MARKTHOMPSON
LIFESCIENCES

Visual Inspection & Packaging Parenteral Products

Overview

100% Visual Inspection of Parenteral products is a regulatory requirement and always of interest to inspectors.

This 2 day course covers Manual, Semi automated and Automated Visual Inspection of Parenteral Products in a range of presentations, including Lyophilised product.

Qualification of VI processes is always based upon Manual Inspection benchmarks therefore the course starts there and develops through automating to fully automating the inspection process.

Qualification approaches are presented starting with Knapp and Kushner as the standard benchmark as well as alternative approaches.

The course will also cover the approach developing Automated VI Program as well as the ongoing monitoring, trending and revue.

Target Audience

Professionals involved in the specification, development and management of Visual Inspection Programmes together with the Qualification resources applied would benefit from this course. Even experienced VI professionals would gain useful benchmarking with the wider industry.

About the Lecturers

Chris Gardner has over 30 years in VI processes and is currently Visual Inspection Lead for GSK Barnard Castle, UK. Prior to this Chris worked for TEVA, GE Healthcare and the NHS in a number of Pharmaceutical manufacturing roles. Chris currently supports consultancy work and on site training for MTL.

Course Programme

DAY 1:

- Regulatory Framework and Guidance
- What are we looking for? Defining the defects and inspection criteria.
- Defect libraries
- Manual Visual Inspection
- Practical demonstration and involvement
- Creation of test sets
- Qualification of Manual Visual Inspection
- Qualification of non standard inspection methods.

DAY 2:

- Semi automated visual inspection (Pro's and Con's)
- Validation of Semi automated processes
- Automatic Visual Inspection
- Cycle / Recipe development for products on Automated VI
- Qualification Strategy for Automated VI
- Ongoing Review and Requalification Strategy
- Inspection readiness; Regulatory and Industry trends.

| Consultancy & training in sterile product manufacture |
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