An Introduction to Visual Inspection

A hands-on training course

Overview

This training course covers the fundamentals of visual inspection methods and their application to injectable products. The detection and identification of visible particles is a key part of the course content, though container and closure defects are discussed as well. Attendees combine classroom review of current regulatory requirements and inspection methods with hands-on laboratory exercises to develop and practice practical inspection skills. The skills developed through this combination of classroom and laboratory exercises may be applied to manual human inspection, semi-automated and automated machine inspection methods. This is also an excellent opportunity to discuss your specific inspection questions and challenges with expert instructors.

Who Should Attend:

- Injectable Drug Product Manufacturing Professionals and Management
- Quality Professionals and Management
- Validation and Manufacturing Engineers
- Technical Support Staff
- Product Development Scientists
- Inspection Equipment Manufacturers

Learning Objectives:

Upon completion of this course, the attendee will be familiar with:

- Understand current global regulatory and compendial requirements for visual inspection
- Understand patient risk associated with visible particles in injections
- Implement a technically sound and compliant inspection process
- Assess inspection performance
- Have basic knowledge about computer vision

John G. Shabushnig, *PhD, Principal Consultant, Insight Pharma Consulting, LLC*

John Shabushnig is the founder of Insight Pharma Consulting, providing expert guidance in all aspects of visual inspection. He has over 30 years of industry experience starting as a Research Scientist at The Upjohn Company and most recently as a member of Pfizer's Global Quality Operations, where he was responsible for providing microbiology and aseptic manufacturing technical support. John holds a B.S. in Chemistry from Carroll College and a Ph.D. in Analytical Chemistry from Indiana University. He is an active member of the Parenteral Drug Association (PDA), having served on the Board of Directors (2003-2011) and as Chair (2008-2009) and is the founder and leader of the Visual Inspection Interest Group. He serves on the United States Pharmacopeia (USP) Dosage Forms Expert Committee and chairs the Visual Inspection of Parenterals Expert Panel. He has published and presented numerous papers on the subjects of spectroscopic analysis, process analytical technology (PAT), rapid microbiological test methods and the visual inspection of pharmaceutical products.

Markus Lankers, *PhD, MIBIC*

Markus is one of the co-founders of MIBIC GmbH that develops rapid bacteria identification systems. Within MIBIC Markus is responsible for research and development of new spectroscopic methods for bacteria analysis. He has 25 years of experience in the field of particle identification. In 2002, he founded rap.ID Particle systems GmbH and served as Managing Director until the sale of the company in 2018. Prior to this position, he worked as a scientist in different development departments at Schering AG, Berlin, Germany. Markus holds a diploma in Chemistry and a Ph.D. in Physical Chemistry from the University of Würzburg. He is an active member of the Parenteral Drug Association (PDA). Since 2003, he has supported the 'Visual Inspection of Parenterals' Interest Group in Europe as Interest Group Leader. He has served as program co-chair for the PDA Visual Inspection Forum from 2001 to 2018 in Europe and the USA.

Thursday, 23 April 2020 — 9:00 – 18:00

9:00 **Welcome and Introduction**
- Why We Inspect
- Patient Safety
- Regulatory Requirements
- Compendial Requirements

10:30 **Coffee Break**

11:00 **Inspection Methods and Technologies**
- Critical Parameters (lighting, time, contrast and motion)
- Manual Visual Inspection (MVI)
- Semi-Automated Visual Inspection (SAVI)
- Automated Visual Inspection (AVI)

12:30 **Lunch Break**

13:30 **Particle Identification**

14:30 **Laboratory Exercise: Manual Visual Inspection**
- Light Measurement
- Assessment Effect of Changing Critical Variables
  - Time (10 sec vs. 20 sec)
  - Lighting (2,500 lux vs. 1,250 lux)
  - Motion/Agitation (with vs. without)

15:30 **Coffee Break**

16:00 **Continue Laboratory Exercise**

17:30 **Wrap-up Discussion / Q&A**

18:00 **End of Day 1**

Friday, 24 April 2020 — 9:00 – 16:30

9:00 **Inspection Data Review**
- From previous day's laboratory exercise

10:00 **Defect Classification Strategies**
- Risk Classification Definitions
- Critical, Major and Minor Defects

10:30 **Coffee Break**

11:00 **Acceptance Sampling**
- Sampling Plan Variables
  - Sample Size
  - AQL and UQL
- Common Standards
  - ANSI/ASQ Z1.4
  - ISO 2859

12:00 **Inspection Strategies**
- Reinspection
- 2-Stage Inspection
- Focused Inspection
- Empty Vial Inspection

12:30 **Lunch Break**

13:30 **Inspector Selection and Qualification**
- Vision Screening
- Initial Training
- Initial Qualification
- Requalification

14:00 **Inspection Validation**
- Inspection Performance Assessment
  - Knapp Method
- Acceptance Criteria

14:30 **Coffee Break**

15:00 **Hot Topics from the 2019 Visual Inspection Forum**
- US FDA Comments on Visible Particles and VI
- Application of AI/Deep Learning to VI
- Methods for Difficult to Inspect Parenteral (DIP) Products
- Tracking and Trending of VI Data
- Clinical Relevance of Particles in Injections

16:00 **Wrap-up Discussion / Q&A**

16:30 **End of Training Course**