MedPharmPlast Europe & Toxikon Joint Event

28-29 June 2017 - Leuven

PROGRAMME

28 June - Toxikon Workshop on Material Characterisation

10:00 - 10:30	Registration & Welcome Coffee
10:30 - 10:45	**Welcome by MedPharmPlast Europe & Toxikon**
10.45 - 11:15	**Compendial [EP/USP]: what's new & changing?** *- Frank De Smedt, Toxikon*
11:15 - 11:45	**What's the additional information from an extractables study vs a compendial study?** *- Piet Christiaens, Toxikon*
11:45 - 12:15	**A view from a Notified Body on Medical Device Regulations (chemical characterization)** *- Françoise Schlemmer, The European Association for Medical Devices of Notified Bodies*
12:15 - 13:15	Networking Lunch
13:15 - 13:45	**Incorporation of compendial and extractables testing in the strategy of a raw material supplier** *- James Stern, Application Marketing Manager - Healthcare, Borealis*
13:45 - 14:15	**A case study from routine Compendial / Extractables testing** *- Nolwenn Stephan, Nemera*
14:15 - 15:00	**Chemical characterization of medical devices: what's important and will be important?** *- Sophie Michel, Toxikon*
15:00 - 15:30	**Selection of materials and biocompatibility studies from the perspective of a starting medical device company** *- Vanessa Vankerckhoven & Koen Beyers, Novasanis*
15:30 - 16:00	**Development of the definition of Medical Grade** *- Mike Freudenstein, Director Marketing Healthcare, ALBIS*
16:00 - 17:00	**Company visit & lab tour**
17:00	Networking Drinks

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29 June - MedPharmPlast Europe Conference 2017

09:00 - 10:00	Registration & Welcome Coffee
10:00 - 10:15	**Welcome** - *Christian Meusinger, MPPE President*
10:15 - 10:45	**Change Control: can you meet regulations if you don't manage material changes?** *- James Stern, Healthcare Application Marketing Manager, Borealis* *- Steve Duckworth, Head of Global Segment Medical & Pharmaceutical BU Masterbatches, Clariant*
10:45 - 11:15	**Applying Pharmacopeia and Chemical Characterization Testing on Medical Tubings** *- Frank De Smedt, Department Head Analytical Services, Toxikon Europe*
11:15 - 11:45	**The use of Hazardous Phthalates in Medical Devices: a Report for the European Commission** *- Patrick de Kort, Regulatory Compliance Analyst, Polymer Comply Europe*
11:45 - 12:45	Networking Lunch
12:45 - 13:30	**Update on the implementation of the Medical Device Regulation** *- Gavia Taan, Medicines and Healthcare Products Regulatory Agency (MHRA)*
13:30 - 14:00	**Risk to supply chain - threat from counterfeit** *- Steve Duckworth, Head of Global Segment Healthcare Polymer Solutions, Clariant*
14 :00 - 14 :30	Networking Coffee
14:30 - 15:00	**RecoMed – Recycling single use medical devices from hospitals** *- Jane Gardner, Principal Consultant, Axion Consulting*
15:00 - 15:30	**Developments in the Materials Section in the European Pharmacopoeia** *- Hugo Peeters, Office of the German Pharmacopoeia Commissions - Pharmacopoeia Unit - Federal Institute for Drugs and Medical Devices*
	Closing

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SPEAKERS' BIOGRAPHIES

28 June - Toxikon Workshop on Material Characterisation

Frank De Smedt – Department Head Analytical Services, Toxikon Europe

Frank obtained a PhD in Chemistry from the University of Leuven before joining Toxikon Europe NV in 2007 as a Study Director for method validations in extractable and leachable studies.
In 2009, Frank became Head of the Analytical Departments of Toxikon. In this role, he's responsible for all analytical methods, including method development and validation, used in extractable and leachable projects. Compendial work on materials, Toxikon's R&D and Medical Device Characterization, is also performed in the Analytical Department.

Piet Christiaens – Scientific Director, Toxikon Europe

Piet received his PhD from the Analytical Chemistry Department of the University of Leuven (Belgium) in 1991. From 1992 to 1997, he was Lab Manager in two CRO's. From 1997 to 2000, he worked as an independent consultant with Shell Chemical Company in Houston, TX (US) working on hydrogenated triblock co-polymers. Since 2001, Piet holds the position of Scientific Director at Toxikon Europe where he develops analytical methods and protocols for both extractable and leachable studies for the pharmaceutical and medical industries. Piet oversees all laboratory operations at Toxikon and is also giving support to the business development.

James Stern – Healthcare Application Marketing Manager, Borealis

After an academic career in synthetic bio-organometallic chemistry, James joined Shell's polypropylene company Montell in 1999. Through successor companies, he held technical, commercial and business development roles in both Europe and the US. Since 2008, his specialist area has been the global healthcare business.
In 2012, James joined Borealis as Healthcare Application Marketing Manager with a core activity to engage with key industry decision makers in order to further develop the support and portfolio Borealis provides to the Healthcare industry.

Nolwenn Stephan – Material Expert, Nemera

Nolwenn joined Nemera – previously Rexam Healthcare – in 2011 as Material Expert.
After an Ingénieur Master degree in polymer science at the ECPM from Strasbourg, she spent 10 years within the R&D center of Millipore for Process Monitoring Tools before joining Nemera.
Nolwenn supports Nemera development teams in selecting best-in-class materials for their drug delivery devices. In the strongly regulated environment of the pharmaceutical industry, materials criteria and associated tests have evolved to guarantee patient safety. Nolwenn makes sure that such criteria are fulfilled for the Nemera material portfolio.

Françoise Schlemmer – Director, Team-NB (European Association for Medical Devices of Notified Bodies)

Biochemist from the University of Liège, Françoise worked for medical devices manufacturers as well as a Notified Body, and created the consulting office Quasys Consult. Quasys Consult mainly offers services to medical devices manufacturers to obtain CE marking (+ FDA), to maintain their certifications and realise tasks in subcontracting.
She is Director of TEAM-NB since its founding in 2001. At present, the association has 21 members. These 21 Notified Bodies active in the medical devices sector emit more than 80% of certificates worldwide. In this context, Françoise represents the association among others by attending meetings (e.g. Medical Devices Expert Group, NB-Med, working groups, etc.). She is the contact person to communicate with all the stakeholders (EC, CAs, press and user groups). She also conducts talks on drafts of new European regulations.

Sophie Michel – Toxikon Europe

Sophie got her PhD in Biomedical Engineering at Maastricht University in 2014. Thanks to her experience in chemistry and biocompatibility evaluation, she integrated in 2015 the team of Study Directors in Toxikon Europe, where she soon specialized in the biological evaluation of Medical Devices through classical biocompatibility tests, chemical characterization and toxicological assessment.

Vanessa Vankerckhoven – CEO, Novasanis

Vanessa is CEO and co-founder of Novosanis, a medical device company and spin-off from the University of Antwerp, Belgium. She is a passionate entrepreneur and is in charge of Sales & Business Development next to medical development of Novosanis' devices. She holds a PhD in Medical Sciences and has a profound interest in medical devices, infectious diseases, diagnostics, microbiology and vaccinology.

Koen Beyers – Chief Technology Officer, Novasanis

Koen is appointed Chief Technology Officer (CTO) at Novosanis. He obtained a Master degree in Industrial Design and Product Development at Artesis University College and is an expert in product innovation, engineering, design optimization and rapid prototyping. Koen is member of the board, and leading the R&D team. In his CTO position, he is managing new product development & design evolutions, material selection, regulatory affairs, design validation and manufacturing.
Koen is also founder and Managing Director of Voxdale, a design & engineering agency, and is working for clients in processing and automotive industries as well as in medical and aerospace sectors.
Koen started his career in 1998 at the R&D department of Barco (visualization technologies for space, aerospace and medical appliances) as mechanical design engineer. From 2001 on, he was technology manager and responsible for new product architectures and technology integration.
Koen successfully managed dozens of technical and scientific projects and is co-inventor on a number of patent applications.

Mike Freudenstein – Director Marketing Healthcare, ALBIS

Starting from 1991, Mike worked in various management positions in BASF, Elenac and LyondellBasell. Here he gained experience mainly in marketing and sales of polymers. Since long healthcare applications are the key area of his activities. Since 2012, Mike is heading the dedicated Marketing Healthcare and Business Development team at ALBIS PLASTIC GMBH Hamburg as Director Marketing Healthcare.

29 June - MedPharmPlast Europe Conference 2017

Christian Meusinger – MedPharmPlast Europe President

Christian is Vice President Quality & Regulatory at Nemera. Coming with an industrial engineering background in several functions, he has now more than 15 years of experience in quality within a plastics converting company, always focused on pharmaceutical primary packaging and medical devices.
Since autumn 2014, Christian is also the new President of MedPharmPlast Europe.

James Stern – Healthcare Application Marketing Manager, Borealis

After an academic career in synthetic bio-organometallic chemistry, James joined Shell's polypropylene company Montell in 1999. Through successor companies, he held technical, commercial and business development roles in both Europe and the US. Since 2008, his specialist area has been the global healthcare business. In 2012, James joined Borealis as Healthcare Application Marketing Manager with a core activity to engage with key industry decision makers in order to further develop the support and portfolio Borealis provides to the Healthcare industry.

Steve Duckworth – Head of Global Segment, Medical and Pharmaceutical - Clariant International, Business Unit Masterbatches

Steve is a graduate in Applied Chemistry with over 30 years spent in the polymers and compounding industries in R&D, marketing and operations functions in USA, Europe and Asia, with leading international companies such as Raychem, General Electric, DSM, PolyOne and working as an independent consultant for market analysis, M&A, and Asia entry strategies. He joined Clariant in 2007. Clariant is a leading provider of plastics colors and functional additives that modify the look and performance of polymers across multiple industries.
Steve initiated and led a global project to address the medical, pharmaceutical and healthcare sector that radically changed how Clariant approaches this market. Since January 2011, he is the head of a newly-formed segment for medical devices and pharmaceutical packaging, and leads a team of dedicated specialists based in USA, Europe and Asia. The team initiates and manages developments with pharmaceutical and medical devices and their supply chain in areas such as drug delivery devices, IVD, and invasive devices such as catheters, focused around an approach of 'minimization and management of risk of changes'.

Frank De Smedt – Department Head Analytical Services, Toxikon Europe

Frank obtained a PhD in Chemistry from the University of Leuven before joining Toxikon Europe NV in 2007 as a Study Director for method validations in Extractable and Leachable studies.
In 2009, Frank became Head of the Analytical Departments of Toxikon. In this role, he's responsible for all analytical methods, including method development and validation, used in Extractable and Leachable projects. Compendial work on materials, Toxikon's R&D and Medical Device Characterization, is also performed in the Analytical Department.

Patrick de Kort – Regulatory Affairs, Polymer Comply Europe (PCE)

Patrick has a Bachelor in Biomedical Sciences, performed an internship at the European Parliament, and joined EuPC's Regulatory Compliance Department nearly two years ago. In this time he has been involved in the Plastics Exposure Scenario Team, assigned the co-chair of the MedPharmPlast Europe Regulatory Taskforce, and worked on several substance specific issues including TiO2.

Gavia Taan – Medicines and Healthcare Products Regulatory Agency (MHRA)

Gavia joined the UK's Civil Service in 2014 to advise Ministers on Government commercial contracts. She has since joined the MHRA (Medicines and Healthcare products Regulatory Agency) as a programme manager, currently focused on preparing the UK Government and its stakeholders for the implementation of the new EU Medical Device Regulation and the In Vitro Diagnostic Medical Device Regulation. As part of this work, she has also been involved in the European CAMD (Competent Authority for Medical Devices) Implementation task force, who has been tasked with exploring opportunities for system collaboration.

Jane Gardner – Principal Consultant, Axion Consulting

Jane joined resource recovery specialists Axion in 2005 and since then has developed expertise in setting up and running successful industry led collection and recycling trials and schemes covering a broad range of materials including textiles, medical waste and plastics. Axion is also the UK agent for Recovinyl and Jane has been part of the team responsible for setting up the scheme in the UK since its inception.
In her role as Principal Consultant, Jane is currently working in collaboration with the British Plastics Federation to set up RecoMed, a recycling scheme for single use medical items from hospitals in the UK funded by Vinyl Plus.

Hugo Peeters – Office of the German Pharmacopoeia Commissions

Hugo Peeters studied Chemistry at the Technical University of Berlin where he earned a PhD for his work on the biosynthesis of peptide antibiotics. Following a two-year stint as visiting scientist at the Boyce Thompson Institute at Cornell University in New York, he was the Head of the analytical laboratory responsible for QC and QA at a mid-sized pharmaceutical company in Germany. After serving as an assessor of quality at BfArM in Bonn he became the Secretary of the German Pharmacopoeia Commissions.