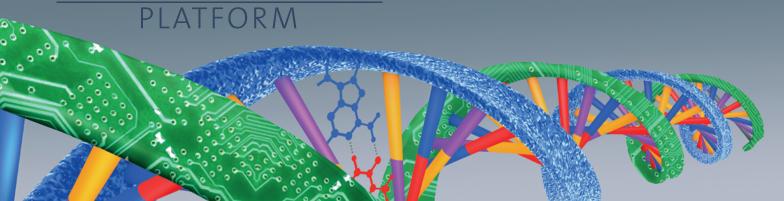
MEDTECH E PHARMA



Innovation at the Interface

October, 30 - 31 2014

Swissôtel Oerlikon Zurich CH-8050 Zurich

Information and registration: www.medtechandpharma.com

medical cluster ^l



Two Industries - One Market

Historically, there has been a clear dividing line between companies of the Medtech and Pharma industries. However, recent years have seen a trend towards the combined development of drugs, devices and *in vitro* diagnostics (IVDs) that encompass characteristics of both drugs and devices/IVDs. Accordingly, significant technological developments have already found their way into medical practice and are still warranted to meet further medical needs. In addition, forthcoming revisions of legislation are going to influence the development and evaluation of innovative devices, IVDs and combination products.

The conference

Be part of the first International Medtech & Pharma Platform entitled "Innovation at the Interface", that brings together professionals from the Medtech and Pharma industry as well as regulators. Benefit from interdisciplinary discussions of technological, regulatory and market access aspects that aim to facilitate:

- Joining forces and sharing experiences in the development of innovative health care products
- Bridging gaps in the understanding of interdependencies between drug, device, IVD components and combination products
- Accessing new technologies in drug delivery
- Minimising risk to investments
- Understanding regulatory affairs and market access aspects affecting the development of innovative products

Session Topics

- Innovations and trends in developing new solutions for medical needs
- Technological developments for combination products
- Approval and conduct of clinical studies
- Regulatory frameworks applying at the interface of drugs, devices and IVDs
- Intellectual property from the perspective of increasing transparency requirements
- Market access and pricing

Tabletop Exhibition

Showcase your company's products and services to professionals from Industry & Government attending the "Medtech & Pharma Platform". The tabletop exhibition will take place during the conference (exhibitor fee CHF 1'800 excl. VAT). Exhibitors have the opportunity to give a one minute talk after the first session.

To register, please go to:

www.medtechandpharma.com/index.php/registration

Program Committee Members

Benjamin Reinmann (Ypsomed), Manfred Mäder (Novartis), Thomas Fischer (Novartis), Laurent Wagnière (Ferring), Gregoire Bagnoud (MPS), Urban Schnell (Helbling Technik)

Point of Contact

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Innovation at the Interface

Meeting program Thursday, 30th October 2014

09:00 - 10:00	Registration & Welcome Coffee
10:00 - 10:15	Welcome Introduction from Conference Organisers
	Shayesteh Fürst-Ladani & Peter Biedermann
	Session 1 - Innovations and trends in developing new solutions for medical needs Chair: Manfred Mäder, Head GCA, Devices & Combination Products, Novartis, Switzerland
	Chair: Mainred Madel, Flead GCA, Devices & Combination Floudets, Novartis, Switzerland
10:15 - 10:45	Adapting the R&D operating model to support innovation in developing drug device combination
	products
	Anke Liewald, Head Operations & Project Management, Sanofi Aventis, Germany
10:45 - 11:15	Personalized medicine: Challenges and potential solutions
	Tim Kievits, Chair of Personalised Medicine Group, EuropaBio, Belgium
11:15- 11:45	Bridging Gaps between Medtech and Pharma for the development of drug delivery systems
	James Godfrey, Device Technology Manager, GlaxoSmithKline, United Kingdom
11:45 - 12:15	Flash presentations exhibitors
12:15 - 13:30	Lunch & Exhibition
	Session 2 - Technological developments for combination products
	Chair: Urban Schnell, Senior VP, Partner, Helbling Technik, Switzerland
13:30 - 14:00	Challenges in the development of drug-device combination products in a Pharma company
14.00 14.20	Mark Chipperfield, Head of Device Development, F. Hoffmann-La Roche Ltd., Switzerland
14:00 - 14:30	Combination products: Sustainable business opportunity for medtech? Felix Baader, VP Technology, Biotronik AG, Switzerland
14:30 - 15:00	Innovation in Spray and Aerosol drug delivery technologies: Packaging systems or constituents of
14.50	combination products - A Marketing perspective
	Pierre Carlotti, VP Marketing & Communication, Aptar Pharma, France
15:00 - 15:30	Coffee Break & Exhibition
	Session 3 - Approval and conduct of clinical studies
	Chair: Theresa Jeary, Technical Manager, LRQA, United Kingdom
15:30 - 16:00	The Clinical Trials Regulation from an Industry perspective
	Thomas Kühler, VP Regulatory Policies & Intelligence, Novo Nordisk, Denmark
16:00 - 16:30	Notified Body Expectations on clinical trials for combination products
	Theresa Jeary, Technical Manager, LRQA, United Kingdom
16:30 - 17:00	Overview of pros and cons performing clinical studies with devices for regenerative medicine in
	the US and Europe Kenneth Kleinhenz, VP Global Regulatory Affairs, Cytori Therapeutics, United States
17:00 - 10:00	
17:00 - 19:00	Apero & Exhibition
19.00 -22:00	Networking Dinner



Innovation at the Interface

Meeting program Friday, 31st October 2014

08:00 - 09:00	Registration & Welcome Coffee
	Session 4 - Regulatory frameworks applying at the interface of drugs, devices and IVDs Chair: Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs & Scientific Com., Switzerland
09:00 - 09:30	Overview of the European legislation impacting Pharma and Medtech companies Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs & Scientific Communication, Switzerland
09:30 - 10:00	Case Study: How to differentiate a biosimilar medicine by using an innovative injection device Richard Peck, Executive VP, Director Regulatory Affairs, Finox Biotech, Switzerland
10:00 - 10:30	The conformity assessment Requirements under the proposed IVD regulation for companion diagnostics Nick Baker, Technical Manager-IVD, LRQA, United Kingdom
10:30 - 11:00	Coffee Break & Exhibition Session 5 - Intellectual property in perspective of increasing transparency requirements Chair: Alexander Natz, Secretary General, Eucope, Belgium
11:00 - 11:30	Pharmaceutical perspective, EMA transparency policy & new clinical trial transparency Alexander Natz, Secretary General, Eucope, Belgium
11:30 - 12:00	Transparency and confidentiality under the current MDD and the draft EU Medical Devices Regulations Erik Vollebregt, Lawyer, Axon Lawyers, the Netherlands
12:00 - 12:15	Questions & Answers
12:15 - 13:30	Lunch & Exhibition
	Session 6 - Market access and pricing Chair: Ian Thompson, VP Business Development, Ypsomed, Switzerland
13:30 - 14:00	Who evaluates the price of an NCE in a new device, and what is the outcome? Andreas Wildi, Attorney at Law, Counsel, meyerlustenberger - lachenal, Switzerland
14:00 - 14:30	Market access and reimbursement challenges for molecular profiling test Andreas Voss, VP Clinical Affairs, Caris LifeScience, Switzerland
14:30 - 15:00	Market access in the 21st century: What can we learn from recent successes and failures? Stefan Walzer, General Manager, MArS Market Access & Pricing Strategy, Germany
15:30	End of Conference

MEDTECH & PHARMA PLATFORM

Innovation at the Interface

Registration Fees

Members of Medical Cluster & Partners, CHF 750.-*
Standard Rate, CHF 850.- *
Government/Academia, CHF 350.-*
One Day Rate, CHF 500.-*
Students, CHF 200.Networking Dinner, CHF 89.-

All prices excl. 8 % VAT.

The prices above include conference entry, materials and documentation and all meals during the meeting.

*A discount of 10% on your registration fee will be applied to participants who register before 30 September 2014.

Registration

Please register by 23 October 2014 at: www.medtechandpharma.com/index.php/registration

Transfer Policy

You are entitled to transfer your registration to a colleague prior to the start of the conference. However, sharing a conference ticket (i.e., Pay one fee and share the daily attendance with another colleague) is not permitted. Please notify the organiser`s office of any transfers as soon as possible.

Cancellation Policy

All cancellations must be submitted via email (office@medtechandpharma.com) and be received by the Event Manager, five working days prior to the conference start date. Cancellations are subject to an administrative fee.

Venue

Swissôtel Oerlikon Schulstrasse 44 CH-8050 Zurich http://www.swissotel.de/hotels/zurich/

Accommodation

Choose between two categories for your upcoming stay at the Swissôtel:

Classic Room: CHF 240.- per room/night Premier Room: CHF 255.- per room/night

Please visit www.medtechandpharma.com to make your individual reservation until 30 September 2014.

Sponsors













Event partners







