03. - 17. Juli 2026

MEGRA NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

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: *03 - July - 2026*
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

Download website data in JSON data format
Published on: *07 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/about-website/download-website-data-json-data-format

EMA and EISMEA boost cooperation to accelerate health innovations
Published on: *15 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/news/ema-eismea-boost-cooperation-accelerate-health-innovations

Horizon scanning: Identifying emerging trends
Published on: *17 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/working-parties-other-groups/eu-innovation-network-eu/horizon-scanning-identifying-emerging-trends

Highlights - European Medicines Agency (EMA) / European Chemicals Agency (ECHA) joint meeting with industry stakeholders
Published on: *17 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/highlights-european-medicines-agency-ema-european-chemicals-agency-echa-joint-meeting-industry-stakeholders_en.pdf

Pharmakovigilanz – PRAC

PRAC recommendations on signals adopted at the 8-11 June 2026 PRAC meeting
Published on: *06 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-8-11-june-2026-prac-meeting_en.pdf

Article 57 product data
Published on: *10 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/article-57-product-data_en.xlsx

Humanarzneimittel - EMA

User manual for the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) user interface (XEVMPDweb)
Published on: *10 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/user-manual-extended-eudravigilance-medicinal-product-dictionary-xevmpd-user-interface-xevmpdweb_en.pdf

Coding of indications in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)
Published on: *10 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/coding-indications-extended-eudravigilance-medicinal-product-dictionary-xevmpd_en.pdf

Post-authorisation safety studies (PASS)
Published on: *13 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/post-authorisation-safety-studies-pass

List of substances and products subject to worksharing for signal management
Published on: *15 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/list-substances-products-subject-worksharing-signal-management_en.xlsx

Zulassung – Regulatory Affairs

List of medicines currently in PRIME scheme
Published on: *07 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/list-medicines-currently-prime-scheme_en.xlsx

Type-II variations: questions and answers
Published on: *13 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/variations-including-extensions-marketing-authorisations/type-ii-variations-questions-answers

Type-IB variations: questions and answers
Published on: *13 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/variations-including-extensions-marketing-authorisations/type-ib-variations-questions-answers

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Worksharing: questions and answers
Published on: *13 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/variations-including-extensions-marketing-authorisations/worksharing-questions-answers

Extensions of marketing authorisations: questions and answers
Published on: *13 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/variations-including-extensions-marketing-authorisations/extensions-marketing-authorisations-questions-answers

Transfer of marketing authorisation: questions and answers
Published on: *13 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/transfer-marketing-authorisation-questions-answers

Pre-authorisation guidance
Published on: *13 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/pre-authorisation-guidance

Medicinal products for human use: monthly figures - June 2026
Published on: *14 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/medicinal-products-human-use-monthly-figures-june-2026_en.pdf

Applications for new human medicines under evaluation: July 2026
Published on: *14 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/applications-new-human-medicines-under-evaluation-july-2026_en.xlsx

PRIME eligibility requests: 2027 deadlines for submission and timetable for assessment
Published on: *14 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/prime-eligibility-requests-2027-deadlines-submission-timetable-assessment_en.pdf

Questions and answers: Article 31 non-pharmacovigilance referrals
Published on: *15 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/referral-procedures-human-medicines/questions-answers-article-31-non-pharmacovigilance-referrals

Humanarzneimittel - EMA

Questions and answers: Article 29(4) referral procedures
Published on: *16 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/referral-procedures-human-medicines/questions-answers-article-294-referral-procedures

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Scientific recommendations on classification of advanced therapy medicinal products
Published on: *10 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/scientific-recommendations-classification-advanced-therapy-medicinal-products_en.xlsx

Qualität – Quality

Guidance on good manufacturing practice and good distribution practice: Questions and answers
Published on: *13 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers

Clinical pharmacology and pharmacokinetics: questions and answers
Published on: *14 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/clinical-pharmacology-pharmacokinetics-guidelines/clinical-pharmacology-pharmacokinetics-questions-answers

Concept paper on the revision of the guidelines on Good Manufacturing Practice for medicinal products - Annex 15 - Qualification and validation – Corrigendum
Published on: *15 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-revision-guidelines-good-manufacturing-practice-medicinal-products-annex-15-qualification-validation-corrigendum_en.pdf

Humanarzneimittel - EMA

(Prä-) Klinische Forschung – Research and Development

Qualification of novel methodologies for medicine development
Published on: *07 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-advice-protocol-assistance/qualification-novel-methodologies-medicine-development

ICH E6 Good clinical practice - Scientific guideline
Published on: *15 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline

Clinical Trial Information System (CTIS) - Sponsor handbook
Published on: *17 - July - 2026*
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

No news published

Pflanzliche Arzneimittel – Herbal medicines

Draft reflection paper on particulars for safety signals for (traditional) herbal medicinal products
Published on: *15 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/scientific-guideline/draft-reflection-paper-particulars-safety-signals-traditional-herbal-medicinal-products_en.pdf

Events and Video recording

SPOR and XEVMPD status update webinar - Q3 2026
Presentation available
Published on: *07 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/spor-xevmpd-status-update-webinar-q3-2026

Humanarzneimittel - EMA

EMA workshop on the challenges in drug development, regulation and clinical practice in immune thrombocytopenia
Presentations available
Published on: *07 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-workshop-challenges-drug-development-regulation-clinical-practice-immune-thrombocytopenia

European Commission

New documents - Study supporting the monitoring of availability of medical devices on the EU market
Published on: *03 - July - 2026*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/new-documents-study-supporting-monitoring-availability-medical-devices-eu-market-2026-07-03_en

Updated - List of joint clinical assessments
Published on: *08 - July - 2026*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/updated-list-joint-clinical-assessments-2026-07-08_en

Questions and answers (version 22) - Safety features for medicinal products for human use
Published on: *10 - July - 2026*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/questions-and-answers-version-22-safety-features-medicinal-products-human-use-2026-07-10_en

General Principles on the use of Artificial Intelligence in the preparation of the JCA dossier
Published on: *16 - July - 2026*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/general-principles-use-artificial-intelligence-preparation-jca-dossier-2026-07-16_en

EDQM

Second issue of Pharmeuropa EDSForm published: two new draft European Drug Shortages Formulary monographs are now available for public consultation
Published on: *06 - July - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/second-issue-of-pharmeuropa-edsform-published-two-new-draft-european-drug-shortages-formulary-monographs-are-now-available-for-public-consultation

Certification monthly report of activities: End of June 2026
Published on: *07 - July - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/certification-monthly-report-of-activities-end-of-june-2026

Council of Europe publishes a follow-up position paper on the implementation of the EU's Medical Devices Regulation in the substances of human origin sector
Published on: *07 - July - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/council-of-europe-publishes-a-follow-up-position-paper-on-the-consequences-of-implementing-the-eu-s-medical-device-regulation-for-the-substances-of-human-origin-sector

Outcome of the 185th session of the European Pharmacopoeia Commission
Published on: *09 - July - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/outcome-of-the-185th-session-of-the-european-pharmacopoeia-commission

Medizinprodukte

List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment
Published on: *10 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/list-clinical-evaluation-consultation-procedure-cecp-opinions-issued-medical-devices-awaiting-finalisation-conformity-assessment_en.pdf

Publication of dashboard version 3.5 for the Study supporting the monitoring of availability of medical devices on the EU market
Published on: *14 - July - 2026*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/monitoring-availability-medical-devices-eu-market-2024-01-09_en

Updated – Submission request template for medical devices
Published on: *16 - July - 2026*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/updated-submission-request-template-medical-devices-2026-07-16_en

CMDh

No news published

Humanarzneimittel - Deutschland

Veröffentlichung auf dem Zentralen Terminologieserver: Valuesets für Health Device Data Transfer (HDDT) als FHIR-Package
Veröffentlicht am: *06 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Kodiersysteme/News/Terminologieserver_Veroeffentlichung_HDDT.html?nn=986770

Fachausschüsse der Deutschen Arzneibuch-Kommission
Veröffentlicht am: *06 - Juli - 2026*
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

Geschäftsverteilungsplan der registrierten Ethik-Kommissionen für das Jahr 2026
Veröffentlicht am: *08 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/klin-pr/ethikKomm/GVP.html?nn=986770

Besonderer Geschäftsverteilungsplan für auf bestimmte Verfahren spezialisierte registrierte Ethik-Kommissionen der Länder 2026 - klinische Prüfungen bei Minderjährigen
Veröffentlicht am: *08 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/klin-pr/ethikKomm/Besonderer_GVP.html?nn=986770

Informationen zu Rote-Hand-Briefen und Informationsbriefen
Veröffentlicht am: *10 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Rote-Hand-Briefe/Zusatzinformationen/_artikel.html?nn=986770

Informationen zu Einreichung und Genehmigung von Schulungsmaterial
Veröffentlicht am: *13 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/Zusatzinformationen/_artikel.html?nn=986770

Arzneimittel-Lieferengpass-bekämpfungs- und Versorgungs-verbesserungs-gesetz (ALBVVG)
Veröffentlicht am: *13 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/ALBVVG/_artikel.html?nn=986770

Humanarzneimittel - Deutschland

Liste der Veröffentlichungen von Zusammenfassungen von Risikomanagementplänen nach § 34 Abs. 1a AMG, Stand 01.05.2026
Veröffentlicht am: *13 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/RMP/liste-rmp-summary.html?nn=986770

Versagungen und Rücknahmen BfArM Januar - Juni 2026
Veröffentlicht am: *16 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Statistik/AM-Statistik/versagungen-2026.html?nn=986770

Rohdaten der Stoffbezeichnungen
Veröffentlicht am: *17 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Arzneimittel-recherchieren/Stoffbezeichnungen/_artikel.html?nn=986770

Humanarzneimittel - Österreich

Übertragung
Veröffentlicht am: *06 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/uebertragung-gem-25-amg

CHMP Meeting Highlights Mai 2026
Veröffentlicht am: *09 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/marktbeobachtung/amtliche-nachrichten/detail/chmp-meeting-highlights-mai-2026

CHMP Meeting Highlights Juni 2026
Veröffentlicht am: *09 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/marktbeobachtung/amtliche-nachrichten/detail/chmp-meeting-highlights-juni-2026

0726_Register Arzneimittelvermittler.xlsx
Veröffentlicht am: *10 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/04_Marktbeobachtung/%C3%96ffentliche_Register/0726_Register_Arzneimittelvermittler.pdf

0726_Bearbeitungsstand
Veröffentlicht am: *10 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/04_Marktbeobachtung/%C3%96ffentliche_Register/0726_Bearbeitungsstand.pdf

0726_Register bewilligter AM Betriebe Österreich.xlsx
Veröffentlicht am: *10 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/04_Marktbeobachtung/%C3%96ffentliche_Register/0726_Register_bewilligter_AM_Betriebe_%C3%96sterreich.pdf

Serialisierung und Verifizierung Neu
Veröffentlicht am: *13 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/konsumentinnen/illegaler-markt/serialisierung-und-verifizierung

PRAC signal recommendation: Gemcitabin
Veröffentlicht am: *08 - Juli - 2026*
Weitere Informationen finden Sie unter:
Mustertext Gemcitabin
Link zur Webseite der EMA

Humanarzneimittel - Österreich

PRAC signal recommendation: Valproat und verwandte Stoffe
Veröffentlicht am: *08 - Juli - 2026*
Weitere Informationen finden Sie unter:
Mustertext Valproat
Link zur Webseite der EMA

PRAC signal recommendation: Röntgenkontrastmittel
Veröffentlicht am: *08 - Juli - 2026*
Weitere Informationen finden Sie unter:
Mustertext Röntgenkontrastmittel
Link zur Webseite der EMA

Humanarzneimittel - Schweiz

CIRS-Studie zu Zulassungszeiten von Humanarzneimitteln mit neuen Wirkstoffen bestätigt Wettbewerbsfähigkeit von Swissmedic im internationalen Vergleich
Veröffentlicht am: *06 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/internationale-studie-zlzeiten-2025.html

Swissmedic Journal
Veröffentlicht am: *08 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/publikationen/swissmedic-journal.html

Neue Informationen zur Einführung von eCTD v4.0
Veröffentlicht am: *14 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/services/submissions/ectd-v4-0-2.html

EU: Neue GMP-Durchführungsverordnungen für Tierarzneimittel
Veröffentlicht am: *16 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/eu-neue-gmp-durchfuehrungsverordnungen-fuer-tierarzneimittel.html

Checkliste für eine Inspektion der Materiovigilance in Spitälern
Veröffentlicht am: *16 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/checkliste-fuer-eine-inspektion-der-materiovigilance-in-spitaelern.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *17 - Juli - 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: *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-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

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

Veranstaltungen / Events – Behörden und andere Veranstalter

Q&A clinic on Substance, Organisation, Referentials Management Services - 2026
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *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-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

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

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

Joint European Commission (EC) / European Medicines Agency (EMA) multi-stakeholder workshop on regulatory sandbox
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *21 - September - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/joint-european-commission-ec-european-medicines-agency-ema-multi-stakeholder-workshop-regulatory-sandbox

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%3DLl4b0kqf

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

Veranstaltungen / Events – Behörden und andere Veranstalter

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

Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the EudraVigilance system
Where: *Bucharest, Romania*
Date: *26 to 28 - October - 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-59

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course (Bucharest) - October 2026
Where: *Hotel Capital Plaza Bucharest, Bucharest, Romania*
Date: *29 to 30 - October - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-bucharest-october-2026

Workshop on the use of external controls for evidence generation in regulatory decision-making
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *03 - November - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/workshop-use-external-controls-evidence-generation-regulatory-decision-making

HMA/EMA multistakeholder AI and Data forum: Build trustworthy AI on strong data foundations
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *12 to 13 - November - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/hma-ema-multistakeholder-ai-data-forum-build-trustworthy-ai-strong-data-foundations

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