The Parenteral Drug Association presents:

2017 PDA Europe Conference, Exhibition

Particles in Injectables

Taking place parallel to the 10th Workshop on Monoclonal Antibodies

Register by 30 July 2017 and SAVE!

26–27 September 2017

Sofitel Berlin Kurfürstendamm

Berlin | Germany

pda.org/eu/particles2017

Dear Colleagues,

This year marks the 2nd edition of the conference on **Particles in Injectables in Berlin, 26–27 September,** and the 10th Anniversary of PDA Europe's Monoclonal Antibodies Workshop. Both events and its respective Education Program will join forces as part of the **PDA Exchange meeting format.** This meeting format combines two meetings in the same place, allowing the audience to swap between the two meetings and attend different sessions with just one meeting ticket.

The Particles in Injectables conference provides you with a summary of information on the risks to human health associated with particulate matter. Particles can arise from many sources: foreign, intrinsic, or inherent to the product. Particulate matter, visible or subvisible, in sterile parenteral products is regarded a critical quality attribute, impacting patient safety. A session will focus on the nature and sources of these particles in parenterals and in infusion sets used in clinical studies and hospitals. The difference between particles in drugs and clinical infusions will be highlighted. Furthermore, packaging materials, such as glass vials, syringes and rubber stoppers are known to be major sources of particulate contamination. A session will discuss defects in packaging materials and strategies employed to detect and control them. Last but not least, manual inspection continues to provide the critical reference method for all compendial inspection activity. Therefore, the concluding session will look at the use of particle standards to qualify manual and automated inspection systems, control of critical inspection parameters, as well as the development of an inspection method.

So register for one, get access to two & attend those topics of interest to you in either meeting!

We look forward to welcoming you to Berlin!








SCIENTIFIC PROGRAM
PLANNING COMMITTEE

1 **Markus Lankers,** *rap.ID – Chair*

2 **John Shabushnig,** *Insight Pharma Consulting – Chair*

3 **Roman Veillon,** *GlaxoSmithKline*

4 **John Ayres,** *Eli Lilly*

5 **Irene Kraemer,** *Johannes Gutenberg-University*

6 **Volker Luibl,** *Pall*

7 **Falk Klar,** *PDA Europe*

8 **Melanie Decker,** *PDA Europe*

SCHEDULE AT A GLANCE

25 September	9:00 – 17:30	Particle Identification in Parenterals	Training Course
26 September	9:00 – 18:00	Particles in Injectables	Conference, Exhibition
26 September	19:30 – 22:00	Networking Event	
27 September	9:00 – 16:30	Particles in Injectables	Conference, Exhibition
28 September	9:00 – 18:00	Tailor-Made Strategies for High Level Expression of Biologicals	Training Course
28 September	9:00 – 17:00	Testmethoden für vorbefüllte Spritzen – Course in German	Training Course
28 September 29 September	9:00 – 17:00 9:00 – 16:30	Best Compliance Practices im GMP Prüflabor – Course in German	Training Course
28 September 29 September	9:00 – 17:00 9:00 – 17:00	CMC Regulatory Compliance for Biopharmaceuticals	Training Course
28 September 29 September	9:00 – 18:00 9:00 – 16:30	DoE Basics for Validation by Design	Training Course
28 September 29 September	9:00 – 18:00 9:00 – 16:30	An Introduction to Visual Inspection: A hands-on Course	Training Course
28 September 29 September	9:00 – 17:30 9:00 – 16:30	Mastering Automated Visual Inspection	Training Course
28 September 29 September	9:00 – 18:00 9:00 – 16:30	Extractables and Leachables	Training Course

For latest information, please visit: **pda.org/eu/particles2017**

Tuesday, 26 September 2017

9:00	**Welcome and Introduction**	Markus Lankers, *rap.ID* John Shabushnig, *Insight Pharma Consulting*

Session 1 Regulatory and Pharmacopoeial Guidance on Particles in Parenterals — *Moderator:* **Markus Lankers,** *rap.ID*

Many different regulations govern the methods used to determine particles in parenterals and the limits associated with these methods. Some of these differences are regional and others are the result of varying interpretation of general guidelines. This session has been organized to provide current benchmarking and developments in this important element of the quality systems associated with parenteral medicines. This is also an excellent opportunity to discuss concerns and issues with current regulations.

9:15	**Visible Particulates in Injections: A Regulatory Perspective**	FDA
9:45	**Unique Status of mAbs in Europe, Requirements for Injectable Products**	PEI
10:15	**USP Activities**	Insight Pharma Consulting
10:45	**Q & A, Discussion**	
11:00	**Coffee Break, Poster Session & Exhibition**	

Session 2 Studies on Particles in Clinics, Sources of Particles — *Moderator:* **John Shabushnig,** *Insight Pharma Consulting*

Particulate matter, visible or subvisible, in sterile parenteral products is regarded a critical quality attribute, impacting patient safety. Particles can arise from many sources foreign, intrinsic, or inherent to the product. This session discusses the nature and sources of these particles in parenterals and tools used in the clinical environment e.g. infusions sets. The differences between particles in drugs and clinical infusions will be highlighted.

11:30	**Application of Bedside Filtration – a Tool to Reduce Protein Aggregates Risks Dramatically**	Ludwig Maximilian University of Munich
12:00	**Production Related Particles in Drugs and Infusion Sets**	Rap.ID
12:30	**Particulate Contaminants in Single-Use Systems: Measurement Challenges**	Sartorius Stedim
13:00	**Q & A, Discussion**	
13:15	**Lunch Break, Poster Session & Exhibition**	

Session 3 Sources of Particles, Measurements, Particle Loads — *Moderator:* **John Ayres,** *Eli Lilly*

This session will include a review and discussion of particle types, sources, numbers and potential clinical impact. Measurement challenges and the impact of subvisible particles will be explored.

14:15	**Linking Process Capability and Patient Risk to Establish SVP Acceptance Limits**	Eli Lilly

14:45	**Industry Approaches to Visible Particles**	LONZA
15:15	**Requirements of Glass Quality of Primary Packaging Materials**	Universitätsspital Basel
15:45	**Q & A, Discussion**	
16:00	**Coffee Break, Poster Session & Exhibition**	
Session 4	**Panel Discussion on Pharmaceutical Manufacturing**	*Moderator:* **Markus Lankers,** *rap.ID*
16:30	**Feedback from a National Quality Reviewer**	Swiss Medic
17:00	**Panel Discussion**	
18:00	**End of Day 1**	
19:30	**Networking Event**	

19:30 h - Meeting Point: Hotel Lobby
20:00 h - Hofbräu Berlin Karl-Liebknecht-Straße 30, Berlin
22:00 h - End of Networking Event

HOFBRÄU MÜNCHEN
WIRTSHAUS BERLIN

* Bavarian expression, meaning 'it's tapped'. At noon on the first day of Oktoberfest, the Mayor of Munich traditionally taps the first keg of beer, exclaiming the above phrase, which marks the official opening of the festival.

Wednesday, 27 September 2017

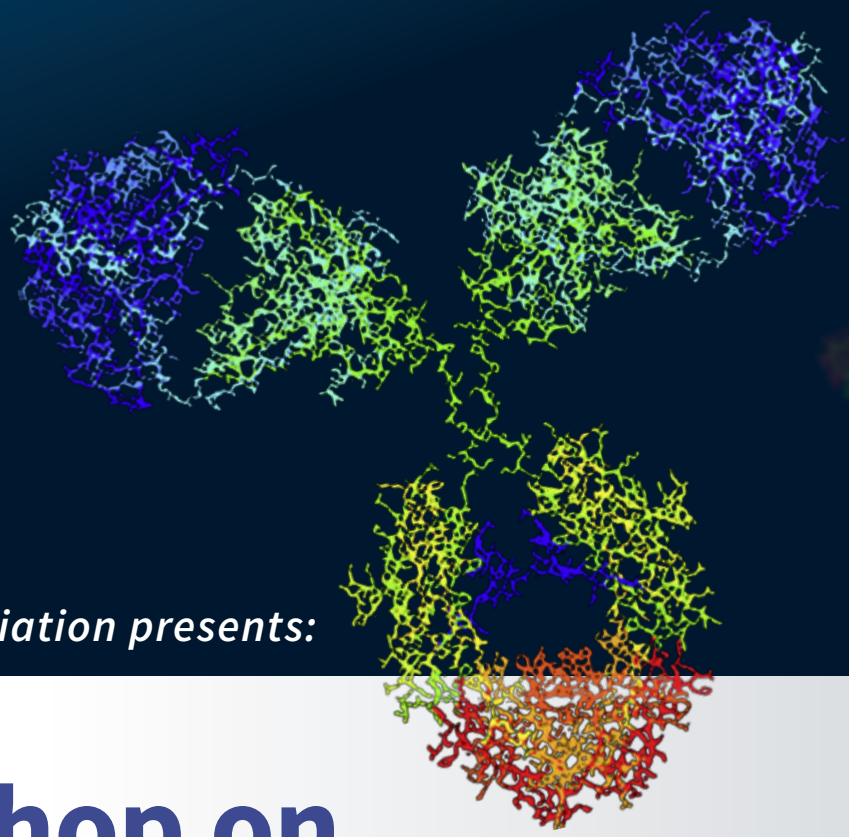
Session 5	**Medical Impact of Particles**	*Moderator:* **Roman Veillon,** *GlaxoSmithKline*
9:00	**Y-Site Compatibility of Intravenous Medications for Children**	University of Wolverhampton
10:00	**Coffee Break, Poster Session & Exhibition**	
10:30	**Sepsis, Systemic Inflammatory Response Syndrome (SIRS)**	Hannover Medical School
11:00	**The Effect of In-Line Filtration to Reduce Systemic Inflammatory Response Syndrome**	APHP
11:30	**Interactions and Effect of Nanoparticles in the Healthy and Diseased Microvasculature**	University of Munich
12:00	**Q & A, Discussion**	
12:30	**Lunch Break, Poster Session & Exhibition**	
Session 6	**Reducing Particle Load and Risk Mitigation, Improving the Patients Situation: Possible Strategies to Reduce Particle Load, e.g. Manufacturing, Use of Filters, Risk Assessment**	*Moderators:* **Volker Luibl,** *PALL* **Romain Veillon,** *GlaxoSmithKline*

Clinical guidelines for healthcare providers regarding the risk mitigation of particles vary strongly from country to country or do not exist currently. In order to establish these guidelines, it is not only critical to quantify and qualify particles that may be infused in patients but also to evaluate the consequences within different clinical scenarios and patient profiles. Eventually a global consensus will lead to patient safety based on the outcome of these studies.

13:30	**In-Line Filtration Reduces Postoperative Phlebitis: A Randomized Clinical Trial on Abdominal Surgical Patients**	University of Florence
14:00	**How many Particles enter the Body during Infusion Therapy**	Philipps-University Marburg
14:30	**Coffee Break, Poster Session & Exhibition**	
15:00	**Are We Ready for Global Consensus on Filtration Practice?**	WoCoVa
15:30	**Closing Panel Discussion** **Topics:** • Many Aspects In-Line Filtration in Clinical and Pharmaceuticals • Qualifications of Filters	
16:30	**Farewell Remarks & End of Conference**	

PDA Parenteral Drug Association

10 YEARS MONOCLONAL ANTIBODIES



The Parenteral Drug Association presents:

2017 PDA Europe

10th Workshop on Monoclonal Antibodies

Be sure to check out the program agenda of the parallel event!

https://goo.gl/TU6vAB

BUY ONE TICKET, ACCESS BOTH EVENTS!

Register by 30 July 2017 and SAVE!

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pda.org/eu-Monoclonals2017

TO EXHIBIT:

PDA meetings and conferences are a great opportunity for your company to gain on-site exposure in front of highly-qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Exhibition and Sponsorship Opportunities are available. A basic exhibition package for this event is priced **1.895 Euro net (table-top).** For more information please contact **expo-europe@pda.org**

Exhibitor	Table Top
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OMPI	7
GE	8
Quality Assistance	12

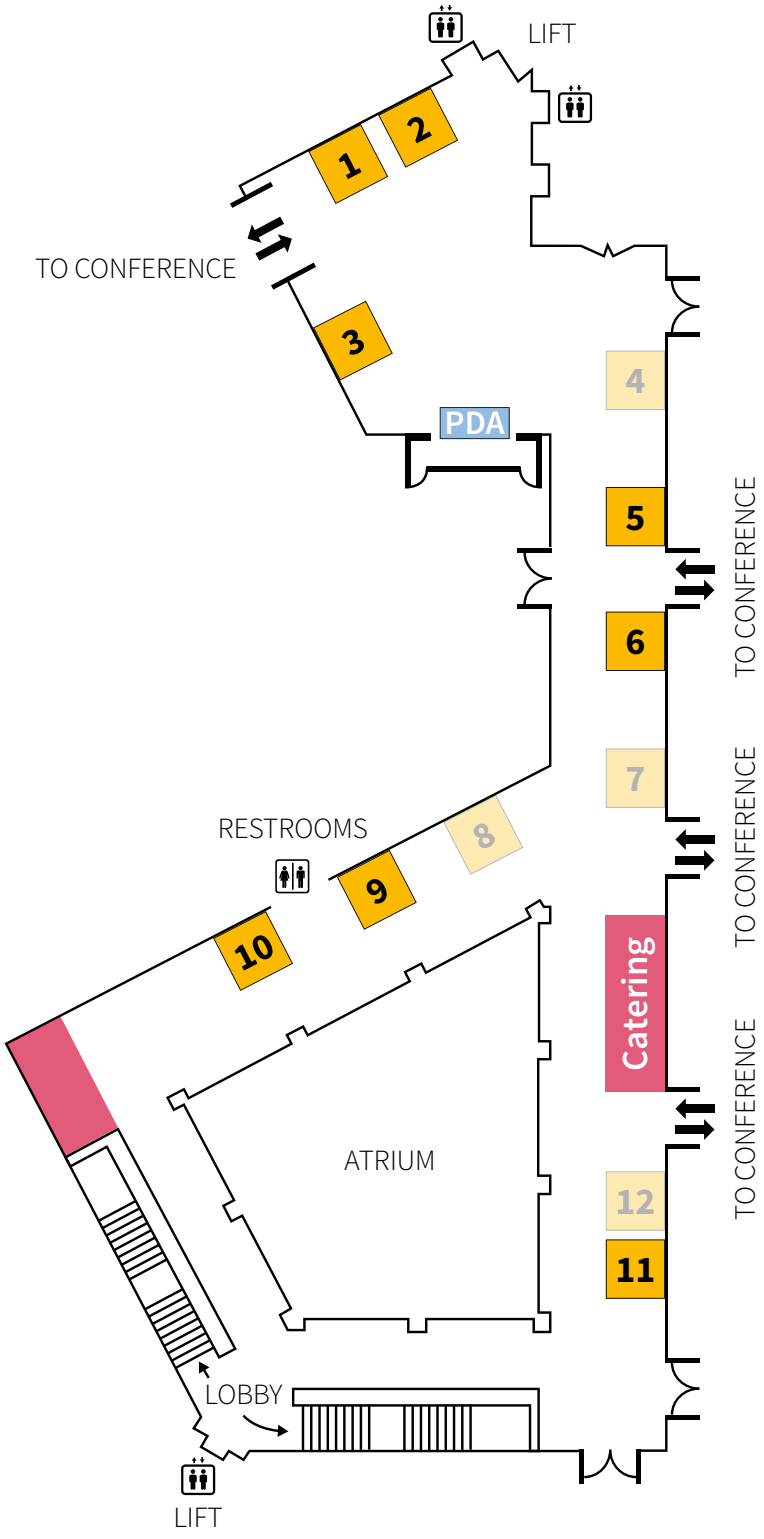

Table Top 2 m x 2 m (4m²)

PDA Registration/Lounge

Catering

LAST TABLE TOPS AVAILABLE!

Training & Education Program

europe.pda.org

PDA Education offers courses that are developed and taught by experts. They are uniquely targeted to professionals involved in the development and manufacturing of quality pharmaceutical and biopharmaceutical products.

Facts that Make a Difference

- Up-to date training courses and workshops taught by internationally renowned instructors
- Wide range of training courses with hands-on experience to drive expertise, awareness, and innovation
- Customized in-house training courses and workshops available

PDA Education Program

25 September 2017
Particle Identification in Parenterals
One-Day Training Course

28 September 2017
Tailor-Made Strategies for High Level Expression of Biologicals
One-Day Training Course

28 September 2017
Testmethoden für vorbefüllte Spritzen
One-Day Training Course

COURSE IN GERMAN

28–29 September 2017
Extractables and Leachables
Two-Day Training Course

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Best Compliance Practices im GMP Prüflabor
Two-Day Training Course

COURSE IN GERMAN

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

Monday, 25 September 2017	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.

Tailor-Made Strategies for High Level Expression of Biologicals

Overview

Biologicals, well-known proteins with a diversity of distinct bioactivity, are involved in many biological processes. Nearly identical to naturally produced in the human body, these biomolecules play an active role as targets for pharmaceutical and diagnostic applications. However, the realization of future applications in the medical field requires tailor-made strategies for the *in vitro* production of recombinant proteins. The synthetic access to these "artificial complex compounds" is still challenging. Following the mission statement from "gene to product", this lecture will provide an overview on the development of efficient strategies for high level expression of biologically active molecules.

Who Should Attend:

The course will focus on individuals that are involved in the biopharmaceutical area. This includes the following functions within pharmaceutical or biotech industry including drug substance manufacturers.

- Research & Process Development
- Analytical Development
- Manufacturing & Technical Operations
- Engineering
- Quality Control
- Quality Assurance
- Regulatory Affairs
- Supply Chain Management
- Project Management

THE COURSE IS DEDICATED TO THE FOLLOWING SPECIFIC JOB FUNCTIONS:

- CMC Team Leaders
- Managers/Supervisors in manufacturing and QC/QA
- Researchers
- Technicians
- Regulatory Affairs Specialists
- Supply Chain Managers
- Project Managers

Learning Objectives:

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

- Explain the routes from genes to native proteins
- Apply the routes from genes to recombinant proteins
- Evaluate the differences between eukaryotic and prokaryotic expression systems
- Understand the importance of profound knowledge of complex proteins and underlying challenges for heterologous production of biologicals
- Explain tailor-made strategies for efficient production of biologically active compounds

Leonie Engels, *PhD*

Leonie Engels was research associate at the Institute of Biotechnology/Laboratory for Biomaterials and Helmholtz-Institute for Biomedical Engineering RWTH Aachen from 2005-2015. In over 10 years she gained a profound knowledge in cloning and expression of genes in microbial host organisms and in DNA/protein sequence analysis. Her broad experience in identification, production, purification and characterization of novel enzymes for the *in vitro* synthesis of natural and modified glycans is attested in seven publications and one granted patent. Her work was funded by the German "Federal Ministery for Education and Research" (BMBF) and the DECHEMA Max Buchner Foundation. As PhD student she joined Genentech Inc., South San Francisco, USA (Department: Early stage cell culture) for an internship in 2013. Leonie Engels obtained her M.S in Biology and her PhD degree from the RWTH Aachen University.

31 Jul 2017

Thursday, 28 September 2017 — 9:00 – 18:00

9:00 Welcome and Introduction

9:10 The Revolution of Molecular Biotechnology:

- History of molecular biotechnology
- From genes to native proteins
- Basics of DNA recombination
  - Restriction endonucleases
  - Cloning vectors
  - Ligation
  - Transformation and selection
  - Sequencing

10:30 Coffee Break

11:00 Gene Expression in Prokaryotes

- Expression vectors
- Fusion proteins
- Loss of expression
- Transport and localization
- Advantages and limitations
- Class exercise I – Designing a cloning experiment - Step I

12:30 Lunch Break

13:30 Gene Expression in Eukaryotes

- In yeast
- In insect cells
- In plant cells
- In mammalian cells
- Advantages and limitations
- Class exercise II – Designing a cloning experiment - Step II

15:00 Coffee Break

15:30 Tailor-made Solutions for Efficient Production of Recombinant Proteins:

- Bioengineering operations
- Mutagenesis methods – protein design
- Conclusions
- Questions and answers

18:00 End of Training Course

Testmethoden für vorbefüllte Spritzen

Kursbeschreibung

Vorbefüllte Spritzen werden für verschiedenste Anwendungen und in den unterschiedlichsten therapeutischen Bereichen eingesetzt. Sie sind erhältlich aus Glas oder Kunststoffen, in den Versionen Luer Konus, Luer Lock oder bereits als Nadelspritze. Vorbefüllte Spritzen haben zwei Hauptaufgaben, sie dienen als Aufbewahrungsbehälter, aber auch gleichzeitig als Injektionsvorrichtung, in ein und demselben System.

Je mehr Komponenten solch eine Spritze beinhaltet, desto komplexer wird das ganze System, vor allem, wenn vorbefüllte Spritzen in Autoinjektoren verwendet werden.

Dieser 1-Tageskurs gibt einen Einblick in die Eigenschaften der verwendeten Materialien, die in der Entwicklung und Fertigung von solchen Spritzensystemen eingesetzt werden. Der Fokus dieses Workshops liegt jedoch auf den relevanten Test Methoden, anwendbar für den jeweiligen Entwicklungsstand und Einsatz der Spritze.

Zielgruppe

Dieser Trainingskurs wendet sich an alle Personen, die in den folgenden Bereichen tätig sind:

- Produktentwicklung
- Qualitätsmanagement
- Regulatory Affairs / Zulassung
- Fertigung von Spritzensystemen und verwandten Geräten

Lernziele

Nach Abschluss des Kurses

- Kennen Sie die Vor- und Nachteile der verschiedenen Materialien für vorbefüllte Spritzen
- Können Sie bestehende Standards und Monografien der spezifischen Spritzentests anwenden
- Können Sie die Gründe erklären, warum die jeweiligen Testmethoden in den verschiedenen Phasen angewendet wurden
- Können Sie einen eigenen Testplan für Ihre konkrete Anwendung erstellen

Horst Koller, *CEO, HK Packaging Consulting GmbH*

Bevor Horst Koller als Berater tätig wurde, arbeitete er mehr als 20 Jahre für Abbot Diagnostik und SCHOTT Pharmaceutical Packaging in der Industrie. Sein Beratungsunternehmen fokussiert sich auf die Technische, Regulatorische und QM-Unterstützung im Bereich Primär- und Sekundärpackmittel sowie Medizinprodukte. Er ist ein aktives Mitglied in den ISO TC 76 und TC 84 Ausschüssen und ein aktiver Sprecher bei internationalen Kongressen. Horst Koller ist Dipl.-Ing. der Biotechnologie, FH Mannheim.

Donnerstag, 28 September 2017	**9:00 – 17:00**
9:00	**Willkommen**
9:15	**Einführung in Spritzensysteme und Komponenten** • Kunststoff-Spritzen • Glas-Spritzen • Gummi-Komponenten und –Verschlüsse
10:15	**Luer Konus und Luer Lock Compliance Tests für Polymer- und Glas-Spritzen**
11:00	**Kaffeepause**
11:30	**Anforderungen an die leere, sterile, vormontierte und zum Befüllen bereite Spritze** • Konus Bruch • Fingerflansch Bruch • Leckage
12:30	**Mittagspause**
13:30	**Anforderungen an die leere, sterile, vormontierte und zum Befüllen bereite Spritze - Fortsetzung** • Haft- / Gleitreibung • Nadeleinstichkraft • Partikelanforderungen (nicht sichtbare Partikel) • Endotoxin Spezifikation
14:30	**Anforderungen an die bereits vorbefüllte Spritze** • Arzneimittelbücher (Pharmacopoeia) • FDA Anforderungen
15:30	**Kaffeepause**
16:00	**Weitere Tests für die Anwendung in nadelbasierten Injektionssystemen** • Autoinjektoren
17:00	**Ende des Trainingskurses**

Best Compliance Practices im GMP Prüflabor

Kursbeschreibung

Dieser Kurs gibt den Teilnehmern ein vertieftes Verständnis zur Umsetzung der relevanten cGMP Anforderungen in einem modernen Qualitätskontrolllabor eines pharmazeutischen Unternehmens. Der Kurs vermittelt nicht nur eine zusammenfassende Darstellung der für ein Kontrolllabor wichtigsten cGMP-Regularien (OOS-Management, Probenmanagement, Methodenvalidierung, Training, Dokumentation, Datenmanagement). Vielmehr werden diese Regularien in Workshops zu den jeweiligen Themen vertieft und in intensiven Diskussionen der Teilnehmer entsprechende Umsetzungslösungen erarbeitet. Gemeinsam mit den Referenten werden die gefundenen Lösungen im Plenum besprochen. Somit erhält der Kursteilnehmer neben dem notwendigen Wissen auch die Fähigkeit, dieses vor Ort am eigenen Arbeitsplatz umzusetzen.

Zielgruppe:

Der Kurs richtet sich vor allem an Mitarbeiter und Vorgesetzte in Qualitätskontrolllaboren der pharmazeutischen Industrie, die im Tagesgeschäft immer wieder vor der Aufgabe stehen, die teilweise komplexen cGMP-Regularien effizient und effektiv im Labor umzusetzen.

- Laboranten: MTA, PTA, CTA
- Arbeitsgruppenleiter oder Teamleiter im QK Labor
- Supervisor
- Mitarbeiter der Qualitätssicherung mit Schwerpunkt Qualitätskontrolle, z.B. Quality-on-the-floor

Zielsetzung:

- Verständnis zur Anwendung der wesentlichen cGMP-Anforderungen im Qualitätskontrolllabor
- Entwickeln von GMP-gerechten Lösungsansätzen im Rahmen der Umsetzung der GMP-Compliance am Arbeitsplatz der Qualitätskontrolle unter Berücksichtigung deutscher und internationaler Regelwerke
- Befähigung zur Umsetzung der Anforderungen zur Dateninteg rität im Qualitätskontrolllabor (z.B. Audittrail Review)
- Eigenständiges Bearbeiten von OOS-Ergebnissen
- Erstellung von Probenahmeprogrammen unter Anwendung einfacher statistischer Methoden
- Umsetzung von Trainingskonzepten im Qualitätskontrolllabor

Dirk Feldmann, *PhD, Apotheker, Leiter Quality Operations und sachkundige Person bei Bausch+Lomb Berlin*

Dirk Feldmann absolvierte sein Studium der Pharmazie an der FU Berlin und promovierte an der TU Berlin/Fachbereich Lebensmittelchemie mit dem Thema “Modellberechnungen zum Verhalten und Verbleib von Arzneimittelrückständen im Krankenhausabwasser und Beurteilungsmöglichkeiten ihres ökotoxikologischen Gefährdungspotentials“. 1996 übernahm er die Position als Laborleiter verschiedener analytischer Labore am Zentralen Institut der Bundeswehr Berlin. Seit 2006 ist er in verschiedenen Positionen bei Bausch+Lomb Berlin tätig (Leiter Bulk-Fertigwaren-Stabilitätskontrolle, Qualitätssicherung und sachkundige Person sowie Leiter der Herstellung). Aktuell ist Dirk Feldmann Leiter Quality Operations und sachkundige Person bei Bausch+Lomb Berlin. Darüber hinaus fungierte er von 2010 - 2012 als Beratender Apotheker an der Saint Luke Foundation / Kilimanjaro School of Pharmacy (Moshi / Tansania) im Rahmen der Internationalen Zusammenarbeit.

Klaus von Jan, *PhD, CRS Compliance and Regulatory Services*

Nach seinem Studium der Chemie an der TU Stuttgart und der Promotion in Organischer Chemie mit einem Thema zur Synthese und Strukturaufklärung von Oligonukleotiden, leitete Klaus von Jan von 1988 bis 1995 die Qualitätskontrolle und Qualitätssicherung der Millipore BioSyntech GmbH in Hamburg. Von 1996 bis 2005 war er als Director Quality Assurance Bulk Manufacturing Germany bei Chiron Vaccines in Marburg tätig. Seit 2005 ist Klaus von Jan unabhängiger Unternehmensberater in der Pharmazeutischen Industrie mit den Schwerpunkten: Aseptische Herstellung, Vaccines, Qualitätskontrolle, CSV und Datenmanagement, FDA Vor- und Nachbereitung sowie Interimsmanagement. Er war Mitbegründer und Geschäftsführer der Compliance Systems GmbH; Softwaresysteme für die Pharmazeutische Industrie und ist seit 2008 Mitbegründer und Co-Eigner der Schweizer pmc-support GmbH.

31 Jul 2017

Donnerstag, 28 September 2017 — 9:00 – 17:00

9:00	**Begrüßung der Teilnehmer, Vorstellung der Trainer und Teilnehmer, Erwartungen, Organisatorisches**	Klaus von Jan Dirk Feldmann
9:45	**Grundlegende GMP Anforderungen im QC Labor – eine kurze Übersicht** • OOS – Ergebnisse / abgebrochene Tests • Methodenvalidierung / Methodenverifizierung • Probenmanagement • Sampling Datenmanagement • Dokumentation • Training	Klaus von Jan
10:30	**Kaffeepause**	
11:30	**CASE STUDY 1:** **Beispiel eines OOS – Ergebnisses; eventuell Finding aus einer Inspektion** • Erläuterung des Falles • Erwartung an die Teamarbeit • Präsentation der Ergebnisse • Abgleich der Ergebnisse mit den Erwartungen (Best Practice)	Klaus von Jan
13:30	**Sachkundige Probenahme im QK-Labor** • Auftretende Fehlertypen bei der täglichen Arbeit • Probenahmefehler • Erstellung von Probenplänen • statistische Verfahren zur Bestimmung der Probengröße	Dirk Feldmann
15:00	**Kaffeepause**	
15:30	**CASE STUDY 2:** **Gruppenarbeit zum Thema Probenahme** • Erstellen eines Probenahmeplans und Festlegung des Probenumfangs anhand der vorgestellten Methoden • Vorstellung und Diskussion der Ergebnisse	Dirk Feldmann
17:00	**Ende des ersten Tages**	

Freitag, 29 September 2017 — 9:00 – 16:30

9:00	**Rückblick auf den ersten Tag**	Klaus von Jan Dirk Feldmann
9:30	**Grundlegendes zum Thema Datenmanagement:** • 21 CFR Part 11 / Annex 11 • Neue Erwartungen der EU Behörden (MHRA) • Datenintegrität • Audittrailreview • Dokumentation und Datensicherheit	Klaus von Jan
10:30	**Kaffeepause**	
11:30	**CASE STUDY 3:** **Bearbeitung eines FDA – 483 Findings zum Thema Datenmanagement und Umsetzung des Audittrailreviews. Diskussion der Ergebnisse; Dokumentation des Audittrailreviews**	Klaus von Jan
12:30	**Mittagspause**	
13:30	**CASE STUDY 4:** **Methodenvalidierung / Methodenverifizierung: Erstellung einer Aktivitätenliste beim Umzug eines Sterilitätslabors**	Klaus von Jan
14:30	**Kaffeepause**	
15:00	**CASE STUDY 5:** **Umsetzung eines Trainingskonzeptes im QC Labor** • Wie lässt sich eine Vielzahl von Methoden trainieren • Erfolgskontrolle • Entwicklung eines Trainingskonzeptes	Dirk Feldmann
16:00	**Offene Fragen / Zusammenfassung / Feedback / Verabschiedung**	Klaus von Jan Dirk Feldmann
16:30	**Ende des Trainingskurs**	

CMC Regulatory Compliance for Biopharmaceuticals

Overview

Biopharmaceuticals (i.e., biological medicines sourced from genetically-engineered living systems) for treatment of human diseases have become a significant percentage of the pharmaceutical industry. And not just the recombinant DNA-derived proteins and monoclonal antibodies (both from the innovators and biosimilars); but now, an increasing awareness of the importance of gene therapy and genetically engineered cellular medicinal products.

These biopharmaceuticals are being developed by many companies whose Chemistry, Manufacturing & Control (CMC) teams have varying degrees of familiarity or experience with the regulatory requirements for these challenging products. Companies clearly understand the critical importance of their human clinical study strategy, but frequently, the development of a strategy for CMC is an afterthought. Add the frequent lack of CMC regulatory compliance experience in some companies, coupled with the complexity of the biological manufacturing processes and products, and this can be a recipe for disaster.

This course will provide insights and practical guidance for the CMC teams to develop an acceptable cost-effective, risk-based CMC regulatory compliance strategy for biopharmaceuticals (recombinant proteins, monoclonal antibodies, genetically engineered viruses and human cells) from early clinical stage development through market approval. The course emphasis will include FDA, EMA and ICH guidance.

Who Should Attend:

This course is designed specifically for those involved in 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, you will be able to:

- Explain the importance and underlying principles of an effective CMC regulatory strategy for biopharmaceuticals to move your products through clinical development into the marketplace
- Explain the importance and underlying principles for CMC regulatory compliance of biopharmaceuticals and how this leads regulatory agencies to have different CMC regulatory requirements for biotech products compared to pharmaceuticals of chemical origin.

John Geigert, *PhD, BioPharmaceutical Quality*

John Geigert is President of BioPharmaceutical Quality Solutions, which for the last 15 years has specialized in providing CMC regulatory strategy consulting for the biopharmaceutical industry. He has over 40 years of CMC industrial experience and leadership in the biopharmaceutical industry. He has held senior management positions as Vice President of Quality at both IDEC Pharmaceuticals Corporation in San Diego and Immunex Corporation in Seattle, and he was Director of Product Development at Cetus Corporation in Berkeley. At these companies, he helped lead the CMC efforts to obtain regulatory approvals for 6 biopharmaceutical products now commercially available in the U.S. and in Europe. John Geigert has served on the PDA Board of Directors, currently chairs the PDA Biopharmaceutical Advisory Board, and has served as an expert member of the USP Biotechnology Committee. He is the author of the book The Challenge of CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics 2nd Edition, and has written extensively for RAPS Focus (What Senior Management Needs to Know About CMC Regulatory Compliance for Biotech Products (Aug-Nov 2009, 4-part series)), Demystifying CMC Regulatory Strategy (Sept 2011-Mar 2012, 4-part series). John Geigert obtained his B.S. in Chemistry from Washington State University and his Ph.D. degree in Organic/Analytical Chemistry from Colorado State University.

31 Jul 2017

Thursday, 28 September 2017 — 9:00 – 17:00

9:00	Welcome and Introduction
CMC Regulatory Challenges for Biopharmaceuticals are Different	
9:10	– Painting the Terminology Landscape: Biologic, specified biologic, biopharmaceutical, biosimilar, CBER, CDER, EMA, …
10:30	Coffee Break
11:00	– Understanding the CMC Differences of Biopharmaceutical Regulation between FDA and EMA – Biopharmaceuticals are not Chemical Drugs – Regulatory Compliance Consequences of the four Major CMC Differences
12:30	Lunch Break
How to Develop an Effective Corporate CMC Risk-Managed Control Strategy for Biopharmaceuticals	
13:30	– Three Major Forces that Shape the CMC Regulatory Compliance Strategy of all Biopharmaceuticals – Five Key Elements of an Effective Corporate CMC Regulatory Compliant Strategy
15:00	Coffee Break
15:30	– Impact of the Quality by Design (QbD) on Biopharmaceutical CMC Strategy – Necessity of a Clinical Phase - Appropriate CMC Regulatory Compliance Strategy
17:00	End of Day 1

Friday, 29 September 2017 — 9:00 – 17:00

Applying a CMC Risk-Managed Control Strategy to the Biopharmaceutical Manufacturing Process	
09:00	– Four Myths about Biopharmaceutical Starting Material – the Master Cell Bank – Necessity of Confirming Clonality and Genetic Stability
10:30	Coffee Break
	– Importance and Limitations of small-scale Studies for Biopharmaceuticals
	– Clinical Phase - Appropriate Control of the Biopharmaceutical Manufacturing Process
	– Formulation and Container-Closure Challenges for Biopharmaceuticals – Impact of Components on the Biopharmaceutical (e.g., protein aggregation) and Impact of the Biopharmaceutical on Components (e.g., glass delamination)
12:30	Lunch Break
Challenge of Managing Manufacturing Process Changes and Demonstrating Biologic Product Comparability – Not an Easy Task!	
13:30	– Need for Risk-based, Sequential and Clinical Phase - Appropriate Comparability Studies – Demonstrating Biologic Product Comparability – Justifying CMC Differences
15:00	Coffee Break
15:30	– "Comparability Protocol" and "Post Approval Change Management Protocol"
	– Extreme Comparability of Biosimilars: Limitations of CMC Comparison, Fingerprinting – CMC Biosimilarity Successes and Failures
17:00	End of Training Course

Design of Experiments (DoE) Basics for Validation by Design®

Overview

If done right, DoE should cost as much or less than the traditional approach to pharmaceutical development. This two-day course is a practical introduction to experimental design basics with applications to research, process & assay development, and validation. A non-theoretical approach presents the concepts using arithmetic and simple graphics to support and communicate your understanding of multifactor interactions.

- World Health from FDA's 2011 Process Validation Guidance to ICH Q8 requires the study of multivariate interactions. The Design of Experiments is how to do this.
- The Quality By Design approach can either be budget crushing, time pushing additions at the end of development or it can be a cost saving tool built into the fabric of your organization with which to balance the quality of the information gained against the time it's going to take and the resources available before committing any monies to a project.
- Agility and flexibility in the pharmaceutical industry requires the ability to manage complex post-approval change. The Design of Experiments is one such framework within which to capture, expand upon, and communicate knowledge.
- This class looks at DoE strategy and introduces more advanced techniques for both understanding variation and demonstrating that the commercial process is capable of producing quality product.

Who Should Attend:

Research & Process Development

Manufacturing & Technical Operations

Analytical Development

Regulatory Affairs

Quality Assurance / Quality Control

Specific Job Functions:

- Manager / Leader / Supervisor
- Researcher / Technician
- Strategists & Auditors

Learning Objectives:

At the completion of this course, participants will have the ability to:

- Select appropriate, cost effective designs.
- Efficiently identify and communicate cause and effect relationships.
- Demonstrate the five step method to design studies.
- Calculate main effects and multifactor interaction effects.
- Plot graphs for main effects and interaction effects.
- Test normallity at a glance, interpret, and communicate the results.
- Explain the pitfalls and opportunities of confounding effects.

Jason J. Orloff, *Chemical Engineer & Statistician, PharmStat*

Jason J. Orloff, a chemical engineering applied statistician, is principal statistical consultant at PharmStat. An international consultant, he specializes in applied statistics and experimental design for development, quality assurance, quality control, validation, and production under the cGXP's. Current activities include an author of ISPE's Baseline Guide for Q10 chapter "Process Performance and Product Quality Monitoring", contributing authorship of the PDA's Technical Report 59 on "Utilization of Statistical Methods for Production and Business Processes", and publications in the Journal of Pharmaceutical Technology. Jason brings twenty years of experience in pharmaceutical manufacturing, quality, and regulatory affairs. Areas of expertise include PAT, OOS, SQC, SPC, assay validation and setting specification criteria. A Chemical Engineer with real-life expertise at applying statistics in a highly regulated environment, Jason is able to work effectively across all levels of an organization as well as make high level concepts accessible to a variety of audiences. Jason has worked with a wide variety of companies including pharmaceuticals, parenterals, biotechnology, fine chemicals, medical devices, food, and nanotechnology. He holds a BS in Chemical Engineering from UW-Madison and an MS degree in Applied Statistics from DePaul University.

31 Jul 2017

Thursday, 28 September 2017	9:00 – 18:00
09:00	Welcome
	Instructor Lead discussion on DoE fundamentals from management's role to ensure that funds are spent most efficiently for the good of the corporation to the researcher's responsibility to deliver actionable outcomes within budget and on time.
10:30	Coffee Break
11:00	Examples of the prioritization of resources through risk assessment will be introduced using Japan's National Institute of Health Sciences, Sakura, and the PDA's iVAX case studies.
	The incremental change to traditional scientific methods will be explored in the Pharmaceutical context.
12:30	Lunch Break
13:30	Both a classical and a fractional factorial study will be designed by hand using "an intern's plastic syringe extrusion project" as a start point.
	Basic concepts using only addition, subtraction, and division
15:30	Coffee Break
	Basic concepts continued – no computers necessary.
18:00	End of Day 1

Bring a Calculator App!

Friday, 29 September 2017	9:00 – 16:30
09:00	The way you present the data influences how we think about the data: Analysis using Graphical Tools
10:30	Coffee Break
11:00	Numerical Analysis: "If you doubt it, count it." ~ Francis Galton
	Understanding & Presenting Results
12:30	Lunch Break
13:30	Pharmaceutical Case Studies from 30 years of Scientific Literature
15:00	Coffee Break
15:30	Case Studies continued (Placket Berman Designs for validation as time permits)
16:30	End of Course

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. Students 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

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.

Thursday, 28 Sep 2017 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, 29 Sep 2017 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 Inspector Selection and Qualification
- Vision Screening
- Initial Training
- Initial Qualification
- Requalification

12:30 Lunch Break

13:30 Inspection Strategies
- Reinspection
- 2-Stage Inspection
- Focused inspection
- Empty Vial Inspection

14:00 Inspection Validation
- Inspection performance Assessment
  - Knapp Method
- Acceptance Criteria

14:30 Coffee Break

15:00 Mythbusting
- Common misperceptions in visual inspection

15:30 Wrap-up Discussion / Q&A

16:30 End of Training Course

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.

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

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
- 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

Romain Veillon, *Senior Manager Visual Inspection & Leak testing, Global MSAT, GSK Vaccines*

Romain Veillon is Senior Manager Visual Inspection & Leak Testing at GSK Vaccines, in Global MSAT Manufacturing Technologies. Currently Romain focuses on Visual Inspection in a global function to support and advise GSK sites in the fields of Quality Integration Lead, Technology Development, Validation Strategy, Capability, Asset Management, Performance Improvement, and Develop Equipment strategy. Furthermore, he is managing a network of vision experts to develop visual Inspection expertise within GSK Vaccines. During the last 18 years he has worked in the area of parenteral manufacturing and has gained experience at Sanofi Pasteur, Eli Lilly and GSK Vaccines in different functions. Romain has developed innovative vision systems with some academic collaboration and is a frequent speaker at PDA conferences.

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.

Thursday, 28 Sep 2017 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

10:30 **Coffee Break**

11:00 **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

12:30 **Lunch Break**

13:30 **Theory 3: Considerations on Primary Containers and Product Properties**

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

14:30 **Exercise 1: Developing an URS Considering the Triangle Cost / Quality / Time**

15:30 **Coffee Break**

15:45 **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, 29 Sep 2017 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 **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

11:15 **Coffee Break**

11:45 **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

12:45 **Lunch Break**

13:45 **Exercise 2: Principle Basic Image Processing Using an Open Source Library**

14:45 **Coffee Break**

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

15:45 **Theory 8: Operation and Maintenance of Automated Inspection Systems**

16:15 **Q & A**

16:30 **End of Training Course**

Extractables & Leachables

Including: Important Regulatory Updates – Case Study Section: Selection of Toxikon's most interesting Case Studies, presented over the last 10 years!

Overview

When making Parenteral Drug Products, pharmaceutical companies are faced with the need to further investigate the materials that will be in contact with the drug product, either during manufacturing, intermediate storage, storage in its final packaging, or during the delivery of the drug to the patient. While historically, the potential safety issues were the main driver in these kinds of investigations, recently, also quality issues – i.e. for biopharmaceuticals – have become an additional concern. This workshop will look at "Extractables & Leachables" from many different angles: Definitions, Regulatory, Material & Polymer Science, Analytical E/L Methodologies, Safety Assessments, Study Design for different parenteral primary packaging systems, as well as for injection devices.

Learning Objectives

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

- Explain in detail the current regulatory requirements for container/closure qualification form an E/L perspective.
- Explain the upcoming changes in regulations, standards and recommendations from PQRI, USP and BPOG and how these changes could impact a future evaluation of a pharmaceutical C/C-system.
- Understand the materials of construction – and their composition – of container closure systems, and how they could impact the safety and quality of a parenteral drug product.
- Put together an evaluation program (review of provided documentation, analytical testing) of different types of parenteral drug product container/closure systems.
- Perform a safety/risk assessment of analytical results, obtained after completion of an E/L study.

Who Should Attend

- Pharmaceutical Packaging and Device Engineers
- Production Engineers, using SU systems
- Regulatory Affairs Officers
- Pharmaceutical R & D Managers
- Analytical Chemists, working on E/L
- Quality Assurance Officers

Dennis Jenke, *PhD, Chief Executive Scientist, Triad Scientific Solutions*

Dennis Jenke is the Chief Executive Scientist for Triad Scientific Solutions, a provider of science-based solutions to plastic/product compatibility challenges associated with packaging, manufacturing equipment and delivery devices in the pharmaceutical, cosmetic, food and related industries. He was a Distinguished Scientist at Baxter Healthcare Corporation where for more than three decades he lead a team whose primary responsibility includes the assessment of material/product compatibility, specifically with respect to establishing the suitability for use of packaging systems, manufacturing systems and administration devices for pharmaceutical products (for example, extractables/leachables and product ingredient binding). He has published extensively in the areas of analytical chemistry, environmental science and material/solution compatibility and serves as an expert reviewer for numerous pharmaceutical and analytical journals. He is the author of the book Compatibility of Pharmaceutical Solutions and Contact Materials; Safety Considerations Associated with Extractables and Leachables and a contributing author to the Leachables and Extractables Handbook. Dennis Jenke is a member of numerous industry groups whose charter is to establish best demonstrated practices in the area of material/solution compatibility.

Thursday, 28 September 2017 9:00 – 18:00

Introduction on Extractables & Leachables (E/L)

- What is the importance of a good E/L-qualification?
- Historical cases of leachables, impacting the quality or the safety of a drug product
- Regulatory requirements (FDA, EMA…) for primary packaging

Understanding the Materials, Used in the Manufacture of Pharmaceutical Containers & Closures

- Types of polymers – examples in medical/pharmaceutical use
- Understanding the composition of polymers
- The issues with glass in parenteral applications

Analytical Techniques to Perform Extractables & Leachables Research

- The importance of sample preparation: the corner stone in E/L research
- What are the target compounds for material research
- How does a classification of these compounds assist in finding the right analytical technique
- From basic "screening" methodologies to state-of-the-art equipment

How to Set-up Extractables & Leachables Studies

- Selecting the right conditions for extraction
- How to select the right compounds to monitor in a leachable study
- Designing a leachable study

FULL Session on Updates of E/L- Regulations, Standards and Recommendations

- Pharma Packaging:
  - Preview of the final PQRI Parenteral Drug Product (DPD) & ODP Chemistry group
  - Update on the most recent developments on the USP <661> chapters
- Devices
  - Chemical characterization of devices according to ISO 10993-18: What changes are coming up?
  - Upcoming Revisions of the USP <87> and USP <88>: Where could it go to?
- (Bio)Pharmaceutical Manufacturing
  - The BPOG protocol
  - Where is USP with the update on the USP <661.3> Plastic Manufacturing Components standard

How to Perform a Safety Evaluation – Risk Assessment on Extractables & Leachables

- Toxicology 101
- EMA Guideline on Genotoxic Impurities
- ICH M7 (DNA reactive Impurities) and its suggested staged approach
- The Threshold Concept of PQRI (OINDP and PDP/ODP)
- Examples

Piet Christiaens, *PhD, Scientific Director, Toxikon Europe*

Piet Christiaens received his Ph.D. from the Analytical Chemistry Department of the University of Leuven (Belgium) in 1991. From 1992 to 1997, he was Lab Manager in two Analytical Contract Laboratories. From 1997 to 2000, he worked as an independent consultant with Shell Chemical Company in Houston, Texas where he conducted research on a new hydrogenation catalyst system for Hydrogenated Triblock Co-Polymers (Kraton Polymers). Since 2001, Mr. Christiaens has been Scientific Director at Toxikon Europe where he develops analytical methods and protocols for both extractables and leachables studies for the Medical and Pharmaceutical Industries. Mr. Christiaens oversees all laboratory operations at Toxikon Europe and is also supports the European business development team.

Friday, 29 September 2017 9:00 – 16:30

E/L Testing for a Pre-filled Syringe (Glass & Polymer)

- Glass Syringes: the issues with tungsten, glue residues and silicone oil and glass metals leaching
- The Issue with rubbers: the plunger, the needle shield or the tip cap: different approaches needed?
- The impact of secondary packaging – option or necessity?
- Setting up extractable & leachable studies for a pre-filled Syringe

E/L Testing for Lyophilized Drug Products

- Primary packaging for the lyophilized drug product – modus of interaction with the DP
- Impact of the "21CFR Part 4" on combination products, used in the administration of a lyo DP
- Critical aspects when designing leachable studies for lyophilized DP
- Integration of the administration procedure (e.g. IV-set, pump system) in leachables evaluation

How to Look at Injection Devices from an E/L Perspective

- Medical device regulations versus pharma packaging
- Test selection process for devices: What to do?
- USP and ISO 10993 series for biocompatibility testing
- Case: Injection device

Large Volume Parenterals

- The challenge in E/L testing for LVP's
- Primary packaging for LVP's – critical materials and components
- Secondary packaging for LVP: critical points to consider

E/L Testing for Disposable and Single-Use Systems in Bioproduction

- How to classify the risk of different single-use systems in the bioproduction process?
- Understanding BPSA & BPOG recommendations, and how they can be implemented in the study design
- Performing E/L studies on filters: potential approaches

John Iannone, *Director of Extractables/Leachables and Impurities, Albany Molecular Research, Inc. (AMRI)*

John Iannone has a background in Biomedical Engineering from Boston University, where he later became a research engineer. Since going from Academia to Industry 13 years ago, John has assisted multiple pharmaceutical & medical device companies with the development of their product safety evaluation strategies. Previously a Technical Specialist at Toxikon, he now is the Director of Extractables/Leachables and Impurities at Albany Molecular Research, Inc (AMRI). His areas of expertise include Material Qualification & Biocompatibility, Extractables & Leachables, Chemical Characterization, and attainment of Biological or Toxicological risk assessments for medical devices, pharmaceutical container systems, bioprocessing systems, and combination products. John has given numerous technical presentations and has led several workshops on Extractable & Leachable Considerations, Biocompatibility, Microbiology, and Regulatory Testing Requirements. He also participates in the development of both industry groups' recommendations and regulatory guidelines through Expert Panel membership, global Technical Committees, and industry collaborations. Additional responsibilities have included providing technical consultation to clients regarding unique testing requirements in an effort for them to meet global regulatory expectations.

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21-22 November 2017

Roomers Design Hotel

Munich | Germany

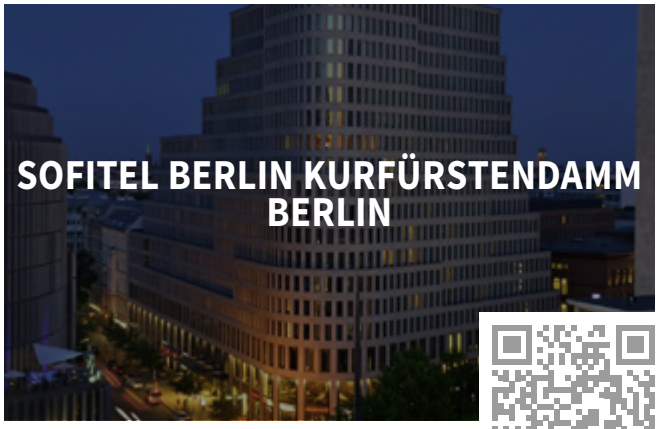
pda.org/EU-Outsourcing2017

VENUE

Sofitel Berlin Kurfürstendamm
Augsburger Strasse 41
10789 Berlin
Germany
Tel: +49 30 800 99 90
sofitel-berlin-kurfuerstendamm.com

Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

DIRECTIONS



© Google For directions click on the picture, scan the QR-code or go to **https://goo.gl/maps/NTaDPM4fvKu**

ORGANIZER

PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin, Germany
Tel: +49 30 436 55 08-0
Fax: +49 30 436 55 08-66

TO EXHIBIT:

Exhibition and Sponsorship Opportunities are available. PDA meetings and conferences are a great opportunity for your company to gain on-site exposure in front of highly-qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Exhibit at PDA events and let your company's products or services become a valuable tool or resource for our attendees.

SPECIAL REQUIREMENTS

If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to registration-europe@pda.org.

CONTACT INFORMATION

Conference Inquiries
Melanie Decker
Director Events & Exhibitions
decker@pda.org

Conference Program Inquiries
Sylvia Becker
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Registration Customer Care
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Education Program Inquiries
Elke von Laufenberg
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Exhibition / Sponsorship Inquiries
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Nadjeschda Gomez-Stahl
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Lufthansa Austrian brussels airlines
Eurowings SWISS

Special offer: Discounted travel with Lufthansa Group Airlines

Lufthansa Group Partner Airlines offer a comprehensive global route network linking major cities around the world. We offer special prices and conditions to participants, visitors, exhibitors, invited guests as well as employees of the Contracting partner and their travel companions. To make a reservation, please click on **www.lh.com/event-flight-booking** and enter the access code **DEZJPAJ** in the "Access to Your Special Lufthansa Offer" area. This will open an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

NOTE: Pop-ups must be enabled otherwise the booking platform window will not open.

These promotional fares are also available through your IATA / ARC travel agent. Travel agents can obtain ticketing instructions by sending an email to **lufthansa.mobility@dlh.de** and providing the access code as a reference.


SOFITEL

PDA Europe Conference Registration

Registration Form
Page 1

26–27 September 2017 | Berlin | Germany

Your registration is only complete upon filling in and submitting both pages of this form.

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

1 Registration

EARLY BIRD DISCOUNT ☐ Book by 30 July 2017 to receive € 150* off the conference fee only

All fees given in Euro, excluding VAT (7 %)

26–27 September	Conferences only	Conferences Fee	
☐ **Particles in Injectables**		PDA Member	☐ **1495**
☐ **10th Workshop on Monoclonal Antibodies**		**Nonmember	☐ **1795**
As part of the PDA Exchange meeting format, you can attend the two meetings with just one ticket		*** Early Bird 670 €** **Regulatory/Academic	☐ **750**

☐ **Poster Presenter please mark here** (written approval required, conference fee applies)

25 September **Particle Identification in Parenterals**	**One-Day Training Course**	**Training Course Fee** All Participants	☐ **845**
28 September **Tailor-Made Strategies for High Level Expression of Biologicals**	**One-Day Training Course**	**Training Course Fee** All Participants	☐ **845**
28 September **Testmethoden für vorbefüllte Spritzen – Course in German**	**One-Day Training Course**	**Training Course Fee** All Participants	☐ **845**
28–29 September 2017 **Best Compliance Practices im GMP Prüflabor – Course in German**	**Two-Day Training Course**	**Training Course Fee** All Participants	☐ **1495**
28–29 September 2017 **CMC Regulatory Compliance for Biopharmaceuticals**	**Two-Day Training Course**	**Training Course Fee** All Participants	☐ **1495**
28–29 September 2017 **Extractables and Leachables**	**Two-Day Training Course**	**Training Course Fee** All Participants	☐ **1495**
28–29 September 2017 **DoE Basics for Validation by Design**	**Two-Day Training Course**	**Training Course Fee** All Participants	☐ **1495**
28–29 September 2017 **An Introduction to Visual Inspection: A hands-on course**	**Two-Day Training Course**	**Training Course Fee** All Participants	☐ **1495**
28–29 September 2017 **Mastering Automated Visual Inspection**	**Two-Day Training Course**	**Training Course Fee** All Participants	☐ **1495**

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given. The fee does not include the hotel accommodation. PDA Europe has secured a limited number of rooms at a special group rate.

****Registration fee includes a one-year PDA membership** if no further special discount is granted. If you do not wish to join PDA and receive the benefits of membership, please check here (same rate applies). ☐

Group Registration Discount Register 5 colleagues for the conference at the same time and receive the **5th registration free.** For more information on group discounts please contact Antje Petzholdt at registration-europe@pda.org. Other discounts cannot be applied.

☐ Discount for Exhibiting Companies

Please mark here if your company is an exhibitor to this event and you will receive the conference ticket at the **special price of 995 Euro per ticket.** No further discounts are applicable with this option (as PDA Membership Discount or Group Ticket discount).

PDA Europe Conference Registration

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

26–27 September 2017 | Berlin | Germany

3 WAYS TO REGISTER

1. **ONLINE: pda.org/eu/particles2017**
2. **FAX: +49 30 436 55 08-66**
3. **EMAIL: registration-europe@pda.org**

1 Your Contact Information

If this form is an update to a previously submitted form, please check here. ☐

☐ Mr. ☐ Ms. ☐ Dr. ☐ Nonmember ☐ **I want to become a PDA Member.** Please send me a subsription form

☐ PDA Member ID Number

Name (Last, First, MI) *

Job Title *

Company* Department

Mailing Address

City Postal Code

Country Email *

Business Phone Fax

☐ Substituting for

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

2 Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

3 Payment Options

☐ **By Bank Transfer**

Beneficiary: PDA Europe gGmbH
IBAN: DE73 1007 0024 0922 8735 00
BIC (SWIFT-Code): DEUTDEDBBER
Bank Address:
Deutsche Bank, Welfenallee 3-7,
D-13465 Berlin, Germany

☐ **By Credit Card**

☐ American Express ☐ MasterCard ☐ VISA

For your credit card information safety:
Please send your details by fax only.

☐ **Purchase Order**

Purchase Order Number

Billing Address: ☐ Same as contact information address above.
If not, please send your billing address to: registration-europe@pda.org

Your Company VAT I.D.:

This number starts by your country code with two characters
(example: PDA Europe's country code starts with: DE | followed by the number)

PDA Europe VAT I.D.: DE254459362

Your registration is only complete upon filling in and submitting both pages of this form.

Date Mandatory Signature

CONFIRMATION: Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** A letter of confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **26 August 2017,** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at **info-europe@pda.org or fax to +49 30 4365508-66. DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.

2017 PDA EUROPE CONFERENCES

19 – 20 September	Pharmaceutical Freeze Drying Technology	* Cologne, Germany
26 – 27 September	Particles in Injectables	* Berlin, Germany
26 – 27 September	10th Workshop on Monoclonal Antibodies	* Berlin, Germany
10 – 11 October	Pharmaceutical Cold & Supply Chain Logistics	* Prague, Czech Republic
7– 8 November	The Universe of Pre-filled Syringes and Injection Devices	* Vienna, Austria
21 – 22 November	Outsourcing & Contract Manufacturing	* Munich, Germany

Subject to change | For latest info: **pda.org/pda-europe** | Shortlist 31 Jul 2017

*** Events with additional Education Program. More information – http://t1p.de/7p9z**

General Information
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PDA® Parenteral Drug Association

Connecting People, Science and Regulation ®

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