Mastering AVI

Part8: Visual inspection life-cycle 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

PDA Parenteral Drug Association

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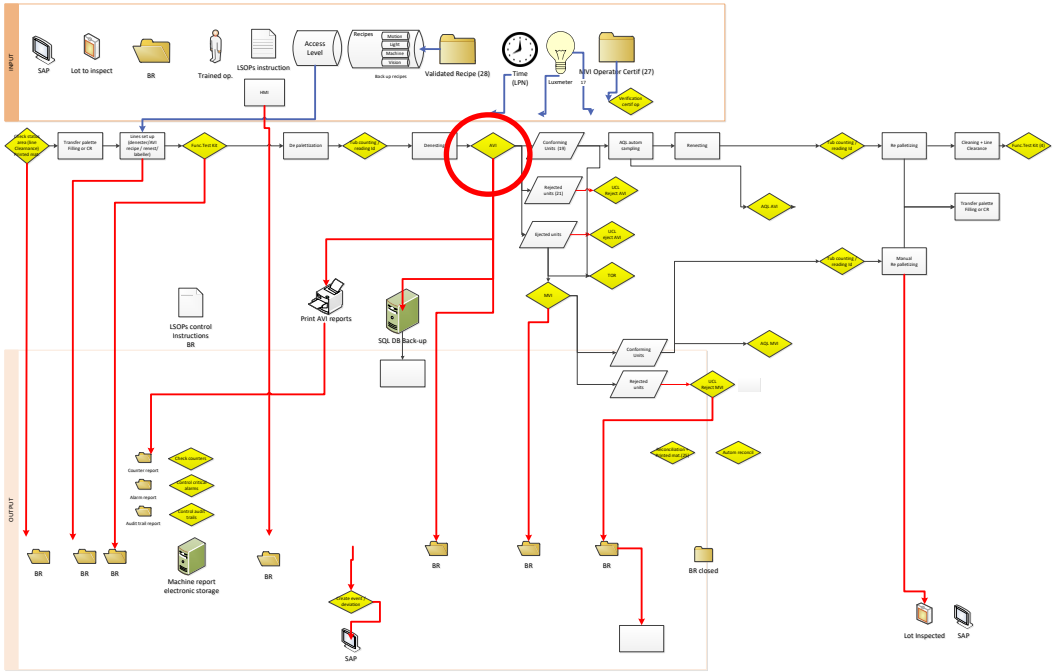
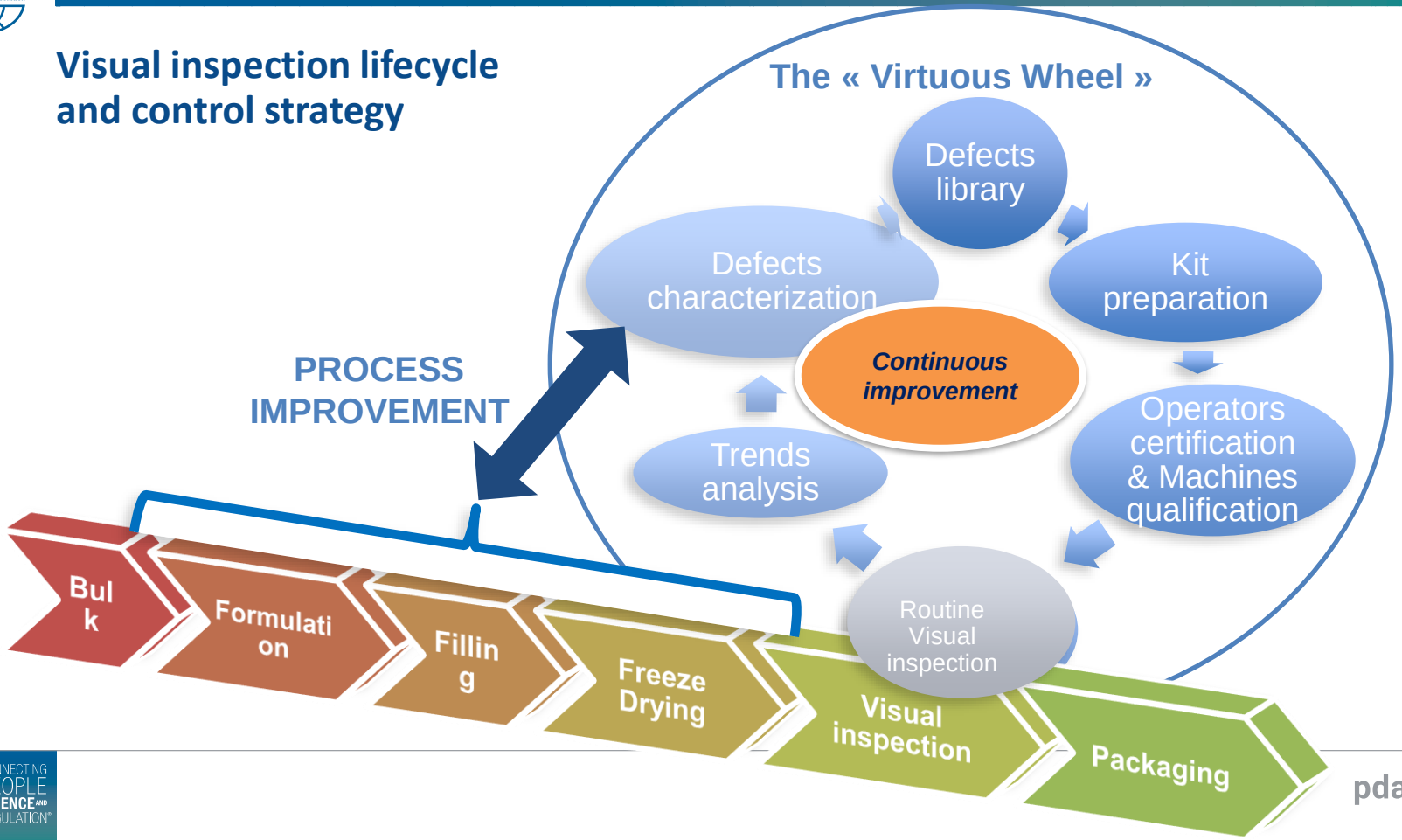
Mastering Automated Visual Inspection

…….control strategy is key

AVI Equipment is part of an overall VI process

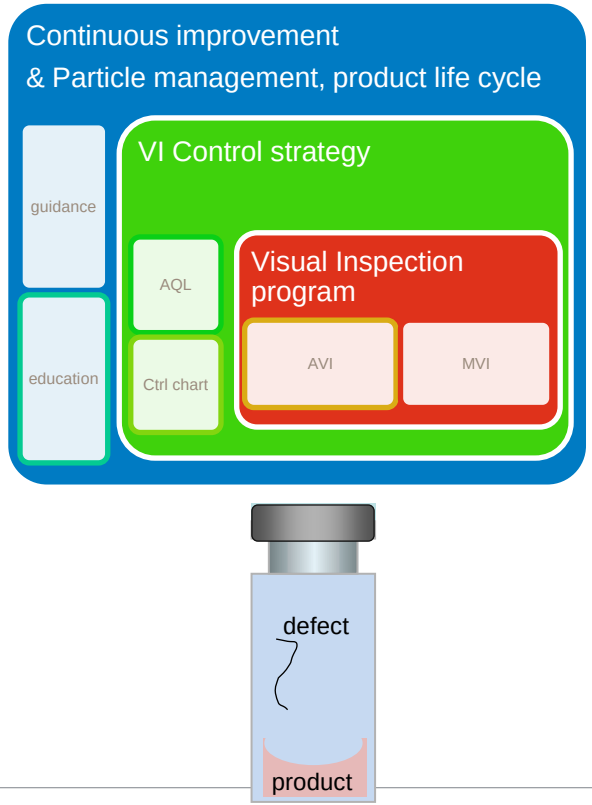


Visual inspection lifecycle and control strategy

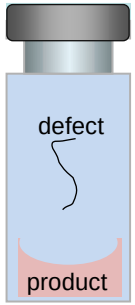


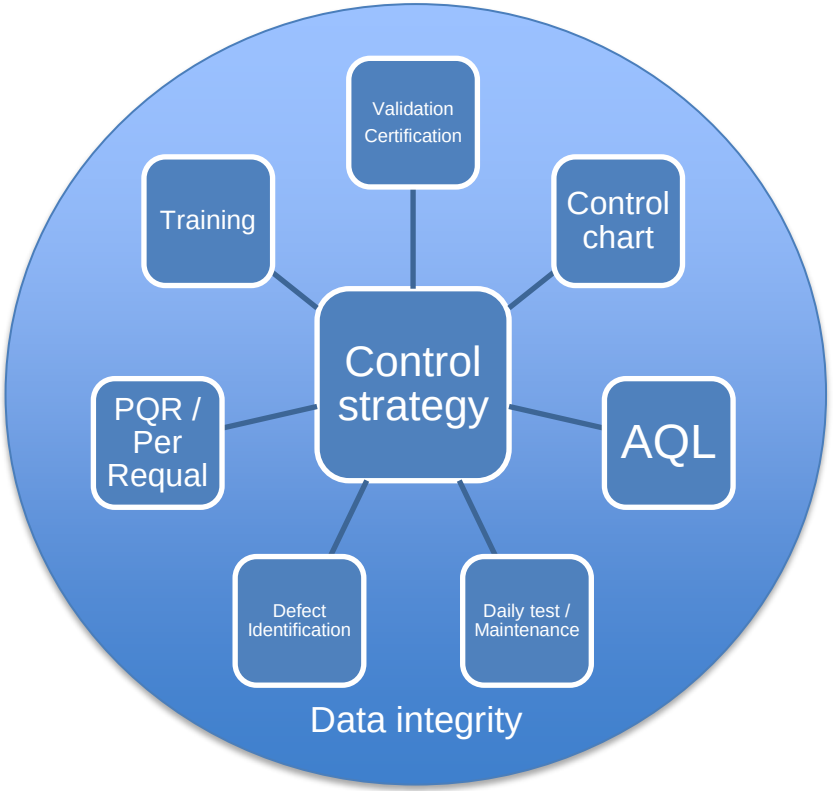
Visual inspection program in 3 layers:

- -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



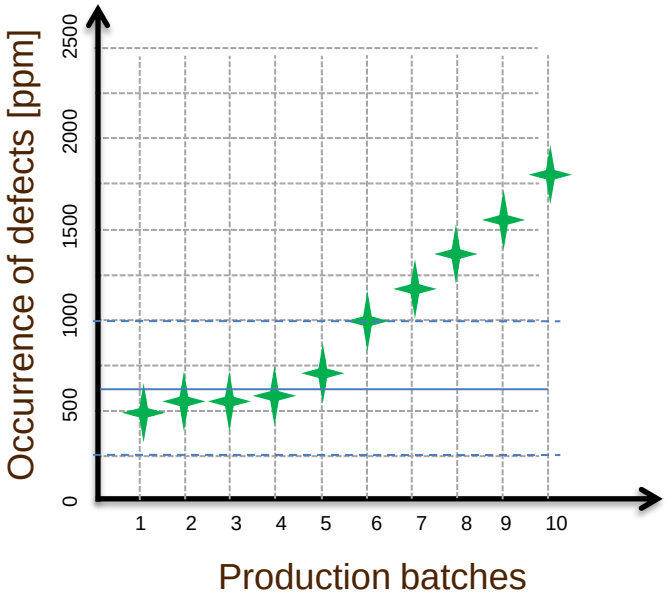
Control strategy

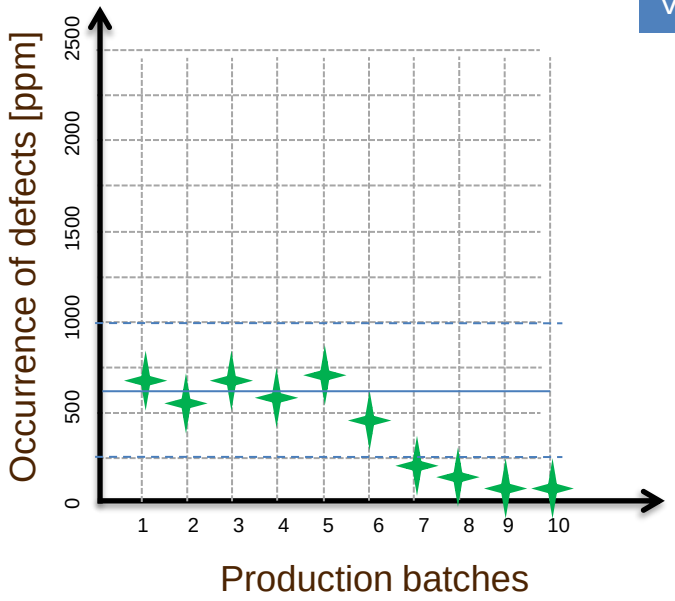




Why defect trending is key ?

Key take-away:
SPC trend chart is a way to control absence of drift of VI process

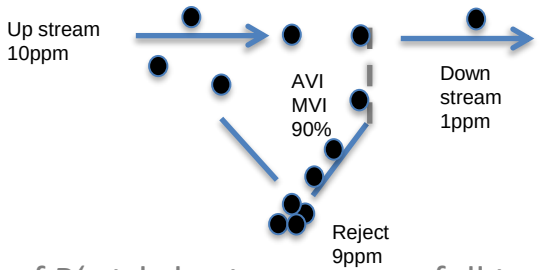


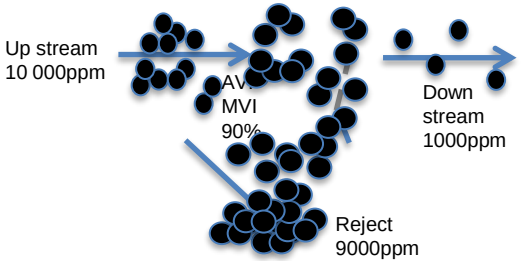


Why a robust SPC is key for VI ?

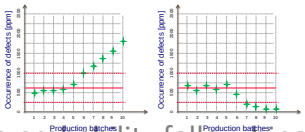
Key take-away:
AVI is probabilistic
So it is key to control source contamination upstream even if AVI is validated

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





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

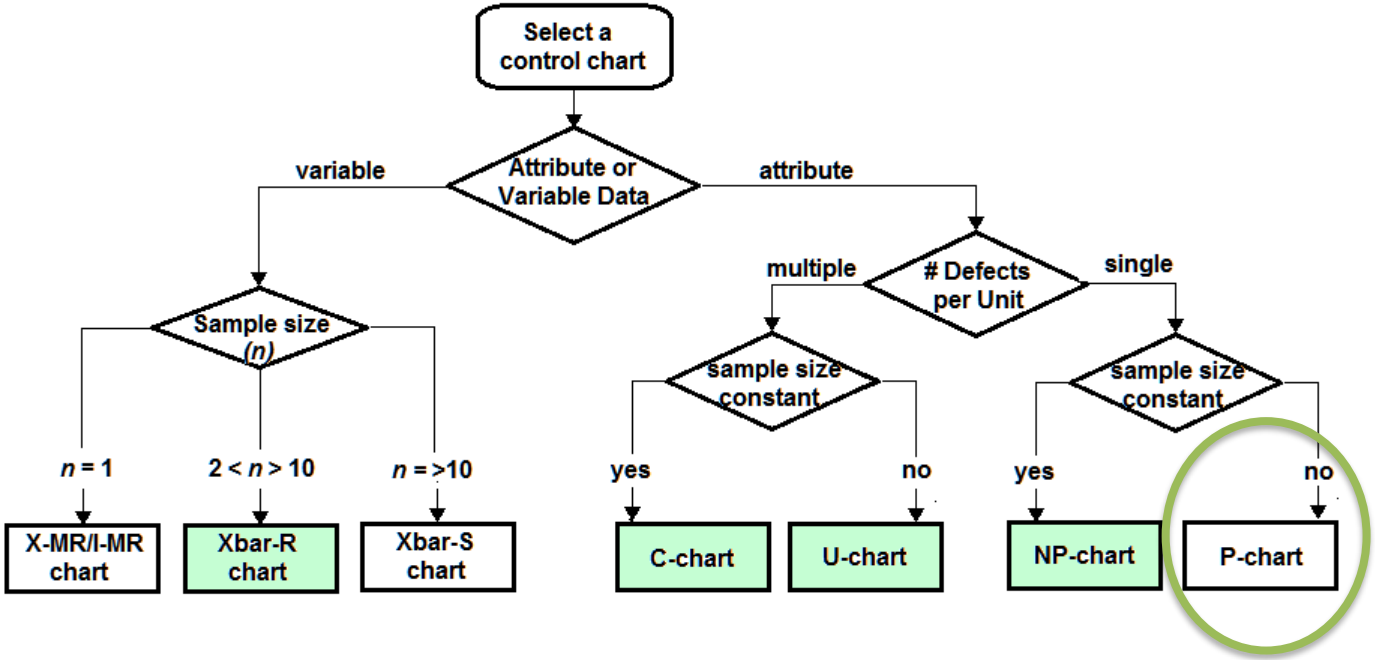


$$UCL = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n_i}}$$

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

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

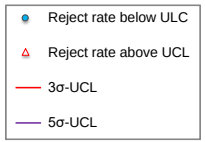
Type of control charting

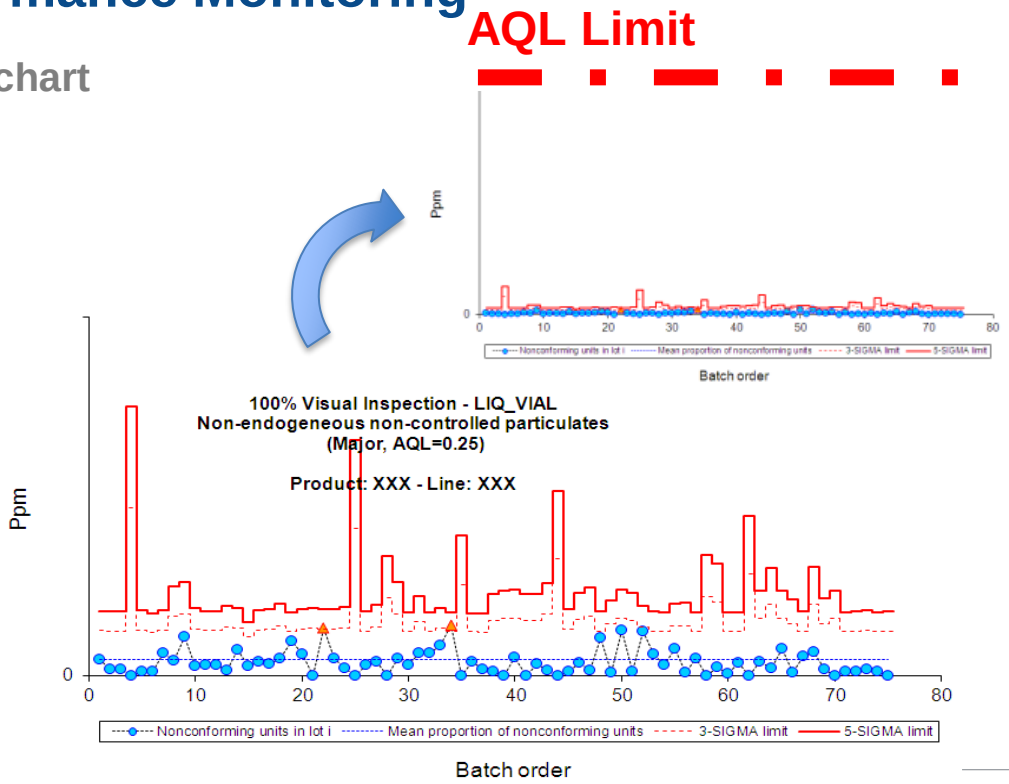


Continuous Performance Monitoring

- Control Strategy- Ctrl chart

Take AWAY: Even with a low probability of detection (non NULL!!)
the UCL limit is the strength of the control strategy, it has the ability to discard atypical lots in term of occurrences.
It has a far lower detection than AQL

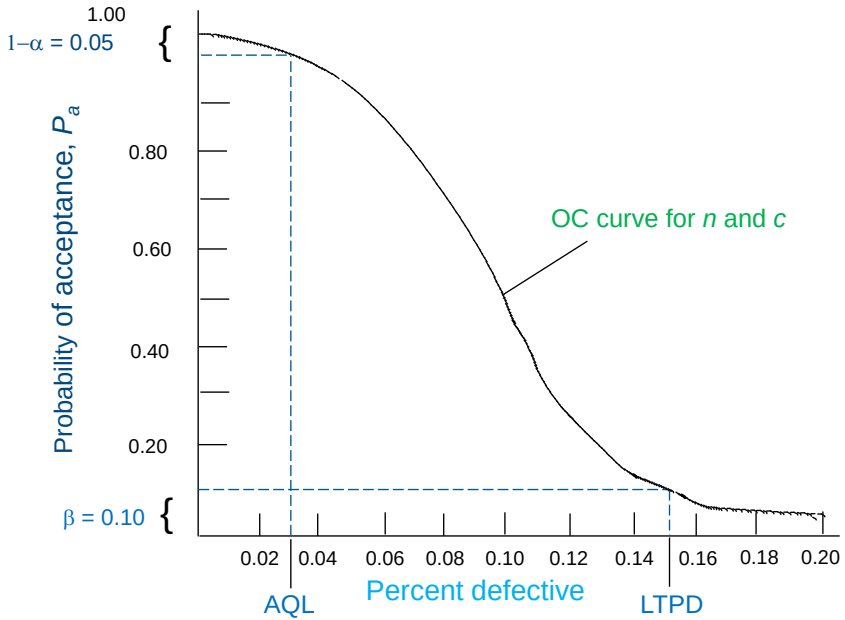




AQL Sampling

- AQL done in MVI
- AVI qualification is compared to MVI reference
- Use ISO tables
- AQL is a quality decision test
- AQL is under quality unit reponsibility

AQL Sampling and OC curve



- **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

AQL Sampling and ISO tables

Table 2-A — Single sampling plans for normal inspection (Master table)

Sample size code letter	Sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (normal inspection)																													
		0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1 000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31				
B	3	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45				
C	5	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧				
D	8	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧	⇧				
E	13	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧	⇧	⇧				
F	20	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧				
G	32	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧				
H	50	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧				
J	80	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧				
K	125	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧				
L	200	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧				
M	315	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧				
N	500	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧				
P	800	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧				
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R	2 000	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧				

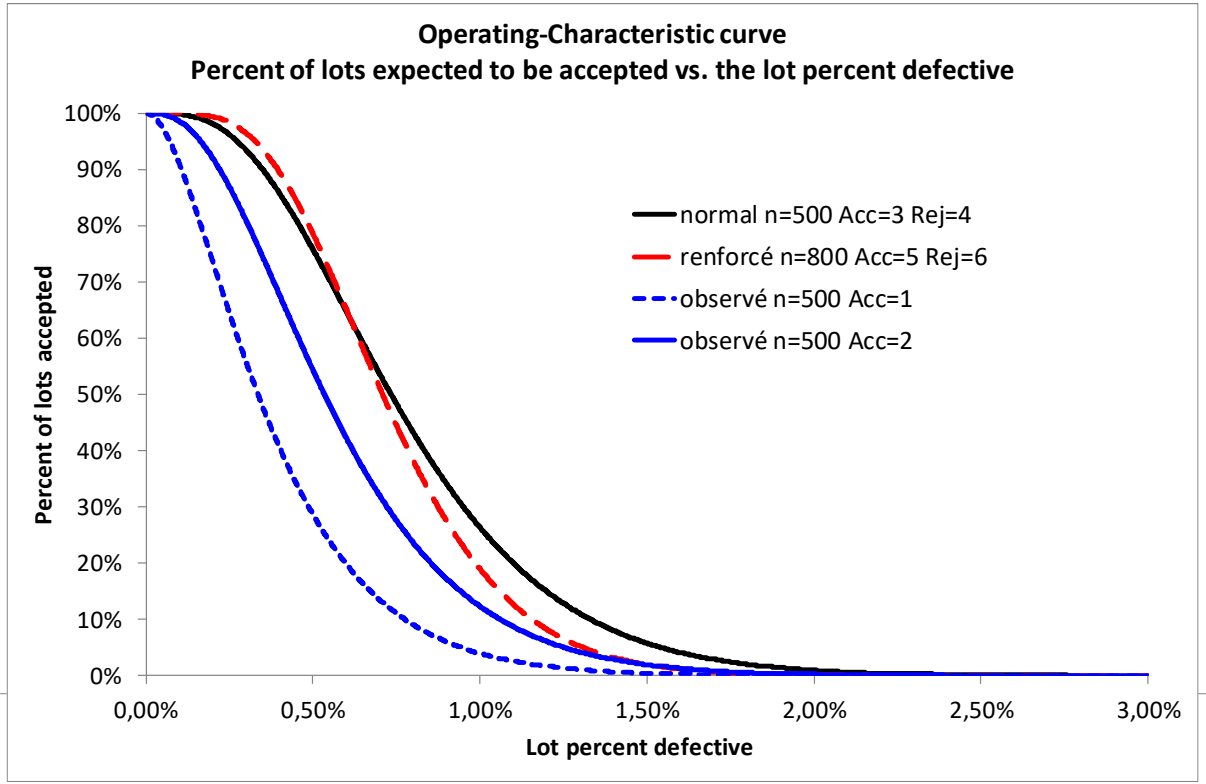
⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

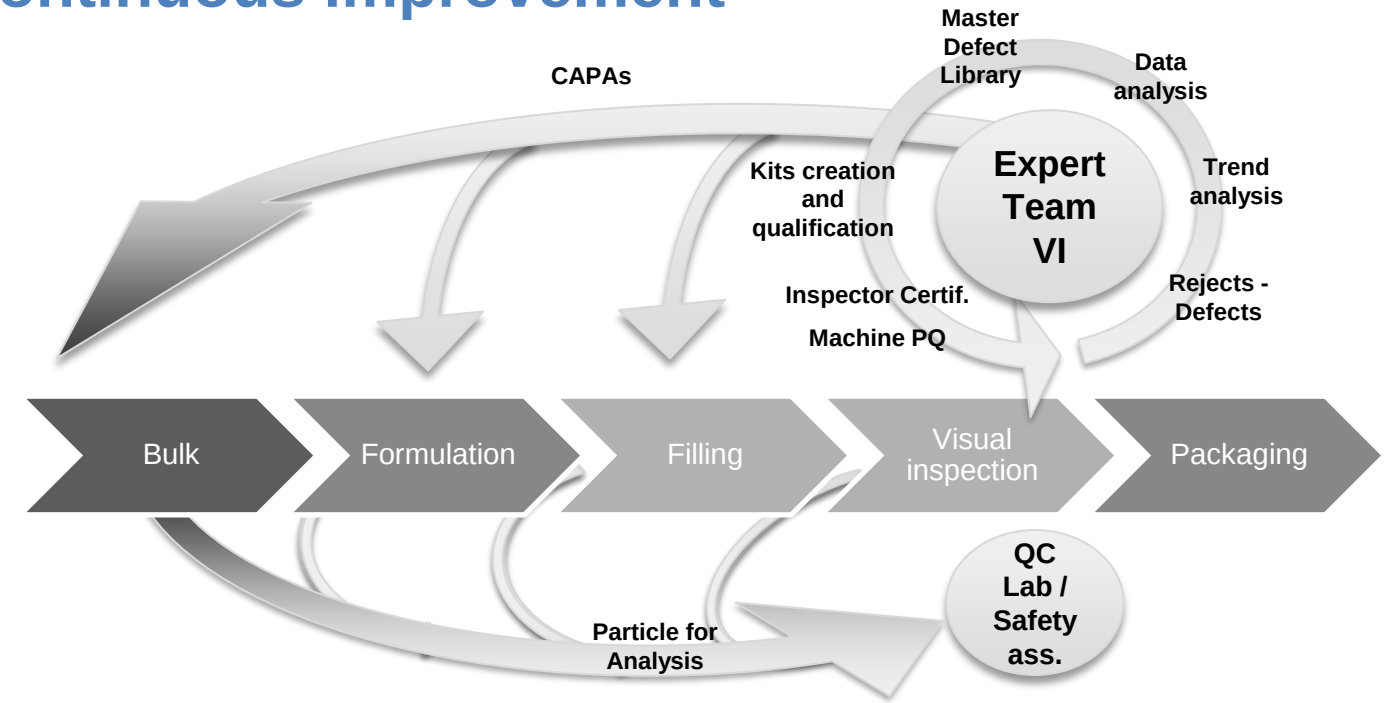
Ac = Acceptance number

Re = Rejection number

Why do we need to perform Tightened AQL in special cases ?



Continuous improvement



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