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 October 2026 – DAY 1

Time	Session
13:00-14:00	**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 and Principal Regulatory Consultant, Exellerium AB, Sweden • Marta Provencio, Regulatory Affairs Manager, EUCOPE, Belgium
	Speakers will include… • Shekhar Natarajan, Vice-President of Regulatory Affairs, Dyne Therapeutics Europe, United Kingdom
15:20–16:00	**Lunch 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 at RareGeniX Consulting, RareGeniX Consulting, United Kingdom • Dima Al-Hadithi, Partner – CMC, RareGeniX Consulting, United Kingdom
	Speakers coming soon... • Jan Mothes, Senior Regulatory Affairs Manager, Cell & Gene Therapy Catapult, United Kingdom • Julia Vitarello, Founder and Chair/CEO, Mila's Miracle Foundation, United States of America [*Online*]
17:20–17:25	**Closing Speech – Day 2**

End of Day 1

Wednesday 21 October 2026 – DAY 2

Time	Session
08:50–09:00	**Welcome to Day 2**
09:00–10:20	**SME3 – The Criticality of Regulatory and Product Strategy for Innovative Drug Companies**
	SMEs increasingly taking on the role of drug discovery and providing a product pipeline for the Pharmceutical 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 Neckebroeck, 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
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, SparingVision, France
	Speakers will include... • Fred Marin, Chief Executive Officer, USIL Therapeutics, Luxembourg
12:40–14:00	**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 round-table discussion 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 two early development 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, Regulatory CMC Consultant, Minaret Consulting Limited • Jan Mothes, Senior Regulatory Affairs Manager, Cell & Gene Therapy Catapult, United Kingdom

End of the SME Symposium