19. September -
02. Oktober 2025

MEGRA NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

Quarterly System Demo – Q3 2025, Event 17 September 2025
Presentation and Video recording available
Published on: *23 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/quarterly-system-demo-q3-2025

Innovation Task Force briefing meetings (updated)
Published on: *25 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/innovation-task-force-briefing-meetings

A path to better include patients' perspectives in the regulation of medicines
Published on: *29 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/path-better-include-patients-perspectives-regulation-medicines

Artificial intelligence (updated)
Published on: *29 - September - 2025*
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

Referral: Ixchiq
Published on: *19 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/ixchiq

Referral: Oxbryta
Published on: *22 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/oxbryta

Referral: Azithromycin-containing medicinal products for systemic use
Published on: *25 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/azithromycin-containing-medicinal-products-systemic-use

Humanarzneimittel - EMA

Inclusion/exclusion criteria for the Important Medical Events (IME) list (updated)
Published on: *23 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/inclusion-exclusion-criteria-important-medical-events-ime-list_en.pdf

MedDRA important medical event terms list - version 28.1
Published on: *23 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/meddra-important-medical-event-terms-list-version-28_1_en.xlsx

List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)
Published on: *25 - September - 2025*
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: *26 - September - 2025*
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

PRAC recommendations on safety signals (updated)
Published on: *29 - September - 2025*
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 centrally authorised products with safety-related changes to the product information (updated)
Published on: *30 - September - 2025*
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

Information on the Member States requirement for the nomination of a pharmacovigilance (PhV) contact person at national level (updated)
Published on: *01 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/information-member-states-requirement-nomination-pharmacovigilance-phv-contact-person-national-level_en.pdf

Humanarzneimittel - EMA

Zulassung – Regulatory Affairs

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 15-18 September 2025
Published on: *19 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-15-18-september-2025

Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - August 2025, Event 28 August 2025 and 18 September 2025
Video recording available
Published on: *19 - September – 2025 and 24 - September – 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-august-2025
https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-september-2025

New variations guidelines to streamline lifecycle management of medicines (updated)
Published on: *22 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/new-variations-guidelines-streamline-lifecycle-management-medicines

Training session on human variations web-based electronic application form (eAF) for CAPs, Event 15 September 2025
Prensentation and Video recording available
Published on: *22 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/training-session-human-variations-web-based-electronic-application-form-eaf-caps

Start of procedure: Type II variation - Extension of indication under evaluation by the CHMP (22 August 2025 - 18 September 2025)
Published on: *23 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/start-procedure-type-ii-variation-extension-indication-under-evaluation-chmp-22-august-2025-18-september-2025_en.xlsx

PRIME: priority medicines (updated)
Published on: *26 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/prime-priority-medicines

Humanarzneimittel - EMA

Advice on end of year submission dates for type I variations in 2025 (updated)
Published on: *02 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/advice-end-year-submission-dates-type-i-variations-2025

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Committee for Advanced Therapies (CAT) workshop on gene editing, Event 16 September 2025 Video recording available
Published on: *23 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/committee-advanced-therapies-cat-workshop-gene-editing

Scientific recommendations on classification of advanced therapy medicinal products (udated)
Published on: *23 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/scientific-recommendations-classification-advanced-therapy-medicinal-products_en.xlsx

CAT meeting minutes Datum (udated)
Published on: *30 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/committee-advanced-therapies-cat

Qualität – Quality

Quality of medicines questions and answers: Part 1 (updated)
Published on: *30 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/quality-medicines-qa-introduction/quality-medicines-questions-answers-part-1

(Prä-) Klinische Forschung – Research and Development

Engineered living materials for in situ production of therapeutics - EU-IN Horizon Scanning Report
Published on: *23 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/engineered-living-materials-situ-production-therapeutics-eu-horizon-scanning-report_en.pdf

New targets for clinical trials in Europe
Published on: *23 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/new-targets-clinical-trials-europe

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Product-specific bioequivalence guidance (updated)
Published on: *25 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/clinical-pharmacology-pharmacokinetics/product-specific-bioequivalence-guidance

Clinical Trials Information System (CTIS): Walk-in clinic September 2025, Event 24 September 2025 Video recording available
Published on: *29 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-walk-clinic-september-2025

Scientific guideline: Clinical investigation of medicinal products for the treatment of idiopathic pulmonary fibrosis (IPF)
Published on: *30 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/clinical-investigation-medicinal-products-treatment-idiopathic-pulmonary-fibrosis-ipf-scientific-guideline

Scientific guideline: Clinical investigation of medicinal products for the treatment of psoriatic arthritis (updated)
Published on: *30 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/clinical-investigation-medicinal-products-treatment-psoriatic-arthritis-scientific-guideline

Scientific guideline: Clinical evaluation of medicinal products intended for treatment of hepatitis B (updated)
Published on: *30 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/clinical-evaluation-medicinal-products-intended-treatment-hepatitis-b-scientific-guideline

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 (updated)
Published on: *02 - October - 2025*
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

Humanarzneimittel - EMA

Kinderarzneimittel – Paediatrics

Enpr-EMA Coordinating Group and networks meeting June 2025, Event 11 June 2025
Presentations available
Published on: *26 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/enpr-ema-coordinating-group-networks-meeting-june-2025

Paediatric clinical trials (updated)
Published on: *01 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/paediatric-medicines-research-development/paediatric-clinical-trials

Pflanzliche Arzneimittel – Herbal medicines

Herbal: Combination: Species pectorales, F: Assessment finalised
Published on: *22 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/combination-species-pectorales

HMPC: overview of assessment work - priority list
Published on: *02 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/hmpc-overview-assessment-work-priority-list_en.pdf

European Commission

Commission publishes new measures for the better lifecycle management of medicine authorisations
Published on: *22 - September - 2025*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/67084

Commission authorises medicine to treat early stages of Alzheimer's disease
Published on: *25 - September - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/commission-authorises-medicine-treat-early-stages-alzheimers-disease-2025-09-25_en

New EU4Health calls for proposals under the 2025 Work Programme
Published on: *25 - September - 2025*
For more information, please refer to:
https://hadea.ec.europa.eu/news/new-eu4health-calls-proposals-under-2025-work-programme-2025-09-23_en

EU and Canada advance cooperation on preparedness and response to cross-border health threats
Published on: *26 - September - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/eu-and-canada-advance-cooperation-preparedness-and-response-cross-border-health-threats-2025-09-26_en

EDQM

EDQM to play key role in strengthening African medicines regulation
Published on: *25 - September - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/edqm-to-play-key-role-in-strengthening-african-medicines-regulation

EDQM publishes new guidelines on the classification of active pharmaceutical substances as regards their supply
Published on: *29 - September - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/edqm-publishes-new-guidelines-on-the-classification-of-active-pharmaceutical-substances-as-regards-their-supply

EDQM reference standards monthly newsletter – September 2025
Published on: *01 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/edqm-reference-standards-monthly-newsletter-september-2025

European Drug Shortages Formulary (EDSForm) takes shape: EDQM publishes first EDSForm texts for public consultation
Published on: *01 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/european-drug-shortages-formulary-edsform-takes-shape-edqm-publishes-first-edsform-texts-for-public-consultation

Pharmeuropa 37.4 just released
Published on: *02 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/pharmeuropa-37.4-just-released

CEP holders invited to comment on draft monographs published in Pharmeuropa 37.4
Published on: *02 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/cep-holders-invited-to-comment-on-draft-monographs-published-in-pharmeuropa-37.4

Transform lives – Join the network of the European Pharmacopoeia
Published on: *02 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/transform-lives-join-the-network-of-the-european-pharmacopoeia

Medizinprodukte

No news published

CMDh

UPDATE - Guidance on the application of the revised variations framework
Published on: *22 - September - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/variation/revised-variations-framework.html

UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation
Published on: *24 - September - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/paediatric-regulation/article-45-and-previous-worksharing.html

NEW - Report from the meeting held on 16-18 September 2025
Published on: *24 - September - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/press-releases.html

NEW - Q1-Q2 2025 Statistics for New Applications (MRP/DCP), Variations, Referrals and Paediatric Worksharing procedures
Published on: *25 - September - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/statistics.html

NEW - 22-23 July CMDh minutes
Published on: *25 - September - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/agendas-and-minutes.html

UPDATE - Common request form for RMS in DCP
Published on: *25 - September - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/templates/applications-for-ma.html

UPDATE - RMS Validation Checklist for human medicinal products in DCP
Published on: *25 - September - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/application-for-ma.html

UPDATE - Criteria for selection of products for SmPC Harmonisation
Published on: *25 - September - 2025*
For more information, please refer to:
https://www.hma.eu/referral-art-30-and-31non-pharmacovigilance.html

NEW - Overview referral timetables 2026
Published on: *25 - September - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/cmdh-referrals.html

CMDh

NEW - Art. 45 PAR Pheniramine maleate, naphazoline hydrochloride
Published on: *25 - September - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/paediatric-regulation/assessment-reports/article-45-work-sharing.html

NEW - Art. 46 PAR Havrix
Published on: *25 - September - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/paediatric-regulation/assessment-reports/article-46-work-sharing.html

Humanarzneimittel - Deutschland

Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 24.07.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Hydromorphon
Veröffentlicht am: *22 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Periodic-Safety-Update-Reports_PSURs/PSUR-Single-Assessment/Anlagen/g-l/Hydromorphon3-CMDh-Beschluss.html?nn=986770

Umsetzung des Durchführungsbeschlusses der Europäischen Kommission vom 17.09.2025 zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Azathioprin
Veröffentlicht am: *23 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Periodic-Safety-Update-Reports_PSURs/PSUR-Single-Assessment/Anlagen/a-f/Azathioprin-durchfuehrungsbeschluss-EU.html?nn=986770

PSUR Single Assessment (PSUSA)
Veröffentlicht am: *23 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Periodic-Safety-Update-Reports_PSURs/PSUR-Single-Assessment/_artikel.html?nn=986770

Bekanntmachungen zu Packungsgrößen
Veröffentlicht am: *24 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Packungsgroessen/bekanntmachungen.html?nn=986770

Klinische Prüfung gemäß MDR/IVDR/MPDG
Veröffentlicht am: *24 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte/DMIDS-anleitung-sponsoren-mdr.html?nn=986770

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen
Veröffentlicht am: *25 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770

Informationen zu Einreichung und Genehmigung von Schulungsmaterial
Veröffentlicht am: *25 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/Zusatzinformationen/_artikel.html?nn=986770

Humanarzneimittel - Deutschland

Erklärung zur Validierung
Veröffentlicht am: *25 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/EducationMaterial/weitere-informationen/erklaeung_validierung.html?nn=986770

Bulletin zur Arzneimittel-sicherheit - Informationen aus BfArM und PEI - Ausgabe 3
Veröffentlicht am: *25 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Publikationen/Bulletin/Ausgaben/2025/3-2025.html?nn=986770

Statistiken
Veröffentlicht am: *29 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/_artikel.html?nn=986770

Kurzanleitung zum Anmelden im PharmNet.Bund-Portal "elektronische Standardzulassung"
Veröffentlicht am: *30 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/ZulRelThemen/stdZul_und_Reg/kurzanleitung_portal_estandardzulassung.html?nn=986770

Liste der PRAC-Empfehlungen zu Textanpassungen
Veröffentlicht am: *30 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/textanpassung/Signalbewertung/Textanpassung_PRAC-Empfehlung.html?nn=986770

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme
Veröffentlicht am: *02 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Compassionate-Use/compUse-tabelle.html?nn=986770

Ethik-Kommissionen
Veröffentlicht am: *02 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Ethik-Kommissionen/_artikel.html?nn=986770

Inhaltsverzeichnis der aktuellen Pharmeuropa 37.4
Veröffentlicht am: *02 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/ZulRelThemen/azbuch/50stellungnKommentar/Pharmeuropa_Inhaltsverzeichnis.html?nn=986770

Humanarzneimittel - Österreich

Antrag auf Entschädigung der Mehrkosten durch die Bevorratung
Veröffentlicht am: *22 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/online-service/antrag-auf-infrastruktursicherungsbeitrag/antrag-auf-entschaedigung-der-mehrkosten-durch-die-bevorratung

Europäisches Netzwerk
Veröffentlicht am: *30 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/europaeisches-netzwerk

Vision, Werte und Strategie
Veröffentlicht am: *30 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/vision-werte-und-strategie

PRAC signal recommendation: Diazoxid
Veröffentlicht am: *30 - September - 2025*
Weitere Informationen finden Sie unter:
Link zur Webseite der EMA

PSUR outcome: Timolol (systemische Anwendung)
Veröffentlicht am: *02 - Oktober - 2025*
Weitere Informationen finden Sie unter:
Link zur Webseite der EMA

FAQ Pharmakovigilanz
Veröffentlicht am: *30 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/pharmakovigilanz/faq-pharmakovigilanz

RMS NEWS
Veröffentlicht am: *01 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/oesterreich-als-rms/rms-news

Humanarzneimittel - Schweiz

swissdamed UDI Devices Modul
Veröffentlicht am: *01 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/medizinprodukte-datenbank/swissdamed-informationen/swissdamed-udi-devices-modul.html

Neue Website «Horizon Scanning»
Veröffentlicht am: *02 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/horizon-scanning.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *01 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents/okt-2025.html

Fragen an das Netzwerk

Falls Sie eine Frage haben, die Sie gerne in unserem Netzwerk diskutieren würden, senden Sie uns einfach eine E-Mail an info-as@megra.org zur anonymen Publikation im nächsten Newsletter.*

*Bei der Beantwortung der Fragen handelt es sich um eine Zusammenfassung von persönlichen Meinungen und Erfahrungswerten der MEGRA Mitglieder mit keinem Anspruch auf Rechtssicherheit. Wir empfehlen zur Absicherung die Konsultation entsprechender zugrunde liegender Regularien.

Antwort zur Frage vom letzten Newsletter (KW 37_38)

Frage:

„In wie vielen Landessprachen etikettieren andere Zulassungsinhaber in der Schweiz:

- Arzneimittel, die im vereinfachten Verfahren zugelassen sind
- Arzneimittel, die im meldepflichtigen Verfahren zugelassen sind?

Vielen Dank für die Informationen zu Primär- und Sekundärverpackung!

Es erreichte uns eine Antwort:

In meinem Fall handelt es sich um ein meldepflichtiges Arzneimittel;

Die Verpackung ist 2-sprachig (deutsch-französisch), mit den Wirkstoffen in lateinischer Sprache.

Wichtig: hierbei handelt es sich um Produkt das nur von geschultem Fachpersonal in Spitälern verwendet wird – es wird nicht direkt an Patienten, sondern nur an Spitäler abgegeben.

Danke für Ihre Mithilfe!

Veranstaltungen / Events – Behörden und andere Veranstalter

Deutschland

Gemeinsame Ringvorlesung Wintersemester 2025/2026
Ort: *online*
Termin: *verschiedene 2025 - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Ringvorlesung/Termine/Ringvorlesung_2025-26.html?nn=986770

Klinische Prüfung: BfArM trifft...!
Ort: *online*
Termin: *18 - November - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/2025-11-18-klinische-pruefung-austausch.html?nn=986770

"The Product is the Process – Is it?" Manufacturing and Translation of ATMPs and Tissue- & Cell-based products
Ort: *Investitionsbank des Landes Brandenburg, Babelsberger Straße 21, 14473 Potsdam, Germany*
Termin: *20 - November - 2025*
Weitere Informationen finden Sie unter:
https://www.pei.de/SharedDocs/veranstaltungen-events/DE/2025/2025-11-20-workshop-manufacturing-translation-atmp.html?nn=170994

BfArM meets Europe: Shaping the EHDS
Ort: *BfArm, Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Germany*
Termin: *24 bis 25 - November*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/EN/News/events/2025-Health-Data/_node.html

Österreich

Keine Veranstaltungen veröffentlicht

Schweiz

Keine Veranstaltungen veröffentlicht

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Europa

SPOR and XEVMPD status update webinar
Where: *Live broadcast*
Date: *08 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/spor-xevmpd-status-update-webinar-0

HMA/EMA multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *08 to 09 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/hma-ema-multi-stakeholder-workshop-reporting-qualification-mechanistic-models-regulatory-assessment

Q&A clinic on web-based application form functionalities for CAPs and non-CAPs
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *09 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-web-based-application-form-functionalities-caps-non-caps

Joint EDQM-USP Webinar on "Orthogonal Analytical Methods for the Characterisation of Pharmacopoeial Reference Standards"
Where: *Paris, France*
Date: *09 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/edqm-usp-webinar

Q&A clinic on Substance, Organisation, Referentials Management Services
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *13 - October - 2025, 10 - November - 2025, 15 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-1
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-2
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services

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Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API)
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *14 - October - 2025, 18 - November - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-october-2025
https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-november-2025

Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *14 - October - 2025, 18 - November - 2025, 18 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-1
https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-0
https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service

Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course using the EudraVigilance system
Where: *online*
Date: *13 to 17 - October - 2025, 10 to 14 - November - 2025, 01 to 05 - December - 2025*
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-52
https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-53
https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-54

Unlocking PMS API potential: Edit functionality training for MAHs
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *16 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/unlocking-pms-api-potential-edit-functionality-training-mahs

EMA roundtable with stakeholders on the 20th anniversary of the SME Regulation
Where: *Live broadcast and European Medicines Agency, Amsterdam, the Netherlands*
Date: *17 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-roundtable-stakeholders-20th-anniversary-sme-regulation

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The EU HTA Regulation: Webinar for health technology developers of medicinal products
Where: *online*
Date: *17 - October - 2025*
For more information, please refer to:
https://health.ec.europa.eu/events/eu-hta-regulation-webinar-health-technology-developers-medicinal-products-2025-10-17_en

ICMRA Summit 2025
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *21 to 24 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/icmra-summit-2025

EUHPP Live Webinar: The challenge of climate change and integrating sustainability into breast cancer trials
Where: *online*
Date: *22 - October - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/registration-euhpp-live-webinar-challenge-climate-change-and-integrating-sustainability-breast-2025-09-12_en

CPhI Worldwide & CEP One-to-One Sessions
Where: *Frankfurt, Germany*
Date: *28 to 30 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/cphi-frankfurt

ACT EU multi-stakeholder platform annual meeting
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *29 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/act-eu-multi-stakeholder-platform-annual-meeting-0

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 - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/workshop-use-external-controls-evidence-generation-regulatory-decision-making

First EMA/HMA multi-stakeholder forum on EudraVigilance and signal detection
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *05 - November - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/first-ema-hma-multi-stakeholder-forum-eudravigilance-signal-detection

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CombiStats Online – Training
Where: *online*
Date: *17 to 21 - November - 2025*
For more information, please refer to:
https://www.edqm.eu/en/combistats-online-training

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

How to read a CEP webinar
Where: *online*
Date: *25 - November - 2025*
For more information, please refer to:
https://www.edqm.eu/en/how-to-read-a-cep-webinar

2025 EDQM virtual training programme: independent modules on the Ph. Eur., reference standards and the CEP Procedure
Where: *online*
Date: *01 to 12 - December - 2025*
For more information, please refer to:
https://www.edqm.eu/en/virtual-training-ph-eur-rs-and-cep-procedure

EMA Information Day on submission predictability of initial marketing authorisation December 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *03 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-information-day-submission-predictability-initial-marketing-authorisation-december-2025

EMA/HMA annual data forum
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *09 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-hma-annual-data-forum