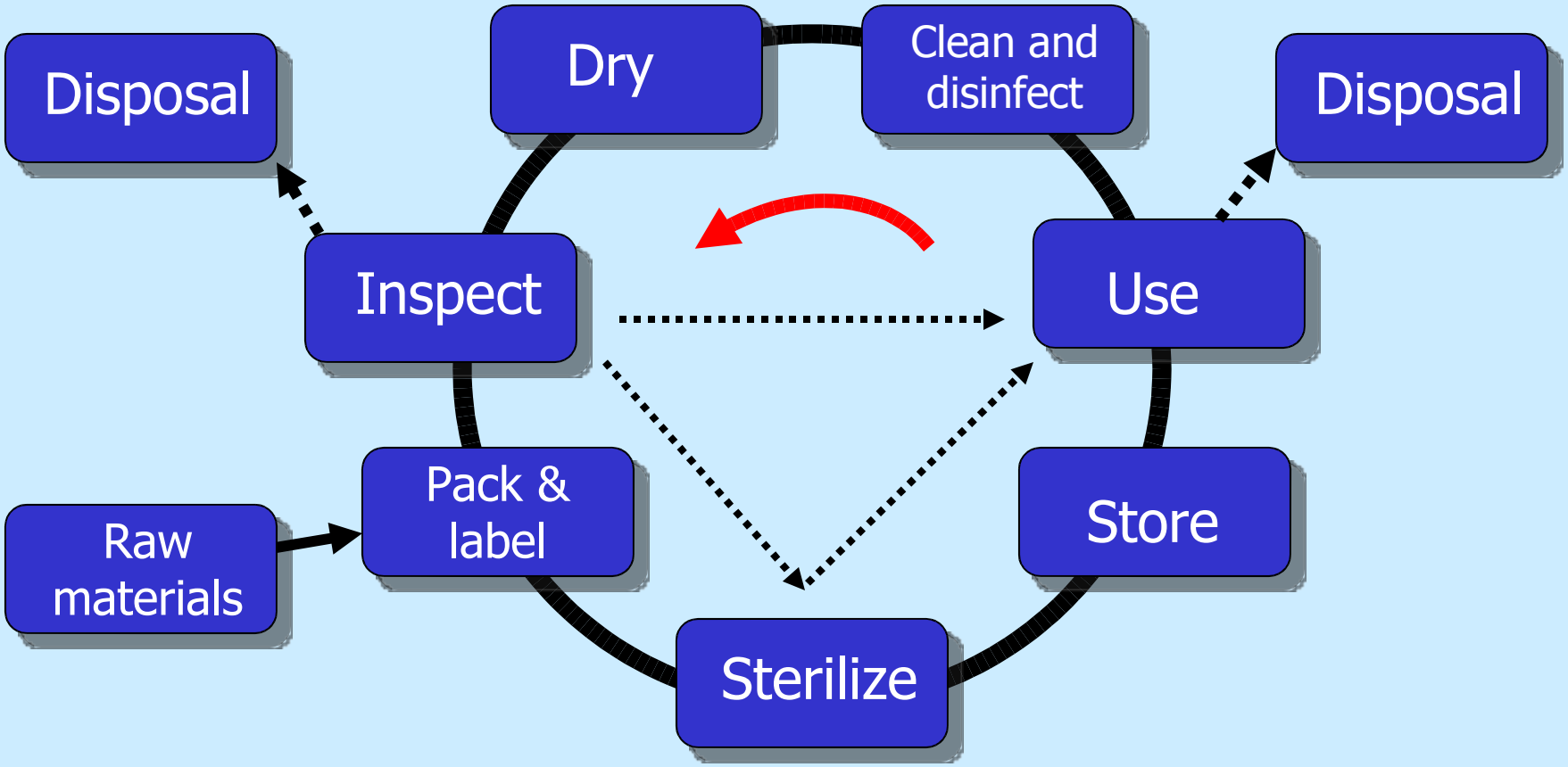
Product release – when?



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Product release – when?

Decontamination stages:

Cleaning – manual

Cleaning - automated

Disinfection

Sterilization

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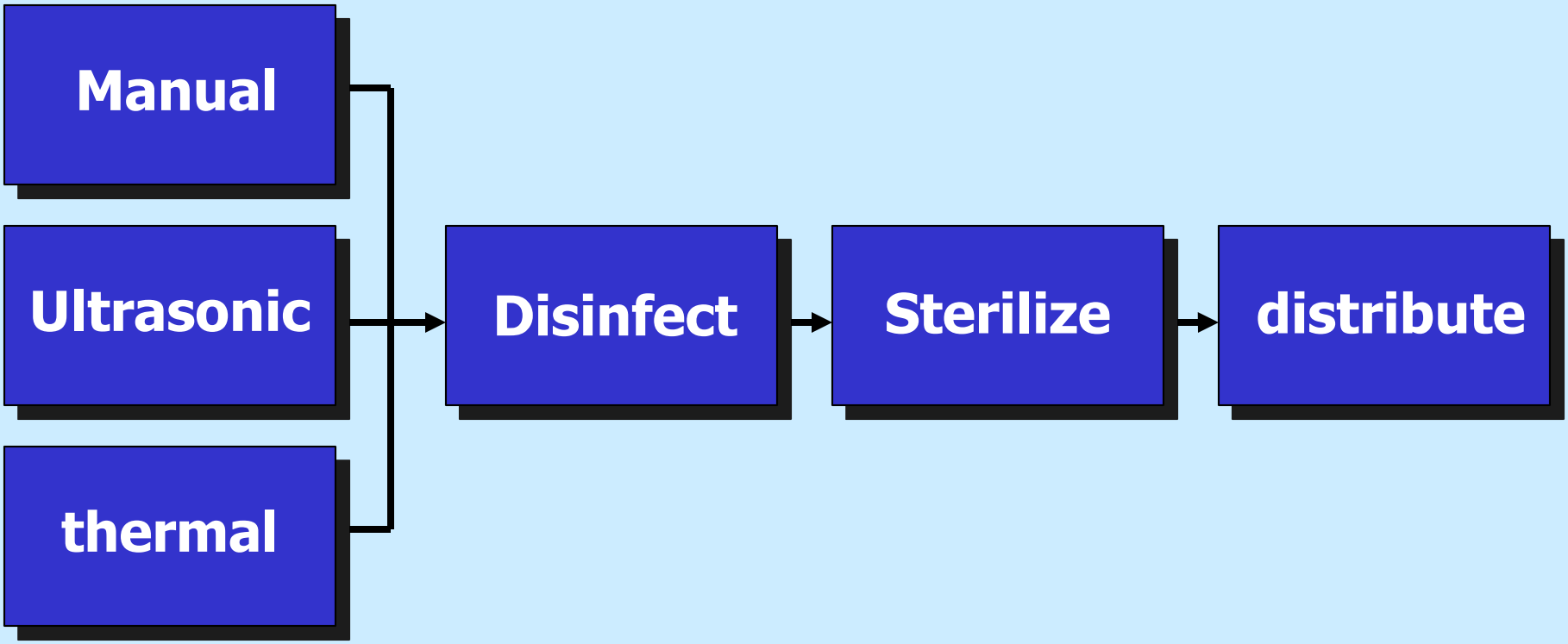
Product release – when?



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Product release – when?

Confirmation at each stage:

… that decontamination that the process has been performed correctly

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Product release – what?

What do we need to know at each stage?

What should happen?

What has happened?

What is the acceptable difference before load is considered unsuitable?

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Product release – what?

What should happen?

What is the desired intent of the equipment performing the process automatically?

i.e. Critical process data

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Product release – what?

How do we check critical process data?

Parametrically

Chemically

Biologically

Process challenge device (PCD)

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Product release – what?

Proposition:

Whichever monitoring system we use the equipment will control itself parametrically

Does this diminish chemical, biological or PCD monitoring:

NO

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Product release – what?

Critical process parameters – Cleaning:

Time

Water temperature

Water quality (by conductivity)

Water pressure

Water flowrate

Detergent delivery

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Product release – what?

Critical process parameters – thermal disinfection:

Time

Water temperature

Water quality (by conductivity)

Peter

Product release – what?

Critical process parameters – drying:

Time

Air temperature

Air quality (by ?)

Peter

Product release – what?

Critical process parameters – steam sterilization:

Time

Temperature

Air removal

Moisture content (by ?)

Peter

Product release – what?

Typically:

Time …..water temperature….water quality…Water pressure…water flowrate…detergent delivery…Air temperature…air quality……steam Temperature…air removal…moisture content

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Product release – how?

Example in EN ISO 15883, washer disinfectors:

3 levels of independent monitoring depending upon the risk of an unsatisfactory cycle:

Highest level for medical devices

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Product release – how?

A monitoring system, independent from the control system which records all the critical parameter values throughout each stage of every process

Decision is made by a human being based on knowledge of the actual and desired results and the acceptable deviation between them

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Product release – how?

Display of independent data must be made at the unloading side of the equipment

Required values of this data must be available

Operator must be trained in how to read this data and apply decision against acceptable deviations from required values

Decision must be documented

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Product release – how?

What about chemical, biological and PCD monitoring?

Can they replace parametric monitoring?

In part, yes

Should we understand the operating principles?

Yes

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Product release – how?

Combined monitoring:

Is there a place for a combination of parametric, chemical, biological and PCD monitoring?

Of course, but……

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Product release – how?

… we must be able to challenge all critical process parameters, **whichever methods are chosen**

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Product release - conclusions

Is this concept possible?

Completely?

No

In part?

Yes

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Product release - conclusions

There will always be an element of risk in determining safety as we cannot monitor every critical parameter on every individual process

Sometimes the risk is increased because we dot not bother to check what is monitored

Sometimes it is not documented

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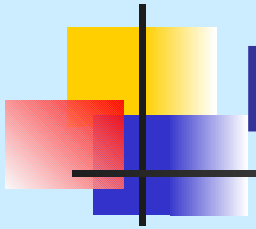

Product release - conclusions

A modern mythology?

To a degree, yes …

… OK, YES

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Product release - conclusions

We either:

Perform and document product release as much as possible, quantify and accept any risk

or ...

... find another way of determining acceptability

Peter

Thank you

Peter