

Lifecycle management of test kits

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Documentation and data of test sets

A testkit should include:

Certificate of manufacturing including

- Date of creation
- Equipment used to produce the defect samples
- Production process (simplified)
- Calibration and measurement of the defects
- Test kit matrix and classification parameters
- Data table

Project:

Date:

Version: 1.0

Certificate

Preparation of reference standards with particles and defects for visual inspection of vials

Name of product 10ml Vial

for

customer, country



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Company	Date	Name, Surname	Signature
M.A.S...		Wählen Sie ein Element aus.	
company			

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Test set qualification

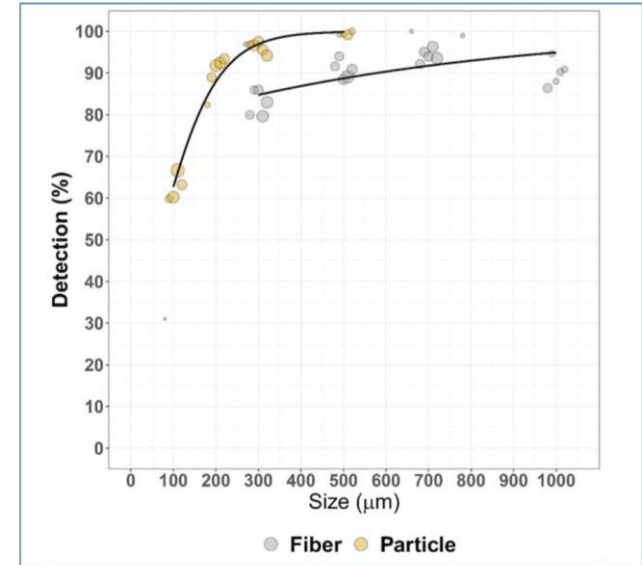
- Test sets are qualified using the Knapp methodology (threshold studies)
 - Define probability of detection (PoD) for a gradient of sizes
 - Define Accept, Grey and Reject zones

Type	Material	Color	Photo	Particle/Fiber Size (µm)							
				100	200	300	500	700	800	1,000	
Particles	Glass	Transparent		X	X	X					
	Rubber	Orange – Cartridges Black – Syringes Gray – Vials (shown)		X	X	X	X				
	Metal	Silver/Gray		X	X	X					
Fibers	Cellulose	White				X	X	X			X
	Plastic	White				X	X	X	X		
	Hair	Brown				X	X				

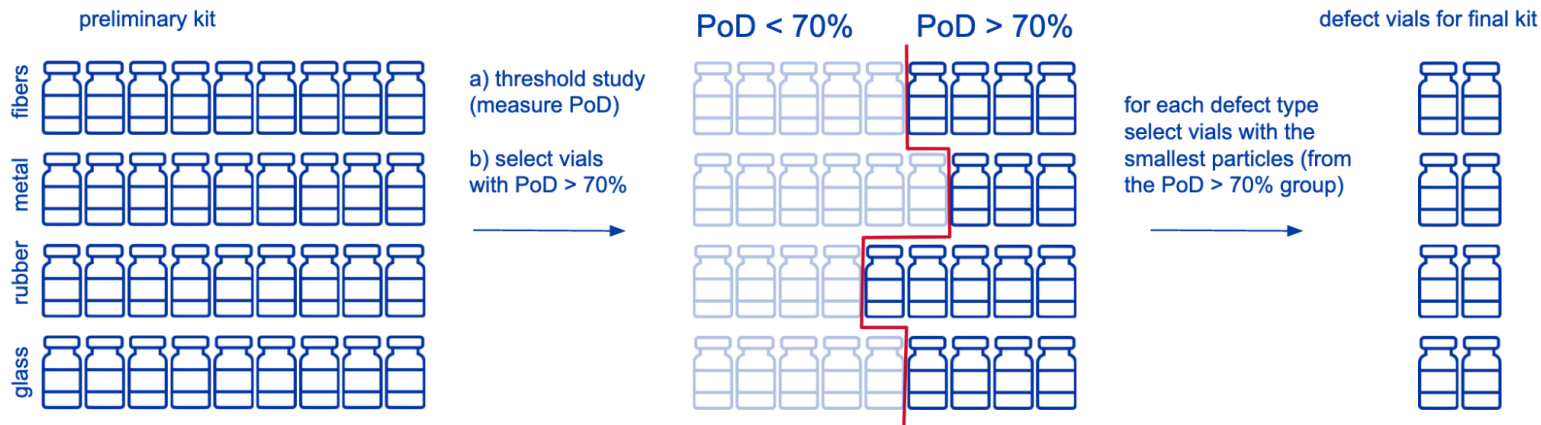
Test set qualification

- Threshold study setup:
 - Inspector panel
 - Inspection rounds
 - Quality attributes – monitoring
 - FRR
 - RZE
 - Outliers
 - Investigations

Examples



Test set qualification



Test set qualification

- Setting up test sets:

A subsets of the threshold study set can be used to compose:

- Introduction/ training test sets
- Inspector qualification test sets

Lifecycle management

Questions that are often raised after ordering a test kit:

- How long can you use a standard reference test kit?
- What are the conditions that a test kit should be stored in?
- How do you ensure a consistent quality level of the test kits?

Lifecycle management

Questions that are often raised after ordering a test kit:

- How long can you use a standard reference test kit?
 - Entirely dependent on factors such as surrogate solution vs original product, sensibility of the container, handling and usage of the test kit...
- What are the conditions that a test kit should be stored in?
 - Storage depends on product characteristics
 - No direct sunlight, no heat...

Maintenance of test kits

- How to ensure a consistent quality of the standard reference test kit ?

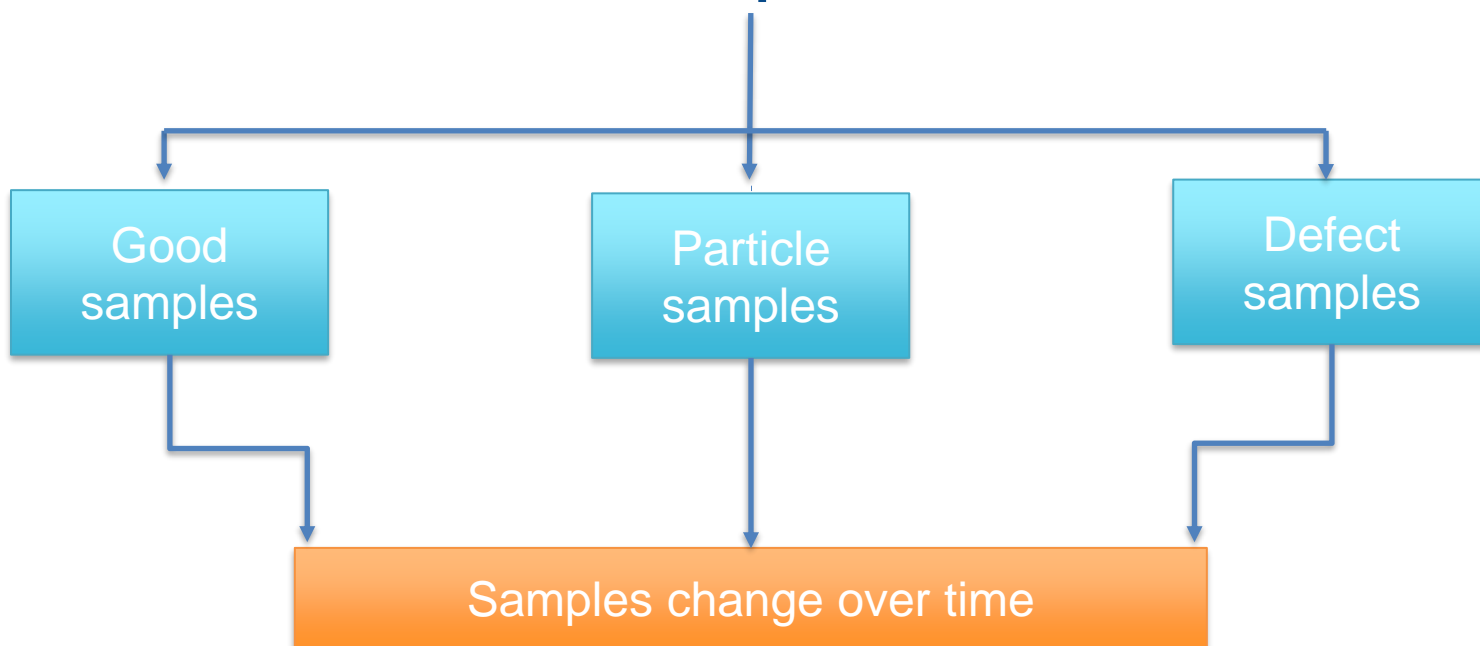
Check Reference Standard Sets on a regular basis for:

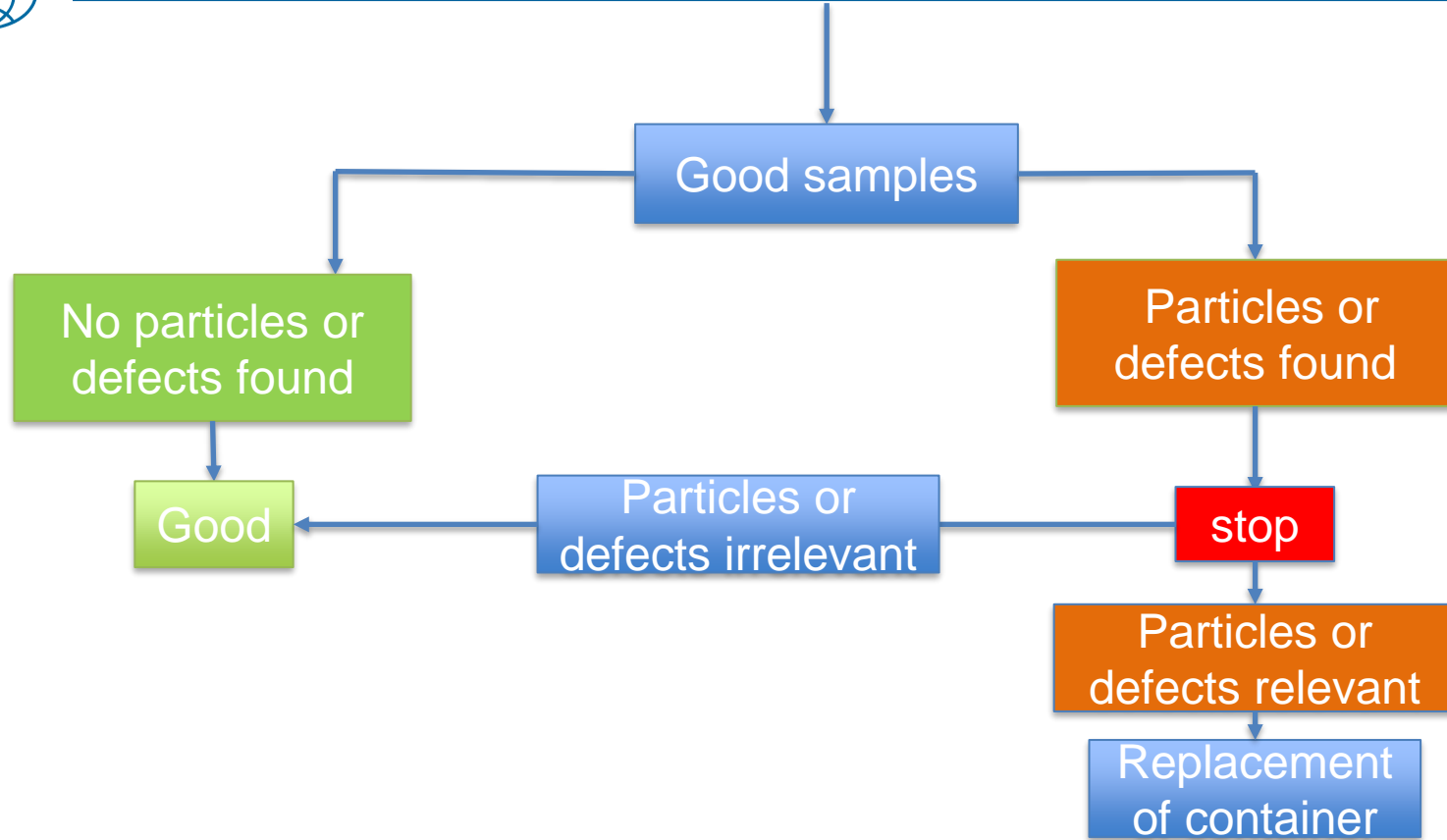
- Lost particles
- Microbiological growth
- Changes in the appearance of the product (e.g. color)
- Container or seal defects

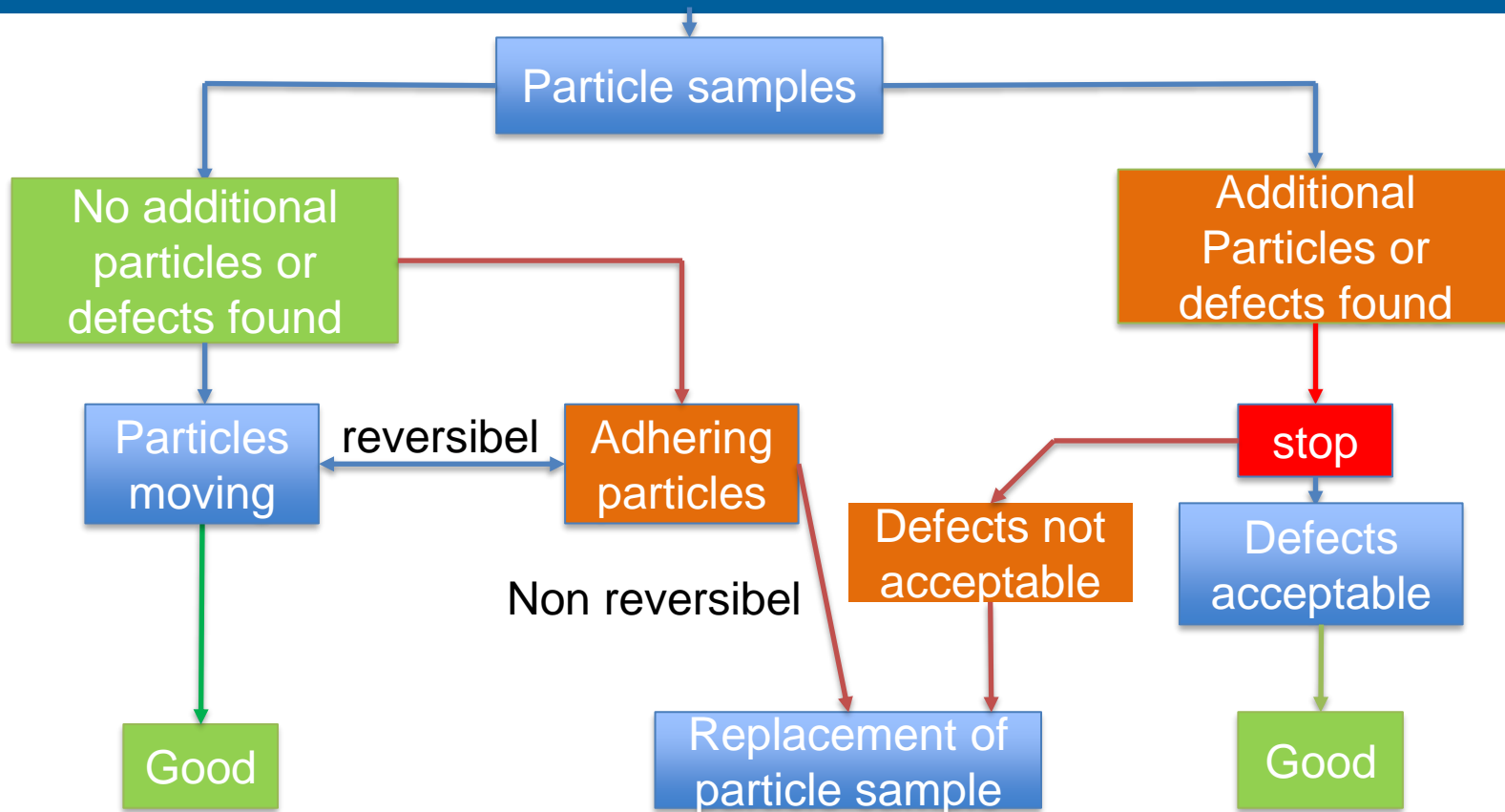
Maintenance of test kits

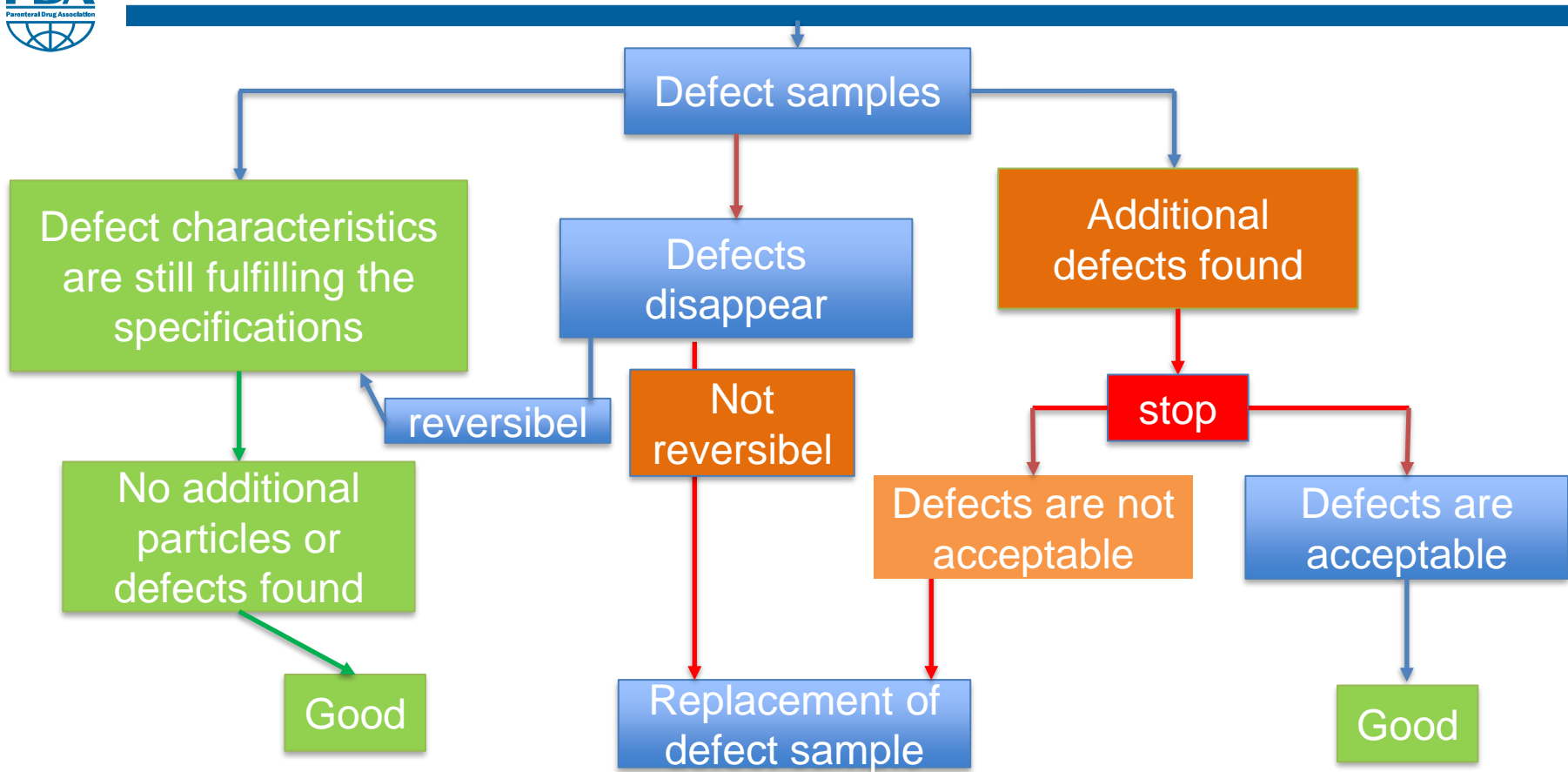
- Common problems:
 - Disappearing defects:
Due to handling and storage standard reference samples change over time and might not fulfil the quality standards anymore
 - Examples:
 - Additional scratches due to handling of the containers
 - Particles adhering to the surface of the container or the stopper
 - Broken containers
 - Microbiological growth

Samples









Maintenance of test kits

- Requalification interval for the test kits and replacement of non-compliant samples
 - At least once a year recommended
- Ordering of spare samples always recommended
 - Saves a lot of time, critical processes won't be impacted
- Recommendation to assign one or more responsible people for the maintenance of the test kits

Training and training certification

- Quality should be **built-in**
 - Training is the fundament of sound VI operations
 - Qualification is the proof

Training and training certification

- Appropriate training may take **weeks**, depending on:
 - Prior experience
 - Context (facility, products, workflows)

Typical training process

1. Theoretical introduction to VI:

- Theory – visual perception, container defects
- Regulatory/ requirements
- Methods
- Products
- Challenges

Typical training process

2. Practical introduction to VI (demonstration):

- Manual Visual Inspection
- Techniques
- Equipment
- Handling of the product
- Considerations

Typical training process

3. Hands-on practice:

- MVI basic techniques
- Handling the equipment
- Product handling
- Considerations

Typical training process

4. Hands-on practice:

- Introduction to defects
- Challenging defects
- DIPs

Typical training process

5. Hands-on practice (advanced):

- Tips and tricks

Training and training certification

- Qualification test sets
- Test administration (test set labelling)
- Requirements
 - Visual acuity
 - Two main approaches
- Certification
- Periodic re-qualification

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