Particle Identification in Parenterals

Overview

Particulate matter contamination has become the #1 reason for recalls of the US-FDA. This one day comprehensive training course taught by industry leading experts will offer strategies for the implementation of a cost effective control through mandatory compliant root-cause investigations.

The program will provide the foundational information needed to properly control, document and investigate foreign particulate matter in parenteral drugs. It will provide the perfect balance of hands-on laboratory and lecture training, equipping you with knowledge, tools and actual experience you can apply immediately on the job. Furthermore, the course will provide insights and practical guidance for the quality teams to develop a cost-effective strategy for the critical routine root-cause investigations to ensure compliance with current good practices.

With a strong emphasis on the hands-on part, the participants will learn the theoretical background of useful microscopic and spectroscopic techniques. **Pre-isolation:** in-situ Microscopy (inverse microscope) and other means of video microscope to visualize and document the particulate matter without opening the container. **Isolation:** Tools and precautions to minimize cross-contamination for the isolation of the micro particles. **Post-isolation:** Pros and Cons of Polarized Light Microscopy and micro-spectroscopic techniques such as: Raman, Laser Induced Breakdown Spectroscopy, LIBS and IR with ATR extension and SEM EDS will be critically discussed.

In the **hands-on part,** each of the attendee works in groups of maximum 5 people on their individual particulate matter reject sample. They will characterize the particulate matter in the closed container and document the particle with micro-imaging techniques. After isolating the particle in a clean-bench, the attendees will use Raman, LIBS and IR/ATR to obtain high quality spectra of the particles and will also match these spectra with pre-recorded library spectra.

Finally, the different steps of the investigation will be summarized and combined with a critical comparison of the different means of particle characterization. The attendees will be able to evaluate results from CMC reports with their own experience.

Who Should Attend:

This course is designed specifically for those involved or interested in the manufacture and control and CMC regulatory issues of biopharmaceuticals, including
Senior Management, Directors and Managers / Supervisors, QA/QC, Regulatory Affairs, Manufacturing and Process Development Personnel

Learning Objectives:

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

- Understand the principles of particulate matter characterization in the closed container by means of micro imaging photo documentation as well as visual observations.
- Explain the strategy of compliant particle root-cause investigations including reference material library building.
- Understand and gauge the results of particulate material identification from micro spectroscopic methods such as: Raman, IR with ATR, EDS and LIBS.

Markus Lankers, *PhD, Managing Director, rap.ID GmbH*

Markus Lankers is one of the co-founders of rap.ID Particle Systems GmbH, a company that develops, manufactures and sells rapid particle identification systems. Within rap.ID Markus is responsible for research and development of specific characterization method of particulate analysis and manages two dedicated particle characterization service labs in Germany and the US. Prior to this position, he worked as scientist in different development departments with Schering AG, Berlin, Germany. He publishes and presents work in the field of particle characterization and spectroscopic analysis. As an active member of the PDA, he has helped establish the PDA Visual Inspection Interest Group in Europe and set up the first company-independent Visual Inspection Trainings Course. He has served as program co-chair for the PDA Visual Inspection Forum in Europe and the USA.

Training Location:
rap.ID Particle Systems GmbH
Köpenicker Strasse 325
House 11 / 12
12555 Berlin | Germany

Tuesday, 10 April 2018	9:00 – 17:30	At rap.ID GmbH, Berlin

8:00	**Bus Transfer from Conference Hotel to rap.ID GmbH (optional)**
09:00	**Welcome & Introduction**
09:30	**Strategies for Particle Classification, Characterization, Particle Isolation**
11:00	**Coffee Break**
11:30	**Hands-on: Particle Detection, In-situ Microscopic Characterization**
12:30	**Lunch Break**
13:30	**Hands-on: Isolation of Particles**
14:30	**Hands-on: Spectroscopic Identification of Particles**
15:30	**Coffee Break**
16:00	**Challenges in Particle Identification**
17:00	**Summary of the Course, Q&A**
17:30	**End of Training Course and Bus Transfer from rap.ID GmbH to Conference Hotel (optional - duration approximately 45 - 60 min.)**

Oliver K. Valet, *PhD, Managing Director, rap.ID Particle Systems GmbH*

Oliver K. Valet is one of the co-founders of rap.ID Particle Systems GmbH, a company that develops, manufactures and sells rapid particle identification systems. Within the last 15 years, their patented technology fuses particle isolation, imaging analysis and spectroscopic technology together to powerful investigation tools. Streamlining particle contamination identification and particle characterization. Within rap.ID, Oliver is responsible for the product development and their worldwide marketing and sales. From the contract testing work performed at both rap.ID sites in Berlin and Princeton, New Jersey, Oliver has more than a decade of experience in the field of industrial and environmental chemical analysis on particles. As an active member of the Respiratory Drug Delivery (RDD), the Royal Chemical Society, the Parenteral Drug Association (PDA), the American Association of Pharmaceutical Science (AAPS) and the Apothekerverband (APV), he has published his work continuously and presented on various conferences.