05. - 19. Juni 2026

MEGRA NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

Real-world evidence (updated)
Published on: *10 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/how-we-work/data-regulation-big-data-other-sources/real-world-evidence

List of eligible industry stakeholder organisations (updated)
Published on: *10 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/list-eligible-industry-stakeholder-organisations_en.pdf

EMA's 2025 annual report shows strong approval numbers for human and veterinary medicines
Published on: *11 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/news/emas-2025-annual-report-shows-strong-approval-numbers-human-veterinary-medicines

How to recognise scams and phishing using EMA credentials (updated)
Published on: *18 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/how-recognise-scams-phishing-using-ema-credentials

Pharmakovigilanz – PRAC

Referral: Tecovirimat SIGA
Published on: *15 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/tecovirimat-siga

Zulassung – Regulatory Affairs

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 (updated)
Published on: *05 - June - 2026*
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

Humanarzneimittel - EMA

Checklist for the submission of Day 215 product information annexes for a post-opinion linguistic review (Word file) (updated)
Published on: *05 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/checklist-submission-day-215-product-information-annexes-post-opinion-linguistic-review-word-file_en.docx

Member states contact points for review of national versions of the content of mobile scanning and other technologies (updated)
Published on: *05 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/member-states-contact-points-review-national-versions-content-mobile-scanning-other-technologies_en.pdf

Member states contact points for translations review (updated)
Published on: *05 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/member-states-contact-points-translations-review_en.pdf

Report - HMA/EMA multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment
Published on: *05 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/report-hma-ema-multi-stakeholder-workshop-reporting-qualification-mechanistic-models-regulatory-assessment_en.pdf

Applications for new human medicines under evaluation: June 2026
Published on: *08 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/applications-new-human-medicines-under-evaluation-june-2026_en.xlsx

Product Management Service (PMS) public API - Frequently asked questions (FAQs)
Published on: *12 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/product-management-service-pms-public-api-frequently-asked-questions-faqs_en.pdf

Substance and product data management services (updated)
Published on: *12 - June - 2026*
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

Humanarzneimittel - EMA

Product Management Service (PMS) User Acceptance Testing (UAT) Application Programming Interface (API) registration process for industry - Chapter 1, Annex A (updated)
Published on: *12 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/product-management-service-pms-user-acceptance-testing-uat-application-programming-interface-api-registration-process-industry-chapter-1_en.pdf

IRIS guide to registration and RPIs (updated)
Published on: *15 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration-rpis_en.pdf

IRIS guide for applicants - How to create, submit and manage IRIS applications, for industry and individual applicants (updated)
Published on: *15 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-applicants-how-create-submit-scientific-applications-industry-individual-applicants_en.pdf

Contacting EMA: post-authorisation (updated)
Published on: *15 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/contacting-ema-post-authorisation

Timetable: Type II variation and worksharing application alternative monthly assessment (updated)
Published on: *16 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/es/media/13188

Timetable: Type II variation and worksharing application weekly assessment (updated)
Published on: *16 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/es/media/19675

Timetable: Type II variation and worksharing application monthly assessment (updated)
Published on: *17 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/es/media/25658

Medicinal products for human use: monthly figures - May 2026
Published on: *17 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/es/media/74144

Humanarzneimittel - EMA

Orphan Drugs und neuartige Therapierichtungen (ATMP)

No news published

Qualität – Quality

No news published

(Prä-) Klinische Forschung – Research and Development

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 for production environments (updated)
Published on: *12 - June - 2026*
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

Product Management Service (PMS) - Implementation of International Organization for Standardization (ISO) standards for Identification of Medicinal Products (IDMP) in Europe: Registration requirements to public PMS API (beta release) - Chapter 1, Annex B
Published on: *12 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/product-management-service-pms-implementation-international-organization-standardization-iso-standards-identification-medicinal-products-idmp-europe-registration-requirements-public-pms-api-beta_en.pdf

Kinderarzneimittel – Paediatrics

Presentations - EnprEMA& ACT EU workshop on paediatric clinical trials
Published on: *08 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/presentation/presentations-enprema-act-eu-workshop-paediatric-clinical-trials_en.pdf

Scientific guideline: Data recommendations for herbal medicinal products and traditional herbal medicinal products used in paediatric patients
Published on: *16 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/data-recommendations-herbal-medicinal-products-traditional-herbal-medicinal-products-used-paediatric-patients-scientific-guideline

Humanarzneimittel - EMA

Pflanzliche Arzneimittel – Herbal medicines

No news published

Events and Video recording

Product Management Service (PMS) information day 2026; Event 09 - Jun - 2026
Presentation and Video recording available
Published on: *11 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/product-management-service-pms-information-day-2026

Webinar on the use of platform approaches in the non-clinical and clinical domains; Event 02 - Mar - 2026
Presentations and Video recording available
Published on: *15 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/webinar-use-platform-approaches-non-clinical-clinical-domains

European Commission

European Commission and WHO convene second Workshop on Pooled Procurement for Medical Countermeasures in Public Health Emergencies
Published on: *09 - June - 2026*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/european-commission-and-who-convene-second-workshop-pooled-procurement-medical-countermeasures-2026-06-09_en

Updated - List of joint clinical assessments
Published on: *09 - June - 2026*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/updated-list-joint-clinical-assessments-2026-06-09_en

EDQM

Certification monthly report of activities: End of May 2026
Published on: *09 - June - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/certification-monthly-report-of-activities-end-of-may2026

The Pharmacopoeial Discussion Group (PDG) held its interim videoconference on 24 March 2026
Published on: *12 - June - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/the-pharmacopoeial-discussion-group-pdg-held-its-interim-videoconference-on-24-march-2026

EDQM publishes guidelines to increase reporting on disappearances of medicinal products from the legal supply chain
Published on: *18 - June - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/edqm-publishes-guidelines-to-increase-reporting-on-disappearances-of-medicinal-products-from-the-legal-supply-chain

Medizinprodukte

Class III implantable devices and Class IIb medical devices intended to administer or remove medicinal products: expert panel opinions (updated)
Published on: *10 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/class-iii-implantable-devices-class-iib-medical-devices-intended-administer-or-remove-medicinal-products-expert-panel-opinions

Update MIR 7.3.1. form – Updated XSD-XSL files for field 4.3.3.d. and Changelog file (SB 11252)
Published on: *11 - June - 2026*
For more information, please refer to:
https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance/pmsv-reporting-forms_en

New harmonised standards for the Regulations on medical devices
Published on: *17 - June - 2026*
For more information, please refer to:
https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en

New guidance document on the "EU REP" symbol for authorised representatives
Published on: *17 - June - 2026*
For more information, please refer to:
https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec17

New MDCG Position Paper: Management of SS(C)P in EUDAMED after mandatory use
Published on: *18 - June - 2026*
For more information, please refer to:
https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec7

CMDh

No news published

Humanarzneimittel - Deutschland

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen
Veröffentlicht am: *09 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770

Häufig gestellte Fragen zu Groupings
Veröffentlicht am: *09 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/_FAQ/Zulassung/Aenderungsanzeigen-Variations/Variations/_artikel.html?nn=986770

Meldeverpflichtungen
Veröffentlicht am: *10 - Juni - 2026*
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: *10 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/Zusatzinformationen/_artikel.html?nn=986770

Informationen zu Rote-Hand-Briefen und Informationsbriefen
Veröffentlicht am: *15 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Rote-Hand-Briefe/Zusatzinformationen/_artikel.html?nn=986770

Übersicht der aktuellen Rechtsgrundlagen zu Grundstoffen
Veröffentlicht am: *17 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Bundesopiumstelle/Grundstoffe/Rechtsgrundlagen/_artikel.html?nn=986770

SAE- und DD-Meldung im Rahmen einer klinischen Prüfung
Veröffentlicht am: *18 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Medizinprodukte/Antraege-und-Meldungen/SAE-melden/klinische-Pruefung/_artikel.html?nn=986770

Statistiken
Veröffentlicht am: *18 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/_artikel.html?nn=986770

Humanarzneimittel - Deutschland

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme
Veröffentlicht am: *19 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Compassionate-Use/compUse-tabelle.html?nn=986770

Humanarzneimittel - Österreich

0626_Register Arzneimittelvermittler
Veröffentlicht am: *10 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/04_Marktbeobachtung/%C3%96ffentliche_Register/0626_Register_Arzneimittelvermittler.pdf

0626_Register bewilligter AM Betriebe Österreich
Veröffentlicht am: *10 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/04_Marktbeobachtung/%C3%96ffentliche_Register/0626_Register_bewilligter_AM_Betriebe_%C3%96sterreich.pdf

0626_Bearbeitungsstand
Veröffentlicht am: *10 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/04_Marktbeobachtung/%C3%96ffentliche_Register/0626_Bearbeitungsstand.pdf

Beratung durch das BASG
Veröffentlicht am: *11 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/arzneimittel-informationen/beratung-durch-das-basg

Humanarzneimittel - Schweiz

Studien von Swissmedic, dem Universitätsspital Zürich und der Universität Zürich analysieren die Bewertung von Krebsmedikamenten
Veröffentlicht am: *08 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/studien-bewertung-krebsmedikamente.html

Swissmedic veröffentlicht Geschäftsbericht und Jahresrechnung 2025
Veröffentlicht am: *12 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/geschaeftsbericht-2025.html

SEND-Datensätze für Neuzulassungsgesuche von Humanarzneimitteln mit neuen aktiven Substanzen
Veröffentlicht am: *15 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/einreichung-send-daten-nas.html

Revidierter Anhang 3a der AMZV
Veröffentlicht am: *18 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/amzv-revision-anhang-3a.html

Aktualisiertes Merkblatt zu den Anforderungen an die Instandhaltung von Sterilcontainer
Veröffentlicht am: *18 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/uebersicht-medizinprodukte/aktualisierung-mb-instandhaltung-sterilcontainer.html

Anpassung der Swissmedic Gebührenverordnung per 1. Juli 2026
Veröffentlicht am: *19 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/smc-anpassung-gebuehrenverordnung.html

Neue Möglichkeiten zur Produktregistrierung in swissdamed: Online-Editor und Machine-to-Machine (M2M) Schnittstelle, sowie Registrierung von Master UDI-DI
Veröffentlicht am: *19 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/medizinprodukte-datenbank/swissdamed-informationen/neu-online-editor-m2m-produktregistierung-master-udi.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *19 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents.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

Internationales Paul-Ehrlich-Seminar (IPES)
Ort: *Stadthalle Langen (bei Frankfurt)*
Termin: *02 bis 05 - September - 2026*
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/newsroom/hp-meldungen/2026/260216-ipes-2026-registrierung-gestartet.html?nn=170852

SNOMED-CT-Basisschulung: ECL
Ort: *online*
Termin: *17 - September - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/2026-09-17-snomed-eclschulung.html?nn=986770

genomDE Symposium
Ort: *Bundeskunsthalle, Bonn*
Termin: *28 bis 29 - September - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/2026-09-28-genom.html?nn=986770

Österreich

Keine Veranstaltungen veröffentlicht

Schweiz

Save the Date: Regulatory & Beyond 2026
Ort: *Kursaal Bern*
Termin: *16 - November - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/services/veranstaltungen/regulatory-beyond-2026.html

Veranstaltungen / Events – Behörden und andere Veranstalter

Europa

PMS Q&A Clinic on Product User Interface (PUI) and Application Programming Interface (API) - 2026
Where: *online*
Date: *25 - June - 2026, 09 - July - 2026, 23 - July - 2026, 10 - September - 2026, 24 - September - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/pms-qa-clinic-product-user-interface-pui-application-programming-interface-api-june-2026-0
https://www.ema.europa.eu/en/events/pms-qa-clinic-product-user-interface-pui-application-programming-interface-api-july-2026
https://www.ema.europa.eu/en/events/pms-qa-clinic-product-user-interface-pui-application-programming-interface-api-july-2026-0
https://www.ema.europa.eu/en/events/pms-qa-clinic-product-user-interface-pui-application-programming-interface-api-september-2026
https://www.ema.europa.eu/en/events/pms-qa-clinic-product-user-interface-pui-application-programming-interface-api-september-2026-0

Quarterly System Demo - 2026
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *25 -June - 2026, 17 - September - 2026, 10 - December - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/quarterly-system-demo-q2-2026
https://www.ema.europa.eu/en/events/quarterly-system-demo-q3-2026
https://www.ema.europa.eu/en/events/quarterly-system-demo-q4-2026

Webinar: Everything you ever wanted to know about the certification of suitability procedure
Where: *Paris, France*
Date: *26 - June - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/webinar-everything-you-ever-wanted-to-know-about-the-certification-of-suitability-procedure-register-now-

EMA workshop on the challenges in drug development, regulation and clinical practice in immune thrombocytopenia
Where: *online*
Date: *30 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-workshop-challenges-drug-development-regulation-clinical-practice-immune-thrombocytopenia

Webinar about new SS(C)P functionality in EUDAMED
Where: *online*
Date: *02 - July - 2026*
For more information, please refer to:
https://health.ec.europa.eu/medical-devices-eudamed/getting-ready_en#trainings-and-other-onboarding-activities

Veranstaltungen / Events – Behörden und andere Veranstalter

SPOR and XEVMPD status update webinar - Q3 2026
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *08 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/spor-xevmpd-status-update-webinar-q3-2026

Q&A clinic on Substance, Organisation, Referentials Management Services - 2026
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *08 - July - 2026, 09 - September - 2026, 07 - October - 2026, 11 - November - 2026, 09 - December - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-july-2026
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-september-2026
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-october-2026
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-november-2026
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-december-2026

Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - 2026
Where: *online*
Date: *09 - July - 2026, 10 - September - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-july-2026
https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-september-2026

Product Management Service (PMS) public API beta release - Technical overview and live demo
Where: *online*
Date: *13 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/product-management-service-pms-public-api-beta-release-technical-overview-live-demo

Managing product data quality in PMS: processes, known issues, current status and best practices
Where: *online*
Date: *21 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/managing-product-data-quality-pms-processes-known-issues-current-status-best-practices

Veranstaltungen / Events – Behörden und andere Veranstalter

Clinical Trials Information System (CTIS) bitesize talk: Annual safety report (ASR) new safety module
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *23 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-bitesize-talk-annual-safety-report-asr-new-safety-module

Webinar: From text to practice: high-throughput sequencing for the detection of extraneous agents under Ph. Eur. general chapter 2.6.41
Where: *live webinar*
Date: *03 - September - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/webinar-from-text-to-practice-high-throughput-sequencing-for-the-detection-of-extraneous-agents-under-ph.-eur.-general-chapter-2.6.41-register-now-

EMA risk management information day
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *08 - September - 2026*
For more information, please refer to:
https://www.diaglobal.org/en/ema/conference-listing/2026/09/ema-risk-management-information-day#showcontent

Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the EudraVigilance System - 2026
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *14 to 18 - September - 2026, 12 to 16 - October - 2026, 09 to 13 - November - 2026, 07 to 11 - December - 2026*
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-55
https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-56
https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-57
https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-58

Veranstaltungen / Events – Behörden und andere Veranstalter

Joint EDQM-USP International Symposium on Pharmaceutical Reference Standards
Where: *EDQM building, Strasbourg, France & Online*
Date: *23 to 24 - September - 2026*
For more information, please refer to:
https://www.edqm.eu/en/irss-event?p_l_back_url=%2Fen%2Fgroup%2Fedqm%2F%7E%2Fcontrol_panel%2Fmanage%3Fp_p_id%3Dcom_liferay_layout_admin_web_portlet_GroupPagesPortlet%26p_p_lifecycle%3D0%26p_p_state%3Dmaximized%26p_p_mode%3Dview%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_tabs1%3Dpages%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_privateLayout%3Dfalse%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_displayStyle%3Dmiller-columns%26p_r_p_selPlid%3D2070%26p_r_p_layoutSetBranchId%3D0%26p_p_auth%3DLl4b0kgf

Regulatory Perspectives on Herbal Medicinal / Botanical Drug Product Development: Joint FDA / EMA Workshop
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *25 - September - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/regulatory-perspectives-herbal-medicinal-botanical-drug-product-development-joint-fda-ema-workshop

CPhI Worldwide & CEP One-to-One Sessions
Where: *Fiera Milano, Milan, Italy*
Date: *06 to 08 - October - 2026*
For more information, please refer to:
https://www.edqm.eu/en/cphi-milan?p_l_back_url=%2Fen%2Fgroup%2Fedqm%2F%7E%2Fcontrol_panel%2Fmanage%3Fp_p_id%3Dcom_liferay_layout_admin_web_portlet_GroupPagesPortlet%26p_p_lifecycle%3D0%26p_p_state%3Dmaximized%26p_p_mode%3Dview%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_tabs1%3Dpages%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_privateLayout%3Dfalse%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_displayStyle%3Dmiller-columns%26p_r_p_selPlid%3D2070%26p_r_p_layoutSetBranchId%3D0%26p_p_auth%3Dun7FrSXJ

Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the EudraVigilance System - 2026
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *06 to 08 - October - 2026, 24 to 26 - November - 2026*
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-2026
https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-november-2026

SAVE THE DATE! EDQM Symposium: Microbiology on the Move
Where: *Strasbourg, France*
Date: *13 to 15 - October - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/symposium-microbio

Veranstaltungen / Events – Behörden und andere Veranstalter

CPHI India & CEP One-to-One Sessions
Where: *IICC, Yashobhoomi, Dwarka, Delhi*
Date: *23 to 25 - November - 2026*
For more information, please refer to:
https://www.edqm.eu/en/cphi-india-cep-one-to-one-sessions?p_l_back_url=%2Fen%2Fgroup%2Fedqm%2F~%2Fcontrol_panel%2Fmanage%3Fp_p_id%3Dcom_liferay_layout_admin_web_portlet_GroupPagesPortlet%26p_p_lifecycle%3D0%26p_p_state%3Dmaximized%26p_p_mode%3Dview%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_tabs1%3Dpages%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_privateLayout%3Dfalse%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_displayStyle%3Dmiller-columns%26p_r_p_selPlid%3D2070%26p_r_p_layoutSetBranchId%3D0%26p_p_auth%3DHQfjd1mP