Mastering Automated Visual Inspection

Overview

Visual Inspection mastery is fundamental in parenteral manufacturing in order to guarantee both patient safety and cost effective supply. The capability of Automated Visual Inspection (AVI) has progressed extensively over the years to the point where, when applied appropriately, it can offer significant advantages over manual and semi-automated inspection processes. This has been made possible thanks to major innovations and technology breakthroughs. In line with these technological advances, the regulatory requirements for this challenging process have been reinforced. As a consequence, AVI machines today are complex and require multidisciplinary project teams for successful implementation and to manage continous improvement.

This course has been devised to support your AVI program development, by addressing critical parameters, key competencies and practical approaches to managing the inherent complexity of AVI. In day 1, after a review of regulatory landscape, key functions of AVI equipment and associated critical parameters will be covered. Then, the participants will look at the interaction between primary packaging component and AVI of the filled drug product. Successful URS development will be covered by a practical workshop in order to address not only user needs but also to produce a comprehensive process flow model. In Day 2, the need for an effective Manual Visual Inspection (MVI) baseline process will be overviewed as a prerequisite to AVI. Then, defect kits and validation strategies will be described. AVI has a scope broader than computer vision alone and the overall control strategy for the process will be covered. 'Vision Engineering for dummies' will be explained during a practical workshop using modern vision equipment and genuine examples of production defects.

Who Should Attend:

This course is designed specifically for those who are involved or interested in moving from manual to automated inspection like

- Managers, supervisors and all decision makers in the visual inspection area
- Quality personnel, Project and Qualification engineersl
- Prerequisites: Basic understanding and practical experience of manual inspection (as conveyed in the PDA course 'Introduction to Visual Inspection')

Learning Objectives:

Upon completion of this course, you will be able to:

- Acquire basics about Regulatory landscape for AVI
- Be ready to design your URS
- Understand Key function of AVI equipment
- Define your defect kits and validation strategy
- Develop your own control strategy around AVI
- Have basic knowledge about computer vision

Fernand Koert, *Consultant, Vision Technology, Dresden GlaxoSmithKline Vaccines*

Fernand was born in the Hague, Netherlands and started his academic career at the Technical University of Delft to study Electronics. Working in that field, he completed career stages from shift leader to assistant plant manager. After gaining extensive practical experience, he started studying Process Technology at the Maritime Faculty in Amsterdam, graduating Cum Laude and working as a process engineer there after. In 2000, Fernand became a freelancer helping companies to set up practical training programs for operators. At Teva Pharmaceuticals, he did the same and became head of the packaging department in 2003. In 2005, he returned to technical engineering by assuming responsibility for reshaping and automation of packaging lines. Since 2011, Fernand has been specializing in vision technology, improving and sampling for test kits and validation. In 2014, he started with GSK, developing recipes for Seidenader AVI, first in Belgium, and currently for GSK in Dresden, Germany.

Sébastien Koch, *Visual Inspection Project and Validation Engineer, Merck Switzerland*

Sébastien has over 18 years field experience in visual Inspection. In 2000 he began his career for Eli Lilly as specialist in Vision technology to carry out Automated Visual Inspection Machines (AVIM) qualification, maintenance and continuous improvement. In 2010, as Green Belt Six Sigma Sébastien became lean manufacturing engineer to drive operational excellence. In 2012, he took over the lead as Responsible Engineer. In 2016, Sébastien joined Merck in Switzerland to support the Aubonne site development as a driver of change and progress. Responsible of the visual Inspection equipment, he leads the strategic roadmap for long term perspectives, the validation strategy and the permanent competitiveness improvements of the manufacturing processes for quality and cost efficiency.

Thursday, 25 October 2018 9:00 – 17:30

09:00 **Welcome & Introduction**

09:30 **Theory 1: Introduction Into Regulatory Requirements of Visual Inspection**

- 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

10:45 **Coffee Break**

11:15 **Theory 2: Introduction Into Technical Principles of Automated Inspection Machines**

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

12:15 **Lunch Break**

13:15 **Theory 2: Introduction Into Technical Principles of Automated Inspection Machines (cont.)**

14:15 **Theory 3: Considerations on Primary Containers and Product Properties**

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

14:45 **Exercise 1: Developing an URS Considering the Triangle Cost / Quality / Time**

15:45 **Coffee Break**

16:15 **Theory 4: Selection and Purchasing of an Automated Inspection System**

- Technical requirements
- Integration into existing processes, lines/ machines and systems
- Cost and effort considerations
- Risk Assessment

17:15 **Exercise 1 (cont.): Presentation of the Results of the Sub-Groups and Discussion of the Results**

Q & A

17:30 **End of Day 1**

Friday, 26 October 2018 9:00 – 16:30

09:00 **Recap of Day 1**

09:15 **Theory 5: Transition from Manual Inspection to Automated Inspection**

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

10:15 **Exercise 2: Principle Basic Image Processing Using an Open Source Library**

11:00 **Coffee Break**

11:15 **Exercise 2 (cont.): Presentation of the Results**

12:00 **Theory 6: Qualification Test Set and Routine Test Set**

- Statistical considerations on number of objects containing defects
- Particle selection, particle size and size uniformity
- Labelling of test set objects
- Supply/purchase of test sets
- Maintaining and lifecycle of test sets
- Sampling from rejects
- Defect master library
- Types of defects
- Quality requirements

13:00 **Lunch Break**

14:00 **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

15:00 **Theory 8: Operation and Maintenance of Automated Inspection Systems**

15:30 **Coffee Break**

16:00 **Future Trend of Automated Visual Inspection**

16:30 **End of Training Course**