19. Juni – 03. Juli 2026

MEGRA NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

Fee regulation working arrangements
Published on: *24 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/fee-regulation-working-arrangements_en.pdf

Reform of the EU pharmaceutical legislation
Published on: *26 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/what-we-do/reform-eu-pharmaceutical-legislation

Annual activity report 2024
Published on: *29 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/annual-activity-report-2024_en.pdf

European Medicines Agency's data protection notice for use of Microsoft Intune for personal and corporate-owned devices
Published on: *30 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-use-microsoft-intune-personal-corporate-owned-devices_en.pdf

Pharmakovigilanz – PRAC

PRAC recommendations on safety signals
Published on: *22 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/signal-management/prac-recommendations-safety-signals

List of medicines under additional monitoring
Published on: *25 - June - 2026*
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)
Published on: *01 - July - 2026*
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

Humanarzneimittel - EMA

Timetable: Post-authorisation safety study (PASS) protocols and final results
Published on: *01 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/timetable-post-authorisation-safety-study-pass-protocols-final-results_en.xlsx

List of centrally authorised products with safety-related changes to the product information
Published on: *01 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/list-centrally-authorised-products-safety-related-changes-product-information_en.xlsx

Timetable: Periodic safety update report (PSUR) and PSUR single assessment (PSUSA)
Published on: *01 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/timetable-periodic-safety-update-report-psur-psur-single-assessment-psusa_en.xlsx

Referral: Rifadin oral suspension and syrup and associated names
Published on: *26 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/rifadin-oral-suspension-syrup-associated-names

Referral: Tavneos
Published on: *26 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/tavneos

Referral: Ipidacrine-containing medicinal products
Published on: *30 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/ipidacrine-containing-medicinal-products

Referral: Sodium oxybate-containing syrup and oral solution for alcohol dependence – referral
Published on: *30 - June - 2026*
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

Zulassung – Regulatory Affairs

Product Management Service (PMS) roadmap
Published on: *30 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/product-management-service-pms-roadmap_en.pdf

PRIME: priority medicines
Published on: *30 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/prime-priority-medicines

Plasma master file certificates
Published on: *01 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/plasma-master-file-pmf-certification/plasma-master-file-certificates

Table of decisions of labelling exemption requests falling under article 63 of Directive 2001/83/EC examined by the Quality Review of Documents (QRD) Group
Published on: *01 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/table-decisions-labelling-exemption-requests-falling-under-article-63-directive-2001-83-ec-examined-quality-review-documents-qrd-group_en.pdf

Orphan Drugs und neuartige Therapierichtungen (ATMP)

CAT quarterly highlights and approved ATMPs - June 2026
Published on: *26 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/committee-report/cat-quarterly-highlights-approved-atmps-june-2026_en.pdf

Timetable: Periodic safety update report (PSUR) and PSUR single assessment (PSUSA) - Advanced therapy medicinal products (ATMPs)
Published on: *01 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/timetable-periodic-safety-update-report-psur-psur-single-assessment-psusa-advanced-therapy-medicinal-products-atmps_en.xlsx

Humanarzneimittel - EMA

Qualität – Quality

No news published

(Prä-) Klinische Forschung – Research and Development

Scientific guideline: ICH E22 General considerations for patient preference studies
Published on: *24 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/ich-e22-general-considerations-patient-preference-studies-scientific-guideline

Clinical Trial Information System (CTIS) - Sponsor handbook
Published on: *26 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-sponsor-handbook_en.pdf

FAQs: Support with workload management by workspace - CTIS Training Programme - Module 04
Published on: *26 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/faqs-support-workload-management-workspace-ctis-training-programme-module-04_en.pdf

Step-by-step guide : Support with workload management in the authority workspace - CTIS Training Programme - Module 04
Published on: *26 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/step-step-guide-support-workload-management-authority-workspace-ctis-training-programme-module-04_en.pdf

Kinderarzneimittel – Paediatrics

No news published

Pflanzliche Arzneimittel – Herbal medicines

No news published

Humanarzneimittel - EMA

Events and Video recording

Clinical Trials Information System (CTIS): Information day, Event 17 - June - 2026
Presentations available
Published on: *23 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-information-day-2

Quarterly System Demo - Q2 2026
Presentation and Video recordings available
Published on: *29 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/quarterly-system-demo-q2-2026

Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - April 2026
Video recording available
Published on: *30 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-april-2026

Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - May 2026
Video recording available
Published on: *30 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-may-2026

Q&A clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - May 2026
Video recording available
Published on: *30 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-may-2026

Q&A clinic on Substance, Organisation, Referentials Management Services - April 2026
Video recording available
Published on: *30 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-april-2026

Humanarzneimittel - EMA

Q&A clinic on Substance, Organisation, Referentials Management Services - May 2026
Video recording available
Published on: *30 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-may-2026

European Commission

Eudralex Volume 4: Reference and Retention Samples (revised, applicable as of 24 September 2026)
Published on: *24 - June - 2026*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/eudralex-volume-4-reference-and-retention-samples-revised-applicable-24-september-2026-2026-06-24_en

COMBINE programme launches phase 2 of the pilot coordinated assessment procedure for combined studies
Published on: *26 - June - 2026*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/76937

EDQM

EU OCABR guidelines revised to remove references to the rabbit pyrogen test
Published on: *24- June - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/eu-ocabr-guidelines-revised-to-remove-references-to-the-rabbit-pyrogen-test

European Pharmacopoeia Issue 13.2 now available
Published on: *01- July - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/european-pharmacopoeia-issue-13.2-now-available

Pharmeuropa 38.3 just released
Published on: *01- July - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/pharmeuropa-38.3-just-released

EDQM reference standards monthly newsletter – June 2026
Published on: *02- July - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/edqm-reference-standards-monthly-newsletter-june-2026

Medizinprodukte

Medical Devices: Delegated acts on well-established technologies published
Published on: *26 - June - 2026*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/77013

Class III implantable devices and Class IIb medical devices intended to administer or remove medicinal products: expert panel opinions
Published on: *26 - 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

CMDh

Meeting with Interested Parties - 25 June 2026
Published on: *30 - June - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/about-cmdh/contacts-with-representative-organisations.html#c7839

CMDH PRESS RELEASES 2026
Published on: *01 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/press-releases.html#c7863

UPDATE - Requirements on submissions for Variations and Renewals within MRP and National Procedures and BPG on the use of eCTD in the MRP/DCP
Published on: *03 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/esubmissions.html

Variation applications – Cover letter
Published on: *03 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/templates/variations.html

Variation Procedure - UPDATE - BPG on the use of eCTD in the MRP/DCP (Chapter 7) / BPG for the processing of grouped applications in MRP (Chapter 6) / BPG for the processing of Type IA minor variations (notifications) in MRP (Chapter 3) / BPG for the allocation of the MRP variation number for Type I notifications, Type II variations, grouping and worksharing (Chapter 1)
Published on: *03 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/variation.html

UPDATE - Q&A on variations / QP Declaration / Post Brexit
Published on: *03 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/questions-answers.html

UPDATE - Instructions for RMS when preparing the PAR based on the FAR
UPDATE - PAR template (empty) when prepared based on FAR
Published on: *03 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/templates/assessment-reports/public-ar.html

UPDATE - DCP D70 Overview AR template (incl. instructions) / UPDATE - DCP D70 Overview AR template (empty)
Published on: *03 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/templates/assessment-reports/dcp-ar/comments.html

CMDh

NEW - Summary ARs for doxazosin mesylate/finasteride
Published on: *03 - July - 2026*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Pharmacovigilance_Legislation/PSUR/Outcome_of_informal_PSUR_WS_procedures/Doxazosin_finasteride_MIP_Pharma_SmAR_PSUR_WS.pdf
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Pharmacovigilance_Legislation/PSUR/Outcome_of_informal_PSUR_WS_procedures/Doxazosin_finasteride_Viatris_SmAR_PSUR_WS.pdf

Humanarzneimittel - Deutschland

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen
Veröffentlicht am: *01 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770

Ergebnisprotokoll zur 40. Sitzung der Gemeinsamen Expertenkommission zur Einstufung von Stoffen
Veröffentlicht am: *01 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Abgrenzung/Gemeinsame-Expertenkommission-zur-Einstufung-von-Stoffen/Sitzungen/Protokolle/40_Sitzung_Protokoll.html

Parallelimport von Arzneimitteln
Veröffentlicht am: *01 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsverfahren/Parallelimport-von-Arzneimitteln/_artikel.html

Sachstandstabelle
Veröffentlicht am: *02 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Expertengruppe-Off-Label/sachstandstabelle.html

Offene ordnungsgemäß eingegangene Anträge auf Zulassung und Registrierung für Arzneimittel im Zuständigkeitsbereich des BfArM
Veröffentlicht am: *03 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/Arzneimittelzulassung/offene-Zulassungsantraege/_artikel.html?nn=986770

Arzneimittel-Lieferengpass-bekämpfungs- und Versorgungs-verbesserungs-gesetz (ALBVVG)
Liste der notwendigen Kinderarzneimittel gemäß § 35 Absatz 5a SGB V
Veröffentlicht am: *03 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/ALBVVG/_artikel.html

Humanarzneimittel - Österreich

Medikamentenkauf auf illegalen Webseiten
Veröffentlicht am: *26 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/konsumentinnen/arzneimittel-im-internet/fernabsatz/medikamentenkauf-auf-illegalen-webseiten

Aktuelle Ausgabe der „RMS NEWS“
Veröffentlicht am: *30 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/marktbeobachtung/amtliche-nachrichten/detail/aktuelle-ausgabe-der-rms-news-20

L_Z55_Leitfaden_eService_Zulassung_und_Lifecycle_ASP
Veröffentlicht am: *01 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/01_Formulare_Listen/Z/L_Z55_Leitfaden_eService_Zulassung_und_Lifecycle_ASP.pdf
FAQ online Service
FAQ Online Service Zulassung & Lifecycle ASP

Gebrauchsinformation barrierefrei
Veröffentlicht am: *01 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/faq-zulassung-life-cycle/gebrauchsinformation-barrierefrei

Gebrauchsinformation barrierefrei - Vermeidung von Lizenzverstößen
Veröffentlicht am: *01 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/zulassungsverfahren/gebrauchsinformation-barrierefrei

Humanarzneimittel - Schweiz

Tagung des ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)
Veröffentlicht am: *22 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/meeting-ich-2026-06.html

Behördenübergreifende Schwerpunktaktion «Peptide 2026»
Veröffentlicht am: *30 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/arzneimittel-aus-dem-internet/drug-safety-current-threats/schwerpunktaktion-peptide.html

Fassung 12.3 der Europäischen Pharmakopöe in Kraft
Veröffentlicht am: *01 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/legal/pharmacopoea/wichtige-informationen/fassung-12-3-eu-pharmakopoeoe.html

swissdamed: Ab 1. Juli 2026 gilt die Registrierungspflicht für Medizinprodukte und In-vitro-Diagnostika
Veröffentlicht am: *01 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/swissdamed-registrierungspflicht.html

AMZV, VAZV: Nachführung der Anhänge
Veröffentlicht am: *01 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/amzv-vazv-nachfuehrung-anhaenge0.html

Safety Update – Aktualisierungen der Fachinformation
Veröffentlicht am: *01 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/risk-management-rmps/safetyupdates.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *03 - 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: *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-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

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

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-

Veranstaltungen / Events – Behörden und andere Veranstalter

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

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

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

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

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