EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SME Info Day – Navigating EMA support: from innovation to marketing authorisation

06 November 2026, 09:15-16:00
Hybrid meeting – Broadcast/Meeting room 2C (EMA, Amsterdam)

The SME Info Day is a training event dedicated to small and medium-sized enterprises in the pharmaceutical sector. This year's event will focus on the challenges commonly faced by SMEs during the marketing authorisation process and how early regulatory support can help address these challenges and facilitate the authorisation of medicines for human use.

The programme will cover topics including early interaction tools, EMA scientific advice, clinical trials in the EU and the Biotech Act, preparation for marketing authorisation dossiers and medical devices.

The Info Day will also help SMEs prepare for the forthcoming new pharmaceutical legislation by raising awareness of key changes and their practical implications for medicines development and authorisation.

SME Info Day

Navigating EMA support: from innovation to marketing authorisation

Chair: Leonor Enes (EMA)

09:15 Welcome and opening remarks

Emmanuel Cormier (EMA)

09:30 Session 1: Navigating the EMA and European medicines regulatory network support to innovation

EMA SME support
Hélène Casaert (EMA)

EMA Innovation Task force
Oriane Blanquie (EMA)

Support to orphan and paediatric medicines
Roberto de Lisa (EMA)

EMA scientific advice & PRIME
Iordanis Gravanis (EMA)

Advice by national competent authorities
Yoana Nuevo Ordóñez (EU-IN)

An SME's experience
Shekhar Natarajan (Dyne Therapeutics)

Questions & answers
Moderated by Leonor Enes (EMA)

10:45 *Coffee break*

11:00 Session 2: The Biotech Act and latest developments in EU clinical trials

The Biotech Act and the Clinical Research Investment Plan
TBC (EC), Romina-Belen Escobar Ramos (EC)

Clinical Trials Information System (CTIS): status update
Pieter Vankeerberghen (EMA)

ACT EU: progress and key actions
Laura Pioppo (EMA)

Clinical trial approvals: experience with FAST EU and COMBINE
Marianne Lunzer (CTCG), tbc (EC)

Panel discussion and questions & answers

Moderated by Ana Zanoletty Perez (EMA)

Panellists: tbc (EC); Romina-Belen Escobar Ramos (EC), Laura Pioppo (EMA), Marianne Lunzer (CTCG)

12:15 ***Lunch***

13:00 Session 3: Dossier preparation and the evolving centralised procedure

Best practices and the future centralised procedure

Francesca Day and Michael Vogel (EMA)

EMA pilot on pre-submission interactions

Gaelle Bec (EMA)

Submission readiness: common challenges and practical lessons for SMEs

Thomas Ballotti (EMA)

Questions & answers

Moderated by Francesca Day (EMA)

14:00 Session 4: Shaping the future

Update on the implementation of the new pharmaceutical legislation

Melania Fanari (EMA)

14:30 ***Coffee break***

14:45 Session 5: Combination products and medical devices: navigating EU regulatory pathways

EMA's role in supporting combination products

Christelle Bouygues & Stiina Aarum (EMA)

Expert panels insights into orphans and breakthrough designations for medical devices

Hilde Bastaerts (EMA)

Questions & answers

Moderated by Hélène Casaert (EMA)

15:45 Session 6: International collaboration for global submissions

An overview of EMA international collaboration initiatives and upcoming developments

Radhouane Cherif (EMA)

16:00 Closing remarks

Leonor Enes and Constantinos Ziogas (EMA)

List of speakers and panellists

Emmanuel Cormier	European Medicines Agency
Constantinos Ziogas	European Medicines Agency
Leonor Enes	European Medicines Agency
Hélène Casaert	European Medicines Agency
Thomas Ballotti	European Medicines Agency
Oriane Blanquie	European Medicines Agency
Roberto de Lisa	European Medicines Agency
Iordanis Gravanis	European Medicines Agency
Ana Zanoletty Perez	European Medicines Agency
Laura Pioppo	European Medicines Agency
Pieter Vankeerberghen	European Medicines Agency
Francesca Day	European Medicines Agency
Michael Vogel	European Medicines Agency
Gaelle Bec	European Medicines Agency
Melania Fanari	European Medicines Agency
Christelle Bouygues	European Medicines Agency
Stiina Aarum	European Medicines Agency
Hilde Bastaerts	European Medicines Agency
Radhouane Cherif	European Medicines Agency
Romina-Belen Escobar Ramos	European Commission, DG RTD
Yoana Nuevo Ordóñez	EU Innovation Network
Marianne Lunzer	Clinical Trials Coordination Group
Shekhar Natarajan	Dyne Therapeutics