



European Directorate for the Quality of Medicines & HealthCare

Council of Europe

edqm
European Directorate
for the Quality
of Medicines
& HealthCare | Direction européenne
de la qualité
du médicament
& soins de santé

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CMC strategy forum
Basel, 21 October 2025
Rapid Fire Session with Regulatory updates

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EDQM**

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European Directorate for the Quality of Medicines & HealthCare, EDQM

- ★ Part of the Council of Europe
- ★ Founded in **1964**
- ★ European Pharmacopoeia: Partial agreement (39 member states & the EU + 33 observers)
- ★ Contributes to **public health and access to good quality medicines and healthcare in Europe**
- ★ Wide scope of activities

Our vision

**Together for
better health,
for all**

Our mission

To contribute to public health protection by engaging with an international community of experts and stakeholders



New Pyrogenicity Strategy

Suppression of the Rabbit Pyrogen Test



Phasing out the Rabbit Pyrogen Test - Communication to stakeholders



Save the date! Follow-up EPAA/EDQM event

25-26 February 2026 Brussels

<https://www.edqm.eu/en/-/save-the-date-joint-edqm-epaa-symposium-pyrogen-testing-2.0-ethical-evolving-and-eco-friendly-implementing-safe-rapid-state-of-the-art-and-sustainable-non-animal-approaches-worldwide-25-26-february-2026>



Rapid Microbiological Methods



Exploring a certification system for rapid microbiological methods



Identification of

- ★ Benefits
- ★ Challenges
- ★ Questions re. stakeholder needs (what would be acceptable/not acceptable)



Concept stage:

Still lots of questions to address



Stakeholders feedback

- ★ Needs
- ★ Embark
- ★ Shape the system



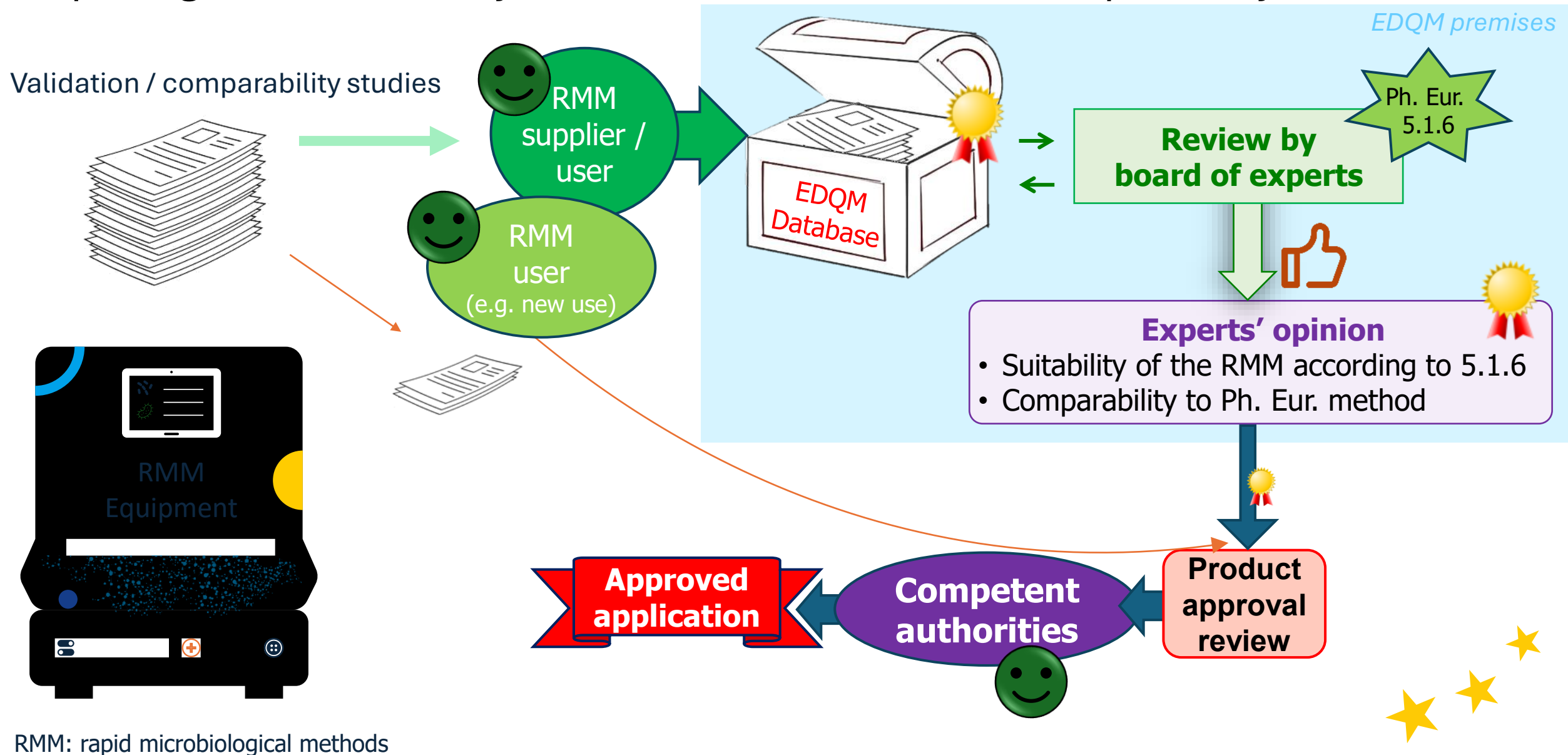
EDQM WORKSHOP

EXPLORING A CERTIFICATION SYSTEM
FOR THE VALIDATION OF RAPID
MICROBIOLOGICAL METHODS

15-16 October 2024, Strasbourg, France



Exploring a certification system for the validation and comparability of RMM



RMM: rapid microbiological methods

Take away message: The EDQM is...

- ★ ...participating in the establishment of **innovative approaches to QC** of medicines in Europe
- ★ ... **listening** to its **stakeholders** to help shaping up these approaches
- ★ ...facilitating the **regulatory framework** in Europe **and beyond** by the establishment of standardised approaches
- ★ promoting **globalisation** of these approaches



*Thank you for your
attention!*

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 <https://go.edqm.eu/Newsletter>

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