MPP 2022

Medtech & Pharma Platform 2022 Annual Conference

(8 September 2022, Basel, Switzerland)

How combined products address health challenges

Conference report

The 9th Medtech & Pharma Platform Association (MPP) Annual Conference (MPP 2022) was held on 8 September 2022, in Basel, Switzerland. The theme of this year's conference was *"How combined products address health challenges".* The MPP Annual Conference focuses on products combining medicinal products, medical devices and software components and aims to promote synergies between the pharmaceutical, medtech and tech industries as well as to foster exchanges on the development of and framework for combined products.

For the first time since the beginning of the pandemic, the conference was held in person, at the Mövenpick Hotel Basel, Switzerland. More than 180 representatives from the pharma, medtech and tech industry, health and regulatory authorities, notified bodies, patient organizations and academia from Europe and beyond registered for the conference.

Program of the conference

The conference was opened by the MPP President, Shayesteh Fürst-Ladani (SFL). Karin Sartorius (Canton Basel-Stadt) welcomed the participants on behalf of the Canton and explained how the city of Basel evolved from the gas industry to the chemical industry and finally, thanks to the pharmaceutical industry, became a global life sciences hub. She illustrated how the city is continuously engaged in creating a globally competitive environment for the life science industry. The MPP 2022 Program Committee Chair, David Haerry (Brussels AIDS Treatment Group), introduced the Program Committee and presented the program of the day.

The **first session**, chaired by Daniel Delfosse (Swiss Medtech) and Christiana Hofmann (TÜV SÜD), focused on regulation and patient engagement. Rahel von Rohr (anteris Helvetia) spoke about the essential regulatory aspects of connected injection systems and how to tap into the potential of healthcare 4.0 and bring connected injection systems successfully into the market. Stephan Affolter (Ypsomed) presented his views on the challenges associated with the implementation of the EU Medical Devices Regulation for the industry and on the benefits of a platform approach. Representing EUPATI, Maria Dutarte illustrated how patient engagement can be enhanced through education and why patients should be involved throughout the lifecycle of development of medical devices, from

mapping the patient needs and setting research priorities, to protocol design, clinical evaluation procedures and all the way through the regulatory assessment and post-market processes. Wrapping up the first session, Atalah Haun (Veristat) gave insights on how technology can improve patient engagement in decentralized clinical trials, while keeping the patient at the center.

The **second session**, chaired by Marisa Papaluca (Imperial College London) and Ruth Foster (MSD), provided insights on the journey from research to clinical development. Claudia Dollins (Bristol Myers Squibb) started the session by presenting perspectives on the clinical development of companion diagnostics and the distinction between regulatory assessments in the US and Europe. Subsequently, San Pun (AiMorphus) shared his experience on the development of an AI-enabled diagnostic system for anti-thrombotic management and showed advantages of connected diagnostic systems in the emerging digital health. Paolo Decuzzi (Italian Institute of Technology) used the example of micro mesh to present the possibilities of innovative combined products for brain tumors and underlined the challenges for clinical integration. Laura Fregonese (European Medicines Agency) rounded off the session by addressing the challenges and opportunities for the regulation of combined products.

During the **lunch break**, Blaise Jacholkowski (Zühlke Engineering) moderated a discussion with Christian Berger (Zühlke Engineering), Ramesh Rajamani (Novartis) and Gullsher Hussain Khan (Amazon Web Services) on the benefits and risks of medical clouds.

Shayesteh Fürst-Ladani, the MPP President, led a **panel discussion** on the framework for combined products with Bernhard Spörri (Swissmedic), Sebastian Fuchs (Swissmedic), Thinh Nguyen (US Food and Drug Agency, FDA), John Weiner (FDA), Sabina Hoekstra-van den Bosch (TÜV SÜD / Team-NB) and Mike Wallenstein (Novartis). Participants had the opportunity to take part in the discussion through interactive polls.

In their opening statements, the panelists provided an overview of the latest development in the regulation of combined products and highlighted challenges ahead, including the transition to the new framework in the EU. The discussion first focused on the potential benefits of platforms and associated issues. The panelists noted an increasing demand from the industry, as an increasing number of companies are becoming combination product companies and underlined that the regulatory processes could be improved. Questions from the audience showed that the regulatory agencies' divergent requirements on the substance of the dossiers is a challenge to launch new products in different markets. The panelists emphasized that they endeavor to overcome these differences and highlighted recent international initiatives in that regard.

Panelists also addressed innovation in the area of combined products. The audience identified the development of new health applications and the use of artificial intelligence (AI) in healthcare as the main drivers for innovation in the field. Panelists stressed that the processes need to be adjusted, for instance to consider the speed of software development. They observe a rise in the number of devices including software, albeit the software remains relatively basic at the moment. In the EU, the future AI Act will regulate the use of AI in healthcare; panelists raised concerns about the added complexity stemming from horizontal rules on AI coming on top of the current regulations. In their closing remarks, the panelists called for increased cooperation between the different stakeholders, to share perspectives and experiences and develop a common understanding and terminology. The necessity to increase predictability for the industry was also highlighted.

Session 3, chaired by Eldin Smajic (Roche), was dedicated to digital health. Frederick Flöther (IBM) opened with a presentation showing how quantum computing can bring radically new solutions for healthcare. He was followed by Antoine Bourrier (Capgemini), who spoke about digital innovations in health care and highlighted learnings from the innovation history of the internet of things. Iain

Simpson (Phillips-Medisize) explained why adherence should be included as a critical measurement in clinical trials and how connected drug delivery devices can capture accurate medication adherence data in real time. The session was complemented by Lada Leyens (Roche), who presented an industry perspective on digital endpoints in clinical trials.

Wrap-up and closing
Shayesteh Fürst-Ladani, President of MPP, thanked the speakers for their presentations and the audience for their interest. David Haerry, Chair of the MPP 2022 Program Committee, briefly summarized the presentations and discussions throughout the day and pointed out outstanding aspects. He emphasized that the value to the patient is essential, and that patients' perspectives need to be taken into consideration at the different steps of the products lifecycle. He stressed the need to collectively define a framework for the collection and use of health data.

Company profiles and networking
In parallel to the conference program, sponsors and exhibitors showcased their products and services in the exhibition space. The conference provided the opportunity for participants to establish new and fruitful contacts across the pharma, medtech and tech sectors.

MPP 2022 Program Committee
The MPP 20222 Program Committee was led by its Chair David Haerry (European AIDS Treatment Group Brussels) and supported by Daniel Delfosse (Swiss Medtech), Ruth Foster (MSD), Marisa Papaluca (Imperial College London), Mike Wallenstein (Novartis), Eldin Smajic (Roche) and Christina Hofmann (TÜV SÜD). The Program Committee defined the conference theme and session topics, selected the speakers and accompanied the preparation of the different sessions.

About the MPP Association
The MPP Association is a cross-sectoral not-for-profit industry association focusing on combined products. The association comprises medtech, pharma and tech companies dedicated to enhancing the synergies between these industries. The association aims to achieve a balanced regulatory framework for combined products in Europe, reduce time to market and improve access to innovative and safe healthcare products.

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