07. – 21. Februar 2025

MEGRA

NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

Supporting innovation
Published on: *11 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/supporting-innovation

Report - HMA/EMA Big Data Stakeholder Forum 2024
Published on: *17 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/report-hma-ema-big-data-stakeholder-forum-2024_en.pdf

Big data
Published on: *17 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/how-we-work/big-data

European medicines agencies network strategy (EMANS) to 2028 webinar, Event 13 – February – 2025
Presentation and Video recording available
Published on: *18 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/european-medicines-agencies-network-strategy-emans-2028-webinar

Artificial intelligence
Published on: *18 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/how-we-work/big-data/artificial-intelligence

Data Analysis and Real World Interrogation Network (DARWIN EU)
Published on: *20 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/how-we-work/big-data/real-world-evidence/data-analysis-real-world-interrogation-network-darwin-eu

Pharmakovigilanz – PRAC

List of signals discussed at PRAC since September 2012
Published on: *10 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/list-signals-discussed-prac-september-2012_en.xlsx

Humanarzneimittel - EMA

Article 57 product data
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/article-57-product-data_en.xlsx

Union list of critical medicines: eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) / Product Management System (PMS) entries (outdated)
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/union-list-critical-medicines-extended-eudravigilance-medicinal-product-dictionary-xevmpd-product-management-system-pms-entries-outdated_en.xlsx

Referral: Finasteride- and dutasteride-containing medicinal products
Published on: *18 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/finasteride-dutasteride-containing-medicinal-products

Zulassung – Regulatory Affairs

Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 27-30 January 2025
Published on: *07 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/chmp-annex/recommendations-eligibility-prime-scheme-adopted-chmp-meeting-27-30-january-2025_en.pdf

PRIME: priority medicines
Published on: *07 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/prime-priority-medicines

Non-clinical Working Party
Published on: *11 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/non-clinical-working-party

Linguistic review – Human
Published on: *10 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/linguistic-review-human

Humanarzneimittel - EMA

Regulation (EU) 2024/568: Questions and answers clinic for the Human Industry stakeholders, Event 10 – February – 2025
Presentation available
Published on: *13 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/regulation-eu-2024-568-questions-answers-clinic-human-industry-stakeholders

Training on human variations web-based electronic application form (eAF) functionalities for non-CAPs variations, Event 11 – February – 2025
Presentation and Video recording available
Published on: *13 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/training-human-variations-web-based-electronic-application-form-eaf-functionalities-non-caps-variations

Substance and product data management services
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services

Union list of critical medicines
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/availability-medicines-during-crises/union-list-critical-medicines

Contact details of national competent authorities for requests of translation exemptions falling under Art. 63.3 of Directive 2001/83/EC and cases of shortages
Published on: *17 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/contact-details-national-competent-authorities-requests-translation-exemptions-falling-under-art-633-directive-2001-83-ec-cases-shortages_en.pdf

International Coalition of Medicines Regulatory Authorities (ICMRA)
Published on: *17 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-initiatives/international-coalition-medicines-regulatory-authorities-icmra

Humanarzneimittel - EMA

Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API), Event 04 – February – 2025
Video recording available
Published on: *18 - February - 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

Transfer of marketing authorisation: questions and answers
Published on: *18 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/transfer-marketing-authorisation-questions-answers

Generic and hybrid applications
Published on: *18 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/generic-hybrid-medicines/generic-hybrid-applications

Biosimilar medicines: marketing authorization
Published on: *19 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/biosimilar-medicines-marketing-authorisation

Orphan Drugs und neuartige Therapierichtungen (ATMP)

No news published

Qualität – Quality

Product-specific bioequivalence guidance – Updated
Published on: *12 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-guidelines/clinical-pharmacology-pharmacokinetics/product-specific-bioequivalence-guidance

ICH M12 on drug interaction studies - Scientific guideline
Published on: *13 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/ich-m12-drug-interaction-studies-scientific-guideline

Humanarzneimittel - EMA

Overview of the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs - Scientific guideline
Published on: *13 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/overview-current-regulatory-testing-requirements-medicinal-products-human-use-opportunities-implementation-3rs-scientific-guideline

(Prä-) Klinische Forschung – Research and Development

ACT EU multi-stakeholder platform annual meeting, Event 22 – October – 2024
Meeting report and Video recording available
Published on: *10 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/act-eu-multi-stakeholder-platform-annual-meeting

Records of data processing activity regarding the processing of personal data in the Clinical Trials Information System (CTIS)
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/records-data-processing-activity-regarding-processing-personal-data-clinical-trials-information-system-ctis_en.pdf

FAQs: Introduction to the Clinical Trials Regulation (EU) No 536/2014 - CTIS Training Programme - Module 01
Published on: *18 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/faqs-introduction-clinical-trials-regulation-eu-no-536-2014-ctis-training-programme-module-01_en.pdf

Quick guide: How to search, view and download a Clinical Trial and a Clinical Trial Application (sponsors) - CTIS Training Programme - Module 09
Published on: *18 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/quick-guide-how-search-view-download-clinical-trial-clinical-trial-application-sponsors-ctis-training-programme-module-09_en.pdf

Quick guide - Introduction: CTIS for SMEs and Academia - CTIS Training Programme - Module 19
Published on: *18 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/quick-guide-introduction-ctis-smes-academia-ctis-training-programme-module-19_en.pdf

Clinical Trial Information System (CTIS) - Sponsor handbook
Published on: *19 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-sponsor-handbook_en.pdf

Humanarzneimittel - EMA

Development of the Clinical Trials Information System
Published on: *20 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-sponsor-handbook_en.pdf

Kinderarzneimittel – Paediatrics

Members of the Coordinating group of European network of paediatric research at the European Medicines Agency (Enpr-EMA)
Published on: *10 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/members-coordinating-group-european-network-paediatric-research-european-medicines-agency-enpr-ema_en.pdf

Pflanzliche Arzneimittel – Herbal medicines

Herbal medicinal product: Boldi folium, C: ongoing call for scientific data
Published on: *11 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/boldi-folium

Herbal medicinal product: Anisi aetheroleum, C: ongoing call for scientific data
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/anisi-aetheroleum

Herbal medicinal product: Anisi fructus, C: ongoing call for scientific data
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/anisi-fructus

Herbal medicinal product: Centaurii herba, C: ongoing call for scientific data
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/centaurii-herba

Herbal medicinal product: Salviae officinalis folium, C: ongoing call for scientific data
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/salviae-officinalis-folium

Humanarzneimittel - EMA

Herbal medicinal product: Valerianae aetheroleum, C: ongoing call for scientific data
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/valerianae-aetheroleum

Herbal medicinal product: Valerianae radix, C: ongoing call for scientific data
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/valerianae-radix

Herbal medicinal product: Combination: Hyperici herba, D: Draft under discussion
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/hyperici-herba

Procedures for monograph and list entry establishment
Published on: *14 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/herbal-medicinal-products/procedures-monograph-list-entry-establishment

Interested Parties to the HMPC
Published on: *17 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/working-parties-other-groups/hmpc-working-parties-other-groups/interested-parties-hmpc

European Commission

Presentation and recording - EUHPP Live Webinar on European Health Data Space (1/3): Primary Use of health data and Electronic Health Record Systems, Event 18 – February – 2025
Published on: *20 - February - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/presentation-and-recording-euhpp-live-webinar-european-health-data-space-13-primary-use-health-data-2025-02-20_en

EDQM

Certification monthly report of activities: End of January 2025
Published on: *12 - February - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/certification-monthly-report-of-activities-end-of-january-2025

Medizinprodukte

MDCG 2019-6 rev.5 - Questions and answers: Requirements relating to notified bodies (February 2025)
Published on: *07 - February - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/mdcg-2019-6-rev5-questions-and-answers-requirements-relating-notified-bodies-february-2025-2025-02-07_en

Guide to manufacturers on the procedure for requesting advice from expert panels on clinical investigations and / or clinical development strategies for high-risk medical devices
Published on: *10 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/guide-manufacturers-procedure-requesting-advice-expert-panels-clinical-investigations-or-clinical-development-strategies-high-risk-medical-devices_en.pdf

Medical devices
Published on: *10 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices

CMDh

HMA Substances Validation Group Key documents
Published on: *10 - February - 2025*
For more information, please refer to:
https://www.hma.eu/about-hma/working-groups/hma/hma-substances-validation-group.html#c7169

EU-IN Introduction and Overview
Published on: *18 - February - 2025*
For more information, please refer to:
https://www.hma.eu/about-hma/working-groups/eu-innovation-network-eu-in/eu-innovation-network-eu-in.html#c5500

CTCG Introduction/Overview/Mandate
Published on: *21 - February - 2025*
For more information, please refer to:
https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group/clinical-trials-coordination-group.html#c7040

Humanarzneimittel - Deutschland

Expertengruppe Off-Label
Veröffentlicht am: *10 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Expertengruppe-Off-Label/_artikel.html?nn=986770

Spezialisierte Ethik-Kommission
Veröffentlicht am: *12 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Das-BfArM/Aufgaben/Spezialisierte-Ethik-Kommission/_verteilerseite.html?nn=986770

Bekanntmachung nach § 35 Absatz 5a Sozialgesetzbuch (SGB) fünftes Buch (V) zu Änderungen in der Liste von Arzneimitteln, die auf Grund der zugelassenen Darreichungsformen und Wirkstärken zur Behandlung von Kindern notwendig sind (BAnz AT 13.02.2025 B4)
Veröffentlicht am: *13 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/amInformationen/Lieferengpaesse/Bekanntmachung_35Abs5a_sgb_v_stand_2025_02_13.html?nn=986770

CHMP Ausschuss für Humanarzneimittel
Veröffentlicht am: *13 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Das-BfArM/EU-und-Internationales/CHMP-Ausschuss/_artikel.html?nn=986770

Häufig gestellte Fragen (FAQ) zur Zulassung
Veröffentlicht am: *14 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/_FAQ/Zulassung/_artikel.html?nn=986770

Arzneimittel-Lieferengpass-bekämpfungs- und Versorgungs-verbesserungs-gesetz (ALBVVG)
Veröffentlicht am: *14 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/ALBVVG/_artikel.html?nn=986770

Meldeverpflichtungen
Veröffentlicht am: *17 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Meldeverpflichtungen/_artikel.html?nn=986770

Informationen zu Einreichung und Genehmigung von Schulungsmaterial
Veröffentlicht am: *17 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/Zusatzinformationen/_artikel.html?nn=986770

Humanarzneimittel - Deutschland

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen
Veröffentlicht am: *18 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770

Besonderheitenliste des BfArM
Veröffentlicht am: *18 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Besonderheitenliste/_artikel.html?nn=986770

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme
Veröffentlicht am: *18 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Compassionate-Use/compUse-tabelle.html?nn=986770

Arzneibuchkommissionen
Veröffentlicht am: *19 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Arzneibuch/Arzneibuchkommissionen/_artikel.html?nn=986770

PSUR Single Assessment (PSUSA)
Veröffentlicht am: *18 - Februar - 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

Humanarzneimittel - Österreich

0225_Bearbeitungsstand
Veröffentlicht am: *10 - Februar - 2025*
Weitere Informationen finden Sie unter:
Gute Herstellungs- / Vertriebspraxis (GMP/GDP)

Leitfaden: eService Zulassung und Lifecycle ASP (L_Z55)
Veröffentlicht am: *10 - Februar - 2025*
Weitere Informationen finden Sie unter:
FAQ online Service
FAQ Online Service Zulassung & Lifecycle ASP

CHMP Meeting Highlights Jänner 2025
Veröffentlicht am: *12 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/marktbeobachtung/amtliche-nachrichten/detail/chmp-meeting-highlights-jaenner-2025

AGES-PHM-minimal-hoch
Veröffentlicht am: *14 - Februar - 2025*
Weitere Informationen finden Sie unter:
Compassionate Use und Heilversuch/Named Patient Use

Kontakt – updated: Weitere Regulatorische Ansprechpartner (L_Z31)
Veröffentlicht am: *18 - Februar - 2025*
Weitere Informationen finden Sie unter:
Kontakt

PSUR outcome: Estradiol / Nomegestrolacetat
Veröffentlicht am: *18 - Februar - 2025*
Weitere Informationen finden Sie unter:
Link zur Webseite der Europäischen Kommission

0225_Register bewilligter AM Betriebe Österreich
Veröffentlicht am: *20 - Februar - 2025*
Weitere Informationen finden Sie unter:
Arzneimittelbetriebe

Humanarzneimittel - Schweiz

Aktualisierung des Positionspapiers von Swissmedic und swissethics zu dezentralisierten klinischen Versuchen (DCTs) mit Arzneimitteln
Veröffentlicht am: *10 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/clinical-trials/klinische-versuche-mit-arzneimitteln/publikationen.html

Swissmedic Portal Release Notes – 14.02.2025
Veröffentlicht am: *17 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/services/egov-services/smc-portal/release-notes/releae-note-170225.html

Überprüfung der Dokumentation zur Überwachung nach dem Inverkehrbringen durch Swissmedic
Veröffentlicht am: *17 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/marktkontrolle-medizinprodukte/schwerpunktaktionen/ueberpruefung-dokumentation-ueberwachung-nach-inverkehrbringen-smc.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *19 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents/feb-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

Workshop der Arbeitsgruppe Chemometrics and Quality Assurance zur Datenvisualisierung
Ort: *Paul-Ehrlich-Institut, Langen*
Termin: *02 bis 03 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.pei.de/SharedDocs/veranstaltungen-events/DE/2025/2025-04-02-gdch-workshop.html?nn=170994

Österreich

Keine Veranstaltungen veröffentlicht

Schweiz

Keine Veranstaltungen veröffentlicht

Europa

Training on human variations web-based electronic application form (eAF) functionalities for CAPs and non-CAPs variations
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *27 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/training-human-variations-web-based-electronic-application-form-eaf-functionalities-caps-non-caps-variations

EMA workshop on the challenges in drug development, regulation and clinical practice for immunoglobulins
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *05 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-workshop-challenges-drug-development-regulation-clinical-practice-immunoglobulins

Clinical Trials Information System (CTIS) bitesize talk: Change of sponsor in CTIS
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *05 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-bitesize-talk-change-sponsor-ctis

Veranstaltungen / Events – Behörden und andere Veranstalter

Webinar on reflection paper on the qualification of non-mutagenic impurities
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *06 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/webinar-reflection-paper-qualification-non-mutagenic-impurities

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: *06 & 13 - March - 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-0
https://www.ema.europa.eu/en/events/qa-clinic-web-based-electronic-application-form-eaf-functionalities-caps-non-caps-variations

DIA Europe 2025
Where: *Congress Centre Basel, Switzerland*
Date: *18 to 20 - March - 2025*
For more information, please refer to:
https://www.edqm.eu/en/w/dia-europe-2025

Clinical Trials Information System (CTIS) sponsor end user training programme - March 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *25 to 28 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-sponsor-end-user-training-programme-march-2025

Quarterly System Demo – Q1 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *26 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/quarterly-system-demo-q1-2025

EDQM Stakeholder Event on "Plasma Supply Continuity"
Where: *Congress Centre Basel, Switzerland*
Date: *26 to 27 - March - 2025*
For more information, please refer to:
https://www.edqm.eu/en/plasma-supply-continuity

Veranstaltungen / Events – Behörden und andere Veranstalter

SPOR and XEVMPD status update webinar
Where: *Live broadcast*
Date: *09 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/spor-xevmpd-status-update-webinar

EMA Open Door Day
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *09 - May - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-open-door-day

Product Management Service (PMS) information day 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *21 - May - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/product-management-service-pms-information-day-2025