

13. - 27. Juni
2025

MEGRA



NEWSLETTER



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<u>Urheberrechtshinweis:</u>	

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Humanarzneimittel - EMA

Allgemeines – General

Human Medicines (updated)

Published on: 16 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/about-us/who-we-are/human-medicines>

Abbreviations used in EMA scientific committees and Coordination Group for Mutual Recognition and Decentralised Procedures (CMD) documents, and in relation to EMA's regulatory activities

Published on: 17 - June - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/abbreviations-used-ema-scientific-committees-coordination-group-mutual-recognition-decentralised-procedures-cmd-documents-relation-emas-regulatory-activities_en.pdf

How we work (updated)

Published on: 19 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/about-us/how-we-work>

Public event: advancing regulatory science research, Event 18 November 2024

Presentations and Video recording available

Published on: 24 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/public-event-advancing-regulatory-science-research>

Pharmakovigilanz – PRAC

New product information wording: extracts from PRAC recommendations on signals adopted at the 7-10 April 2025 PRAC (updated)

Published on: 19 - June - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/prac-recommendation/new-product-information-wording-extracts-prac-recommendations-signals-adopted-7-10-april-2025-prac_en.pdf

Referral: Finasteride- and dutasteride-containing medicinal products (updated)

Published on: 20 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/human/referrals/finasteride-dutasteride-containing-medicinal-products>

Referral: Sodium oxybate-containing syrup and oral solution for alcohol dependence

Published on: 20 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/human/referrals/sodium-oxybate-containing-syrup-oral-solution-alcohol-dependence>

Humanarzneimittel - EMA

Referral: Ipidacrine-containing medicinal products

Published on: 26 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/human/referrals/ipidacrine-containing-medicinal-products>

Article 57 product data (updated)

Published on: 24 - June - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/article-57-product-data_en.xlsx

List of medicines under additional monitoring (updated)

Published on: 25 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/medicines-under-additional-monitoring/list-medicines-under-additional-monitoring>

List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs) (updated)

Published on: 25 - June - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/list-european-union-reference-dates-eurd-frequency-submission-periodic-safety-update-reports-psurs_en.xlsx

Zulassung – Regulatory Affairs

Medicine evaluation figures (updated)

Published on: 18 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines/medicine-evaluation-figures>

Humanarzneimittel - EMA

Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API), several events

Video recording available

Published on: 18 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-4-february-2025>

<https://www.ema.europa.eu/en/events/qa-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-13-february-2025>

<https://www.ema.europa.eu/en/events/qa-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-18-february-2025>

<https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-march-2025>

<https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-april-2025>

<https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-may-2025>

On-boarding of users to Substance, Product, Organisation and Referentials (SPOR) data services (updated)

Published on: 19 - June - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/boarding-users-substance-product-organisation-referentials-spor-data-services_en.pdf

Data access to medicinal products for human use - Chapter 5 Annex A: Product data elements accessible by stakeholder group (updated)

Published on: 19 - June - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/data-access-medicinal-products-human-use-chapter-5-annex-product-data-elements-accessible-stakeholder-group_en.xlsx

Instructions on how to apply for a portfolio & technology meeting (PTM)

Published on: 20 - June - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/instructions-how-apply-portfolio-technology-meeting-ptm_en.pdf

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 16-19 June 2025

Published on: 20 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-16-19-june-2025>

Humanarzneimittel - EMA

Plasma master file certificates (updated)

Published on: 24 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/plasma-master-file-pmf-certification/plasma-master-file-certificates>

PRIME: 5 years' experience

Published on: 26 - June - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/report/prime-5-years-experience_en.pdf

Orphan Drugs und neuartige Therapierichtungen (ATMP)

No news published

Qualität – Quality

No news published

(Prä-) Klinische Forschung – Research and Development

Questions and answers for biological medicinal products

Published on: 16 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-guidelines/biological-guidelines/questions-answers-biological-medicinal-products>

Scientific guideline: Allergen products development for immunotherapy and allergy diagnosis in moderate to low-sized study populations (updated)

Published on: 16 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/allergen-products-development-immunotherapy-allergy-diagnosis-moderate-low-sized-study-populations-scientific-guideline>

Standard for exchange of non-clinical data (SEND): proof-of-concept study

Published on: 16 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/marketing-authorisation-guidance-documents/standard-exchange-non-clinical-data-send-proof-concept-study>

Scientific guideline: Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence (updated)

Published on: 17 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/reflection-paper-use-real-world-data-non-interventional-studies-generate-real-world-evidence-scientific-guideline>

Humanarzneimittel - EMA

Scientific guideline: Epidemiological data on blood transmissible infections (updated)

Published on: 19 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/epidemiological-data-blood-transmissible-infections-scientific-guideline>

Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 1: Registration requirements (updated)

Published on: 19 - June - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/products-management-services-pms-implementation-international-organization-standardization-iso-standards-identification-medicinal-products-idmp-europe-chapter-1-registration-requirements_en.pdf

Pre-authorisation guidance (updated)

Published on: 26 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/pre-authorisation-guidance>

Newsletters

Published on: 26 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/news-and-events/publications/newsletters>

Kinderarzneimittel – Paediatrics

Register of deadlines to put a medicinal product on the market In accordance with Article 33 of the Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006

Published on: 16 - June - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/register-deadlines-put-medicinal-product-market-accordance-article-33-regulation-ec-no-1901-2006-european-parliament-council-12-december-2006_en.pdf

Pflanzliche Arzneimittel – Herbal medicines

Herbal: Zingiberis rhizoma, F: Assessment finalised

Published on: 19 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/herbal/zingiberis-rhizoma>

EU and Canada strengthen cooperation on preparedness and response to cross border health threats

Published on: 24 - June - 2025

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/eu-and-canada-strengthen-cooperation-preparedness-and-response-cross-border-health-threats-2025-06-24_en

All-digital 12th Edition marks a new era for the European Pharmacopoeia

Published on: 24 - June - 2025

For more information, please refer to:

<https://www.edqm.eu/en/-/all-digital-12th-edition-marks-a-new-era-for-the-european-pharmacopoeia>

Medizinprodukte

MDCG 2025-4 - Guidance on the safe making available of medical device software (MDSW) apps on online platforms (June 2025)

Published on: 16 - June - 2025

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/mdcq-2025-4-guidance-safe-making-available-medical-device-software-mdsw-apps-online-platforms-june-2025-06-16_en

Update MDCG 2019-11 rev.1 - Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (June 2025)

Published on: 17 - June - 2025

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/update-mdcq-2019-11-rev1-qualification-and-classification-software-regulation-eu-2017745-and-2025-06-17_en

MDCG 2025-5 - Questions & Answers regarding performance studies of in vitro diagnostic medical devices under regulation (EU) 2017/746 (June 2025)

Published on: 18 - June - 2025

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/mdcq-2025-5-questions-answers-regarding-performance-studies-vitro-diagnostic-medical-devices-under-2025-06-18_en

MDCG 2025-6 - FAQ on Interplay between the Medical Devices Regulation & In vitro Diagnostic Medical Devices Regulation and the Artificial Intelligence Act (June 2025)

Published on: 19 - June - 2025

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/mdcq-2025-6-faq-interplay-between-medical-devices-regulation-vitro-diagnostic-medical-devices-2025-06-19_en

Expert decision and opinion in the context of the Clinical Evaluation Consultation Procedure (CECP)

Published on: 24 - June - 2025

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/expert-decision-and-opinion-context-clinical-evaluation-consultation-procedure-cecp-2025-06-24_en

Commission simplifies instructions for use of medical devices to further digitalise healthcare systems

Published on: 25 - June - 2025

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/commission-simplifies-instructions-use-medical-devices-further-digitalise-healthcare-systems-2025-06-25_en

NEW - 17-19 June CMDh agenda

Published on: 16 - June - 2025

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Agendas_and_Minutes/Agendas/2025_06_CMDh_Agenda.pdf

NEW - 20-21 May CMDh minutes

Published on: 20 - June - 2025

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/agendas-and-minutes.html>

NEW - Report from the meeting held on 17-19 June 2025

Published on: 25 - June - 2025

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/press-releases.html>

CMDH PRESS RELEASES 2025

Published on: 25 - June - 2025

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/press-releases.html#c7615>

Humanarzneimittel - Deutschland

Versagungen und Rücknahmen BfArM Januar bis Mai 2025

Veröffentlicht am: 16 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Statistik/AM-Statistik/versagungen-2025.html?nn=986770>

Fachausschüsse der Deutschen Arzneibuch-Kommission

Veröffentlicht am: 16 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Arzneibuch/Arzneibuchkommissionen/Deutsche-Arzneibuch-Kommission/fachausschuss_DAB-Kom-inhalt.html?nn=986770

Informationen zu Einreichung und Genehmigung von Schulungsmaterial

Veröffentlicht am: 16 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/Zusatzinformationen/artikel.html?nn=986770>

Anzeigeverfahren nach § 32 StrlSchG ab 1. Juli 2025

Veröffentlicht am: 16 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/News/Anzeigeverfahren_Strahlenschutz.html?nn=986770

Genehmigungsverfahren nach § 31 StrlSchG ab 1. Juli 2025

Veröffentlicht am: 16 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/News/Genehmigungsverfahren_Strahlenschutz.html?nn=986770

Organigramm des BfArM

Veröffentlicht am: 23 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Downloads/DE/BfArM/Org/bfarm_organigramm.html?nn=986770

Ausfuhrantrag

Veröffentlicht am: 23 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Formulare/DE/Bundesopiumstelle/Grundstoffe/ausfuhr-grundstoffe_de.html?nn=986770

Einfuhrantrag

Veröffentlicht am: 26 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Formulare/DE/Bundesopiumstelle/Grundstoffe/einfuhr-grundstoffe_de.html?nn=986770

Humanarzneimittel - Deutschland

Bundesoberbehörden

Veröffentlicht am: 23 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Medizinprodukte/Ueberblick/Behoerden-und-Ethik-Kommissionen/Bundesoberbehoerden/_artikel.html?nn=986770

Statistische Auswertungen zu Medizinprodukten

Veröffentlicht am: 24 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Aktuelles/Statistiken/Medizinprodukte/_artikel.html?nn=986770

Medizinforschungsgesetz

Veröffentlicht am: 25 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Medizinforschungsgesetz/_artikel.html?nn=986770

Neue Version des DMIDS-Moduls "Klinische Prüfungen und Leistungsstudien" ab dem 01. Juli 2025

Veröffentlicht am: 24 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Medizinprodukte/Portale/DMIDS/strahlenanwendung.html?nn=986770>

Strahlenschutzrechtliche Anzeige- und Genehmigungsverfahren

Veröffentlicht am: 24 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Medizinforschungsgesetz/Strahlenanwendungen/_artikel.html?nn=986770

Verfahren zu anzeigepflichtigen Strahlenanwendungen ab dem 01.07.2025

Veröffentlicht am: 27 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/Klinische-Pruefungen-und-Leistungsstudien/Verfahren-anzeigepflichtige-Strahlenanwendungen/_artikel.html?nn=986770

PSUR Single Assessment (PSUSA)

Veröffentlicht am: 25 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Periodic-Safety-Update-Reports_PSURs/PSUR-Single-Assessment/_artikel.html?nn=986770

Vorkommnismeldung durch Hersteller und Bevollmächtigte

Veröffentlicht am: 26 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Medizinprodukte/Antraege-und-Meldungen/Vorkommnis-melden/Hersteller-und-Bevollmaechtigte/_artikel.html?nn=986770

Humanarzneimittel - Deutschland

ZEPAI bringt Expertise im Bereich der Pandemievorbereitung und Bereitstellung von Impfstoffen im Europäischen Hub für Impfstoffe ein

Veröffentlicht am: 26 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.pei.de/DE/newsroom/hp-meldungen/2025/250626-zepai-expertise-pandemievorbereitung-evh.html?nn=170852>

Humanarzneimittel - Österreich

Zur Stellungnahme

Veröffentlicht am: 16 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.basq.gv.at/gesundheitsberufe/oesterreichisches-arzneibuch/zur-stellungnahme>

PSUR outcome: Etonogestrel

Veröffentlicht am: 16 - Juni - 2025

Weitere Informationen finden Sie unter:

[Link zur Website der EMA](#)

Homöopathische Arzneimittel

Veröffentlicht am: 16 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.basq.gv.at/fuer-unternehmen/zulassung-life-cycle/faq-zulassung-life-cycle/homoeopathische-arzneimittel>

Informationen zur ESMP für Zulassungsinhaber

Veröffentlicht am: 17 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.basq.gv.at/marktbeobachtung/amtliche-nachrichten/detail/informationen-zur-esmp-fuer-zulassungsinhaber>

Freiverkaufszertifikate

Veröffentlicht am: 18 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.basq.gv.at/fuer-unternehmen/medizinprodukte/freiverkaufszertifikate>

Qualitätsmanagement

Veröffentlicht am: 20 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.basq.gv.at/ueber-uns/qualitaetsmanagement>

Impfstoffe

Veröffentlicht am: 23 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.basq.gv.at/konsumentinnen/wissenswertes-ueber-arzneimittel/arzneimittel/impfstoffe>

Humanarzneimittel - Schweiz

Bundesrat verabschiedet Postulatsbericht zur Überwachung der Arzneimittelsicherheit

Veröffentlicht am: 13 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/br-verabschiedet-postulatsbericht-ueberwachung-am-sicherheit.html>

Risikobewertung bezüglich Nitrosaminen in Wirkstoff und/oder Fertigarzneimittel

Veröffentlicht am: 18 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/risikobewertung-nitrosaminen-in-ws-am.html>

Publikation Versorgungsbericht TAM

Veröffentlicht am: 23 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/tierarzneimittel/informationen/versorgungssicherheit-tam-smc-und-blv-loesungen.html>

Vincenza Trivigno wird neue Direktorin des Schweizerischen Heilmittelinstituts

Veröffentlicht am: 25 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/vincenza-trivigno-wird-neue-direktorin-der-swissmedic.html>

Schnellere Bearbeitung von Anträgen für klinische Versuche

Veröffentlicht am: 27 - Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/schnellere-bearbeitung-von-antraegen-fuer-klinische-versuche.html>

Aktualisierte Vorgabedokumente

Veröffentlicht am: 30 - Juni - 2025

Weitere Informationen finden Sie unter:

https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents/juni-2025.html



Fragen an das Netzwerk

Falls Sie eine Frage haben, die Sie gerne in unserem Netzwerk diskutieren würden, senden Sie uns einfach eine E-Mail an info-as@megra.org zur anonymen Publikation im nächsten Newsletter.*

*Bei der Beantwortung der Fragen handelt es sich um eine Zusammenfassung von persönlichen Meinungen und Erfahrungswerten der MEGRA Mitglieder mit keinem Anspruch auf Rechtssicherheit. Wir empfehlen zur Absicherung die Konsultation entsprechender zugrunde liegender Regularien.

Veranstaltungen / Events – Behörden und andere Veranstalter

Deutschland

KI-gestützte Sprachverarbeitung in der regulatorischen Arbeit von Swissmedic

Ort: Langen, Hörsaal des Paul-Ehrlich-Instituts

Termin: 08 – Juli - 2025

Weitere Informationen finden Sie unter:

<https://www.pei.de/SharedDocs/veranstaltungen-events/DE/2025/kolloquien/renaudin-kolloq.html?nn=170994>

Österreich

Keine Veranstaltungen veröffentlicht

Schweiz

Keine Veranstaltungen veröffentlicht

Europa

Q&A clinic on web-based electronic Application Form (eAF) functionalities for CAPs and non-CAPs variations

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 08 - July - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/qa-clinic-web-based-electronic-application-form-eaf-functionalities-caps-non-caps-variations-1>

Clinical Trials Information System (CTIS) Bitesize talk: Redesign of the CTIS training material for sponsor users

Where: Live broadcast and European Medicines Agency, Amsterdam, the Netherlands

Date: 09 - July - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-bitesize-talk-redesign-ctis-training-material-sponsor-users>

SPOR and XEVMPD status update webinar

Where: Live broadcast

Date: 09 - July - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/spor-xevmpd-status-update-webinar-1>

Veranstaltungen / Events – Behörden und andere Veranstalter

Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API)

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 22 - July - 2025, 28 - August - 2025 and 18 - September - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-july-2025>

<https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-august-2025>

<https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-september-2025>

1st training course on quality management for substances of human origin (SoHO)

Where: online

Date: 27 - August to 13 - October - 2025

For more information, please refer to:

<https://www.edqm.eu/en/training-course-on-quality-management-for-soho>

Q&A clinic on Substance, Organisation, Referentials Management Services

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 08 - September - 2025, 13 - October – 2025, 10 - November – 2025, 15 - December - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-0>

<https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-1>

<https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-2>

<https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services>

Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 18 - September - 2025, 14 - October – 2025, 18 - November – 2025, 18 - December - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-2>

<https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-1>

<https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-0>

<https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service>

Veranstaltungen / Events – Behörden und andere Veranstalter

Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course using the EudraVigilance system

Where: online

Date: 22 to 26 - September - 2025, 13 to 17 - October – 2025, 10 to 14 - November – 2025, 01 to 05 - December - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-49>

<https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-52>

<https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-53>

<https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-54>

Certified for success: using the CEP Procedure to elevate quality and drive trust

Where: Budapest, Hungary

Date: 23 to 24 - September - 2025

For more information, please refer to:

<https://www.edqm.eu/en/certified-for-success>

Virtual live hands-on training course for clinical trials sponsors using EudraVigilance system

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 01 to 03 - October - 2025 and 08 to 10 - December - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-october-2025>

<https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-december-2025>

HMA/EMA multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 08 to 09 - October - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/hma-ema-multi-stakeholder-workshop-reporting-qualification-mechanistic-models-regulatory-assessment>

EMA roundtable with stakeholders on the 20th anniversary of the SME Regulation

Where: Live broadcast and European Medicines Agency, Amsterdam, the Netherlands

Date: 17 - October - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/ema-roundtable-stakeholders-20th-anniversary-sme-regulation>

Veranstaltungen / Events – Behörden und andere Veranstalter

HMA/EMA multi-stakeholder workshop on artificial intelligence

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 20 to 21 - November - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/hma-ema-multi-stakeholder-workshop-artificial-intelligence>