13. - 27. September 2024

MEGRA

NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) (26 June 2024) – Minutes for the meetings held available
Published on: *13 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/what-we-do/crisis-preparedness-management/executive-steering-group-shortages-medicinal-products/executive-steering-group-shortages-safety-medicinal-products-mssg-meetings

Supporting innovation (updated)
Published on: *18 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/supporting-innovation

SME Regulation and reports (updated)
Published on: *18 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/support-smes/sme-regulation-reports

List of eligible industry stakeholder organisations (updated)
Published on: *25 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/list-eligible-industry-stakeholder-organisations_en.pdf

Pharmakovigilanz – PRAC

Pharmacovigilance Risk Assessment Committee (PRAC) criteria to prioritise impact research (Rev.1) (updated)
Published on: *17 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/pharmacovigilance-risk-assessment-committee-prac-criteria-prioritise-impact-research-rev1_en.pdf

Referral: Metamizole-containing medicinal products (updated)
Published on: *20 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/metamizole-containing-medicinal-products-0

Referral: Oxbryta (updated)
Published on: *26 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/oxbryta

Humanarzneimittel - EMA

List of medicines under additional monitoring (updated)
Published on: *25 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/medicines-under-additional-monitoring/list-medicines-under-additional-monitoring

List of European Union reference dates and frequency of submission of periodic safety update reports (PSURs) (updated)
Published on: *25 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/list-european-union-reference-dates-frequency-submission-periodic-safety-update-reports-psurs_en.xlsx

MedDRA important medical event terms list - version 27.1
Published on: *26 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/27-1_ime_list.xlsx

Zulassung – Regulatory Affairs

EMA's human medicines committee elects new Chair
Published on: *18 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/news/emas-human-medicines-committee-elects-new-chair

Environmental risk assessment of medicinal products for human use - Scientific guideline (updated)
Published on: *12 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/environmental-risk-assessment-medicinal-products-human-use-scientific-guideline

Early dialogue with healthcare professional organisations for marketing authorisation applications: 1-year report
Published on: *16 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/early-dialogue-healthcare-professional-organisations-marketing-authorisation-applications-1-year-report_en.pdf

IRIS guide for applicants - How to create and submit scientific applications, for industry and individual applicants
Published on: *16 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-applicants_en.pdf

Humanarzneimittel - EMA

Establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation (updated)
Published on: *16 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/establishing-efficacy-based-single-arm-trials-submitted-pivotal-evidence-marketing-authorisation

Questions and answers on labelling requirements for centrally authorised metered dose inhalers containing fluorinated greenhouse gases
Published on: *19 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/questions-answers-labelling-requirements-centrally-authorised-metered-dose-inhalers-containing-fluorinated-greenhouse-gases_en.pdf

QRD statements for metered dose inhalers containing fluorinated greenhouse gases
Published on: *23 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/qrd-statements-metered-dose-inhalers-containing-fluorinated-greenhouse-gases_en.pdf

List of centrally authorised products with safety-related changes to the product information (updated)
Published on: *25 - September - 2024*
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

Orphan Drugs und neuartige Therapierichtungen (ATMP)

New chair elected for EMA's Orphan Medicinal Products Committee
Published on: *16 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/news/new-chair-elected-emas-orphan-medicinal-products-committee

Information session on the pilot for expert panels' advice for orphan medical devices, Event - 23 - September - 2024 (updated)
Video recording available
Published on: *27 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/information-session-pilot-expert-panels-advice-orphan-medical-devices

Humanarzneimittel - EMA

Qualität – Quality

Compilation of Union procedures on inspections and exchange of information (updated)
Published on: *26 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/compilation-union-procedures-inspections-exchange-information

(Prä-) Klinische Forschung – Research and Development

Clinical Trials Regulation (CTR) Collaborate Stakeholder meeting, supported by ACT EU, Event - 11 - September - 2024 (updated)
Presentations and Video recording available
Published on: *20 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-regulation-ctr-collaborate-stakeholder-meeting-supported-act-eu

Clinical Trial Information System (CTIS) evaluation timelines (updated)
Published on: *20 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-evaluation-timelines_en.pdf

CTIS newsflash - 24 September 2024
Published on: *25 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/newsletter/ctis-newsflash-24-september-2024_en.pdf

Kinderarzneimittel – Paediatrics

No news published

Pflanzliche Arzneimittel – Herbal medicines

Herbal medicinal product: Absinthii herba, F: Assessment finalised (updated)
Published on: *18 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/absinthii-herba

Herbal medicinal product: Rosmarini aetheroleum, F: Assessment finalised (updated)
Published on: *20 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/rosmarini-aetheroleum

Humanarzneimittel - EMA

Herbal medicinal product: Rosmarini folium, F: Assessment finalised (updated)
Published on: *26 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/rosmarini-folium

Superseded community herbal monograph on Rosmarinus officinalis L., aetheroleum (updated)
Published on: *20 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/herbal-monograph/superseded-community-herbal-monograph-rosmarinus-officinalis-l-aetheroleum_en.pdf

Superseded community herbal monograph on Rosmarinus officinalis L., folium (updated)
Published on: *26 - September - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/herbal-monograph/superseded-community-herbal-monograph-rosmarinus-officinalis-l-folium_en.pdf

European Commission

Commission recommends stronger measures on smoke-free environments to better protect public health
Published on: *17 - September - 2024*
For more information, please refer to:
https://ec.europa.eu/commission/presscorner/detail/en/IP_24_4682

Health Technology Assessment: Commission publishes new guidance on validity of clinical studies
Published on: *23 - September - 2024*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/55866

Commission welcomes international declaration on the fight against antimicrobial resistance
Published on: *27 - September - 2024*
For more information, please refer to:
https://ec.europa.eu/commission/presscorner/detail/en/IP_24_4847

EDQM

Publication of two BSP studies on the BINACLE method – In vitro approach to safety testing of tetanus vaccines for human and veterinary use
Published on: *23 - September - 2024*
For more information, please refer to:
https://www.edqm.eu/en/-/publication-of-two-bsp-studies-on-the-binacle-method-in-vitro-approach-to-safety-testing-of-tetanus-vaccines-for-human-and-veterinary-use

Medizinprodukte

MDCG 2021-4 rev.1 - Application of transitional provisions for certification of class D in vitro diagnostic medical devices under Reg (EU) 2017/746 - September 2024
Published on: *23 - September - 2024*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/mdcg-2021-4-rev1-application-transitional-provisions-certification-class-d-vitro-diagnostic-medical-2024-09-25_en

CMDh

CMDh agenda and minutes (updated)
Published on: *23 - September - 2024*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/agendas-and-minutes.html

UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation
Published on: *25 - September - 2024*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/paediatric-regulation/article-45-and-previous-worksharing.html

NEW - Art 45 PAR on Loperamide, loperamide/simethicone
Published on: *25 - September - 2024*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/paediatric-regulation/assessment-reports/article-45-work-sharing.html

UPDATE - Pharmacovigilance Legislation
Published on: *25 - September - 2024*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/questions-answers.html

UPDATE - Request for MRP/RUP / Update assessment report
Published on: *25 - September - 2024*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/templates/rup.html

Best Practice Guide for the exchange of regulatory and administrative information regarding orphan medicinal products between EMA and National Competent Authorities (modified)
Published on: *25 - September - 2024*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/general-info.html#c1772

Humanarzneimittel - Deutschland

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen
Veröffentlicht am: *13 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770

Informationen zu Rote-Hand-Briefen und Informationsbriefen
Veröffentlicht am: *17 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Rote-Hand-Briefe/Zusatzinformationen/_artikel.html?nn=986770

Muster: Dokumentation „Nicht Supervisory Authority Inspektion“
Veröffentlicht am: *17 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Service/mitteil/muster-pharmakovigilanz-non-sa-inspektionen.html?nn=986770

Muster: Dokumentation „Supervisory Authority Inspektion“
Veröffentlicht am: *17 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Service/mitteil/muster-pharmakovigilanz-sa-inspektionen.html?nn=986770

Klassifikationen: BfArM veröffentlicht endgültige Fassung der ICD-10-GM 2025
Veröffentlicht am: *18 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Pressemitteilungen/DE/2024/pm04-2024.html?nn=986770

Versagungen und Rücknahmen BfArM Januar-August 2024
Veröffentlicht am: *18 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Statistik/AM-Statistik/versagungen-2024.html?nn=986770

COMP Ausschuss für Arzneimittel für seltene Leiden
Veröffentlicht am: *18 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Das-BfArM/EU-und-Internationales/COMP-Ausschuss/_artikel.html?nn=986770

Statistiken
Veröffentlicht am: *18 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/_artikel.html?nn=986770

Humanarzneimittel - Deutschland

Meldeverpflichtungen
Veröffentlicht am: *24 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Meldeverpflichtungen/_artikel.html?nn=986770

Humanarzneimittel - Österreich

PSUR outcome: Salicylsäure (topische Anwendung)
Veröffentlicht am: *13 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/07_Unternehmen/PV-Mustertexte/ab_2023/240913_CL_PSUSA_Salicyls%C3%A4ure_signiert.pdf

Link zur Website der EMA

PSUR outcome: Dydrogesteron/Estradiol
Veröffentlicht am: *13 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/07_Unternehmen/PV-Mustertexte/ab_2023/240913_CL_PSUSA_Dydrogesteron_Estradiol_sign.pdf

Link zur Website der EMA

PSUR outcome: Codein/Ibuprofen
Veröffentlicht am: *16 - September - 2024*
Weitere Informationen finden Sie unter:
Link zur Website der EMA

PSUR outcome: Cefpodoxim
Veröffentlicht am: *27 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/07_Unternehmen/PV-Mustertexte/ab_2023/240926_CL_PSUSA_Cefpodoxim_signiert.pdf

Link zur Website der EMA

Humanarzneimittel - Schweiz

Neues Verordnungsrecht gilt ab 1. November 2024
Veröffentlicht am: *16 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/verordnungsrecht-ab-1-nov-2024.html

Internationales Treffen des Permanent Forum on International Pharmaceutical Crime
Veröffentlicht am: *17 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/internationales-treffen-des-permanent-forum-on-international-pharmaceutical-crime.html

Aufforderung zur Überprüfung altrechtlicher Produkte
Veröffentlicht am: *18 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/uebersicht-medizinprodukte/aufforderung-ueberpruefung-altrechtlicher-produkte.html

Unvollständige Angaben auf perforierten Blistern
Veröffentlicht am: *20 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/qualitaetsmaengel-und-chargenrueckrufe/unvollstaendige-angaben-auf-perforierten-blistern.html

Go-live der SwissGMDP Datenbank
Veröffentlicht am: *20 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/bewilligungen_zertifikate/betriebsbewilligungen/swissgmdp.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *24 - September - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents/sept-2024.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.

1) Benötigt das Vereinigte Königreich auch nach der Einführung des Windsor Frameworks noch lineare Strichcodes oder reicht eine 2D Data Matrix Code auf den Faltkartons aus?

2) Benötigt das Vereinigte Königreich eine Seriennummer in einem beliebigen Format?

Und nochmals der Aufruf zur Unterstützung der Masterarbeit:

Im Rahmen einer Masterthesis soll die geplante Abschaffung des Sunset Clauses per vorgeschlagener Reform des EU-Arzneimittelrechts von 2023 untersucht werden. Gerne würde ich neben meinem Standpunkt weitere Argumente der Industrie einbringen und möchte deshalb die MEGRA-Mitglieder um ihre Meinung konsultieren: Könnten Sie mir Ihre Sichtweise zu der Abschaffung des Sunset Clausus mitteilen?

Veranstaltungen / Events – Behörden und andere Veranstalter

Deutschland

"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
Termin: *28 - November - 2024*
Weitere Informationen finden Sie unter:
https://www.pei.de/SharedDocs/veranstaltungen-events/DE/2024/2024-11-28-workshop-manufacturing-translation-atmp.html?nn=170994

Österreich

BASG-Gespräch: Quality Day - Neuigkeiten aus dem Bereich Arzneimittelqualität
Ort: Online via Zoom
Termin: *16 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/basg-gespraech-quality-day-neuigkeiten-aus-dem-bereich-arzneimittelqualitaet-1

Schweiz

Swissmedic Regulatory & Beyond 2024
Ort: Kursaal Bern
Termin: *26 - November - 2024*
Weitere Informationen finden Sie unter:
https://rb-swissmedicevents.ch/

Europa

2024 annual workshop of the European network of paediatric research at EMA (Enpr-EMA)
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *02 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/2024-annual-workshop-european-network-paediatric-research-ema-enpr-ema

Veranstaltungen / Events – Behörden und andere Veranstalter

SPOR and xEVMPD Stakeholder Engagement Webinars : SPOR Data Governance
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *04 to 14 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/spor-xevmpd-stakeholder-engagement-webinars-spor-data-governance

CPhI Worldwide & CEP One-to-One Sessions
Where: *Milan, Italy*
Date: *08 to 10 - October - 2024*
For more information, please refer to:
https://www.edqm.eu/en/cphi-worldwide-cep-one-to-one-sessions

Scientific Symposium on Advanced Therapy Medicinal Products - 'Contribution, evolution, revolution'
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *10 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/scientific-symposium-advanced-therapy-medicinal-products-contribution-evolution-revolution

EDQM workshop: exploring a certification system for the validation of rapid microbiological methods
Where: *Strasbourg, France*
Date: *15 to 16 - October - 2024*
For more information, please refer to:
https://www.edqm.eu/en/edqm-workshop-exploring-a-certification-system-for-the-validation-of-rapid-microbiological-methods-

Training webinar on Product Management Service (PMS) Product User Interface (PUI)
Where: *online*
Date: *16 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/training-webinar-product-management-service-pms-product-user-interface-pui

EUHPP webinar: 25 years of breast cancer research: Past, present and future
Where: *online*
Date: *16 - October - 2024*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/registration-open-euhpp-webinar-25-years-breast-cancer-research-past-present-and-future-16-october-2024-09-17_en

Veranstaltungen / Events – Behörden und andere Veranstalter

Clinical Trials Information System (CTIS) bitesize talk: End of transition period and notifications including serious breach
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *16 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-bitesize-talk-end-transition-period-notifications-including-serious-breach

Clinical Trials Information System (CTIS): Information day
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *17 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-information-day-0

Small and medium-sized enterprises info day
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *18 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/small-medium-sized-enterprises-info-day

ACT EU multi-stakeholder platform annual meeting
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *22 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/act-eu-multi-stakeholder-platform-annual-meeting

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course
Where: *online*
Date: *22 to 24 - October - 2024 and 18 to 20 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-october-2024
https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-november-2024

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: *22 - October - 2024 and 29 - October - 2024*
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-22-october-2024
https://www.ema.europa.eu/en/events/qa-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-29-october-2024

Veranstaltungen / Events – Behörden und andere Veranstalter

New fee regulation: webinar for human industry stakeholders
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *24 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/new-fee-regulation-webinar-human-industry-stakeholders

HMA/EMA multi-stakeholder workshop on Artificial Intelligence
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *05 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/hma-ema-multi-stakeholder-workshop-artificial-intelligence

Third European Medicines Agency (EMA) and European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) bilateral meeting
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *07 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/third-european-medicines-agency-ema-european-confederation-pharmaceutical-entrepreneurs-eucope-bilateral-meeting

Translating innovation into access for ATMPs: 3rd EU-Innovation network multi-stakeholder meeting
Where: *online and Rome, Italy*
Date: *15 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/translating-innovation-access-atmps-3rd-eu-innovation-network-multi-stakeholder-meeting

Clinical Trials Information System (CTIS): Walk-in clinic - November 2024
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *20 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-walk-clinic-november-2024

Everything you've always wanted to know about the certification (CEP) procedure
Where: *online*
Date: *21 - November - 2024*
For more information, please refer to:
https://www.edqm.eu/en/-webinar-cep-procedure

Veranstaltungen / Events – Behörden und andere Veranstalter

EU Health Policy Platform Annual Meeting
Where: *online*
Date: *26 - November - 2024*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/register-now-participate-onsite-or-online-eu-health-policy-platform-annual-meeting-26-november-and-2024-09-20_en

Advancements in gene therapy: the European Pharmacopoeia's new approach
Where: *online*
Date: *03 - December - 2024*
For more information, please refer to:
https://www.edqm.eu/en/advancements-in-gene-therapy-the-european-pharmacopoeia-s-new-approach