22. Mai - 05. Juni 2026

MEGRA NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

Podcast: Inside EMA (updated)
Published on: *28 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/news-events/podcast-inside-ema

SME Regulation and reports (updated)
Published on: *28 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/support-smes/sme-regulation-reports

Artificial intelligence (updated)
Published on: *04 - 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/artificial-intelligence

Pharmakovigilanz – PRAC

Guideline on good pharmacovigilance practices (GVP): Module VII – Periodic safety update report - Explanatory note (updated)
Published on: *22 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vii-periodic-safety-update-report-explanatory-note_en.pdf

Questions and answers on periodic safety update report single-assessment (PSUSA): Guidance document for assessors (updated)
Published on: *22 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/questions-answers-periodic-safety-update-report-single-assessment-psusa-guidance-document-assessors_en.pdf

List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (updated)
Published on: *27 - May - 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

List of medicines under additional monitoring (updated)
Published on: *27 - May - 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

Humanarzneimittel - EMA

List of centrally authorised products with safety-related changes to the product information (updated)
Published on: *29 - May - 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

New product information wording: extracts from PRAC recommendations on signals adopted at the 12-15 January 2026 PRAC (updated)
Published on: *01 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/prac-recommendation/new-product-information-wording-extracts-prac-recommendations-signals-adopted-12-15-january-2026-prac_en.pdf

Referral: Tecovirimat SIGA
Published on: *02 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/tecovirimat-siga

Zulassung – Regulatory Affairs

Medicinal products for human use: monthly figures - April 2026
Published on: *26 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/medicinal-products-human-use-monthly-figures-april-2026_en.pdf

Timetable: Annual reassessment (updated)
Published on: *27 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/timetable-annual-reassessment_en.xlsx

Timetable: Annual renewal application of conditional marketing authorisation (updated)
Published on: *27 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/timetable-annual-renewal-application-conditional-marketing-authorisation_en.xlsx

Timetable: Marketing authorisation renewal application (updated)
Published on: *28 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/timetable-marketing-authorisation-renewal-application_en.xlsx

Humanarzneimittel - EMA

Real-world evidence (updated)
Published on: *28 - May - 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

EMA's API general terms and conditions of use - Terms of use (updated)
Published on: *03 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/es/media/49662

Scientific guideline: Development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making (updated)
Published on: *03 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/es/development-reflection-paper-use-external-controls-evidence-generation-regulatory-decision-making-scientific-guideline

Medicines for human use under evaluation (updated)
Published on: *03 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/es/medicines/medicines-human-use-under-evaluation

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Timetable: Annual reassessment - ATMP (updated)
Published on: *27 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/timetable-annual-reassessment-atmp_en.xlsx

Timetable: Annual renewal application of conditional marketing authorisation - ATMP (updated)
Published on: *27 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/timetable-annual-renewal-application-conditional-marketing-authorisation-atmp_en.xlsx

Timetable: Marketing authorisation renewal application - ATMP (updated)
Published on: *28 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/timetable-marketing-authorisation-renewal-application-atmp_en.xlsx

Qualität – Quality

No news published

Humanarzneimittel - EMA

(Prä-) Klinische Forschung – Research and Development

Accelerating Clinical Trials in the EU (ACT EU) (updated)
Published on: *27 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/accelerating-clinical-trials-eu-act-eu

Clinical pharmacology and pharmacokinetics: questions and answers (updated)
Published on: *28 - May - 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

Product Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 3 (updated)
Published on: *28 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso-standards-identification-medicinal-products-idmp-europe-chapter-3_en.pdf

Kinderarzneimittel – Paediatrics

Enpr-EMA priority activities (updated)
Published on: *29 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/partners-networks/networks/european-network-paediatric-research-european-medicines-agency-enpr-ema/enpr-ema-priority-activities

Pflanzliche Arzneimittel – Herbal medicines

No news published

Events and Video recording

No news published

European Commission

Commission publishes analysis underpinning the Biotech Act proposals
Published on: *27 - May - 2026*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/75672

Health Technology Assessment: New Opportunity to Apply for Joint Scientific Consultations
Published on: *01 - June - 2026*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/75918

EDQM

The European Pharmacopoeia Commission intensifies its efforts on quality control guidance for preparations for inhalation and nasal administration
Published on: *28 - May - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/the-european-pharmacopoeia-commission-intensifies-its-efforts-on-quality-control-guidance-for-preparations-for-inhalation-and-nasal-administration

EDQM reference standards monthly newsletter – May 2026
Published on: *01 - June - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/edqm-reference-standards-monthly-newsletter-may-2026

OMCL Network Symposium reaffirms commitment to combating falsified and other illegal medicines
Published on: *05 - June - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/omcl-network-symposium-reaffirms-commitment-to-combating-falsified-and-other-illegal-medicines

Medizinprodukte

Scientific advice for high-risk medical devices (updated)
Published on: *29 - May - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices/high-risk-medical-devices/scientific-advice-high-risk-medical-devices

Expert panel support for breakthrough medical devices: pilot programme (updated)
Published on: *04 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices/expert-panel-support-breakthrough-medical-devices-pilot-programme

The first four modules of EUDAMED became mandatory since 28 May 2026
Published on: *01 - June - 2026*
For more information, please refer to:
https://health.ec.europa.eu/medical-devices-eudamed/overview_en

CMDh

NEW - Report from the meeting held on 19-20 May 2026
Published on: *27 - May - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/press-releases.html

UPDATE - Non Clinical / Clinical AR for Generics - MRP & DCP
Published on: *27 - May - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/templates/assessment-reports/dcp-ar/comments.html

NEW - 21-22 April CMDh Minutes
Published on: *27 - May - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/agendas-and-minutes.html

Humanarzneimittel - Deutschland

Sachstandstabelle
Veröffentlicht am: *22 - Mai - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Expertengruppe-Off-Label/sachstandstabelle.html?nn=986770

Liste der Mitglieder und Stellvertretungen des Sachverständigen-Ausschusses für Apothekenpflicht
Veröffentlicht am: *26 - Mai - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Gremien/Apothekenpflicht/liste-mitglieder.html?nn=986770

Europäische Datenbank für Medizinprodukte: EUDAMED
Veröffentlicht am: *28 - Mai - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Medizinprodukte/Ueberblick/Europa-und-EUDAMED/EUDAMED/_artikel.html?nn=986770

Anleitung für Anzeigepflichtige Adressanzeigen
Veröffentlicht am: *28 - Mai - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte/DMIDS-anleitung-anzeigepflichtige-adressen.html?nn=986770

Erst- und Änderungsanzeige MP und IVD
Veröffentlicht am: *28 - Mai - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte/DMIDS-anleitung-anzeigepflichtige-mp-ivd.html?nn=986770

Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 26.03.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Epinephrin/Adrenalin (außer nasale Anwendung)
Veröffentlicht am: *28 - Mai - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Periodic-Safety-Update-Reports_PSURs/PSUR-Single-Assessment/Anlagen/a-f/Epinephrin-Adrenalin-CMDh-Beschluss.html?nn=986770

Muster: Dokumentation „Nicht Supervisory Authority Inspektion“
Veröffentlicht am: *28 - Mai - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/muster-pharmakovigilanz-non-sa-inspektionen.html?nn=986770

Humanarzneimittel - Deutschland

Muster: Dokumentation „Supervisory Authority Inspektion“
Veröffentlicht am: *28 - Mai - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/muster-pharmakovigilanz-sa-inspektionen.html?nn=986770

Ein Jahr European Vaccines Hub: Paul-Ehrlich-Institut trägt dazu bei, die europäische Pandemievorsorge nachhaltig zu stärken
Veröffentlicht am: *29 - Mai - 2026*
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/newsroom/hp-meldungen/2026/260529-1-jahr-evh.html?nn=170852

Offene ordnungsgemäß eingegangene Anträge auf Zulassung und Registrierung für Arzneimittel im Zuständigkeitsbereich des BfArM
Veröffentlicht am: *01 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/Arzneimittelzulassung/offene-Zulassungsantraege/_artikel.html?nn=986770

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme
Veröffentlicht am: *02 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Compassionate-Use/compUse-tabelle.html?nn=986770

Informationen zu Einreichung und Genehmigung von Schulungsmaterial
Veröffentlicht am: *02 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/Zusatzinformationen/_artikel.html?nn=986770

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen
Veröffentlicht am: *05 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770

Humanarzneimittel - Österreich

FAQ Bevorratung national
Veröffentlicht am: *28 - Mai - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/online-service/faq-online-service/faq-bevorratung-national

PSUR-outcome: Metronidazol/Neomycin/Nystatin
Veröffentlicht am: *05 - Juni - 2026*
Weitere Informationen finden Sie unter:
Link zur Website der EMA

Humanarzneimittel - Schweiz

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

swissdamed Webinar 28 May 2026: How to register and manage medical device data in swissdamed
Presentation and Video recordings available
Published on: *01 - Juni - 2026*
For more information, please refer to:
https://www.swissmedic.ch/swissmedic/de/home/services/veranstaltungen/swissdamed-webinar.html

Swissmedic Journal
Veröffentlicht am: *04 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/publikationen/swissmedic-journal.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *05 - 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

Mit BfArM und PEI im Dialog: CTR und mehr
Ort: *online*
Termin: *15 - Juni - 2026*
Weitere Informationen finden Sie unter:
https://www.pei.de/SharedDocs/veranstaltungen-events/DE/2026/2026-06-15-ctr-dialog-bfarm-pei.html?nn=170994

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

Q&A clinic on Substance, Organisation, Referentials Management Services - 2026
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *10 - June - 2026, 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-june-2026
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

PMS Q&A Clinic on Product User Interface (PUI) and Application Programming Interface (API) - 2026
Where: *online*
Date: *11 - June – 2026, 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
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

Veranstaltungen / Events – Behörden und andere Veranstalter

Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - 2026
Where: *online*
Date: *11 - June - 2026, 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-june-2026
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

Updates to industry contact management for authorisation products (IRIS)
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *11 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/es/node/281811

European platform for regulatory science research meeting: June 2026
Where: *online*
Date: *16 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/european-platform-regulatory-science-research-meeting-june-2026

Clinical Trials Information System (CTIS): Information day
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *17 - June - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-information-day-2

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: *22 to 26 - June - 2026, 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-inthe-eu-hands-training-course-using-eudravigilance-system-4
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

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

Good manufacturing practice: Multistakeholder workshop on expert contributions to artificial intelligence guidance development (Annex 22)
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *30 - June to 01 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/good-manufacturing-practice-multistakeholder-workshop-expert-contributions-artificial-intelligence-guidance-development-annex-22

EMA risk management information day
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *08 - September - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-risk-management-information-day

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%2F7E%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

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%2F7E%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