

2019 PDA Ireland VISUAL INSPECTION EVENT

Requirements, Practical Implementation and Future Technologies



Date: Friday November 22nd, 2019

Venue: Carton House, Maynooth, Co. Kildare

Thursday 21st, November 2019

19:30 – 21:00 Attendee Evening Networking Event, register to attend email - elizabeth.hunt@pharmalex.com

Friday 22nd, November 2019

8:00 Registration & Complimentary Breakfast

8:30 Welcome & Introduction

Declan Quinlan, President PDA Ireland Chapter

Opening: Housekeeping for the event

Moderator: Valerie Mulholland GMP Services

8:40 Considerations for Design and Use of Container Defect Sets

Eoghan Greene - Pfizer

9:05 Case Study: Manual Inspection Capabilities and Best Practices including Knapp Study

Alan McDonagh - MSD

9.30 Case Study: Qualification of an Automatic Inspection Line for a Parenteral Product

Jonny Parsons- Amgen

9.55 Coffee Break & Visit Exhibitors

Session 2:

Moderator: Valerie Mulholland GMP Services

10.10 Regulatory (FDA) Approaches for Particulate Matter Evaluation in Injectable Drug Products, Analysis of Recent Warning Letters and Recalls due to Particulate Contamination, a Holistic Approach to Particulate Matter Control

Steven Langille - Former Director of the FDA's Division of Microbiology Assessment

10.40 Regulatory (HPRA) Trends, Annex 1, Dealing with Rejects and Difficult to Inspect Products v Issues Challenges and Deficiencies Inspectors Observed

Ann McGee - Pharmalex

11.10 Round Table Discussions

All attendees discuss in smaller groups

11.40 Q&A

Speaker Panel

12.10 Lunch break & Visit Exhibitors

Session 3:

Moderator: Valerie Mulholland GMP Services

13.10 Achieving Zero Defects for Visible Particles in Injectables

John Shabushnig – Insight Pharma Consulting, LLC

13.40 Continuous Improvement of the Automated Visual Inspection Process Using Existing Technology

Ger Neeson - Astellas

14.05 Coffee Break & Visit Exhibitors

14.20 Latest Technology - Deep Learning Solutions for Visual Inspection of Parenterals

Andrea Sardella – Stevanato Group

14.55 Round Table Discussions

All attendees discuss in smaller groups

15.25 Q&A

Speaker Panel

15.55 Closing Comments

Declan Quinlan, President PDA Ireland Chapter

16.15 PDA AGM

Members & Non-Members

Members €250.00; Non-members €300.00 (plus booking fee)

REGISTER AT EVENTBRITE: www.eventbrite.ie or contact **Elizabeth Hunt** elizabeth.hunt@pharmalex.com

Quote **PDA Ireland** conference for a discounted hotel rate at Carton House.