Method & Equipment Validation

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Introduction

- Who Am I?
- What's in it for you?

- In regulated industries such as device manufacturing, pharma and food, validated methods and equipment are important.

Presentation Aims/Outcomes

- At the end of the session, you will be able to state:
  - What is validation
  - Why we need validation
  - What the impact of not having validated processes is
  - The stages of validation
  - The types of validation
  - How will knowing about validation can assist you

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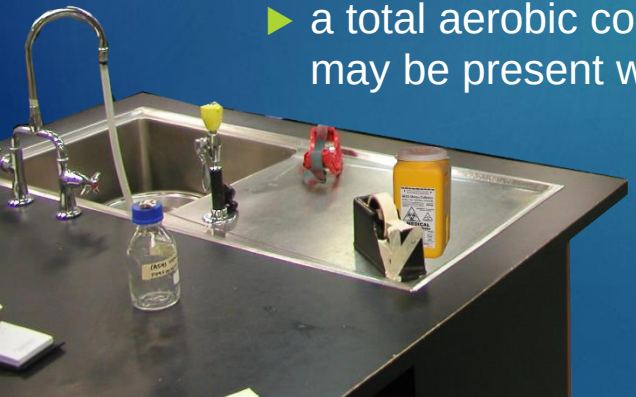
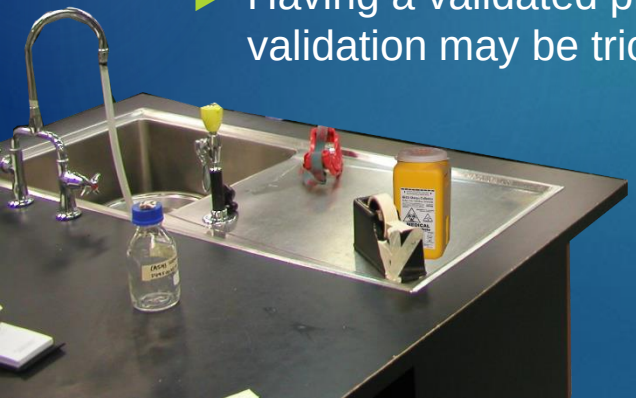
What is Validation?

- Validation is proving that a piece of equipment or a test process does what it is designed to do on a consistent and predictable basis. eg
  - Proving a fridge can maintain temperature within a specified range for as long as required with minimal impact from differences in load or accessing of items in fridge
  - an antibiotic assay can consistently yield the same result from the same test sample
  - a total aerobic count test is capable of recovering microbes that may be present within a sample



Why do we need validation

- It is a basic requirement of quality control is to ensure that test methods are validated. This is stated in documentation from the BP/EP, USP, TGA and PIC/S.
- From a functional perspective, it is unwise to incubate samples in an incubator that has not been proven to maintain the temperatures required, or to conduct an assay on a product where the test cannot produce a valid result.
- Having a validated process makes life easier. Though the initial validation may be tricky, it potentially saves much angst later.



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What is the impact on not validating?

- Unable to prove equipment is suitable for intended use or that it does what the vendor said it is capable of
- Unable to prove test results are valid/accurate
- Can result in difficulties in audits if validation records are not available
- May lead to products being declared to be adulterated

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The Stages of Validation

Equipment Validation

- DQ – design qualification
- IQ – installation qualification
- OQ – operational qualification
- PQ – performance qualification

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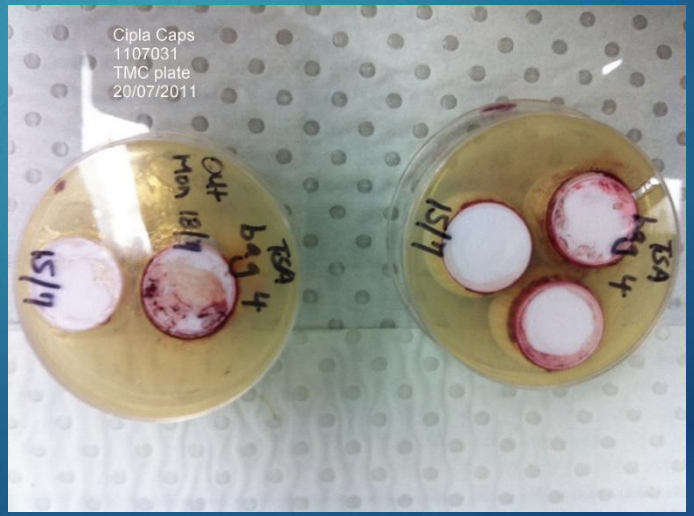
The Stages of Validation

Method Validation

- VP – validation protocol
- VR – validation report



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The Types of Validation

Validation comes in three flavours

- Prospective (preferred)
- Concurrent (for exceptional circumstances)
- Retrospective (for well established, historical methods)

How Will Validation Knowledge Assist You?

- You're and your company will have confidence in it's procedures and products
- When something goes wrong, the validation documentation may be useful in the investigation.
  - Eg temperature mapping of a fridge.
  - An OOS recovered microbes the validation shows could not be recovered
  - Equipment continually breaks down and validation shows a known issue that was approved and low risk

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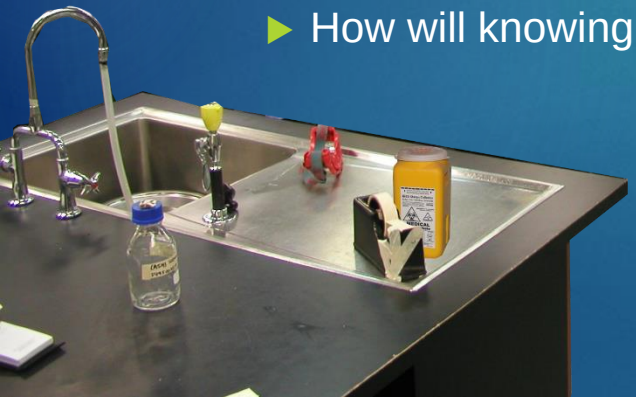
Conclusion

- You will now know:
  - What is validation
  - Why we need validation
  - What the impact of not having validated processes is
  - The stages of Validation
  - The type of validation
  - How will knowing about validation can assist you



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References / Appendix

- PIC/s PE009-14 GMP Guide Part 1 Section 5
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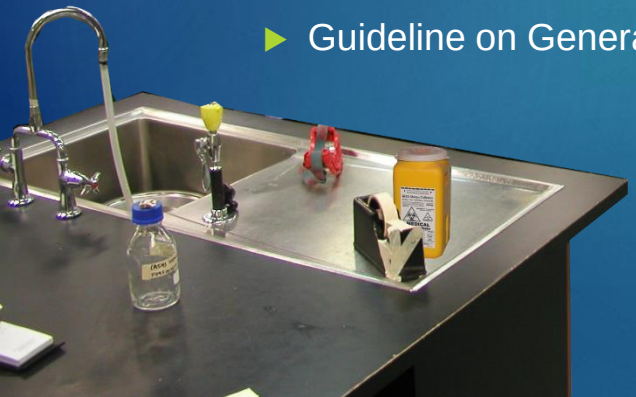
- Guideline on General Principles of Process Validation, FDA May 1987.



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