



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 October 2026
EMA/234496/2026

Agenda – Public System Demo Q4 2026 **Draft**

10 December 2026, 09:00 – 11:30 CEST (Live Broadcast)

Item	Agenda	Time
1.	Welcome / Introductions Jean-Michel Becar Head of Portfolio Management Office, EMA	09:00 – 09:05
Product Lifecycle Management Value Stream (PLM VS)		09:05 – 10:35
2.	Product Management Service (PMS) Marcos Fernandez Gomez Co-Product Owner for PMS, EMA Q&A and feedback session	20 min 09:05 – 09:25
3.	Electronic application forms (eAF) – PLM portal and eSubmissions Mihaela Pereteatcu Product Owner for PLM eAF, EMA Kristiina Puusaari Product Owner for eSubmissions eAF, EMA Q&A and feedback session	15 min 09:25 – 09:40
4.	eCTD v4.0 (Electronic Common Technical Document version 4) Kristiina Puusaari Epic Owner and Product Owner for eCTD v4.0, EMA Q&A and feedback session	15 min 09:40 – 09:55
5.	Electronic product information (ePI) Elizabeth Scanlan Epic Owner and Product Owner for ePI, EMA Evin Drusys Network Product Owner for ePI, AEMPS Q&A and feedback session	15 min 09:55 – 10:10
Break		10 min



6.	Union Product Database (UPD) Beyhan Mustafiov Product Owner for UPD, EMA Saskia Schiemann Network Product Owner for UPD, BVL Q&A and feedback session	15 min 10:20 – 10:35
Monitoring Value Stream (MON VS)		10:35 – 10:55
7.	EudraGMDP¹ - Creation of Wholesale Distribution Authorisation (WDA) and Good Distribution Practice (GDP) certificates Ivana Radic Product Owner for EudraGMDP, EMA Q&A and feedback session	20 min 10:35 – 10:55
Research & Development Value Stream (R&D VS)		10:55 – 11:25
8.	Clinical Trials Information System (CTIS) modernisation Ana Rodriguez Product Owner for CTIS, EMA Q&A and feedback session	30 min 10:55 – 11:25
Closing of the demo		11:25

¹ EudraGMDP is the name for the Union database referred to in article 111(6) of Directive 2001/83/EC as amended, and article 91 of Regulation (EU) 2019/6. It contains the following information: Manufacturing and import authorisations (MIA); Good Manufacturing Practice (GMP) certificates; Statements of non-compliance with GMP; Wholesale Distribution Authorisations (WDA); Good Distribution Certificates (GDP); Statements of non-compliance with GDP; Registration of manufacturers, importers and distributors of active substances located in the EEA (APIreg).