MedPharmPlast Europe

The Expert in Plastic Medical Devices and Pharmaceutical Packaging in Europe

MedPharmPlast
A sector group of EuPC

www.medpharmplasteurope.org

MedPharmPlast Europe Conference

23 June 2015

Clariant Innovation Centre Frankfurt

Industriepark Höchst: Gebäude G 860
August-Laubenheimer-Strasse, 65926 Frankfurt am Main, Germany

09.00 - 10.00	*Registration & Welcome Coffee*

1. SESSION

10.00 - 10.10	**Welcome** Christian Meusinger, President of MedPharmPlast Europe - Nemera
10.10 - 10.40	**Update on MedPharmPlast Regulatory Task Force Activities & Goals** Paul Davidson, Chairman MedPharmPlast Europe Regulatory Task Force - Sabic
10.40 - 11.00	**The EU Institutions & how MedPharmPlast Europe can influence decision-making** Padraig Nolan, Regulatory Affairs Manager - European Plastics Converters (EuPC)
11.00 - 11.30	**An Update on EU Medical Devices Legislation and its implications for the industry** Nigel Talboys, Director Public Policy and Government Affairs EMEA - Terumo BCT
11.30 - 12.00	**Panel debate** Moderator: Steve Duckworth
12.00 - 13.00	*Lunch & Networking*

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2. SESSION

13.00 - 13.15	**Nanomaterials: definition, measurement & regulatory framework** Georges Favre, R&D Programme Manager - Laboratoire national de métrologie et d'essais (LNE)
13.15 - 13.30	**Endocrine Disruptors: definitions & regulatory thresholds** Oliver Okle, Sales & Marketing Manager - hjs consulting
13.30 - 13.45	**Extractables & Leachables and Risk Management for Pharmaceutical Packaging** Steve Duckworth, Head of Global Segment Medical & Pharmaceutical BU Masterbatches - Clariant
13.45 - 14.00	**Analytical Studies for the Pharma and Medical Device Industry** Lise Vanderkelen, Study Director - Toxikon Europe NV Belgium
14.00 - 14.30	**Panel debate** Moderator: Paul Davidson
14.30 - 15.00	*Coffee Break & Networking*

3. SESSION

15.00 - 15.25	**Unannounced Audits: status, implication, impact & management** Michael Bothe, representing TEAM-NB, Association of European Notified Bodies Medical, former Chair of NBRG, WG Leader of the Consensus Document „Testing during unannounced Audits" and Head of Medical, Laboratory and Automation at VDE Testing & Certification Institute
15.25 - 15.55	**Q&A Round** Moderator: Christian Meusinger
15.55 - 16.00	*Closing Remarks*

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Speakers' biographies

Christian Meusinger

President of MedPharmPlast Europe - Nemera

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.

Paul Davidson

Chairman MedPharmPlast Europe Regulatory Task Force - Sabic

Paul studied Materials Science and Technology at Brunel University before completing a PhD at Loughborough University in the field of PET processing. Paul then held a number of posts in Albright and Wilson developing flame retardant compounds before moving to Uniroyal Chemical (now part of Chemtura) as European Technical Manager for plastics additives.

In 2001 Paul joined WRAP (Waste and Resources Action Programme) where he spent 10 years managing national plastics recycling technology and infrastructure development initiatives primarily for the UK Government. During this time Paul was also seconded to UK Government to provide advice on UK plastics strategy and policy.

In 2012 Paul joined SABIC and is now their Senior Business Development Manager Regulatory with a particular interest in European healthcare regulations.

Padraig Nolan

Regulatory Affairs Manager - European Plastics Converters (EuPC)

Padraig is Regulatory Affairs Manager at EuPC since 2010. His main duties at EuPC involve advocacy with the EU institutions and defending the interests of the EU plastics converting industry in EU legislation. Since January 2014 Padraig has also been advising Polymer Comply Europe customers on EU Trade Defense Instruments (e.g. anti-dumping/anti-subsidy complaints and their review), regulatory developments in Brussels and association management.

In the past, Padraig has lobbied the EU institutions on legislative dossiers such as the Green Paper on Plastics Waste, the Circular Economy proposal, various packaging issues and is now working on medical devices and the latest EU legislation affecting the medical devices industry.

Padraig holds a bachelor's degree in law and economics from the National University of Ireland, Galway and a Master's degree in European law from Utrecht University in the Netherlands.

Nigel Talboys

Director Public Policy and Government Affairs EMEA - Terumo BCT

Nigel has global responsibility for Government Affairs and Public Policy for Terumo BCT. He has a wide experience in the Medical Technology field and has worked for a number of multinational companies in a variety of business functions. These companies include Becton Dickinson and C.R. Bard.

During his time in Becton Dickinson, he was involved in the development of new techniques used in regional anesthesia, particularly in creating a market for Combined Spinal and Epidural Anesthesia. In C.R. Bard he developed a new business model in Europe used to treat prostate cancer with brachytherapy.

He has also been involved in several acquisitions and integration projects.

He is Vice Chairperson of the Public Affairs Network, representing industry at the European Trade Association (EUCOMED) and on the steering committee in dialogue with the European Patients Forum (EPF).

A British national, Nigel has spent the last 20 years working outside his home country in France, Germany and now Belgium. He studied Human Biology at Loughborough University in England and attended an Executive Business Program at Harvard University.

Georges Favre

R&D Programme Manager - LNE

Georges is responsible of research planning in the fields of nanosciences and metrology in chemistry at LNE (Laboratoire national de métrologie et d'essais) since 2011. In addition to its commercial activities regarding testing and calibration services, LNE is also the French National Metrology Institute. LNE has on this basis the responsibility to develop the French references (methods, standards, etc.) for all kinds of measurements in order to improve the reliability of data and therefore help public authorities and French industry in the decision-making process.

Within LNE, Georges is in particular involved in the identification of the needs and the dissemination of the scientific outputs on the topic of nanomaterials characterisation. He is also strongly involved in the nanoMetrology Club, a French network created in 2011 and coordinated by LNE, the aim of which is to gather people from public authorities, academia and industry in order to find solutions to nanometrology issues, in particular through R&D projects or the organisation of workshops.

After a PhD in the field of Analytical Chemistry at CEA (French Alternative Energies and Atomic Energy Commission, a French government-funded technological research organisation), Georges had intervened with French SMEs as a consultant to develop advanced materials (fire or corrosion-resistant materials, etc.).

Oliver Okle

Sales & Marketing Manager - hjs consulting

Oliver studied Biological Science at the University of Konstanz, Germany. In his diploma thesis he investigated specific microbiological interactions of a fungus and cyanobacteria. He received his diploma degree in 2009.

After a 6 months internship in a toxicological service laboratory he started his PhD thesis in the Human and Environmental Toxicology Group at the University of Konstanz, Germany. He focused on a neurotoxicological question, in detail on mechanisms underlying the neurotoxic effect of a cyanobacteria-produced toxin. This toxin is supposed to induce Amyotrophic Lateral Sclerosis (ALS). He received his PhD in 2013 and published his work as well as the results of various collaboration projects with industrial partners and research groups in well-known scientific journals.

Currently, Oliver is employed as Sales and Marketing Manager at hjs consulting. He is responsible for scientific customer support (B2C as well as B2B) and for sales and marketing activities concerning products used for research and registration. He also manages the product launch of a new diagnostic tool in the DACH region.

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'.

Lise Vanderkelen

Study Director - Toxikon Europe NV Belgium

Lise received her Ph.D. from the Faculty of Bioscience Engineering at the University of Leuven (Belgium) in 2012. She worked as a postdoctoral fellow at the Universities of Leuven (Bioscience Engineering) and Amsterdam, conducting research in the field of food technology and analytics (structural and functional analysis of bacterial lysozymes inhibitors).

She started at Toxikon Europe in 2013 as study director at the E&L Department, focusing on Injectables and Parenterals.

Today she is leading the group of chemical characterization testing for the medical device industry.

Michael Bothe

Head of Medical, Laboratory and Automation at VDE Testing & Certification Institute, representing TEAM-NB, Association of European Notified Bodies Medical

Michael started his career as R&D Engineer at Group (NBRG) Blaupunktwerke Hildesheim, Germany. Afterwards he worked among others as R&D Manager at Friemann & Wolf Gerätebau, as Managing Director at Rehfeld Magnetics GmbH & Co. KG and as Global Research Director at CEAG AG/FRIWO Group. In 2006 he took over the position as Technical Managing Director at the VDE Testing and Certification Institute in Offenbach, where he later worked as Staff Officer Medical Processes / Systems. Today he is Category Manager Medical, Laboratory and Automation, Deputy Manager of Notified Body Medical as well as the Chairman of the Notified Bodies Recommendation Group (NBRG).

Michael has an Engineering Degree in Telecommunications from the TU Braunschweig, Germany, and an Executive MBA from Henley Management College, U.K.

About MedPharmPlast Europe

MedPharmPlast Europe is a sector group of EuPC created in 2014 by and for companies involved in the whole supply chain of plastic medical devices and pharmaceutical packaging in Europe.

MedPharmPlast Europe assists companies in these industry sectors by keeping them informed about the latest developments in European regulations and their impact on the medical device and pharmaceutical packaging plastics value chain.

As an expert group with other trade bodies, MedPharmPlast Europe furthermore represents the interests of the industry to the European legislators and tries to arrive at regulations that are both workable and protect the patient.

Contact

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