Seeing is Believing: Mastering Design, Qualification and Life Cycle Management of Visual Inspection Test Sets

Atanas Koulov, PhD
Clear Solutions Laboratories AG

CONNECTING PEOPLE SCIENCE AND REGULATION®

PDA Parenteral Drug Association

PDA TRAINING

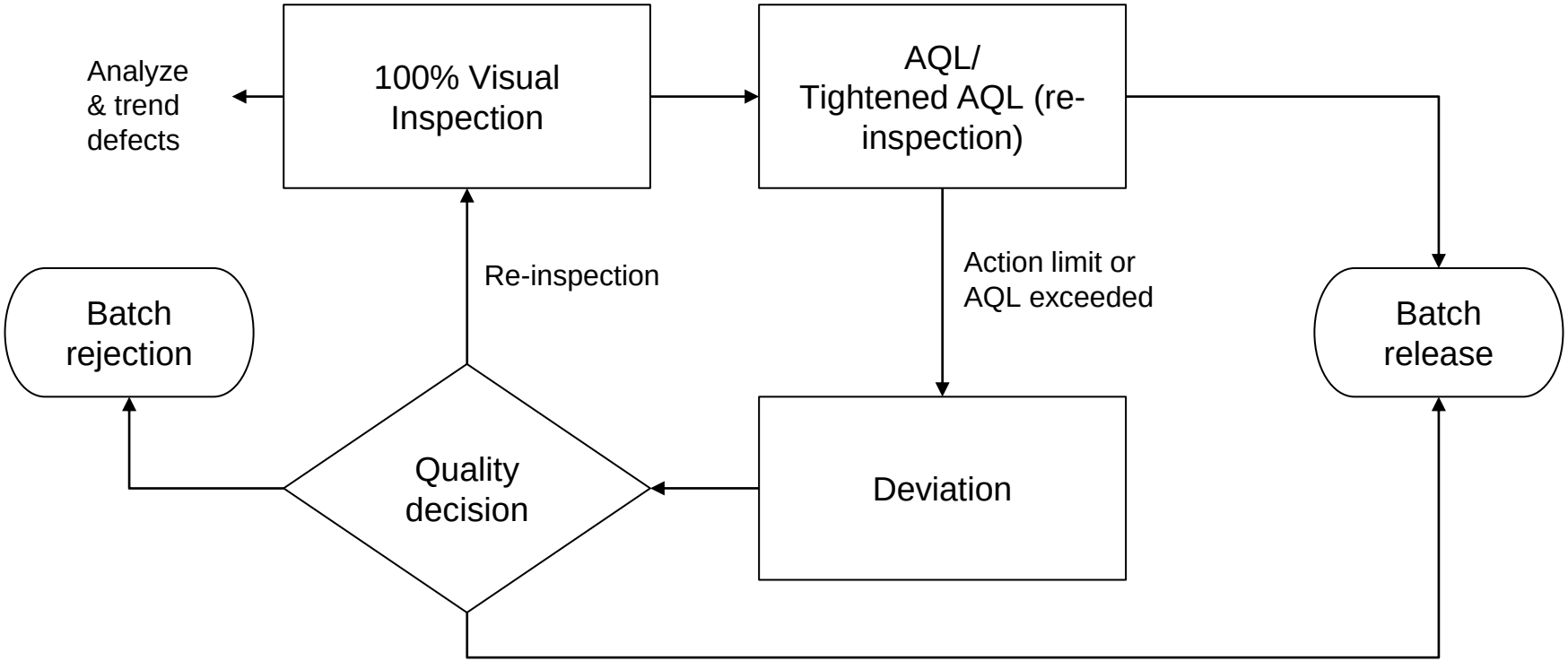
1.2. **VI test sets** - why do we need them? **Background** to the qualification process

VI Test sets - a versatile tool

- VI Test sets are a versatile tool used to qualify:
  - instruments (AVI)
  - inspectors

- Different purpose of VI:
  - 100% VI
  - AQL
  - QC labs - release, and/or stability testing

There are important considerations to **each one** purpose



100% Visual Inspection – a dual role

- 100 % VI is a critical (last) step of the manufacturing process - separation of defective units from the good part of a batch
  - 100% VI's main purpose is eliminate defective units from the batch
- Used for release of clinical and commercial injectable products (Attribute: Appearance/ VPs)
  - But also, to minimize the ingress of particles into injectable DPs
- 100% VI is typically performed (or overseen) by the quality unit. Can be delegated to the manufacturing unit.

AQL

- AQL is in place to provide additional **assurance** that the VI control system operates correctly
- Also, AQL is the last piece of the particle control system
- Typically performed by the quality unit

QC Testing

QC (VI) testing can be carried out as:

1. A release test that requires sampling and destructive testing (e.g. DIPs)
2. Stability testing (**clinical** and commercial)

Note: 1. and 2. are very different - need to be mindful of the purpose

Generation of supportive data for quality investigations/ inspection support

VI test sets are THE key to VI qualification

Typical events that may trigger quality investigations :

- out of trend findings
- atypical defects (particle or container related)
- …

Test set setup and qualification are always the basis for justification of the VI qualification process and control system

pda.org

PDA Parenteral Drug Association

PDA TRAINING