MEDTECH & PHARMA
PLATFORM

Medtech & Pharma Platform 2024 Annual Conference

3 September 2024, Basel, Switzerland

Combined products of tomorrow – Developing solutions for and with patients

About the conference

The 11th Medtech & Pharma Platform Association (MPP) Annual Conference (MPP 2024) was held on 3 September 2024, in Basel, Switzerland. The theme of this year's conference was *"Combined products of tomorrow – Developing solutions for and with patients".* 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. More than 190 participants from the 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 alongside Mike Wallenstein the Chair of the MPP2024 Program Committee (Novartis). They welcomed the participants on behalf of the MPP and introduced the Program Committee members underling the meaningful role played by the MPP, in connecting the pharma, medtech and digital sectors to exchange on combined products and define common solutions.

Theresa Jeary (BSI) and Nathalie Schober-Ladani (SFL, a Veristat company) moderated the first session on **connected combined products**, artificial intelligence, data security and digital solutions. Speakers from the German Research Center, Siemens Healthineers, BSI and Takeda presented and discussed challenges in relation to the design and authorization of AI-based and digital applications, as well as the impact that those technologies have on the healthcare landscape.

The second session on the combined use of ***in vitro*** **diagnostics** (IVDs) and **companion diagnostics** (CDx) with medicinal products was moderated by Marie-Claire Beurier (Roche) and Fanny Barbotin (BD). It delved into the impact of the *In Vitro* Diagnostics Regulation (IVDR) and its interaction with other relevant legislations, with a special focus on combined trials. Experts from the AGES/HMA CTCG and Bayer provided insights on the EU COMBINE project activities and challenges of navigating the medical device and clinical trials legislations in combined trials, while an expert from TÜV SÜD shared insights on the conformity assessment of CDx under the IVDR.

The panel moderated by Mike Wallenstein (Novartis) offered insights into national and regional regulatory strategies, current challenges, recent developments related to the **regulation of combined products** and **ongoing global harmonization efforts**. Each panelist gave a short opening statement. James Bertram from the FDA presented the agency's approach to regulating combined products, recent developments in guidance developments, and approach towards digital health technologies (DHTs) in drug development. Karoline Mathys from Swissmedic delivered a presentation on the Swiss approach for combined studies and international regulatory reliance. Françoise Schlemmer from Team-NB provided insights into the state of play of discussions between the EMA and Notified Bodies

on Art. 117 of the Medical Devices Regulation (MDR). Virginia Rojo from the EMA shared an overview of efforts deployed to support the lifecycle of combined products including the recent updates of relevant guidelines and initiatives such as the EMA pilot on scientific advice on high-risk devices. All panelists agreed on the relevance of fine-tuning legal frameworks and contributing to international harmonization. Theresa Jeary shared BSI's perspectives and experience on issuing Notified Body opinions (NBOp). Ruth Foster from MSD presented industry perspectives around combined trials and the use of digital health technology in clinical trials. After the opening statements, panelists exchanged views and took questions from the audience. During the discussions that followed, panelists highlighted, among other aspects, the benefits of harmonization efforts across different geographies. They also pointed out that it is important to engage with regulators when dealing with borderline products. Separately, challenges in relations to the consistency of the outcomes of Notified Bodies' assessment were mentioned, and Team-NB reported ongoing efforts towards greater harmonization of assessments. Finally, the EMA reported being aware of the overlap between NBOp and the EMA's review in the area of sterility of combined products and it is currently actively discussing the matter to find a solution.

Kaspar Sutter, Head of the Department of Economic Affairs, Social Affairs and the Environment of the Canton of Basel-City welcomed all participants and highlighted Basel's significant role in the global life sciences sector.

The final session was dedicated to **patients' inclusion** and perspectives on the lifecycle of combined products and moderated by Dr. Jasmin Barman-Aksözen from the International Porphyria Patient Network (IPPN, University of Zurich) and Mike Wallenstein (Novartis). The session saw experts from PersonalPulse, Partners for Patients, EUPATI Switzerland and Novartis exchange views and solutions to ensure the meaningful involvement of patients in the development and authorization of combined products. The session concluded on the thought that much more remains to be done to include patients in the lifecycle of combined products.

Throughout the day, attendees engaged in question rounds on the development of products that integrate medicinal products, medical devices, and digital health components, and gained valuable insights from experts, patient representatives, Notified Bodies, regulators and stakeholders from the medtech, pharma, and tech sectors.

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 2024 Program Committee

The MPP 2024 Program Committee was led by its Chair Mike Wallenstein (Novartis) and supported by Marie-Claire Beurier (Roche), Nathalie Schober-Ladani (SFL a Veristat company), Dr. Jasmin Barman-Aksözen (IPPN, University of Zurich), Fanny Barbotin (BD) and Theresa Jeary (BSI). 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, diagnostic, 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.

Contact us

Medtech & Pharma Platform
association@medtech-pharma.com
https://www.medtech-pharma.com/