SYMPOSIUM 2026 UTRECHT

Combination Products Programme

Monday 19 October 2026 – Tuesday 20 October 2026

Beatrix Building, Royal Jaarbeurs, Utrecht, The Netherlands

Please note, the programme may be subject to change.

	MONDAY 19TH OCTOBER 2026
13:30 – 14:40	Lunch Break
14:40 – 16:00	CP1 – Combo Group: Aligning Regulatory Practice for Combination Products
16:00 – 16:40	Networking Break
16:40 – 18:00	CP2 – Global Approaches to Combination Products
	TUESDAY 20TH OCTOBER 2026
09:00 – 10:20	CP3 – Potential gaps in post-market compliance for combination products
10:20 – 11:00	Networking Break
11:00 – 12:20	CP4 – Effectively Managing Changes to Drug-Device Combination Products
12:20 – 14:00	Lunch Break
14:00 – 15:20	HM6/MD7/IVD7 – The Future of Combined IMP/IVD Trials in Europe: COMBINE, CTIS Integration, and the Emerging Regulatory Model
15:20 – 16:00	Networking Break
16:00 – 17:20	CP5 – Combination Products of the Future

Monday 19 October 2026 – DAY 1

Time	Session
13:30 - 14:40	Lunch Break
14:40–14:40	Welcome Speech

Speakers

- Margareth Jorvid, Chief Executive Officer/Chair of the TOPRA Combination Products Symposium Working Party (CPSWP), Methra Uppsala, Sweden

14:50–16:00	CP1 – Combo Group: Aligning Regulatory Practice for Combination Products

As combination products become increasingly more prevalent and complex, regulatory integration between medicinal and device frameworks is becoming critical. These products can experience many challenges in getting to market. The formation of the COMBination products Operational group (COMBO) is a significant step towards strengthening coordination across the EU regulatory framework with regards to this rapidly developing area, involving experts from the EMA, Commission, Medicines Competent Authorities, Device Authorities and Notified Bodies. Two distinct streams MD and IVD will explore solutions on identified issues to clarify and streamline processes and scope of activities under the current frameworks. Priority topics for MD include consultation for ancillary substances, Notified Body opinion and co-packaged devices & labelling. For IVD priority topics include distinction CDs vs IVDs and CDx consultation. This session will explore the challenges the COMBO group aims to address and the progress the group has made since its inception in October 2025.

Session Leaders

- Alberto Gañan Jimenez, Head of Committees and Quality Assurance Department, EMA, The Netherlands

Speakers

- Theresa Jeary, Global Head, Medicinal & Biologics Team, BSI, United Kingdom
- Chiara Orlandi, Policy Officer, European Commission, Belgium
- Christelle Bouygues, Senior Regulatory Affairs Officer, EMA, The Netherlands
- Elisabeth Strutzmann, Head of Unit Quality Assessment of Medicinal Products and IMPDs (chemicals), AGES, Austria

16:00–16:40	Networking Break
16:40–18:00	CP2 – Global Approaches to Combination Products

Whilst combination products present unique regulatory challenges, much like other medicinal products and medical devices, they are subject to divergent pathways across different jurisdictions. As global innovation accelerates,

	understanding the requirements of each region to develop robust global strategies is key for professionals working in this space. This session will compare regulatory pathways and classification approaches for combination products across major global jurisdictions (including Europe and USA) and identify best practices for regulatory strategy. The session will also provide the latest regional updates and explore what each sector can learn from the others regarding regulatory frameworks for combination products.
	Session Leaders • Margareth Jorvid, Chief Executive Officer, Methra Uppsala, Sweden
	Speakers • John Barlow Weiner, Member, Barr Consulting LLC, United States of America • Chiara Orlandi, Policy Officer, European Commission, Belgium • Peter Postert, Project Manager Medical Devices, Hormosan Pharma, Germany • Christelle Bouygues, Senior Regulatory Affairs Officer, EMA, The Netherlands
18:00–18:05	**Closing Speech**

End of Day 1

Tuesday 20 September 2026 – DAY 2

Time	Session
09:00 – 10:20	**CP3 – Potential gaps in post-market compliance for combination products**
	Combination products operate within a complex post-market environment, in which marketing authorisation holders and manufacturers must ensure coherent, compliant and safety monitoring systems. This session will explore how pharmacovigilance and post-market surveillance (PMS) requirements intersect for drug-device combinations, providing insights on what is expected and how to practically implement robust systems. along with case studies from industry experts.
	Session Leaders • Ronald Boumans, Regulatory Affairs Consultant, Boumans Regulatory Consulting B.V., The Netherlands
	Speakers will include… • Jan Bart Hak, Director MedTech Regulatory Sciences, ProPharma, The Netherlands
10:20 – 11:00	**Networking Break**
11:00 – 12:20	**CP4 – Effectively Managing Changes to Drug-Device Combination Products**
	Managing lifecycle changes for combination products in Europe presents distinct regulatory and operational challenges due to the dual oversight of medicinal product and medical device frameworks. Variations to the marketing authorisation may intersect with significant change assessments under the Medical Device Regulation (MDR), requiring coordination between competent authorities, notified bodies, and manufacturers. This session will examine how to plan and implement complex changes to drug-device combinations, such as device design modifications. It will explore regulatory classification of changes, documentation expectations, timelines, and strategies for aligning variation procedures with device conformity assessment requirements. Practical case studies will highlight common pitfalls, including misalignment of change control systems, impact assessments for primary mode of action, and maintaining CE certification during medicinal variations. Attendees will gain insights into proactive lifecycle planning, cross-functional governance, and maintaining compliance while supporting innovation and supply continuity.
	Session Leaders • Janine Jamieson, Editor, European IPQ, Sweden
	Speakers will include… • Louise Place, Senior Director CMC Regulatory Affairs Devices, GSK, United Kingdom • Virginia Rojo Guerra, Head of Office, EMA, The Netherlands
12:20–14:00	**Lunch Break**

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14:00–15:20	HM6/MD7/IVD7 - The Future of Combined IMP/IVD Trials in Europe: COMBINE, CTIS Integration, and the Emerging Regulatory Model

The regulatory landscape for combined clinical trials involving investigational medicinal products (IMPs) and in vitro diagnostic medical devices (IVDs) is undergoing significant transformation. Building on the analysis published in the 2026 February edition of the Regulatory Rapporteur, this session will provide an updated perspective on the latest developments in the European Commission's EC COMBINE initiative, including progress on harmonisation pilots, early CTIS integration concepts, and potential future models for unified IMP/IVD submission pathways.

With the introduction of the new EU Biotech Act, additional changes are expected that may reshape requirements for supporting evidence packages, oversight processes, and the interaction between the Clinical Trials Regulation (CTR) and the In Vitro Diagnostic Regulation (IVDR). Particular attention will be given to how Request for Information (RFI) pathways could evolve under this new legislative framework, and what these changes may mean in practical terms for clinical trial sponsors, especially those conducting biomarker driven or co-development trials.

The session intends to offer a cross-industry view of emerging regulatory and operational expectations, incorporating lessons learned from ongoing engagement across sponsors, competent authorities, and notified bodies. Operational and authority perspectives will be shared by co presenters enabling a multi stakeholder discussion on practical challenges, anticipated system behaviour, and opportunities for greater procedural alignment. Attendees will gain an up to date understanding of current developments, near term industry implications, and forward-looking considerations for planning and executing combined IMP/IVD trials in the EU.

Learning Objectives

- Understand emerging EU requirements for combined IMP/IVD trials under CTR, IVDR, and the COMBINE initiative.
- Analyse how COMBINE outputs and the proposed EU Biotech Act may reframe RFI roles, sequencing, and authority interactions.
- Consider the implications for future regulatory governance and procedural alignment under CTR and IVDR.

Session Leaders

- Amber McNair, Associate Director, Clinical Trials Regulatory, IQVIA, United Kingdom
- Margareth Jorvid, Chief Executive Officer, Methra Uppsala, Sweden

Speakers

- Deepa Subramaniyan, Senior Clinical Trial Regulatory Lead, Roche, Switzerland
- Maurice Steenhuis, Medical Technology Assessor, CCMO, The Netherlands
- Olga Tkachenko, Policy Officer, European Commission, Belgium
- Stiina Aarum, Scientific Officer, EMA, The Netherlands

15:20 – 16:00	Networking Break

16:00–17 :20	CP5 – Combination Products of the Future

The convergence of new technologies, such as cell therapy, is redefining the landscape of combination products. Advanced therapy medicinal products (ATMPs), including engineered cell therapies, increasingly rely on specialised delivery systems, digital monitoring tools and companion devices. These new types of products raise plenty of complex regulatory questions, such as around classification, conformity assessments and long-term follow-up requirements. This session will have innovators who are working on such new technologies, and they how have addressed the regulatory challenges with these products. The session will also have a representative from a national competent authority on how authorities are supporting the advent of these new technologies.

Session Leaders

- Margareth Jorvid, Chief Executive Officer, Methra Uppsala, Sweden

Speakers

- Ilona Reischl-Kok, Assessor, AGES, Austria
- James Wabby, Vice President, Head of Regulatory Strategy: Combination Products and Emerging Medical Technologies, AbbVie, United States of America [*Online*]
- Theresa Jeary, Global Head, Medicinal & Biologics Team, BSI, United Kingdom

- Alberto Gañan Jimenez, Head of Committees and Quality Assurance Department, EMA, The Netherlands

End of the Combination Products Symposium