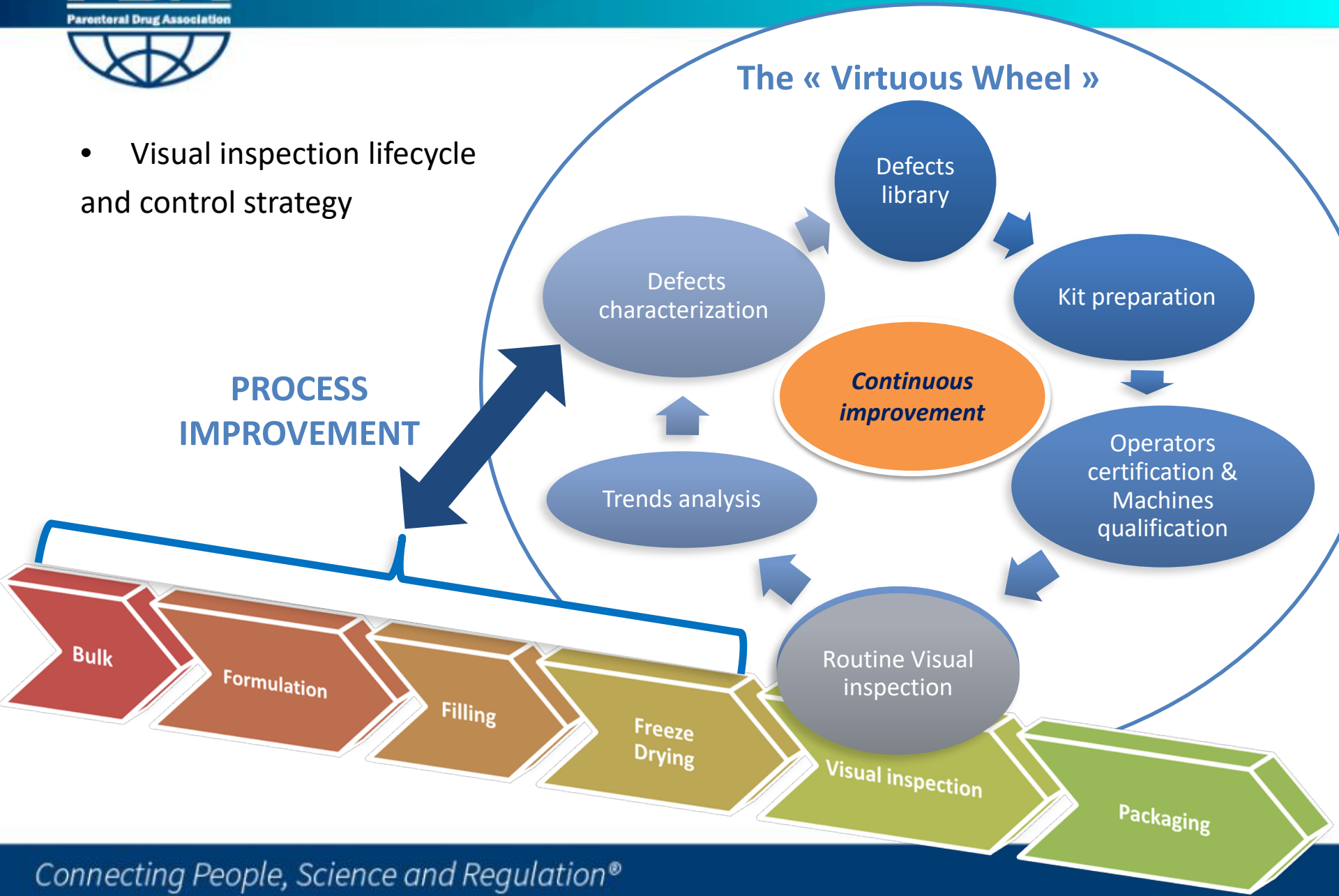
- Theory 7
- Visual inspection lifecycle and control strategy

- Integration of visual inspection into overall manufacturing process
- Elements of lifecycle
- Particle identification/characterization
- Defect libraries as dynamic database
- AQL and control charting

Mastering Automated Visual Inspection

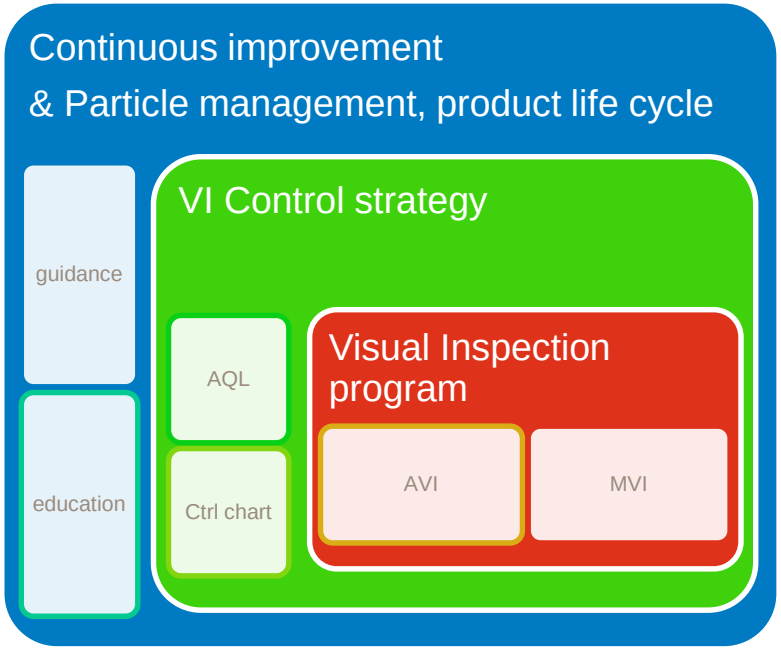
Theory 7: Visual inspection lifecycle and control strategy

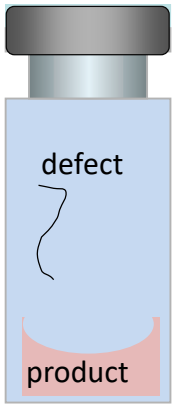
- Visual inspection lifecycle and control strategy



Visual inspection program in 3 layers:

- -The Core is AVI/MVI program, with strategy for DML / standard work / certification / validation
- -The control strategy with ctrl chart and AQL guarantees that VI is kept under control
- -Continuous improvement is the goal of all VI activities with CAPA mngt. The Particle management is a key to success with particle control and associated WOW & education, product life cycle approach

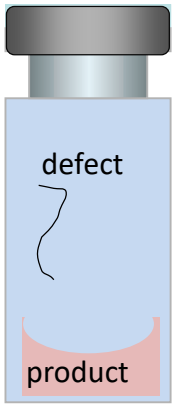


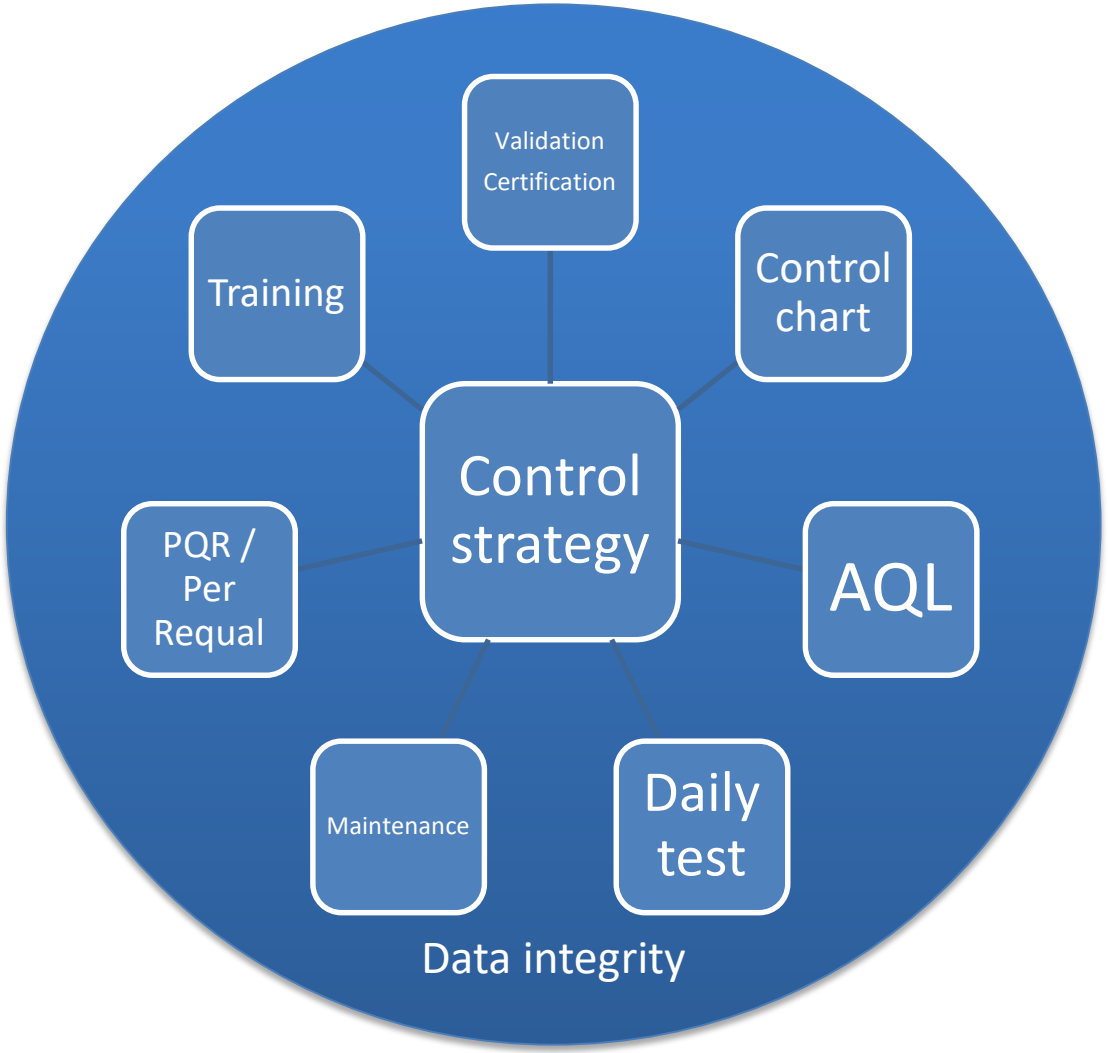


Mastering Automated Visual Inspection

Theory 7: Visual inspection lifecycle and control strategy

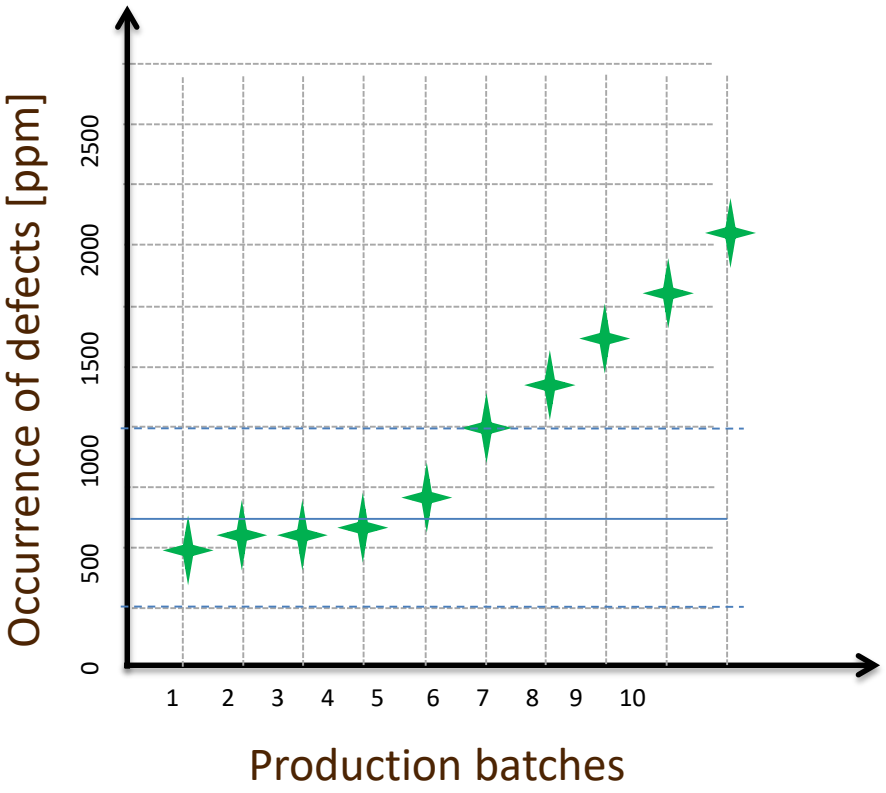
- Control Strategy

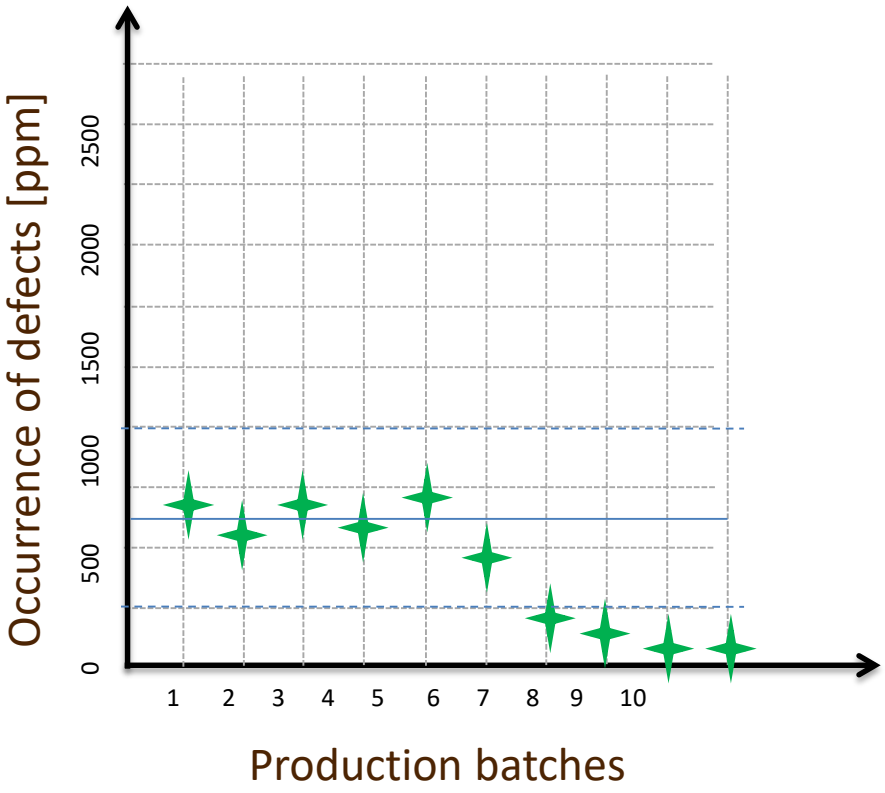




Mastering Automated Visual Inspection

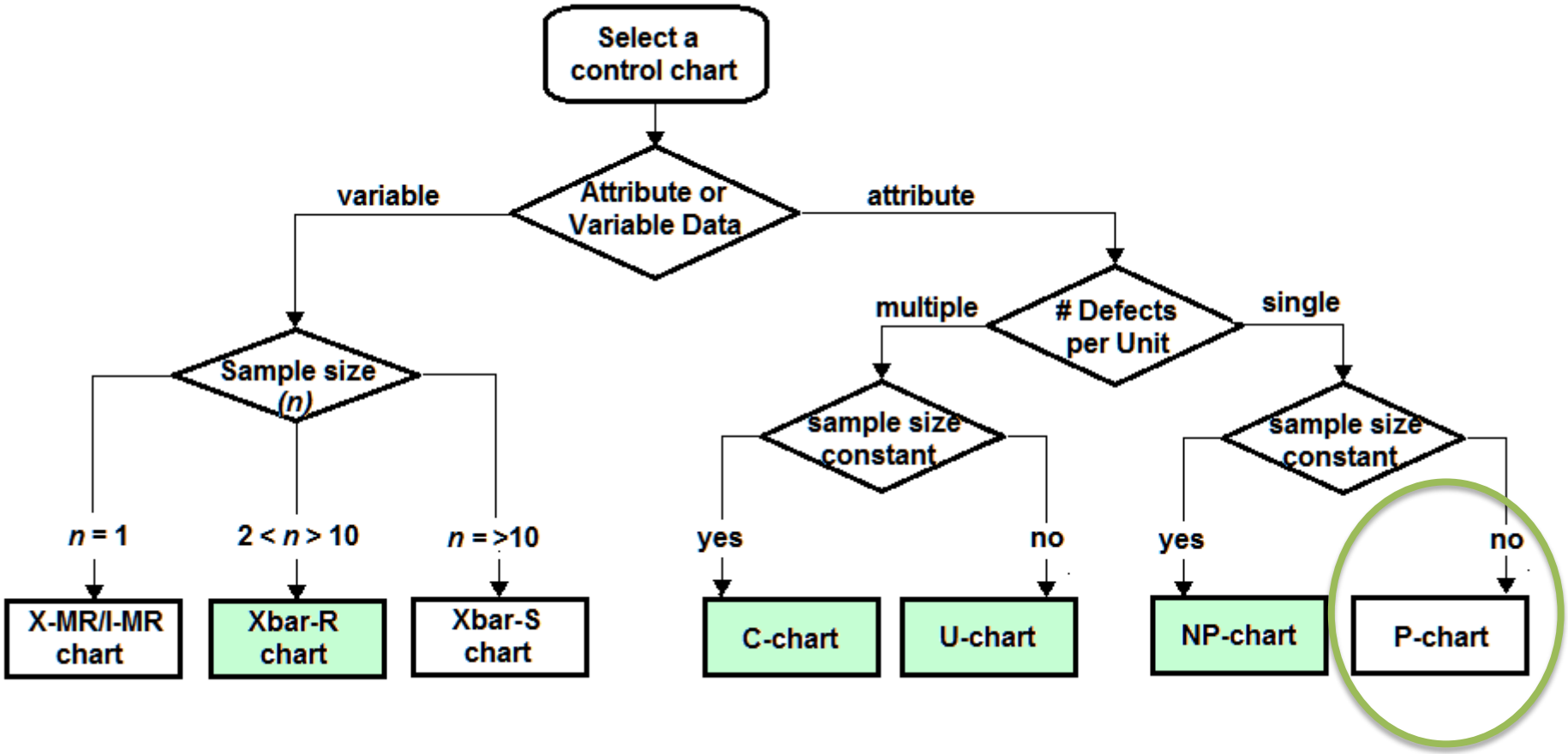
Theory 7: Visual inspection lifecycle and control strategy



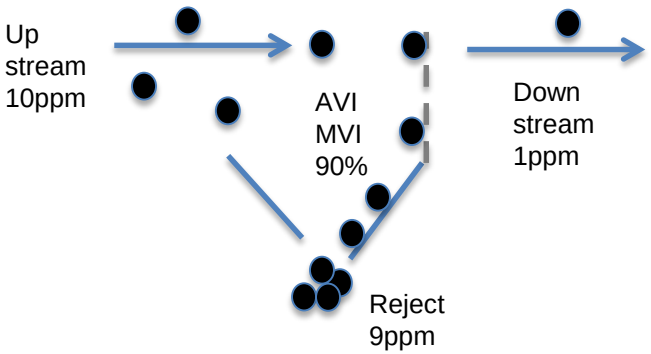


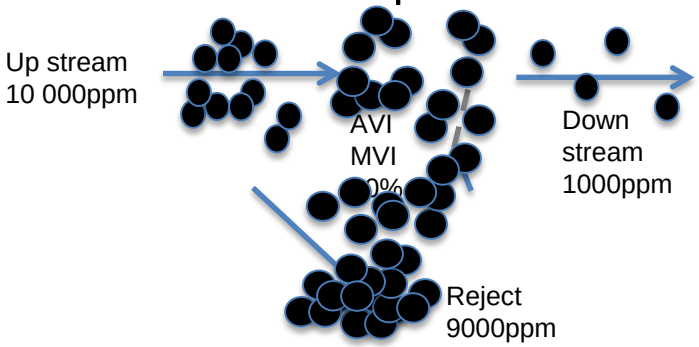
Mastering Automated Visual Inspection

Theory 7: Visual inspection lifecycle and control strategy

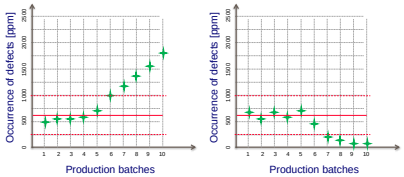


– Use of ctrl chart necessary because VI is a Markov like process





– Use of P‘ ctrl chart very powerfull to track any drift or atypical lot



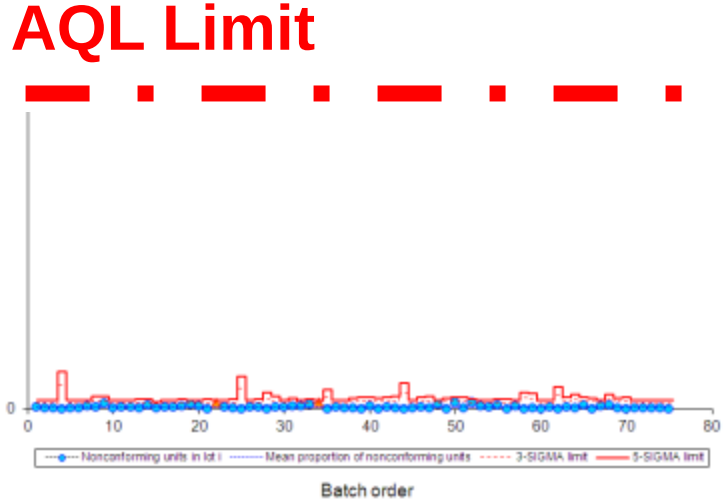
$$UCL = \overline{p} + 3\sqrt{\frac{\overline{p}\,(1-\overline{p})}{n_i}}$$

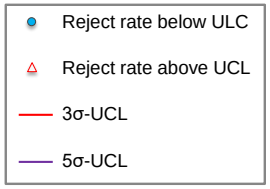
$$UCL = \overline{p} + 3\,s_i s_z$$

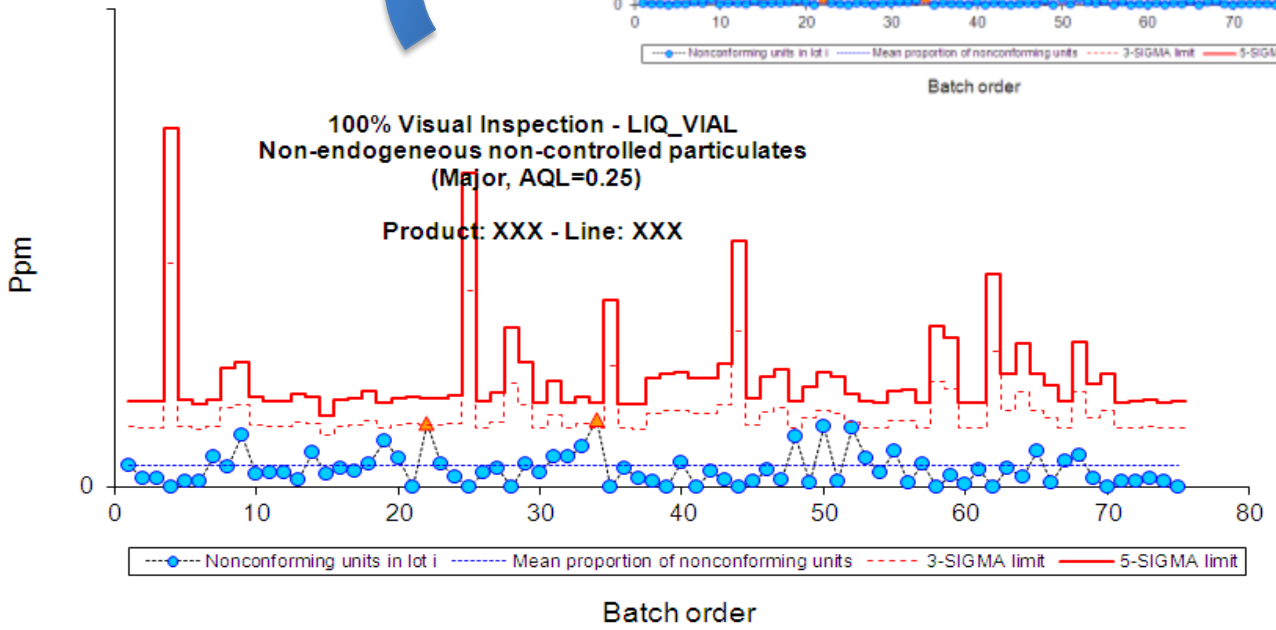
- 3 sigma probability follow binomial law
  with 99,7% proportion of defective units

- **Control Strategy- Ctrl chart**

Take AWAY: Even with a low probability of detection (non NULL!!) the UCL limit is strenght of the control strategy has the ability to discard atypical lots in term of occurrences.







Theory 5: Transition from Manual to automated visual Inspection
Why is it important to maintain MVI ?

- AQL done in MVI
- AVI qualification is compared to MVI reference

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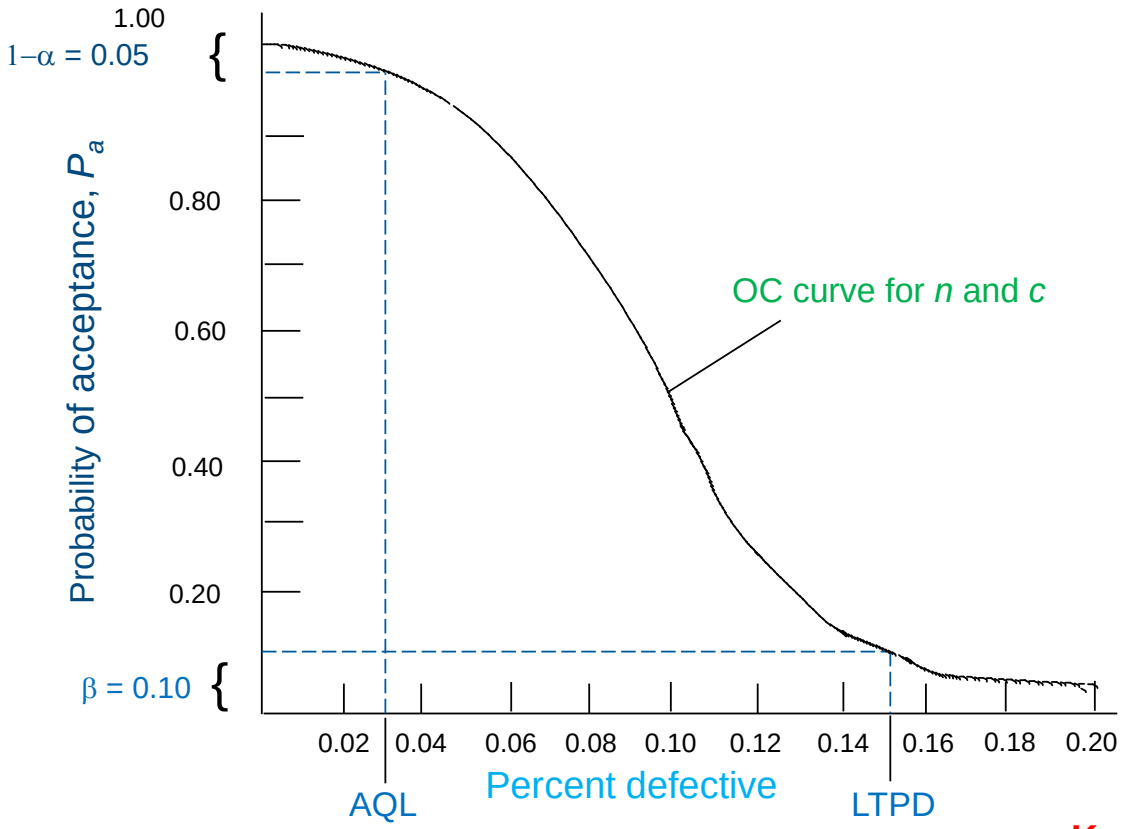
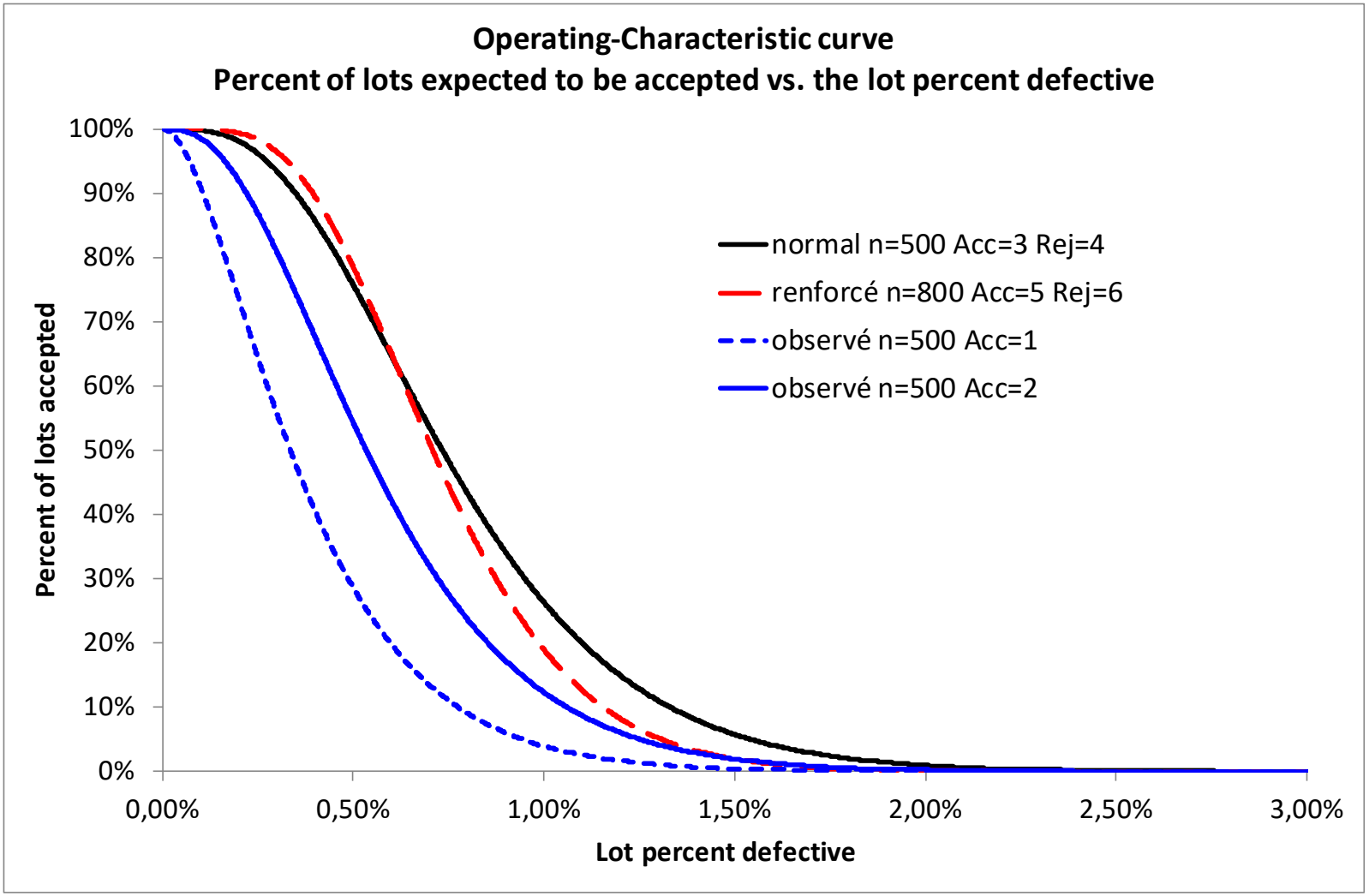
7. Control strategy : AQL Sampling



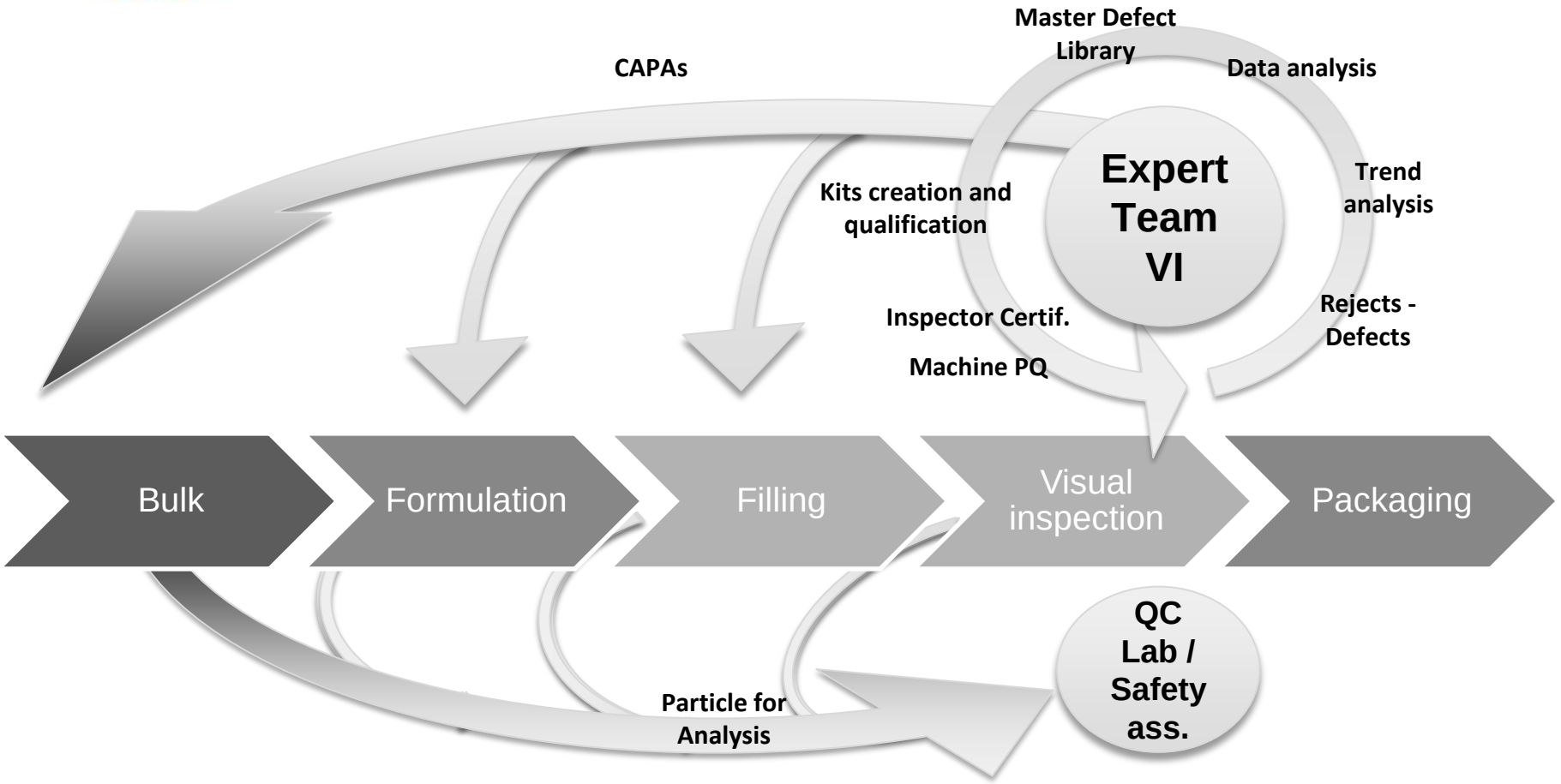
- **Acceptable quality level (AQL)**
  - **Acceptable fraction defective in a lot**
- **Lot tolerance percent defective (LTPD or RQL)**
  - **Maximum fraction defective accepted in a lot**
- **Producer's risk, α**
  - **Type I error = P(reject a lot|probability (defective)=AQL)**
- **Consumer's risk, β**
  - **Type II error = P(accept a lot| probability(defective)=LTPD or RQL)**

Key learning: AQL are always associated to RQL in an OC curve, this is the patient risk

7. Control strategy : AQL Sampling
Why do we need to perform Tightened AQL ?



Visual Inspection of Freeze-Dried Products Continuous Improvement Loop



Key take away:

- In this section you have learnt:

Ctrl strat.	Integration of visual inspection into overall manufacturing process
	Elements of lifecycle
	Particle identification/ characterization
	Defect libraries as dynamic database
	AQL and control charting