



Training Course Agenda

Fundamentals of Automated Visual Inspection (*1-day training course*)

DAY 1

8:30 Welcome and Introductions

Theory 1: Introduction into regulatory requirements

- USP 1, USP 788 and 1788, USP 790 and 1790, PhEur e.g. 2.9.20, JP e.g. 6.06, Annex 1
- Similarities and differences in compendial methods
- 100% inspection and AQL testing
- Definitions and practical examples of inherent, intrinsic and extrinsic particles

10:30 Coffee/Tea Break

Theory 2: Technical principles of Automated Inspection Machines (part I)

- Functionality of automated inspection machines
- Camera systems / light / motion
- Image processing and database system

12:00 Lunch

Theory 2: Technical principles of Automated Inspection Machines (part II)

- Interlinkage of parameters: Speed, Rotation speed, Inspection parameters, Detection probability, False reject rate
- Properties, capabilities and limitations of automated inspection systems
- Scope of Automated Visual Inspection

Theory 3: Considerations on Primary Containers and Product Properties

- Vials, Ampoules, Syringes, Blow – Fill - Seal,
- Viscous liquids, Air bubbles / scratches,
- Refrigerated product containers

14:30 Exercise 1: Principle Basic Image Processing using the Argo benchtop

14:45 Coffee/Tea Break

Theory 4: Transition from Manual to Automated Inspection

- Manual inspection as a prerequisite for transition to automated inspection
- Interpretation of inspection results and validation of data
- Considerations on validation program for automated inspection
- Performance measurement
- Maintaining the manual inspection

16:16 Exercise 2: Test Samples Parametrization

Theory 5: Qualification Test Set and Routine Test Set

- Statistical considerations on number of objects containing defects
- Particle selection, particle size and size uniformity
- Test Sets
- Rejects and Defects
- Quality requirements

17:45 Exercise 3: Quality factors and Knapp simulation with Excel

18:00 End of Training Course