WSQMS Homepage Sep 5, 2022

Guidance for Applicants/MAHs Involved in GMP, GCP and GVP Inspections Coordinated by EMA

On 31 August 2022 the EMA published guidance for applicants/MAHs involved in GMP, GCP and GVP inspections coordinated by EMA, version 3.0.

This document provides the guidance for applicants/MAHs involved in GMP, GCP and GVP inspections. These inspections are requested by the Committee for Medicinal Products for Human Use and/or for Veterinary Use in order to verify compliance with GMP, GCP and GVP of centrally authorized products.

Read the pdf

E11A Pediatric Extrapolation

On 26 August 2022 the FDA published draft guidance on ICH E11A.

The purpose of this guideline is to provide recommendations for, and promote international harmonization of, the use of pediatric extrapolation to support the development and authorization of pediatric medicines. Harmonization of the approaches to pediatric extrapolation should reduce the likelihood of substantial differences between regions. Importantly, harmonization should also reduce exposure of pediatric populations to unnecessary clinical trials and facilitate more timely access to pediatric medicines globally.

Read more online

M12 Drug Interaction Studies

On 26 August 2022 the FDA published draft guidance on ICH M12.

This guideline provides recommendation to promote a consistent approach in designing, conducting, and interpreting enzyme- or transporter-mediated in vitro and clinical drug-drug interaction (DDI) studies during the development of a therapeutic product. A consistent approach will reduce uncertainty for pharmaceutical industry to meet the requirement of multiple regulatory agencies and lead to more efficient utilization of resources.

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Q14 Analytical Procedure Development

On 26 August 2022 the FDA published draft guidance on ICH Q14.

This guideline describes science and risk-based approaches for developing and maintaining analytical procedures suitable for the assessment of the quality of drug substances and drug products. The systematic approach suggested in ICH Q8 Pharmaceutical Development together with principles of ICH Q9 Quality Risk Management can also be applied to the development and lifecycle management of analytical procedures. When developing an analytical procedure, a minimal (also known as traditional) approach or elements of an enhanced approach can be applied.

Furthermore, the guideline describes considerations for the development of multivariate analytical procedures and for real time release testing (RTRT). This guideline is intended to complement ICH Q2 Validation of Analytical Procedures.

Read more online

Q2(R2) Validation of Analytical Procedures

On 26 August 2022 the FDA published draft guidance on ICH Q2(R2).

This guideline presents a discussion of elements for consideration during the validation of analytical procedures included as part of registration applications submitted within the ICH member regulatory authorities. Q2(R2) provides guidance and recommendations on how to derive and evaluate the various validation tests for each analytical procedure. This guideline serves as a collection of terms, and their definitions. These terms and definitions are meant to bridge the differences that often exist between various compendia and documents of the ICH member regulatory agencies.

Read more online

E14 and S7B Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential – Questions and Answers

On 26 August 2022 the FDA published final Q&A guidance on ICH E14 and S7B.

This question-and-answer (Q&A) document is intended to clarify key issues to facilitate implementing the ICH guidance for industry E14 Clinical Evaluation of the QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (October 2005) and S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals (October 2005).

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Revision – Manufacture of Sterile Medicinal Products

On 25 August 2022 the European Commission published the revised guideline for GMP in the EudraLex Volume 4, annex 1.

This Annex 1 provides general guidance that should be used in the design and control of facilities, equipment, systems and procedures used for the manufacture of all sterile products applying the principles of Quality Risk Management (QRM), to ensure that microbial, particulate and endotoxin/pyrogen contamination is prevented in the final product.

The deadline for coming into operation of Annex 1 is 25 August 2023, except for point 8.123 which is postponed until 25 August 2024.

Read more online

FAQs: Transitional Trials from EudraCT to CTIS

On 24 August 2022 EMA published the CTIS training program, module 23, version 1.2.

This Q&A document includes the following information:

- Answers to general questions regarding Transitional trials
- Answers to questions regarding how to create and submit Transitional trials
- Answers to questions regarding how to submit notifications and clinical trial results
- Answers to questions regarding how to complete the evaluation of a Transitional trial
- Answers to questions regarding the roles and permissions involved in the Transitional trial processes

Read the pdf

Sponsors' Guide: Transitional Trials from EudraCT to CTIS (sponsor users)

On 24 August 2022 EMA published the CTIS training program, module 23, version 1.2.

Learning Objectives:

- Remember what a Transitional trial is
- Understand how to submit a Transitional trial
- Understand how to submit notifications and clinical trial results for a Transitional trial
- Understand the roles and permissions involved

Read the pdf

EMA EudraVigilance Registration Manual

On 23 August 2022 EMA published the updated EudraVigilance registration manual.

To set-up a new organisation in EudraVigilance Production or XCOMP (Test system), a series of steps need to be followed. Once the QPPV or RP is registered for the Production EudraVigilance system, they will automatically also be registered for an XCOMP test account for the same organisation.

Read the pdf

Innovation, Quality & Transparency – a Compliance Team 1 Perspective

On 23 August 2022 UK MHRA Inspectorate published a blog on Compliance Matters.

There has been much discussion of late between regulators and industry on how we can ensure that patients and the public get new medicines as quickly as possible - all the way from development to regulatory approval - while still ensuring they are safe, effective and of the required quality.

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Information Event "Regulatory & Beyond"

On 22 August 2022 Swissmedic announced a hybrid information event "Regulatory & Beyond" to be held on 20 September 2022 in Bern.

Swissmedic, the Swiss Agency for Therapeutic Products, is fit for the future! And that applies across the board. We will show how we are using innovative approaches to prepare for the future in therapeutic products regulation, what steps we have already taken in digitalisation and what steps still lie ahead. But that's not all. We have extended our previous familiar "Regulatory News" event and will look beyond the known regulatory issues by offering information all about the life cycle of medicinal products and medical devices.

Read more online

Charging for Investigational Drugs Under an IND – Questions and Answers

On 23 August 2022 FDA published revised draft Q&A guidance. Submit comments by 24 October 2022.

This guidance provides information for industry, researchers, physicians, institutional review boards (IRBs), and patients about the implementation of FDA's regulations on charging for investigational drugs under an investigational new drug application (IND) for the purpose of either clinical trials or expanded access for treatment use (21 CFR 312.8), which went into effect on October 13, 2009. Since 2009, FDA has received a number of questions concerning its implementation of the charging regulations. As a result, FDA issued the final guidance for industry Charging for Investigational Drugs Under an IND — Questions and Answers in June 2016.

When finalized, this guidance will replace the 2016 guidance. Significant changes to the 2016 version include additional recommendations related to the need for submission of a statement by an independent certified public accountant under certain circumstances, and distribution of the manufacturing, administrative, or monitoring costs from the first year over the expected duration of the expanded access IND or protocol.

Read more online

A Regulatory Pharmaceutical Quality Knowledge Management System (PQKMS) to Enhance the Availability of Quality Medicines

On 17 August 2022 ICMRA (International Coalition of Medicines Regulatory Authorities) published a joint reflection paper in support of the regulatory PQ KMS.

This joint Reflection Paper (RP) outlines the coordinated multi-stakeholder approach to harmonization work required to support the development of a regulatory PQ KMS.

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Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices

On 17 August 2022 FDA issued final guidance for industry and FDA staff.

This guidance is intended to update and provide clarity on the Replacement Reagent and Instrument Family Policy for manufacturers of IVD devices and FDA staff to promote consistent application of the concepts in this guidance.

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Should you be interested in a partnership where you will add your personal or your company's technical and professional expertise, please contact any of the Partners as a starting point of a dialogue or write an e-Mail to info@wsqms.com.

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Q3D(R2) – Guideline for Elemental Impurities

On 14 September 2022 the FDA published draft guidance on elemental impurities.

This guidance presents a process to assess and control elemental impurities in the drug product using the principles of risk management as described in the ICH guidance for industry Q9 Quality Risk Management (June 2006) (ICH Q9). This process provides a platform for developing a risk-based control strategy to limit elemental impurities in the drug product.

Read more online

Computer Software Assurance for Production and Quality System Software

On 13 September 2022 the FDA published draft guidance on computer software assurance for industry and FDA staff. Submit comments by 14 November 2022.

FDA is issuing this draft guidance to provide recommendations on computer software assurance for computers and automated data processing systems used as part of medical device production or the quality system.

Read more online

Policy for Monkeypox Tests to Address the Public Health Emergency

On 13 September 2022 the FDA published final guidance on monkeypox tests for laboratories, commercial manufacturers and FDA staff.

This guidance describes FDA's review priorities of emergency use authorization (EUA) requests for monkeypox diagnostic tests, describes FDA's enforcement policies for certain diagnostic tests that are developed by and performed in a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) that meets the requirements to perform tests of high complexity, provides recommendations for diagnostic test validation, describes FDA's enforcement policies for FDA-cleared or authorized monkeypox diagnostic tests that are modified, and describes FDA's enforcement policies for certain serology tests.

Read more online

Certificates of Free Sale to Danish Manufacturers of Medical Devices

On 12 September 2022 the Danish Medicines Agency updated the medical devices guidance on certificates of free sale.

The Danish Medicines Agency issues Free Sales Certificates (FSC) to manufacturers and authorized representatives of medical devices, who are headquartered in Denmark and registered with the Danish Medicines Agency. Free Sale Certificates are issued for products which are exported outside of the European Economic Cooperation and to countries without a mutual recognition agreement with the EU.

Read more online

Statement of Identity and Strength — Content and Format of Labeling for Human Nonprescription Drug Products

On 8 September 2022 the FDA published draft guidance on content and format of labeling for human nonprescription drug products. Submit comments by 8 November 2022.

This draft guidance provides recommendations on the labeling of human drug products for the content and format of the required statement of identity and the drug product's strength.

The recommendations in this draft guidance are intended to help manufacturers, packers, distributors, applicants, re-labelers, and sponsors ensure consistent content and format of the statement of identity and strength for all human nonprescription drug products.

Labeling for nonprescription drug products is intended to enable consumers to self-select appropriately and safely without the supervision of a health care practitioner.

Read more online

Quantitative Labeling of Sodium, Potassium, and Phosphorus for Human Over-the-Counter and Prescription Drug Products

On 8 September 2022 the FDA published the draft guidance on quantitative labeling. Submit comments by 8 November 2022.

This guidance provides recommendations for quantitative labeling of sodium, potassium, and phosphorus present in human prescription and nonprescription (commonly referred to as over-the-counter (OTC)) drugs. This guidance addresses sodium, potassium, and phosphorus when present as constituents of active or inactive drug ingredients (e.g., sodium as a constituent of the inactive ingredient anhydrous trisodium citrate, phosphorus as a constituent of the inactive ingredient dibasic calcium phosphate, or sodium as a constituent of the active ingredient naproxen sodium). Products within the scope of this guidance's recommendations are orally ingested products and injectable medications containing an amount of 5 mg or more of sodium, potassium, or elemental phosphorus per maximum

single dose. Individuals or entities responsible for drug product labeling are encouraged to engage with FDA for advice on specific cases.

Read more online

Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products

On 8 September 2022 the FDA published the final guidance on real-world data and real-world evidence.

To facilitate FDA's internal tracking of submissions to the Agency that include real-world data (RWD) and real-world evidence (RWE), this guidance encourages sponsors and applicants to identify in their submission cover letters certain uses of RWD/RWE. This guidance does not address FDA's substantive review of the RWD/RWE submitted as part of the Agency's standard review process.

This guidance applies to submissions for investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) that contain RWD/RWE intended to support a regulatory decision regarding product safety and/or effectiveness.

Read more online

Medical Devices: Software Applications (Apps)

On 8 September 2022 the MHRA published updated guidance on software apps as medical devices.

This guidance provides information on what a software application medical device is and how to comply with legal requirements. Appendices 1 - 4 have been added as attachments to this guidance.

Read more online

EMA IRIS Industry Training for GVP Inspections

On 8 September the EMA published their online training sessions of IRIS for GCP inspections.

Following the go-live of IRIS for Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) inspections, EMA is publishing GVP Inspections on the IRIS platform with an expected go-live planned for Q3 2022.

This training outlines the IRIS industry training for GVP Inspections processes, highlighting the changes and addressing any potential questions from industry users.

The following topics were addressed:

- IRIS overview
- IRIS access management
- GVP Inspections business process, including demo of the Industry Portal
- Guidance and support

Read the pdf

General Clinical Pharmacology Considerations for Pediatric Studies of Drugs, Including Biological Products

On 7 September 2022 the FDA published draft guidance on clinical pharmacology considerations for pediatric studies.

This guidance assists sponsors of investigational new drug applications (INDs) and applicants of new drug applications (NDAs) under section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), biologics license applications (BLAs) under section 351(a) of the Public Health Service Act (PHS Act), and supplements to such applications who are planning to conduct clinical studies in pediatric populations. In addition, this guidance assists clinical investigators in the design and planning of, and Institutional Review Boards (IRBs) in the assessment of, clinical studies in pediatric populations.

Read more online

Updated IRIS Guide for Applicants

On 5 September the EMA published version 2.12 of the IRIS guide on how to create and submit scientific applications, for industry and individual applicants.

This guide has been produced to show applicants how to use the IRIS platform to prepare and submit an application and/or data for a scientific procedure (orphan designation application, scientific advice, ITF briefing meeting requests, marketing status reports, inspections and veterinary signal management) and related activities.

Read the pdf

Swissmedic Online Information Event: New Regulations on In Vitro Diagnostic Medical Devices

On 5 September Swissmedic announced an online information event for new regulations on in vitro diagnostic medical devices.

The new legal requirements for IVDR entered into force on 26 May 2022, at the same time as the application of the IVDR in the EU. The aim of the new regulations is to improve patient safety through the introduction of stricter conformity assessment procedures and performance studies, which ensure the safety and quality of in vitro diagnostic medical devices. In addition, new requirements apply for monitoring, traceability and transparency following placement on the market.

At the online information event, the topics will cover the new and changed requirements and clarify the specifications in Switzerland. The online event will take place on 3 November 2022 and participation is free of charge.

Read more online

Accelerating Clinical Trials in the EU (ACT EU) Multi-Annual

Workplan 2022-2026

On 2 September the EMA published the updated ACT EU multi-annual workplan.

The ACT EU 2022 – 2026 multi-annual workplan was adopted in August 2022 and introduces each of the priority actions and outlines their key deliverables. The workplan is anchored in the recommendations of the European Medicines Regulatory Network (EMRN) strategy to 2025 and the European Commission's Pharmaceutical Strategy for Europe. The plan builds on the entry into application of the Clinical Trials Regulation (Regulation (EU) No 536/2014) and the activities already underway in the European regulatory network to support clinical trials. The workplan highlights key focus areas to further facilitate innovation in clinical trials, stakeholder engagement and regulatory network collaboration.

Read the pdf

Manual on Borderline and Classification for Medical Devices under Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

In September 2022 the European Commission published version 1 of the manual on borderline and classification for medical devices.

This document, hereafter called the Manual, records the agreements reached by the Member State members of the Borderline and Classification Working Group (BCWG) following the exchanges under the Helsinki Procedure under Regulation (EU) 2017/745 on medical devices (the MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (the IVDR). The purpose and operation of the Helsinki procedure is described in the dedicated document here. The BCWG is chaired by the European Commission and consists of representatives of competent authorities from all Member States with a number of stakeholder associations as observers.

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