EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Scientific Evidence Generation Department

Call for expression of interests for companies, consortia or any other organisations developing software platforms to participate in a multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment

Background

Mechanistic models are increasingly being used to support the development of medicinal products for human use. The regulatory assessment of mechanistic models is focussed on determining whether the models are qualified for their intended use. Guidance documents on the requirements for reporting on and qualification of mechanistic models, covering different types of models (physiologically based pharmacokinetic models and quantitative systems pharmacology models) are currently being developed or updated.

The EMA is organising a multi-stakeholder workshop that will bring together academia, regulators and industry to discuss the experience with the current regulatory landscape around the application of mechanistic models to support drug development.

The aims of the workshop are to:

- Hear the views of stakeholders and experts on the current regulatory framework around the assessment of mechanistic models.
- Share the regulatory challenges associated with the assessment of mechanistic models with stakeholders and experts.
- Identify opportunities for future regulatory qualification of mechanistic models.
- Define how the current EU regulatory framework can be refined to streamline the use and assessment of mechanistic models.

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Delegates from companies or consortia developing software platforms

The EMA is issuing this open invitation for delegates from companies or consortia, or any other organisations, developing software platforms for mechanistic models (PBPK, QSP, PBBM) that would be willing to deliver a 20 min presentation (incl. 5 min for questions) during session 3: "The qualification of mechanistic models through the EMA qualification framework and beyond.", organised on 8 October 2025 from 13:30 – 17:00 (see draft agenda for more details). Priority will be given to platforms that can demonstrate broad cross-industry uptake in drug development, through the provision of use-cases.

In this session EMA wishes to interact with its stakeholders on the current landscape around the qualification of mechanistic models to support regulatory decision making. Topics covered during the presentation should include, but are not limited to: Evaluation of platform performance and qualification for specific CoU (for definition see EMA PBPK guideline) including the standards for benchmarking performance and reproducibility, required level of external evidence, reporting SOPs, version control and software product life cycle.

In addition, delegates are expected to join as panellists for a Q&A, moderated by EMA, at the conclusion of the session.

Companies or consortia, or any other organisations, developing software platforms for mechanistic models (PBPK, QSP, PBBM) are invited to submit proposals for delegates by 15 June 2025. Submissions should be accompanied by a CV of the delegate and a brief presentation of their experience with software platforms for mechanistic models. The EMA will review the proposals received and issue formal invitations, ensuring the broadest possible representation of stakeholders and of the current landscape in the development of software platforms for mechanistic models. In any way the choice of delegates should not be interpreted as the EMA endorsing a particular software platform or supporting a particular stakeholder.

Contact point: MechanisticModelsWorkshop@ema.europa.eu