24. Januar -
07. Februar 2024

MEGRA NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

EMA celebrates 30 years of progress in science and medicines in the European Union
Published on: *27 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/ema-celebrates-30-years-progress-science-medicines-european-union

History of EMA
Published on: *30 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/history-ema

One Health approach
Published on: *30 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/partners-networks/one-health-approach

EU Innovation Network (EU-IN)
Published on: *03 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/working-parties-other-groups/eu-innovation-network-eu

Pharmakovigilanz – PRAC

Information on the Member States requirement for the nomination of a pharmacovigilance (PhV) contact person at national level – Human medicines requirements (updated)
Published on: *14 - January - 2025*
4.a H Survey - pharmacovigilance contact person at national level_H

List of medicines under additional monitoring
Published on: *29 - January - 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

Referral: Metamizole-containing medicinal products
Published on: *29 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/metamizole-containing-medicinal-products-0

Humanarzneimittel - EMA

List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs) (updated)
Published on: *05 - February - 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

EudraVigilance training and support (updated)
Published on: *06 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/pharmacovigilance-research-development/eudravigilance/eudravigilance-training-support

Zulassung – Regulatory Affairs

Product Management Service (PMS) roadmap
Published on: *24 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/product-management-service-pms-roadmap_en.pdf

Medicinal products for human use: Monthly figures - December 2024
Published on: *24 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/medicinal-products-human-use-monthly-figures-december-2024_en.pdf

CHMP opinions on consultation procedures
Published on: *24 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices/consultation-procedure-ancillary-medicinal-substances-medical-devices/chmp-opinions-consultation-procedures

European Shortages Monitoring Platform fully operational for monitoring of shortages in the EU
Published on: *29 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/european-shortages-monitoring-platform-fully-operational-monitoring-shortages-eu

Falsified medicines: overview (updated)
Published on: *30 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/falsified-medicines-overview

Humanarzneimittel - EMA

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 27-30 January 2025
Published on: *31 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-27-30-january-2025

List of centrally authorised products with safety-related changes to the product information (updated)
Published on: *31 - January - 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

SPOR Status Update, Event 22 January 2024
Presentation and Video recording available
Published on: *31 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/spor-status-update-1

New combination of medicines to treat parasitic worm infections
Published on: *31 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/new-combination-medicines-treat-parasitic-worm-infections

Member states contact points for translations review (updated)
Published on: *31 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/member-states-contact-points-translations-review_en.pdf

Availability of medicines before and during crises (updated)
Published on: *03 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/availability-medicines-during-crises

Nanotechnology-based medicinal products for human use EU-IN Horizon Scanning Report
Published on: *03 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/nanotechnology-based-medicinal-products-human-use-eu-horizon-scanning-report_en.pdf

CHMP: Working parties and other groups (several updated working groups)
Published on: *04 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp-working-parties-other-groups

Humanarzneimittel - EMA

Questions and answers clinic on post-authorisation procedure management in IRIS, Event 08 January 2024
Video recording available
Published on: *04 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/questions-answers-clinic-post-authorisation-procedure-management-iris

Questions and answers clinic on post-authorisation procedure management in IRIS, Event 17 January 2024
Video recording available
Published on: *05 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/questions-answers-clinic-post-authorisation-procedure-management-iris-17-jan-2025

Medicine shortages and availability issues (updated)
Published on: *06 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues

Product Management Service (PMS) webinar on Product User Interface (PUI) edit functionalities for industry users, Event 28 January 2024
Presentation and Video recording available
Published on: *06 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/product-management-service-pms-webinar-product-user-interface-pui-edit-functionalities-industry-users

Plasma master file certificates (updated)
Published on: *06 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/plasma-master-file-pmf-certification/plasma-master-file-certificates

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Committee for Advanced Therapies (CAT), Event 4-6 December 2024
Minutes available
Published on: *28 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/minutes/minutes-cat-meeting-4-6-december-2024_en.pdf

Humanarzneimittel - EMA

Procedural advice for orphan medicinal product designation: Guidance for sponsors (updated)
Published on: *30 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-orphan-medicinal-product-designation-guidance-sponsors_en.pdf

COMP work plan 2025
Published on: *30 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/work-programme/comp-work-plan-2025_en.pdf

Committee for Advanced Therapies (CAT): Work Plan 2025
Published on: *03 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/work-programme/committee-advanced-therapies-cat-work-plan-2025_en.pdf

Submission deadlines for orphan designations (updated)
Published on: *06 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/orphan-designation-research-development/applying-orphan-designation/submission-deadlines-orphan-designations

Qualität – Quality

ICH E6 Good clinical practice - Scientific guideline (updated)
Published on: *27 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline

Guidance on good manufacturing practice and good distribution practice: Questions and answers
Published on: *31 - January - 2025*
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

Qualification of non-mutagenic impurities - Scientific guideline (updated)
Published on: *03 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/qualification-non-mutagenic-impurities-scientific-guideline

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(Prä-) Klinische Forschung – Research and Development

Clinical trial information system (CTIS) public portal full trial information (updated)
Published on: *29 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-public-portal-full-trial-information_en.pdf

Product-specific bioequivalence guidance (updated)
Published on: *31 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-guidelines/clinical-pharmacology-pharmacokinetics/product-specific-bioequivalence-guidance

Clinical Trials Regulation becomes fully applicable
Published on: *31 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/clinical-trials-regulation-becomes-fully-applicable

Clinical Trials Information System (CTIS): Walk-in clinic, Event 29 January 2025
Video recording available
Published on: *31 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-walk-clinic-january-2025

Clinical Trials Information System (CTIS): training and support (updated)
Published on: *05 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/clinical-trials-information-system-ctis-training-support

Page: Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials - Scientific guideline (updated)
Published on: *06 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/guideline-quality-non-clinical-clinical-requirements-investigational-advanced-therapy-medicinal-products-clinical-trials-scientific-guideline

Kinderarzneimittel – Paediatrics

No news published

Humanarzneimittel - EMA

Pflanzliche Arzneimittel – Herbal medicines

HMPC: overview of assessment work - priority list (updated)
Published on: *28 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/hmpc-overview-assessment-work-priority-list_en.pdf

Document: Committee on Herbal Medicinal Products (HMPC): Work Plan 2025
Published on: *30 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/work-programme/committee-herbal-medicinal-products-hmpc-work-plan-2025_en.pdf

Draft reflection paper on the use of information in European Union herbal monographs and assessment reports for borderline issues
Published on: *31 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/scientific-guideline/draft-reflection-paper-use-information-european-union-herbal-monographs-assessment-reports-borderline-issues_en.pdf

European Commission

EU Health Policy Platform: The 2024 Thematic Networks cycle has come to an end – what's next?
Published on: *29 - January - 2025*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/59624

Is the EU Health Policy Platform right for you? Find out, by taking a quick look at these two infographics
Published on: *03 - February - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/eu-health-policy-platform-right-you-find-out-taking-quick-look-these-two-infographics-2025-02-03_en

The Commission opens first request submission period for joint scientific consultations
Published on: *03 - February - 2025*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/59790

New pandemic preparedness facilities inaugurated under HERA's EUFab network
Published on: *03 - February - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/new-pandemic-preparedness-facilities-inaugurated-under-heras-eufab-network-2025-02-03_en

New HERA study maps global pandemic preparedness structures
Published on: *04 - February - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/new-hera-study-maps-global-pandemic-preparedness-structures-2025-02-04_en

Coordinated assessment for clinical investigations: a call for expression of interest
Published on: *06 - February - 2025*
For more information, please refer to:
https://health.ec.europa.eu/medical-devices-clinical-investigations-and-performance-studies/pilot-coordinated-assessment-cips_en

EDQM

EDQM reference standards monthly newsletter – January 2025
Published on: *03 - February - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/edqm-reference-standards-monthly-newsletter-january-2025

Medizinprodukte

Revised versions and new guidance are available in the EMDN section
Published on: *28 - January - 2025*
For more information, please refer to:
https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

Questions and answers on implementation of the medical devices and in vitro diagnostic medical devices Regulations ((EU) 2017/745 and (EU) 2017/746)
Published on: *05 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/questions-answers-implementation-medical-devices-vitro-diagnostic-medical-devices-regulations-eu-2017-745-eu-2017-746_en.pdf
or
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/questions-answers-implementation-medical-devices-vitro-diagnostic-medical-devices-regulations-eu-2017-745-eu-2017-746-tracked-changes_en.pdf *(track change version)*

CMDh

CMDH PRESS RELEASES 2025
Published on: *05 - February - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/press-releases.html#c7615

Request for RMS in a Decentralised Procedure, medicinal products for human use
Published on: *06 - February - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/templates/applications-for-ma.html#c1665

Procedural Advice on Repeat Use
Published on: *06 - February - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/application-for-ma/mrp/rup.html#c1636

CMDh SOP on decision-making process for new active substance status or extension of marketing protection or data exclusivity
Published on: *06 - February - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/application-for-ma.html#c4986

Best Practice Guides (BPGs) for the Submission and Processing of Variations in the Mutual Recognition Procedure
Published on: *06 - February - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/variation.html#c2126

Best Practice Guide on (1) Introduction of substances/combinations onto the EURD list and setting the initial PSUR DLP and frequency and (2) Assessment of PSURs of products where the EU Reference Date is not yet legally binding/followed
Published on: *06 - February - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/pharmacovigilance/psur/bpg-on-1-introduction-of-substances/combinations-onto-the-eurd-list-and-setting-the-initial-psur-dlp-and-frequency-and-2-assessment-of-psurs-of-products-where-the-eu-reference-date-is-not-yet-legally-binding.html#c7149

Humanarzneimittel - Deutschland

Arzneibuchkommissionen
Veröffentlicht am: *27 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Arzneibuch/Arzneibuchkommissionen/_artikel.html?nn=986770

BfArM erweitert öffentlichen Zugang zu Arzneimittel- und Zulassungsdaten
Veröffentlicht am: *29 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Pressemitteilungen/DE/2025/pm01-2025.html?nn=986770

Derzeit gültige Monografien der Standardzulassung für Humanarzneimittel (Stand 29.01.2025)
Veröffentlicht am: *29 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/ZulRelThemen/stdZul_und_Reg/aktuell_gueltige_liste_standardzulassungen.html?nn=986770

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen
Veröffentlicht am: *30 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770

Statistik "Besondere Therapierichtungen und Traditionelle Arzneimittel"
Veröffentlicht am: *03 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/Arzneimittelzulassung/Besondere-Therapierichtungen/_artikel.html?nn=986770

Arzneimittelinformationssystem AMIce
Veröffentlicht am: *03 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Arzneimittel-recherchieren/AMIce/_artikel.html?nn=986770

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme
Veröffentlicht am: *03 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Compassionate-Use/compUse-tabelle.html?nn=986770

Umsetzung des Durchführungsbeschlusses der Europäischen Kommission zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Pemetrexed vom 23.01.2025
Veröffentlicht am: *03 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Periodic-Safety-Update-Reports_PSURs/PSUR-Single-Assessment/Anlagen/m-r/Pemetrexed2-durchfuehrungsbeschluss-EU.html?nn=986770

Humanarzneimittel - Deutschland

Arzneimittel-Lieferengpass-bekämpfungs- und Versorgungs-verbesserungs-gesetz (ALBVVG)
Veröffentlicht am: *04 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/ALBVVG/_artikel.html?nn=986770

Förderung der Nutzung von SNOMED CT durch die EU Kommission
Veröffentlicht am: *06 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Kodiersysteme/Terminologien/SNOMED-CT/eu-foerderung/_artikel.html?nn=986770

Informationen zu Einreichung und Genehmigung von Schulungsmaterial
Veröffentlicht am: *06 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/Zusatzinformationen/_artikel.html?nn=986770

Clinical Trials Information System – CTIS
Veröffentlicht am: *06 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/CTIS-Clinical-Trials-Information-System/_artikel.html?nn=986770

Humanarzneimittel - Österreich

BASG "All-in-One Register"
Veröffentlicht am: *24 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/marktbeobachtung/oeffentliche-register/basg-all-in-one-register

Arzneispezialitäten Übersicht 2024
Veröffentlicht am: *29 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/02_Ueber_Uns/Statistik/Arzneispezialit%C3%A4ten_%C3%9Cbersicht_2024.pdf

Zulassungen Registrierungen Zusatzdaten 2024
Veröffentlicht am: *29 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/02_Ueber_Uns/Statistik/Zulassungen_Registrierungen_Zusatzdaten_2024.pdf

Registrierung in IRIS
Veröffentlicht am: *29 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/zulassungsverfahren/registrierung-in-iris

Pharmakovigilanz-Inspektion
Veröffentlicht am: *30 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/pharmakovigilanz/pharmakovigilanz-inspektion

RMS NEWS
Veröffentlicht am: *31 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/oesterreich-als-rms/rms-news

PSUR outcome: Metformin
Veröffentlicht am: *04 - Februar - 2025*
Weitere Informationen finden Sie unter:
Mustertext Metformin

Link zur Webseite der EMA

PSUR outcome: Fentanyl (transdermales Pflaster, Injektionslösung)
Veröffentlicht am: *04 - Februar - 2025*
Weitere Informationen finden Sie unter:
Mustertext Metformin

Link zur Webseite der EMA

Humanarzneimittel - Österreich

PSUR outcome: Pemetrexed
Veröffentlicht am: *07 - Januar - 2025*
Weitere Informationen finden Sie unter:
Mustertext Pemetrexed

Link zur Webseite der EC

PSUR outcome: Ambrosia artemisifolia (sublinguale Anwendung)
Veröffentlicht am: *04 - Februar - 2025*
Weitere Informationen finden Sie unter:
Mustertext Ambrosia artemisifolia (sublinguale Anwendung)

Link zur Webseite der EMA

PSUR outcome: Promethazin
Veröffentlicht am: *04 - Februar - 2025*
Weitere Informationen finden Sie unter:
Link zur Webseite der EMA

PSUR outcome: Nebivolol
Veröffentlicht am: *04 - Februar - 2025*
Weitere Informationen finden Sie unter:
Mustertext Nebivolol

Link zur Webseite der EMA

PSUR outcome: Oxaliplatin
Veröffentlicht am: *06 - Februar - 2025*
Weitere Informationen finden Sie unter:
Mustertext Oxaliplatin

Link zur Webseite der EMA

Beratung durch das BASG
Veröffentlicht am: *05 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/basg-veroeffentlichungen/geschaeftsordnung

Statistiken
Veröffentlicht am: *06 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/statistiken

Humanarzneimittel - Schweiz

Vermeintlich pflanzliche Produkte
Veröffentlicht am: *28 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/arzneimittel-aus-dem-internet/drug-safety-current-threats/warnung_pflanzlichen_produkten.html

Neue Schweizerische Gute Praxis für die Instandhaltung von Medizinprodukten
Veröffentlicht am: *31 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/wiederaufbereitung---instandhaltung/instandhaltung.html

Revidierte Auslegung des Mutual Recognition Agreement (MRA) zwischen der Schweiz und Kanada
Veröffentlicht am: *31 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/abkommen-ca-und-ch.html

Swissmedic Journal
Veröffentlicht am: *07 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/publikationen/swissmedic-journal.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *06 - Februar - 2025*
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

Gemeinsame Ringvorlesung Wintersemester 2024/2025
Ort: *online*
Termin: *verschiedene 2024 - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Ringvorlesung/Termine/Ringvorlesung_2024-2025.html?nn=986770

Workshop der Arbeitsgruppe Chemometrics and Quality Assurance zur Datenvisualisierung
Ort: *Paul-Ehrlich-Institut, Langen*
Termin: *02 bis 03 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.pei.de/SharedDocs/veranstaltungen-events/DE/2025/2025-04-02-gdch-workshop.html?nn=170994

Österreich

Keine Veranstaltungen veröffentlicht

Schweiz

Keine Veranstaltungen veröffentlicht

Europa

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course - February 2025
Where: *online*
Date: *10 to 12 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-february-2025

ACT EU workshop on ICH E6 R3 (principles and Annex 1)
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *19 to 20 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/act-eu-workshop-ich-e6-r3-principles-annex-1

Veranstaltungen / Events – Behörden und andere Veranstalter

Virtual live hands-on training course for clinical trials sponsors using EudraVigilance system
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *18 to 20 - February - 2025, 05 to 07 - May - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-february
https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-may

European Shortages Monitoring Platform (ESMP) training on crisis and MSSG-led preparedness reporting for marketing authorisation holders (MAHs)
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *19 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/european-shortages-monitoring-platform-esmp-training-crisis-mssg-led-preparedness-reporting-marketing-authorisation-holders-mahs

European Shortages Monitoring (ESMP) - Question and answer clinic for marketing authorisation holders on shortage reporting via ESMP
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *25 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/european-shortages-monitoring-esmp-question-answer-clinic-marketing-authorisation-holders-shortage-reporting-esmp

Q&A 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: *04, 11, 18, 25 - February - 2025*
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-4-february-2025
https://www.ema.europa.eu/en/events/qa-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-11-february-2025
https://www.ema.europa.eu/en/events/qa-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-18-february-2025
https://www.ema.europa.eu/en/events/qa-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-25-february-2025

Veranstaltungen / Events – Behörden und andere Veranstalter

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: *24 to 28 - February - 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-47

Training on human variations web-based electronic application form (eAF) functionalities for CAPs and non-CAPs variations
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *27 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/training-human-variations-web-based-electronic-application-form-eaf-functionalities-caps-non-caps-variations

EMA workshop on the challenges in drug development, regulation and clinical practice for immunoglobulins
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *05 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-workshop-challenges-drug-development-regulation-clinical-practice-immunoglobulins

Clinical Trials Information System (CTIS) bitesize talk: Change of sponsor in CTIS
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *05 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-bitesize-talk-change-sponsor-ctis

Webinar on reflection paper on the qualification of non-mutagenic impurities
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *06 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/webinar-reflection-paper-qualification-non-mutagenic-impurities

Veranstaltungen / Events – Behörden und andere Veranstalter

Q&A clinic on web-based electronic Application Form (eAF) functionalities for CAPs and non-CAPs variations
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *06 & 13 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-web-based-electronic-application-form-eaf-functionalities-caps-non-caps-variations-0
https://www.ema.europa.eu/en/events/qa-clinic-web-based-electronic-application-form-eaf-functionalities-caps-non-caps-variations

DIA Europe 2025
Where: *Congress Centre Basel, Switzerland*
Date: *18 to 20 - March - 2025*
For more information, please refer to:
https://www.edqm.eu/en/w/dia-europe-2025

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

EDQM Stakeholder Event on "Plasma Supply Continuity"
Where: *Congress Centre Basel, Switzerland*
Date: *26 to 27 - March - 2025*
For more information, please refer to:
https://www.edqm.eu/en/plasma-supply-continuity

SPOR and XEVMPD status update webinar
Where: *Live broadcast*
Date: *09 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/spor-xevmpd-status-update-webinar

Product Management Service (PMS) information day 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *21 - May - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/product-management-service-pms-information-day-2025