



SYMPOSIUM 2026 UTRECHT

SME Programme

Tuesday 20 October 2026 – Wednesday 21 October 2026

Beatrix Building, Royal Jaarbeurs, Utrecht, The Netherlands



Please note, the programme may be subject to change.

TUESDAY 20 TH OCTOBER 2026	
12:20 – 14:00	Lunch Break/Registration
14:00 – 15:20	SME1 – How can SMEs navigate the regulatory legislative wave: small but compliant
15:20 – 16:00	Networking Break
16:00 – 17:20	SME2 – Rare disease regulatory pathways. Plausible mechanisms, prior knowledge and novel licensing pathways
WEDNESDAY 21 ST OCTOBER 2026	
09:00 – 10:20	SME3 – The Criticality of Regulatory and Product Strategy for Innovative Drug Companies
10:20 – 11:00	Networking Break
11:00 – 12:20	SME4 – From Innovation to Investment: Using Regulatory Strategy to Win Grants and Funding
12:20 – 14:00	Lunch Break
14:00 – 15:20	SME5 – Lessons Learned from SMEs Taking Their First Asset to Clinic

Tuesday 20 October 2026 – DAY 1

Time	Session
13:00-14:00	Registration (Lunch Served During Registration)
14:00-14:10	Welcome Speech

Speakers

- Anna Koptina, PhD, CEO and Principal Regulatory Consultant, Exellerium AB, Sweden

14:10-15:20 SME1 – How can SMEs navigate the regulatory legislative wave: small but compliant

SMEs and mid-caps in the life sciences sector will face a rapidly evolving regulatory landscape shaped by the implementation of the revised EU Pharmaceutical Legislation—including structural changes within the EMA—as well as the rollout of the CTR, the HTA Regulation, and the MDR/IVDR frameworks. In addition to “medicines-specific” legislation, companies must also comply with broader environmental legislation or other types of legislations (i.e., AI Act) that might affect the manufacturing of medicines or their ingredients. These overlapping developments present both opportunities and challenges, particularly for smaller companies with limited regulatory and strategic capacity. The Commission has begun addressing some of these issues through new structures introduced under the Biotech Act, which aim to support SMEs in navigating regulatory challenges.

This session will examine how these reforms may affect the development planning and launch strategies of SMEs and mid-caps in Europe, and what additional support may be needed from regulators to help companies navigate this complex environment. A key focus will be assessing where SME-tailored measures under the Biotech Act may provide meaningful support, and where gaps remain—especially for mid-caps that are often too large to qualify for SME-specific incentives but too small to absorb increasing administrative or compliance burdens. The session will also explore how the Commission and EMA can reduce uncertainty by offering clearer transition guidance, ensuring continuity of scientific expertise, and maintaining accessible, predictable regulatory tools for innovators.

Expected outcomes include a shared understanding of the regulatory risks and opportunities introduced by the new legislative cycle, identification of areas where further clarification or support is needed, and practical insights on how SMEs and mid-caps can continue contributing to innovation in Europe despite a rapidly shifting regulatory landscape.

Session Leaders

- Anna Koptina, PhD, CEO, Exellerium AB, Sweden
- Marta Provencio de Olmo, Regulatory Affairs Manager, EUCOPE, Belgium

Speakers will include...

- Shekhar Natarajan, Vice President- International Regulatory Affairs and Policy, Dyne Therapeutics Europe, United Kingdom
- Alexander Natz, Secretary General, EUCOPE, Belgium



- Thomas Balotti, Scientific Specialist, EMA, The Netherlands

15:20–16:00 Networking Break

16:00–17:20 SME2 – Rare disease regulatory pathways. Plausible mechanisms, prior knowledge and novel licensing pathways

One in three children with rare disease die before the age of five. Ten thousand rare diseases remain without satisfactory treatment options. Only 5% of rare diseases have medicinal products approved through the regulatory procedures. Developing therapies for rare diseases demands scientific ambition in the face of profound constraints at every step of development. With small and geographically dispersed patient populations, limited natural history data, and often scarce resources, innovators must navigate uncertainty at every stage of development. This panel discussion brings together experts who are currently navigating these challenges to explore how teams generate meaningful evidence, design feasible trials and collaborate across academic, clinical, and regulatory communities. Speakers will share practical strategies for advancing promising therapies despite data gaps, operational hurdles, and funding pressures.

Session Leaders

- Christine Grew, Partner, RareGeniX Consulting, United Kingdom
- Dima Al-Hadithi, Partner – CMC, RareGeniX Consulting, United Kingdom

Speakers will include...

- Leoni Mahal, Senior Regulatory Affairs Manager, Cell & Gene Therapy Catapult, United Kingdom
- Julia Vitarello, Mila's Mom, Founder, Mila's Miracle Foundation, United States of America [Online]
- Kiki Tzogani, Senior Scientific Officer, EMA, The Netherlands

17:20–17:25 Closing Speech – Day 2

End of Day 1

Wednesday 21 October 2026 – DAY 2

Time	Session
08:55–09:00	Welcome to Day 2
09:00–10:20	SME3 – The Criticality of Regulatory and Product Strategy for Innovative Drug Companies

SMEs are increasingly taking on the role of drug discovery and providing a product pipeline for the Pharmaceutical Industry. There are two important areas to address: the importance of developing a successful regulatory and product strategy and how to harness new technologies.

SMEs increasingly must take their pipeline assets further in the development process. Funders are becoming more demanding during the due diligence process requiring increased supporting data and regulatory certainty. The likelihood of regulatory success has become a critical indicator frequently requested by VC and Pharma companies.

Understanding this and how to incorporate a sophisticated regulatory and product strategy are increasingly important concepts for SMEs.

The application of new technologies such as robotics, in silico testing, AI, machine learning and microfluidics, new modalities has enabled companies to expedite the discovery and development process, however adoption of a satisfactory regulatory framework dictates the application of these technological advances within a regulated environment.

Session Leaders

- Wim Neckebroek, Director of Regulatory Affairs, Kintiga, United Kingdom

Speakers will include...

- Stephen Liggett, Executive Director Future Medicines Institute, Future Medicines Institute, United Kingdom
- Alex Yates, Founder & Advisor, Agyra Ltd, United Kingdom
- Lisa Bell, Global Head of Regulatory Affairs, Argenx, Belgium
- Thomas Balotti, Scientific Specialist, EMA, The Netherlands



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10:20–11:00 **Networking Break**

11:00–12:20 **SME4 – From Innovation to Investment: Using Regulatory Strategy to Win Grants and Funding**

For small and medium-sized life science companies, a strong regulatory strategy can be a powerful tool for attracting funding and securing grants. This session explores how SMEs can use their Target Product Profile (TPP) and regulatory roadmap to clearly communicate product value, development feasibility, and risk mitigation to investors and grant reviewers. Speakers will discuss practical ways to align regulatory planning with funding milestones, translate regulatory insights into compelling pitch narratives, and demonstrate credibility to non-regulatory stakeholders. Attendees will gain actionable guidance on turning regulatory thinking into a strategic asset that strengthens investment cases and increases success in competitive funding environments.

Session Leaders

- Marie Uguen, Chief Regulatory & Quality Officer, SpringVision, France

Speakers will include...

- Fred Marin, Chief Executive Officer, USIL Therapeutics, Luxembourg
- Thomas Balotti, Scientific Specialist, EMA, The Netherlands

12:20–14:00 **Lunch Break**

14:00–15:20 **SME5 – Lessons Learned from SMEs Taking Their First Asset to Clinic**

Bringing a therapy from proof-of-concept to clinic is a defining milestone for any start-up. The journey from discovery to regulatory approval is fraught with complexity, resource constraints, and the need to orchestrate multiple stakeholders. This session invites regulatory professionals who find themselves at the heart of this challenge, balancing the demands of CDMOs, CROs, consultants, regulatory and clinical operations, budgets, and clinical supply chains, all whilst ensuring compliance and timely delivery.

Drawing on the real-world experiences of innovators who have recently secured EU Clinical Trial Application (CTA) and/or US Investigational New Drug (IND) approvals, we will dissect the regulatory journey step by step. Together, we will explore the practical logistics of authoring and managing regulatory documents, establishing efficient systems and processes, and overcoming common hurdles faced by lean organisations.

Session Leaders

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

Speakers will include...

- Christine Grew, Director, Canopy Life Sciences, United Kingdom
- Dima Al-Hadithi, Partner – CMC, RareGeniX Consulting, United Kingdom
- Jan Mothes, Regulatory Affairs Lead, Cell & Gene Therapy Catapult, United Kingdom
- Annabella Amatulli, Head of Regulatory Affairs, Enterprise Therapeutics, Italy

End of the SME Symposium