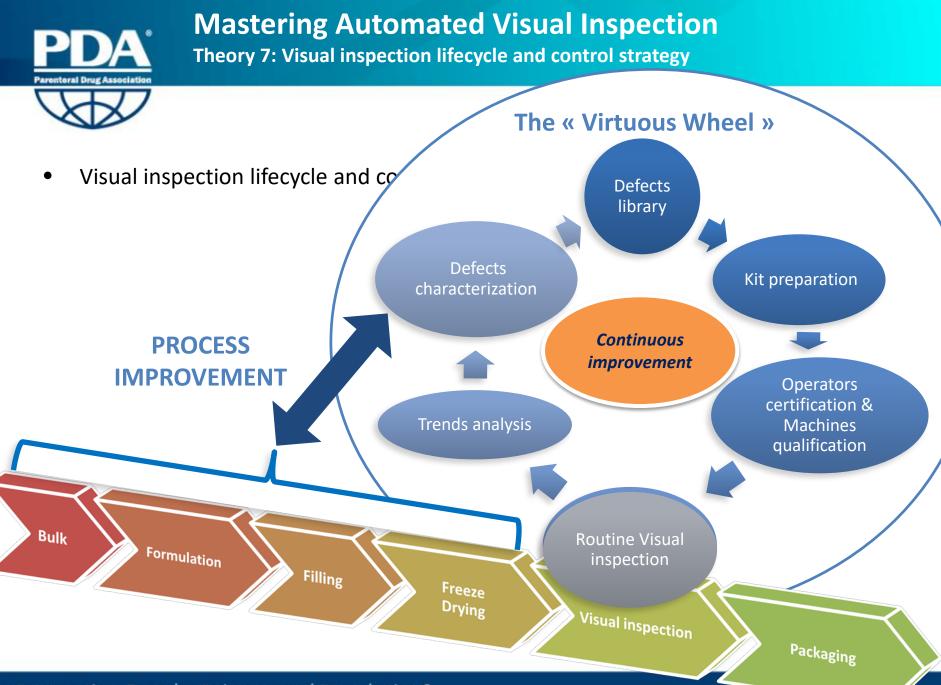


Theory 7

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

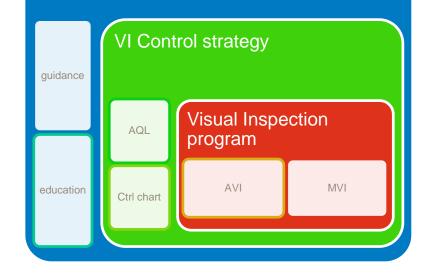




Theory 7: Visual inspection lifecycle and control strategy

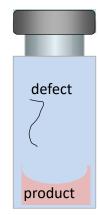
Visual inspection program in 3 layers:

- -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



& Particle management, product life cycle

Continuous improvement





Theory 7: Visual inspection lifecycle and control strategy

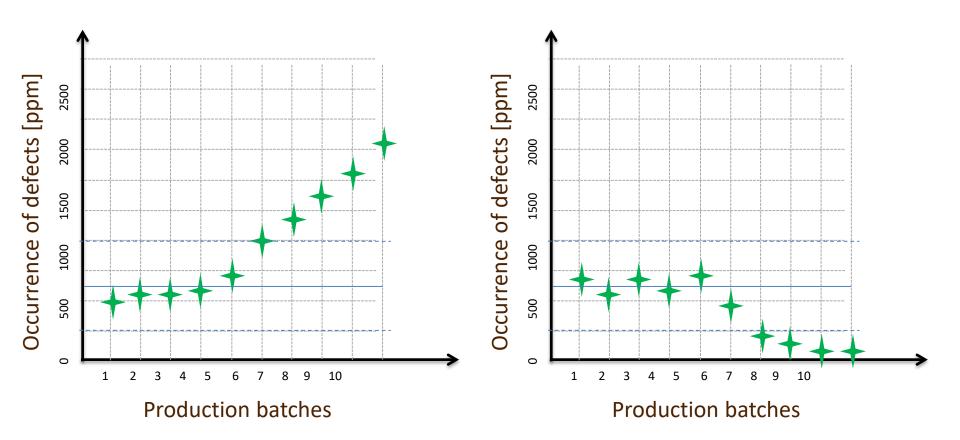






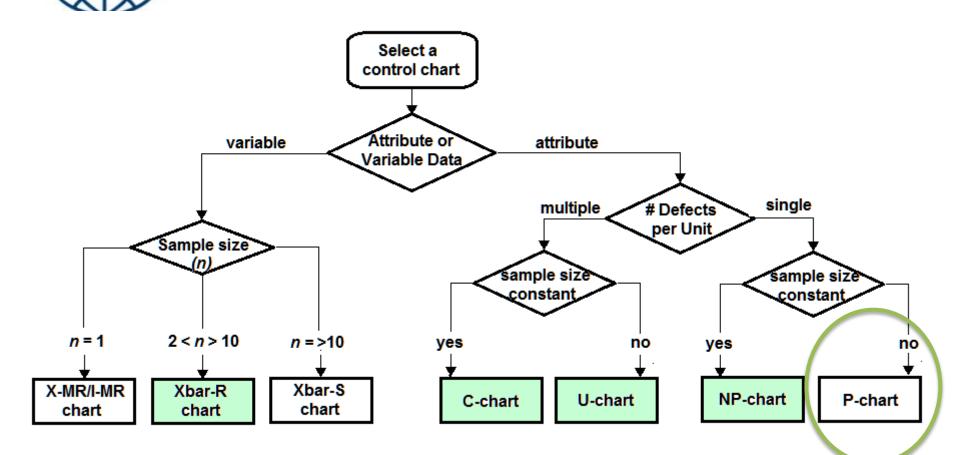


Theory 7: Visual inspection lifecycle and control strategy



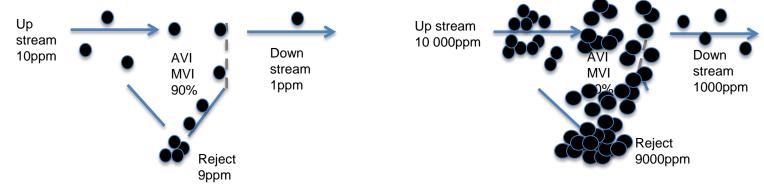


Theory 7: Visual inspection lifecycle and control strategy









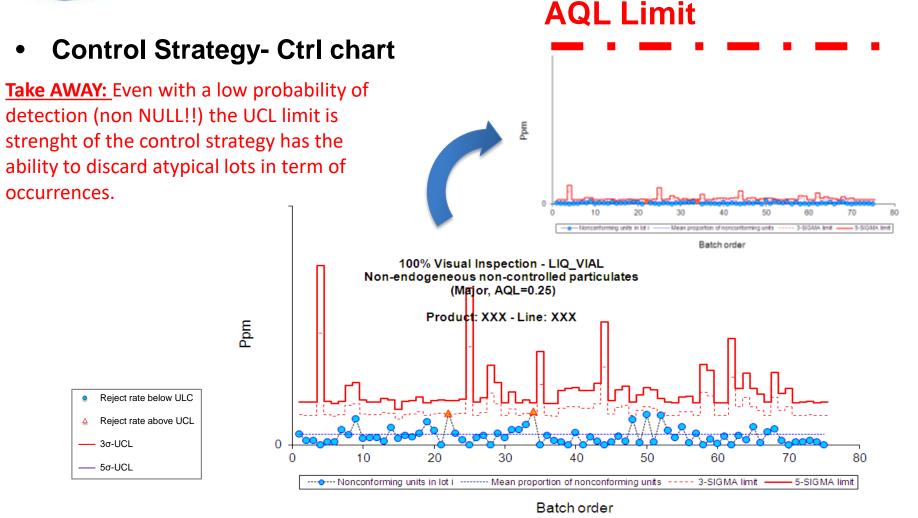
- Use of P' ctrl chart very powerfull to track any drift or atypical lot

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

• 3 sigma probability follow binomial law

with 99,7% proportion of defective units

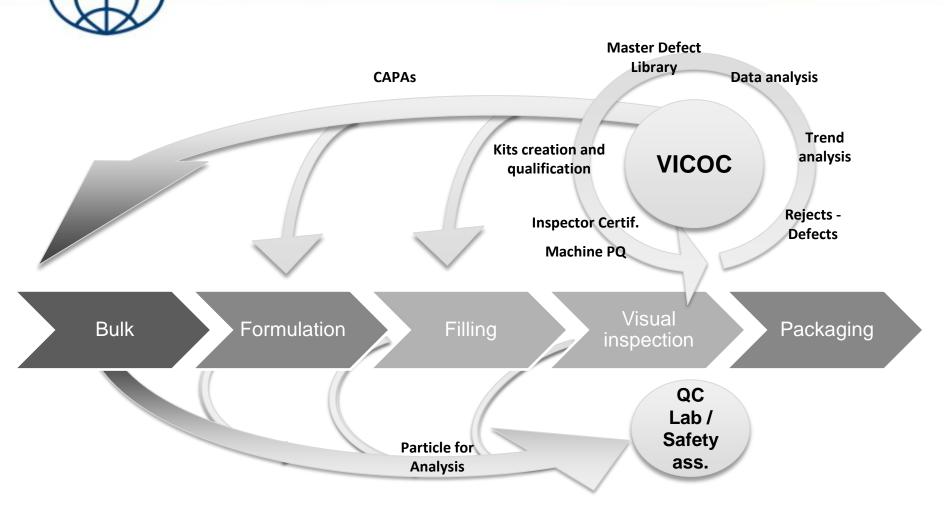


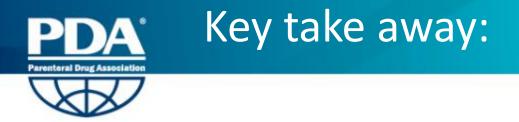




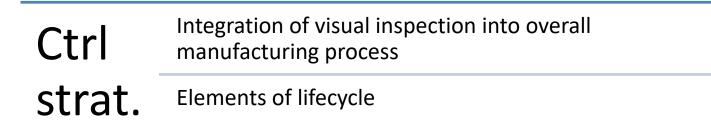
Visual Inspection of Freeze-Dried Products

Continuous Improvoment Loor





• In this section you have learnt:



Particle identification/ characterization

Defect libraries as dynamic database

AQL and control charting