MEDTECH Et PHARMA
PLATFORM

MPP Virtual Annual Conference

22 – 23 October 2020

Organizers

Solutions For Life sciences

SWISS MEDTECH

Sponsors

YPSOMED SELFCARE SOLUTIONS

ALTRAN Part of Capgemini

zühlke empowering ideas

DASSAULT SYSTEMES

Roche

NOVARTIS

Event partner

Basel

Networking partners

BASEL AREA. SWISS

Swiss Biotech Association

EuropaBio

Content

For any questions, please contact the MPP team:

office@medtech-pharma.com
+41 78 832 68 92
www.medtech-pharma.com

Welcome to the MPP Annual Conference 2020

Dear Colleagues,

Since 2017 the MPP Annual Conference has been under the umbrella of the MPP Association, which advocates for a robust and proportionate regulatory framework for combined products. Such regulations support high quality innovation, preserve competitiveness, and encourage development and delivery of patient-centric products with improved treatment outcomes.

Our ultimate goal is to foster innovation by creating a forum in which pharmaceutical, medtech and ICT companies can come together, share knowledge, and explore business opportunities to improve the development of novel therapies. This Annual Conference is a key component to attaining that goal, and so I thank you for joining us this year.

The Program Committee has ensured an exciting program on the theme of **"Achieving patient-centricity under the new MDR-balancing stakeholder interests".** It will address development and manufacturing of combined products in topic areas including cutting-edge technologies, innovative approaches, advances in development and manufacturing, EU medical devices regulations, patient-centric and value-based healthcare, and digital health.

As MPP goes digital this year, our virtual conference platform will facilitate new opportunities to engage, interact, and exchange your ideas with other participants and expert speakers during the session presentations and panel discussions.

The virtual conference platform also hosts Sponsor and Exhibitor profiles from leading companies, showcasing their innovative products and technologies. On these profiles, you can identify the company representatives attending MPP2020 and directly book 1-1 video meetings to discuss partnering opportunities. Even colleagues who are not registered to the conference can be invited to these video meetings to advance your discussions.

I encourage you to take full advantage of all these opportunities that the conference offers to network and build lasting business partnerships.

I wish you all an enjoyable and successful MPP Annual Conference 2020.

Shayesteh Fürst-Ladani
President
Medtech & Pharma Platform Association

Introduction

The MPP is an international industry association enhancing synergies between pharmaceutical, medtech and ICT companies. It represents a forum for exchange of knowledge, collaboration in areas of innovation, technology, product development and device regulations. Its goal is to coordinate advocacy work, reduce the time to market for combined products, devices/IVD/software and drugs, and ultimately improve patients' access to innovative products.

To achieve this, the Association seeks to engage with, and understand the needs of, patients, companies and all other stakeholders in the combined products field.

Our activities

Since its foundation in 2017, the MPP Association has established its presence at the European level through outreach activities providing expertise and dialogue to European Union institutions, competent authorities and associations in the field..

As the only industry association focusing on combined products at the European level, the MPP has formed two Working Groups to proactively shape future policies for such products. These groups focus on Combined Products and, Connected Combined Products, and related regulatory challenges during development, registration and post-marketing.

MPP activities of the last three years include publication of a position paper on connected combined products and a Reflection paper on the impact of new MDR legislation on co-packaged drug-device combinations (DDCs), as well as being a co-signatory on various joint industry association submissions and papers in response to regulatory changes. Please visit the MPP profile on the conference platform to find out more on these activities, or get a copy of these documents.

Further, the Association also offers regular accredited expert trainings on specialized regulatory topics.

Our annual meeting

The MPP Annual Conference is the flagship event of the MPP Association.

MPP2020 brings together diverse stakeholders to explore advances in development, manufacturing and regulations relevant to combined products.

With the Medical Devices Regulation (MDR, 2017/745) to come fully into application in 2021, its impact on combined products will be addressed in a keynote address from the European Medicines Agency's Head of the Digital Business Transformation Task Force and a panel discussion with representatives from the European Commission and key stakeholder organizations. In recognition of the vital importance of combined products and cross-sectoral cooperation for future healthcare applications, we welcome increas-

ing stakeholders from the medtech, pharma and ICT sectors as the conference continues to grow.
The MPP Annual Conference aims at fostering cooperation between the pharma, medtech and the ICT sectors based on the foundation of three key pillars.

Knowledge exchange — Exhibition — 1-on-1 partnering

Knowledge exchange

Expert speakers share their insights across various session topics, providing insights into current and future opportunities and challenges in the development of innovative combined products in the medical device field.

Exhibition & Sponsor company profiles

Visit the Exhibitors and Sponsors profiles from leading engineering, manufacturing, pharma, tech and services companies, for video partner meetings and the latest innovative services, products and technologies throughout the two days of the Conference.

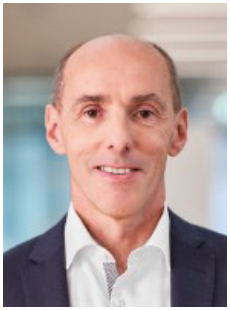
1-on-1 video networking

Expand your business network through direct video meetings via the Conference platform. This aspect has always been highly appreciated by our attendees, it is a perfect opportunity to network with many high-profile industry players

Board of the Medtech & Pharma Platform

Shayesteh Fürst-Ladani
SFL Group of Companies

Shayesteh Fürst-Ladani is the CEO of SFL Group of Companies and President of the Medtech & Pharma Platform and Rare Disease Action Forum Associations. Before founding SFL Group, she held senior positions in various biotech and major pharmaceutical companies.
Shayesteh has longstanding experience in formulating development strategy for drugs, devices and combination products. She is author of various publications regarding combination products.
Shayesteh is Special Coach for regulatory and clinical strategy for Innosuisse, as well as Lecturer for Regulatory Affairs at IFAPP/Kings College and Expert at Digital Pulse (DH^2). She received her MSc in Microbiology from the University of Vienna, Austria, and an MBA from the Open University Business School, Milton Keynes, UK.



Daniel Delfosse
Swiss Medtech

Daniel Delfosse is Head of Regulatory Affairs at Swiss Medtech, the medtech association in Switzerland. He has had several business experiences in the fields of materials science and medical device development and innovation. Prior to joining Swiss Medtech, Daniel spent almost 20 years as the head of various departments at a leading Swiss medical orthopedics device company.
Daniel also spent many years in academic research. He holds an Engineering degree in Materials Science from ETH Zurich and a Doctorate in Material Sciences from EPFL Lausanne.

Manfred Mäder
Novartis

Manfred Mäder is Head Device Development & Commercialization in GDD (Global Drug Development) since October 2015.
Prior to this, he held the position Head of Global Compliance & Audit for Devices and Combination Products overseeing all Alcon, Pharma, and Sandoz sites producing this type of products, as well as Global QA Head of Technical Research and Development at Novartis Pharma starting in February 2011.
Prior to this position he was Senior VP of Quality Management & Regulatory Affairs at Ypsomed, a company producing Medical Devices and Combination Products starting in 2007. Previously, he was responsible for Quality Assurance Management at Sanofi-Aventis for the Frankfurt Injectables site. Before then, being based in Kansas City/ US, he had a global responsibility for Quality and Regulatory for one of the Aventis Blockbuster products. Prior to that, he held several positions in QA and QC. He is also a trained pharmacist and holds a doctorate in pharmaceutical analytics and statistics from the University of Würzburg, Germany.

Stefan Affolter
Ypsomed

Stephan Affolter is Board member of MPP and currently the Regulatory + Quality Intelligence Manager at Ypsomed, having started working in the Drug delivery Device / Diabetes care industry more than 19 years ago, and has held various positions in Quality Management and Regulatory Affairs, including several management functions. Stephan has also been involved in development of current standards and guidance documents in national and international standards committees (ISO) and working groups (i.e. PDA, MPP, Swiss Medtech). Stephan is a board member of the industry association the Medtech & Pharma Platform (MPP), which supports collaboration across the different industries with a focus on combined products.
Stephan Affolter studied Chemical Engineering at the University of Applied Sciences in Burgdorf, Switzerland and also obtained a degree as a Chemist (dipl. FH, BS), before spending almost 10 years working in the Food, Drug and Biotech industries in different leading QC/ QA/QM/RA and Production functions, including as a Qualified Person.

Board of the Medtech & Pharma Platform

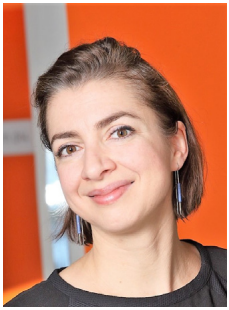
Thomas Kühler
Sanofi

Thomas Kühler is a PhD chemist by training with a post-doctoral degree obtained with late Nobel Prize Laureate Donald J. Cram. In recognition of his contributions to the field of Medicinal Chemistry and longstanding experience in drug development he was appointed Associate Professor in Medicinal Chemistry at Uppsala University in Sweden.

Thomas has garnered his work experience from Hässle AB in Sweden (now AstraZeneca), the Swedish drug regulator, the Medical Products Agency, Novo Nordisk A/S in Denmark, and most recently Sanofi in France. Thomas has served on the Board of the Drug Information Association in the US. He also was a member of the Board, and the chair of the Board, of The Organisation for Professionals in Regulatory Affairs in the UK.

Daniel Diezi
Gerresheimer

Daniel Diezi is Chair of the Medtech & Pharma Platform Annual Conference Program Committee (Committee Member since 2017) and Vice President Digitalization & New Business Model at Gerresheimer AG. In his role, he assumes responsibility for Gerresheimer's overall digital strategy including products, services and new business models. Previously, Daniel held positions of Global Product Manager and Area Director of APAC & North America at a medical device company. As Area Director, he led the department responsible for strategic business development, global sales and geographic market expansion.
Daniel holds degrees in Business Engineering and Business Administration, and has completed executive programs at the IMD in Lausanne, the MIT Sloan School of Management and the Harvard Business School in Boston.



Clotilde Aubertin-Jordan
GSK

Clotilde Aubertin is currently the Director of External innovation for Consumer Healthcare Pain rRlief and Respiratory Health. She leads activities responsible for innovation partnership, development of products, technologies, devices and services. She also she leads the innovation pillar of an unique GSK initiative, The Clean Breathing institute, dedicated to the impact of air pollution into the respiratory conditions. She has been recently appointed as co-leader of the Women Leadership Initiative for GSK Switzerland.
Clotilde's previous roles include at CNRS, INSERM and Nestle supporting the scientific policy, partnerships and strategy. As Innovation Partnership and Licensing Manager at Nestlé she also oversaw the Scientific & Technical competitive intelligence activities positioning the RD strategy of the company. Clotilde has been a Member of the Medtech & Pharma Platform Annual Conference Program Committee since 2019.

MPP2020 Program Committee

Michel Dard
Straumann

Professor Michel M. Dard, DDS, MS, PhD is Global Medical Director for the Straumann Group and an Associate Professor at Columbia University, New York, USA. Trained in dentistry and oral medicine in France, he started his career at Merck research, before joining Institut Straumann in 2003, holding roles as the Head of Pre-Clinical Research and the Head of Medical Affairs prior to becoming the Global Medical Director in 2016. Among other activities, he mentors worldwide at Straumann Advanced Education Centers dedicated to real-world evidence (RWE) clinical activities and disruptive continuous education, and oversees Straumann's global University Partnership program.
Professor Dard is a pioneer in Communities of Practice management integrating the Peer to Peer Partnership (P2P) concept. He has been active in academia as a faculty member at New York University prior to his position at Columbia, and continues to lecture globally at major international congresses, symposiums, University seminars and before scientific societies on medical devices and related areas in dentistry. He has authored more than 160 peer-reviewed international publications and book chapters or monographs. Michel has been a Member of the Medtech & Pharma Platform Annual Conference Program Committee since 2019.

David Haerry
European AIDS Treatment Group Brussels

David Haerry has been a treatment writer and conference reporter since 1996. He is the founder and Chair of Positive Council Switzerland and co-authors a database on travel and residency restrictions for people living with HIV (www.hivtravel.org). Since 1986, David has been living with HIV.

David has been involved in HIV and hepatitis C virus (HCV) drug development since 2005, as well as being active in a wide variety of HIV/AIDS-related areas related to treatment and therapy. These include regulatory affairs, research ethics, personalized medicine, risk communication, pharmacovigilance, observational studies, and biomedical prevention and research, across which he has co-authored numerous peer reviewed publications.

David is a member of numerous EU and Swiss boards, advisory and working groups. He is Secretary General for the Swiss Academic Foundation on Education in Infectious Diseases SAFE-ID, a core team member in the Patvocates Network and a member of the Executive Team at the Patient Focused Medicines Development Initiative, and involved since 2012 with the European Patients' Academy on Therapeutic Innovation Innovative Medicines Initiative project EUPATI-IMI. He was also co-chair of the Patient and Consumer Working Party at the European Medicines Agency from 2013 to 2016, and is the current co-chair of the Swissmedic working group for patient and consumer organizations.

MPP2020 Program Committee

Marie Picci
Novartis

Marie Picci is Director, Delivery Systems Strategy at Novartis Pharma, Basel and is responsible for establishing and implementing the strategy on parenteral delivery systems for the Novartis clinical development and commercial pipeline. This includes drug-device combination products, cell and gene therapy and digital products. During her time at Novartis she was Group Head of Device Portfolio Management responsible for the development and commercialization of medical devices and combination products, from early phase clinical development to post-launch.
Prior to joining Novartis, she held several positions in project leadership and worked at Eli Lilly and Valois of America in the US. She has a MBA from the University of Connecticut, a M.S. Degree in Chemical Engineering, holds a diploma in Pharmaceutical Medicine and has over 20 years of industry experience. She is an active member of the Combination Product Coalition for clinical bridging studies.

Dorit Prüfer
Roche

Dorit Pruefer is Regional Head of Device Quality Basel at Roche and a biomedical engineer by training. She and her team support Device and Packaging Development with design control and risk management expertise in clinical and commercial phases of various drug delivery devices and combination products. Previously she worked in external quality with suppliers of device constituent parts.
Before Roche, Dorit gained extensive expertise with complex medical devices, including Ventricular Assist Devices (VAD) in different quality and regulatory functions. She drove the first IDE submission for a VAD of the company Berlin Heart and established a quality system for a US site of the company and was a Lead Audior. She is an active member of the CPC (Combination Product Coalition) Quality Systems working group and a Member of the 2019 and 2020 Medtech & Pharma Platform Annual Conference Program Committee.

Andy Tonazzi
Konplan systemhaus

Andy Tonazzi is an entrepreneur with a proven track record and high dedication to the Swiss Medtech Industry. He has extensive expertise in medical device development and innovation, organizational and cultural change management. Before joining Konplan in 2009, Andy was a consultant for Talent Recruitment and Development. He was named CEO of Konplan in 2010 and closed a Management Buy Out in 2012.
Andy has successfully grown the company from 12 to 60 employees. Andy is very passionate about bringing useful inventions to successful innovations. He is a member of the Program Committees of the Swiss MedTech Day, Swiss MedTech Expo, and since 2019, for the Medtech & Pharma Platform Annual Conference.

Karin Schulze
SFL

Karin Schulze is Head of Medical Devices at SFL. She leads the Medtech & Pharma Platform's Combined Products Working Group on the new MDR and IVDR, and is an Annual Conference Program Committee Member since 2019.
Karin is a well-recognized medtech expert with extensive knowledge in the development of medical devices and in vitro diagnostics (IVDs). Before joining SFL, Karin led a Swiss notified body for many years, where she conducted numerous conformity assessments of medical devices (all classes), combination products and IVDs and was responsible for CE certification decisions. She has extensive knowledge of QMS and since 2010 has been an authorized auditor for the Canadian Regulation (SOR-98/262). Karin is a member of NB MED and has actively worked with the European Commission on various guidelines, including the MDR/IVDR, as well as on a variety of projects with Competent Authorities. She is also an active member of the SIT group at Swiss Medtech, SAQ Fachgruppe Medizinprodukte and Technical Committee TC 210 for medical devices.

Thursday, 22 October 2020

09:00 - 9:30

Conference opening
Shayesteh Fürst-Ladani, President MPP Association

Welcome address
Karin Sartorius, Office of Economy and Labor, Canton of Basel-Stadt

MPP2020 Program Committee Chair's introduction
Daniel Diezi, Gerresheimer

09:30 - 10:15

Keynote address
Zaïde Frias, European Medicines Agency

10:15 - 10:45

Break & 1-on-1 partnering powered by Zühlke

10:45 :12:15

Session 1

New and emerging technologies
Chair: Michel Dard, Straumann

Data-driven business models – delivering value in the pharma & healthcare IoT
Daniel Weber, Detecon

Point-of-care transformation: bringing personalized care to the home setting
Frederik Mortier, Verhaert

Devices for drug delivery to the brain
Nico Stohler, Roche

12:15 - 13:30

Break & 1-on-1 partnering powered by Zühlke

13:30 : 15:00

Session 2

Panel discussion on the Medical Devices Regulation and Combined Products
Chair: Shayesteh Fürst Ladani, President MPP Association

Erik Hansson, DG SANTE, European Commission
Ilona Reischl, Austrian Agency for Health and Food Safety – Austrian Medicines and Medical Devices Agency (AGES-MEA)
Julia Frese, TÜV SÜD
Stephan Affolter, Ypsomed, MPP
Serge Mathonet, Sanofi, EFPIA
Merlin Rietschel, Medtech Europe

15:00 : 15:30 **Break & 1-on-1 partnering powered by Zühlke**

15:30 : 17:00

Session 3

From ideation to innovative products
Chair: Karin Schulze, SFL

Smart data in the service of patient safety
Goranka Tanackovic Abbas-Terki, Gene Predictis

Automated production of artificial personalized skin - A closed system for process automation
Daniela Marino, Cutiss & Reto Frei, Zühlke

Patenting strategies for startups, spinoffs and other projects based on patentable innovations at early stages
Christoph Klöckner, Winter, Brandl, Fürniss, Hübner, Röss, Kaiser, Polte – Partnerschaft

Friday, 23 October 2020

08:45 - 9:00

Conference opening
Daniel Delfosse, MPP Board of Directors

09:00 - 10:30

Session 4

Innovation for successful development of healthcare products
Chair: Andy Tonazzi, Konplan systemhaus

Using modeling and simulation in the design of closed-loop medical devices
Sébastien Dupertuis, MathWorks

Using platforms to reduce the time and effort to bring new drug delivery combination products to the market
Christoph Muenzer, Novartis

Moore4Medical: towards open technology platforms for medical devices
Ronald Dekker, Philips

10:30 - 11:00

Break & 1-on-1 partnering powered by Zühlke

11:00 - 12:30

Session 5

Patient/user needs in development of combined products
Chair: Dorit Prüfer, Roche

Promoting patient safety through new supply chain controls under the medical device regulation (MDR) and the falsified medicines directive (FMD)
Barbara Polek, SFL

Impact of falsified medicines – the patient perspective
Jan Geissler, Patvocates

Human centered design - process design for usability
Raimund Erdmann, Erdmann Design

12:30 - 13:45 **Break & 1-on-1 partnering powered by Zühlke**

13:45 - 15:15 **Session 6**

Value-based healthcare in the combined products field and patient engagement
Chair: Marie Picci, Novartis & David Haerry, European AIDS Treatment Group

Effectively engaging patients to support product development and post-market success
Dominique Hamerlijnck, EUPATI

Building Trusted AI in Healthcare
Andrew Koubatis, Altran

Rising to the challenge of VBR, and other healthcare trends, using '4D' therapeutic systems
Alex Booth, Full Spectrum Innovation

15:15 - 15:30 **Closing remarks**
Shayesteh Fürst Ladani, President MPP Association

Welcome Speaker

Karin Sartorius-Brüschweiler
Department of Economic, Social and Environmental Affairs of the Canton of Basel-Stadt

Karin Sartorius is Manager Life Sciences of the Economic Development Unit of the Department of Economic, Social and Environmental Affairs of the Canton of Basel-Stadt. She joined the team in 2019. The Economic Development Unit is committed to ensuring that companies in the canton of Basel-Stadt encounter the best possible conditions for their success. We provide services to Basel companies and those who plan to settle here as well as internal services to the government. We foster collaboration and innovation by providing industry programs and provide convention support, rental relief, commercial guarantees and real estate support. Another key service and pillar of our unit is the Technologiepark Basel. It provides office space and fully equipped laboratories for early-stage tech start-ups.
Karin received a Master degree from the University of Basel in Marketing & Economics and a Bachelor degree from the Arizona State University in Biomedical Engineering. She held various molecular research positions and positions in medtech and pharma companies in the area of research & development, product management and leadership development. Karin is a member of the congress board Basel.

Zaïde Frias
European Medicines Agency

Zaïde Frias has degrees in Pharmacy and Business Administration. Prior to joining the European Medicines Agency she worked in Pharmaceutical Industry. She joined the EMA in 1999; she was appointed Head of Human Medicines Research and Development Support Division in 2013 and Head of Head of Human Medicines Evaluation Division in 2016.

In March 2020, she took the position of Head of Digital Business Transformation Task Force. The Digital Business Transformation Task Force was created to drive complex, disruptive change initiatives that have a profound impact on the strategy of EMA, its operational structure and operation in relation to the EU medicines regulatory network, its partners and stakeholders. The Task Force will conduct business and regulatory intelligence, and drive the translation of legislative initiatives (incl. medical devices and in vitro diagnostics regulations) and their design and implementation into EMA operations. The Task Force will be in charge of designing policies and will set up governance frameworks to support a high standard of quality in EMA decision-making.

Discussion panelists

Erik Hansson
European Commission (DG Sante)

Erik is Deputy Head of the Medical devices and Health technology assessment unit of the DG for Health and Food safety (DG SANTE) of the European Commission
Erik joined the medical devices unit of the European Commission in 2012 to lead the implementation of the PIP Action plan, followed by the negotiations on the new Regulations. Erik is responsible for several EU working groups (such as MDCG), heads the EU delegation to the multilateral regulatory cooperation in IMDRF, deals with bilateral trade related issues in the sector and is coordinating the cooperation with national Competent Authorities in the CAMD framework.
Erik received a Master degree in law from the University of Uppsala, Sweden, and held various positions in law courts and then in Swedish ministries and agencies coordinating preparations for EU-membership. Since joining the European Commission in 1997 Erik has mainly dealt with policies relating to the single market for goods as well as finance and strategic policy planning.

Illona Reischl
Austrian Agency for Health and Food Safety – Austrian Medicines and Medical Devices Agency

Ilona Reischl joined the Austrian Medicines and Medical Devices Agency (AGES-MEA) in March 2006 and has been affiliated with the Clinical Trials Unit since then and headed the division until 2019. This division in the Institute Surveillance is responsible for clinical trials with medicinal products or medical devices and GCP inspections. After an initial degree in pharmacy, a PhD in immunology/ allergology and postdoctoral experience at an industrial research institute (AT), post-doctoral positions followed at the University of Southampton (UK) and the National Institutes of Health (USA) in immunology. The current regulatory focus started with a dual research/ regulatory position at the US Food and Drug Administration (FDA).
Ilona Reischl is a quality assessor and the Austrian member of the European Medicines Agency Committee for Advanced Therapies and the Biologics Working Party. She is actively involved in manufacturing, procedural and scientific issues pertaining to biotech products in general and ATMPs in particular. Her regulatory expertise covers clinical trials with medicinal products and medical devices. Her particular interest is in legal and regulatory interface issues in the context of combination products and in vitro diagnostics.

Julia Frese
TÜV-SÜD

Julia Frese is the Department Manager at the Centre of Combination Products for the German Notified Body TÜV-SÜD. Julia has extensive experience in development and regulatory approval of combination devices and ATMP products. She was responsible for the development of the article 117 service within the organization. She is currently also co-chair of the Team NB working group for article 117.
Julia's previous roles included heading the division of Medical and Health Services at TÜV SÜD Japan, as well as contributing to the development of standards for ATMP products. Julia was trained in Germany as a biomedical engineer and also holds a Master degree in business administration.

Stephan Affolter
Medtech & Pharma Platform Association

Stephan Affolter is Board member of MPP and currently the Regulatory + Quality Intelligence Manager at Ypsomed, having started working in the Drug delivery Device / Diabetes care industry more than 19 years ago, and has held various positions in Quality Management and Regulatory Affairs, including several management functions. Stephan has also been involved in development of current standards and guidance documents in national and international standards committees (ISO) and working groups (i.e. PDA, MPP, Swiss Medtech). Stephan is a board member of the industry association the Medtech & Pharma Platform (MPP), which supports collaboration across the different industries with a focus on combined products.
Stephan Affolter studied Chemical Engineering at the University of Applied Sciences in Burgdorf, Switzerland and also obtained a degree as a Chemist (dipl. FH, BS), before spending almost 10 years working in the Food, Drug and Biotech industries in different leading QC/QA/QM/RA and Production functions, including as a Qualified Person.

Discussion panelists

Serge Mathonet
European Federation of Pharmaceutical Industries and Associations

Serge Mathonet is a Global Regulatory Affairs Lead at the Biologics Center Chemistry, Manufacturing and Controls (CMC) Interface at Sanofi-Aventis and a senior advocacy expert at the EFPIA/EBE. At EFPIA/EBE, Serge is a core member of the EBE Biomanufacturing group and leads the EBE working groups on combination products, advocating in coordination with 7 Industry groups, including the Medtech & Pharma Platform.
Serge has more than 14 years of regulatory affairs experience in CMC, focusing on biologics and biologics/device combination product development, licensing and launch/life cycle management activities. Prior to joining Global Regulatory Affairs, Serge has held various positions in Sanofi Industrial Quality Operations in API Regulatory Compliance activities either at corporate or industrial site level.

Merlin Rietschel
Medtech Europe

Merlin Rietschel is currently the leading coordinator of activities related to Notified Bodies at MedTech Europe. He previously held the position of Senior Manager in MedTech Europe's International Affairs department. He joined Eucomed (now MedTech Europe) in January 2011 and worked for the Regulations and Industrial Policy department. He also held various positions within international pharmaceutical companies (Bristol-Myers Squibb and GlaxoSmith-Kline Biologicals) and at the European Medicines Agency (EMA) in London, UK. Overall, he has over 11 years of experience in the field of European regulatory affairs, and in the pharma sector he has successfully dealt with an extensive number of regulatory submissions in life-cycle management and marketing authorization applications.
Merlin was raised in Germany where he received a French/German multicultural education. He also lived in the United States and now lives in Belgium since 1995. He has a Master degree in pharmaceutical science from the Université Catholique de Louvain in Belgium, as well as a post graduate degree in pharmaceutical industry. A German and French national, he is also fluent in English.

Daniel Weber
Detecon

As a consultant, Daniel Weber leads customers in their digital transformation by leveraging innovative technologies to create a sustainable business impact.
Over the last years, he has specialized in the area of Internet of Things and data-driven business models in technology-driven environments such as Pharma & Healthcare, Manufacturing, and Telecommunications.

Frederik Mortier
Verhaert New Products & Services

Frederik Mortier is medical program coordinator at Verhaert New Products & Services, part of the Masters in Innovation group.
He holds a MSc. in electromechanical engineering and has always been interested in complex multidisciplinary challenges and has been involved in product development activities throughout his career. Within the role of program coordinator, he follows up on all medical projects and is part of the quality team at Verhaert.

Session speakers

Nico Stohler
Roche

Nico holds a degree in mechanical engineering from the University of Applied Sciences Northwestern Switzerland, Mulhouse University Institute of Technology (F) and Baden-Wuerttemberg Cooperative State University Loerrach (D).
He has more than 15 years of experience in developing medical devices from the early innovation phase to global product launch and product life cycle management, with contributions to pre-clinical studies and surgical observations. Starting his career developing custom made craniofacial implants, he continued running projects to serve patients with novel solutions for bone fracture treatment including permanent and degradable metal implants, as well as bone substitute materials. Nico is also a Certified professional project manager. His most recent work is in the field of combination products with a focus on smart technologies and drug delivery to the brain.

Goranka Tanackovic Abbas-Terki
Gene Predictis SA

Goranka Tanackovic Abbas-Terki was trained as a scientist and holds PhD degrees from the University of Zagreb and University of Geneva. In parallel with her PhD studies, she successfully completed an entrepreneurship program at Babson College, Wellesley, USA. During her academic career, she successfully led various research projects, obtained numerous research grants, and results of her work are recognized through their publication in high-impact per-reviewed journals. Since 2011, she is the CEO of Gene Predictis SA, a pioneering Swiss company specialized in precision medicine offering innovative diagnostic tools based on genetics that allow tailored treatments for patients.
Under her direction, the company developed first-in-class diagnostic products answering important medical needs (e.g. measuring the risk of thrombosis for women using contraceptive pills) and paving the way to highly personalized medical advice; it grew significantly and obtained numerous prizes. Since 2017, Dr Tanackovic Abbas-Terki is also teaching courses on personal genomics and predictive genetics for the Certificate in Industrial Life Science (CILS) program of the University of Geneva. She is passionate about translating progresses in scientific research into health-care solutions for patients.

Daniela Marino
Cutiss

Daniela Marino completed her master's degree in Biotechnology in Milan in 2005. Afterwards she came to Zurich and did a doctorate in Vascular Biology, exploring stem cells, skin and pharmacology at the Institute of Pharmaceutical Sciences, ETH. After receiving her PhD in 2009, she worked in various functions in the Department of Surgery at the University Children's Hospital Zurich, before founding her own company Cutiss AG in March 2017. Since then she has successfully managed the company in the role of CEO.

Retro Frei
Zühlke

Reto Frei is project manager and has been with Zühlke since April 2010. After graduating with a degree in mechanical engineering in 2005, Reto Frei began his professional career as a development engineer in product development, with a focus on lightweight construction. For the last ten years he has focused on the development of medical devices, solutions for the pharmaceutical industry, industrial applications and home appliances where he is responsible for project delivery.

Session speakers

Christoph Klöckner
Winter, Brandl, Fürniss, Hübner, Röss, Kaiser, Polte – Partnerschaft

Christoph Klöckner is a German and European Patent Attorney in the Chemistry/Life Science department of Winter, Brandl and Partners. One of his main interests is advising startup projects in the Medtech and Pharma fields on obtaining optimal protection for their Intellectual Property in view of attracting and negotiating with potential investors, as well as advising investors in assessing potential investment targets and their respective IP portfolios.
Christoph is lecturing on Intellectual Property at the Ludwig-Maximilians-University of Munich and regularly shares his expertise with audiences across Europe, as well as in Singapore and Japan.
Christoph is qualified as a German and European Patent and Trademark Attorney and holds a Diploma in Cell Biology and Biochemistry from the Ludwig-Maximilians-University of Munich and a PhD in Biochemistry from the University of Heidelberg.

Sébastien Dupertuis
MathWorks

Sébastien Dupertuis is a senior application engineer at MathWorks. He works in the area of design automation with a focus on signal processing and code generation technologies targeting heterogeneous embedded systems. Sébastien held software engineering-related positions for over five years at Institut d'Automatisation Industrielle, as well as Swissvoice in Switzerland. At Swissvoice, he was in charge of developing the audio part and the automatic testing framework for DECT phones.
Sébastien graduated as a telecommunication engineer from La Haute Ecole d'Ingénierie et de Gestion du Canton de Vaud and as a physicist from the University of Geneva.

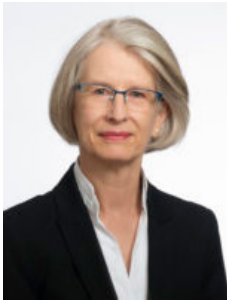
Christoph Muenzer
Novartis

Chris Muenzer is the Team Lead for the System Engineering and Modeling group at Novartis in Basel, Switzerland. Located within Device Development & Commercialization, his team advances the use of engineering and data driven processes to support injectable device development for Novartis' diverse portfolio of drugs.
Mr. Muenzer has over 20 years of development experience with a focus on drug delivery devices and has filed several patents in the field. Prior to joining Novartis, he developed drug delivery and medical devices at Roche and at the Battelle Memorial Institute in Columbus, OH. Mr. Muenzer holds a BSME from Carnegie Mellon University in Pittsburgh, Pennsylvania in the US.

Ronald Dekker
Philips

Ronald Dekker received his MSc in Electrical Engineering from the Technical University of Eindhoven and his PhD from the Technical University of Delft. He joined Philips Research in 1988 where he worked on the development of RF technologies for mobile communication.
Since 2000 his focus has shifted to the integration of complex electronic sensor functionality on the tip of the smallest minimal invasive instruments, such as catheters and guide-wires. In 2007 he was appointed part time professor at the Technical University of Delft with a focus on Organ-on-Chip and bioelectronics medicines. Since 2013 he has been the initiator of a number of large European initiatives that all have in common the development of open technology platforms for electronic medical devices. In 2018 he initiated the ECSEL joint undertaking; Health.E lighthouse. He has published in leading Journals and conferences, and holds in excess of 70 patents.

Session speakers



Barbara Polek
SFL

Ms Polek supports SFL's clients with the setup of tailored product distribution solutions in Switzerland and the European Union. Prior to joining SFL, Barbara held line and project management positions in supply chain management and medicinal product distribution, both in a large international pharma company and in small to medium size biotech companies.
Barbara holds a master's degree (lic. rer. pol.) in Economics from the University of Basel, Switzerland, and a MSc in International Pharmacoeconomics and Health Economics from Cardiff University, UK.

Jan Geissler
Patvocates

Jan Geissler is the founder and CEO of Patvocates, a think tank, consultancy and social enterprise on patient advocacy, health policy and patient engagement in research. He was the Director of the European Patients Academy (EUPATI) from 2012-2017 and still leads the German EUPATI platform.
Jan is a work package leader of the IMI2-funded EU project HARMONY on big data for better outcomes in hematology. A leukemia survivor since 2001, Jan co-founded the patient organizations LeukaNET/Leukaemie-Online.de in 2002, the European Cancer Patient Coalition in 2003, the CML Advocates Network in 2007, the Leukemia Patient Advocates Foundation in 2011, WECAN in 2015 and the Acute Leukemia Advocates Network in 2016. Jan represents patients on a number of advisory boards and committees, e.g. European Cancer Organisation, EHA, ISPOR, Berlin Institute of Health, EuroBloodNET, International CML Foundation, the EU Cancer Mission Assembly, the German National Decade Against Cancer and the Ethics Committee of the Bavarian Chamber of Physicians.

Raimund Erdmann
Erdmann Design

Raimund Erdmann studied Industrial Design at the Zurich University of Design. In 1977 Raimund founded the consultancy Erdmann Design for Medical Design and Corporate Branding. Since then Erdmann Design AG develops Human Centered Design for international corporate clients.
Raimund's consulting firm specializes in design development from conceptual design stages to working prototypes, corporate design, exhibition and furniture design for Swiss and international firms. It provides design management for the industry, trade, and cultural institutions and covers a wide range of design activities from conceptual development, corporate identity programs, to industrial design, prototypes and production. Raimund and his consultancy have received over 50 international Design-Awards for excellence in Industrial Design.Raimund also teaches Experience Design-Methods at Swiss and American Universities. He is a guest Professor for Master Program Design Methods in design departments at various universities including The University of Virginia, The University of Syracuse, The University of Washington, a regular lecturer and advisor at The School of Design Zurich, and an invited lecturer in industrial design in various societies and schools in Europe and USA.

Session speakers

Dominique Hamerlijnck
The European Patients' Academy on Therapeutic Innovation

Dominique Hamerlijnck has a Masters in Philosophy, specialized in ethics from the University Ghent Belgium and a Masters in Business Administration from the Rotterdam School of Management Netherlands. Dominique is one of the European Patients' Academy on Therapeutic Innovation (EUPATI) fellows.
Dominique is working as a project and change manager for more than 30 years. Next to her professional life, for the past 20 years Dominique is also working as a patient expert for the past 20 years especially in the field of severe asthma. She has been involved in many Dutch and EU projects in a patient advisory capacity. She is the patient co-chair for a European Respiratory Society Clinical Research Cooperation on severe asthma: Severe Asthma Heterogeneous Asthma Research Collaboration, Patient-centered (SHARP). She is a member different patient advisory groups: Dutch Lung Foundation, the European Lung Foundation, the European Federation of Allergy and Airways Diseases Patients' Association, HTAi PCIG and ISPOR patient representatives round table and the IMI patient group. She has been successful in getting the patient voice heard and included in development in care and medicine and device development.

Andrew Koubatis
Altran

Andrew Koubatis is Medical Devices Industry Architect for Altran. He coordinates and supports Altran's medical device activities and leads the Digital Therapeutics (DTx) Offer. Since joining Altran in 2005, Andrew's has been involved in the development of medical devices, medical apps and wearable devices, remote patient monitoring systems and combination products. He also supports in regulatory assessments, quality systems optimization, risk management, and human factors engineering.
Andrew studied Mechanical Engineering at McGill University with a focus on automation. He has an MBA in Management of Technology from École Polytechnique Fédérale de Lausanne (EPFL) and a postgraduate diploma in Digital Business from MIT and Columbia Business School.

Alex Booth
Full Spectrum Innovation

Alex founded FSi with his business partner Richard after spending several years working for and with both SMEs and corporates on innovation. He realized while there was significant effort devoted to incremental and consumer focused innovation, there was relatively little successful innovation to address an ever-increasing number of complex challenges with high social impact.

Alex now works via FSi on supporting projects and developing approaches that are aimed at consistent quality innovation in high-tech, highly regulated industries, such as healthcare. He supports projects addressing the 'big' challenges via the use of innovation capable partnerships. This support includes the development, fostering and application of bespoke innovation processes, supporting the journey from ideation to innovation adoption/commercialization, and helping 'hands-on' with a range of strategic and operational support - scientific, technical, and regulatory.

A member of The International Society for Professional Innovation Management's (ISPIM) Innovation Leadership Special Interest Group (SIG), he also works to develop a better understanding of how innovation can be better led and effective innovation leaders developed, particularly when the goal is radical change in a complex, rapidly evolving, yet highly regulated environment, and where the output matters beyond purely commercial considerations.

One Consultancy

Integrated

Team Expertise

Tailored

Pharma & Medtech Solutions

- Regulatory Affairs & Quality Assurance
- Medical Affairs & Pharmacovigilance
- Public Affairs & Regulatory Policy
- Reimbursement & Supply Chain
- Legal & Compliance

Solutions For SFL Life sciences

sfl-services.com

SWISS MEDTECH

FOR A STRONG SWISS MEDTECH INDUSTRY

DASSAULT SYSTEMES

IASO
A LIFE SCIENCES SHOWCASE




3DEXPERIENCE®

Don't miss our speaking slot on **Friday, October 25th at 2:20 p.m.** featuring our IASO life sciences showcase & experience at our booth an interactive playground displaying the end-to-end lifecycle of the IASO combination product in oncology - from upstream thinking to commercialization using the **3DEXPERIENCE** platform.

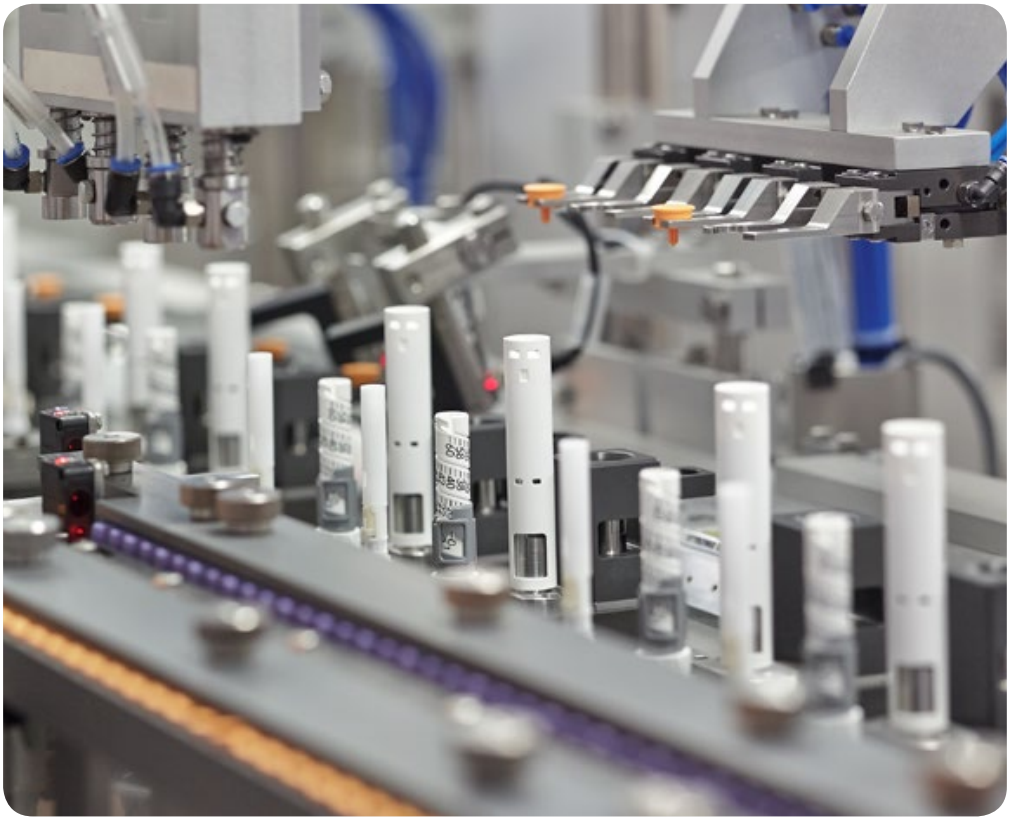
IFWE.3DS.COM/LIFE-SCIENCES

YOU NEED TO KEEP A WATCH ON YOUR HEALTH, WE'LL DESIGN THE BRACELET.

Providing leading-edge apps for an armband to monitor vital signs wherever patients go.

We made it possible for Biovotion.

ALTRAN



The Ypsomed Group is a leading developer and manufacturer of injection and infusion systems for self-medication and a renowned diabetes specialist with over 30 years' experience.

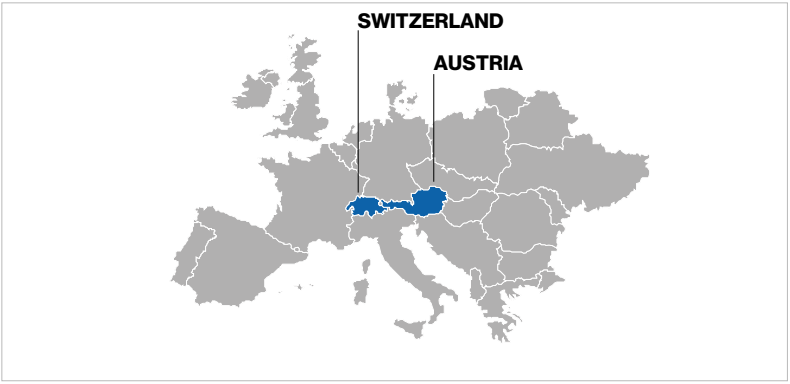
As a leader in innovation and technology, Ypsomed is the preferred partner for pharmaceutical and biotech companies for the supply of injections pens, autoinjectors and infusion systems to administer liquid drugs. Ypsomed promotes and sells its product portfolio under the umbrella brands, mylife™ Diabetescare directly to patients or through pharmacies and clinics, and under YDS Ypsomed Delivery Systems as business-to-business to pharmaceutical companies. Ypsomed has its headquarters in Burgdorf, Switzerland, and operates a global network of manufacturing sites, subsidiaries and distributors. The Ypsomed Group employs around 1 500 employees.

Novartis and Devices

Device Development units in Novartis are focused on rapid development and life-cycle management of medical devices, pharmaceutical packaging and medical apps

Geographies

Located mainly in two locations in the center of Europe device and packaging experts work on medical devices and combination products for the delivery of drug products, cell gene therapies and electronic and connected devices.



People

Experts from many different areas are working together, e.g. bio-chemistry, mechanical engineering, pharmacy, bio-technology, chemistry, medicin, software and human factors engineering.

220 **PEOPLE IN TOTAL**

18 **NATIONALITIES**

154 **IN SWITZERLAND**

60 **IN AUSTRIA**

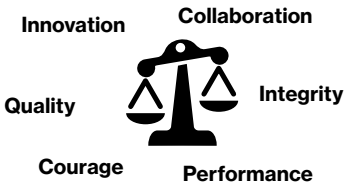
6 **IN US**

Projects

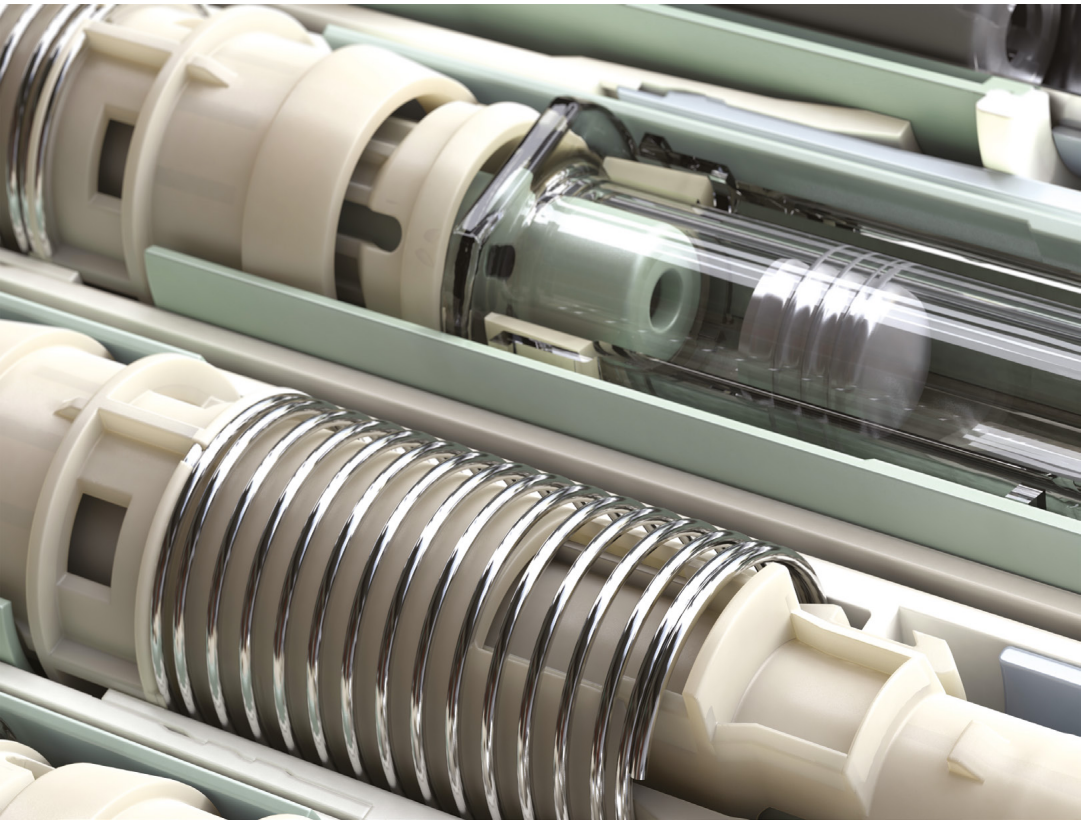
More than 150 active projects and around 200 marketed combination products

Values

In a global environment with a large network of internal and external partners and stakeholders we put a strong focus on our values and baviors to ensure seemless communication and excellent collaboration.



NOVARTIS



At Roche, we work with a purpose.

In Device & Packaging Development,
we develop safe and effective products
to help people live better, longer lives.

Roche


zühlke
empowering ideas
Competitive pressure, demanding users
and new regulations as drivers for innovation?
Sure.
Every challenge holds new opportunities – if you use the right tools.
Being an innovation service provider for more than 50 years, Zühlke has
adopted the lean start-up method: quick, agile, and low-risk. On that way,
we create a space for highly focused work, effective innovation and –
most importantly – competitive advantages for our customers.
zuehlke.com

BRING YOUR DEVICES TO LIFE

Meet Covance Medical Device and Diagnostic Solutions

Say "Hello" to Covance Medical Device and Diagnostic Solutions. A new model for device development that interlaces every stage of your product's life cycle by thoughtfully connecting insights across your development program. At every phase, from upfront consulting through preclinical and clinical trials to post-market support, you gain a strategic approach and expert delivery of tests and trials to get the data you need. You also gain a specialized team of scientific and regulatory professionals as well as access to a powerful collection of resources. With Covance Medical Device and Diagnostic Solutions, you can be sure you'll have the knowledge, expertise and tools to bring even your most ground-breaking devices to life.

TO LEARN MORE CALL

The Americas +1.888.COVANCE

Europe/Africa +00.800.2682.2682

Asia Pacific +800.6568.3000

Or go to **covance.com/device-CRO**

COVANCE

WAREMA Medical Technologies

warema

Dillberg 33
97828 Marktheidenfeld
Germany

Tel: +49 9391 20-9924
Fax: +49 9391 20-169924

Save the date:

October 2021
Congress Center Basel

MEDTECH & PHARMA
PLATFORM