Q&A on the Protection of Commercially Confidential Information (CCI) and Personal Data while Using CTIS

29 March 2023 – the EMA published version 1.1 of the Q&A guidance on how to protect personal data and CCI in CTIS.

This Q&A document has been created to provide preliminary guidance for CTIS users on how to protect personal data and commercially confidential information (CCI) in CTIS, the EU database established in accordance with the requirements of Regulation (EU) No 536/2014 (CTR).

Read the pdf

ICH Guideline Q5A(R2) on Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin

27 March 2023 – the EMA updated scientific guideline on ICH Q5A(R2).

Overview of comments received on ICH guideline Q5A (R2) on Viral safety evaluation of biotechnology products derived from cell lines for Human or Animal origin was published. This document considers testing and evaluation of the viral safety of biotechnology products derived from characterized cell lines of human or animal origin. It outlines data that should be submitted in the marketing application/registration package.

Read the pdf

Clinical Trials Information System (CTIS) Bitesize Talk: Document

and Personal Data in CTIS

22 March 2023 – the EMA updated the presentation slides of CTIS bitesize talk on document and personal data in CTIS.

This bitesize talk on CTIS provides an opportunity for sponsors to learn how to use the 'Publication' and 'Not for publication' requests and remove personal data from Document properties.

Read more online

EMA's Regulatory Science Strategy to 2025

22 March 2023 – the EMA published the mid-point achievements to end 2022.

This report provides an overview of main achievements, from March 2020 to December 2022 in a succinct form with links to more detailed information where available. It is structured along the strategic goals presented in the original strategy as they apply to both human and veterinary areas respectively.

Read the pdf

Clinical Trials Information System (CTIS): Virtual Walk-in Clinics

20 March 2023 – the EMA published the dates for the CTIS virtual walk-in clinics for 2023.

These virtual walk in clinics provide an opportunity for sponsors to receive practical advice about the Clinical Trials Information System by asking CTIS experts questions in real time. They will occur on the following dates from 16:00-17:00 CEST.

19 April 2023 17 May 2023 14 June 2023
19 July 2023 23 August 2023 20 September 2023
10 October 2023 15 November 2023 13 December 2023

Evaluation Guide for GMP Regulatory Compliance Program – Audit Checklist

14 March 2023 – the EMA published revision 3 of the audit checklist for the GMP regulatory compliance program.

The checklist must be used for the assessment/evaluation of GMP regulatory compliance program as regards active pharmaceutical ingredients and medicinal products. This checklist is used as a high level document. It is meant to detail the "WHAT" and not the "HOW". The "HOW" is expected to be covered in a lower level document such as a guidance document or a procedure.

Read the pdf

The New Unique Device Identifier (UDI) Helpdesk is Live

14 March 2023 – the European Commission (EC) announced that the new UDI helpdesk is live.

The UDI Helpdesk provides users with specific guidance and information on the requirements introduced by the unique device identification system.

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Guideline on Computerized Systems and Electronic Data in Clinical Trials

10 March 2023 – the EMA published the guidance on computerized systems and electronic data in clinical trials.

This guideline will describe some generally applicable principles and definition of key concepts. It also covers requirements and expectations for computerized systems, including validation, user management, security, and electronic data for the data life cycle. Requirements and expectations are also covered related to specific types of systems, processes, and data.

Read the pdf

Questions and Answers about the Raw Data Proof-of- Concept Pilot for Industry

8 March 2023 – the EMA published Q&A guidance on the scope, terms of participation and data submission process for the proof-of-concept pilot.

This document provides Answers to commonly asked Questions about the proof-of-concept (PoC) pilot on the submission and analysis of 'raw data' from clinical studies as part of selected initial marketing authorization applications (iMAAs) and post-authorization applications submitted to the EMA.

Q&A 2022 Annual Report

Draft Qualification Opinion for Stride Velocity 95th Centile as Primary Endpoint in Studies in Ambulatory Duchenne Muscular Dystrophy Studies

1 March 2023 – the EMA published the draft qualification opinion for the Stride Velocity 95th centile (SV95C) as primary endpoint in superiority studies.

The SV95C is a clinical outcome assessment (COA) captured by using a digital and passive wearable device and system that was developed by the Applicant. The primary purpose of this request is to seek qualification of the SV95C for use as a primary endpoint in clinical trials from Phase 1 to Phase 4 for the measurement of the maximal stride velocity in real-life of ambulant patients with DMD.

Read the pdf

Identification of Medicinal Products – Implementation and Use

30 March 2023 – the FDA published the final guidance on identifying medicinal products.

This guidance is for sponsors, applicants, and registrants who are involved in the regulatory submission of medicinal product data. The guidance supports the development and implementation of the International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP) standards for substances, terminologies, and other information for use throughout the global medicinal product development lifecycle. The purpose of these standards is to enable improved accuracy, completeness, and consistency in the international exchange of medicinal product information among stakeholders.

Read more online

Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act

30 March 2023 – the FDA published the final guidance on the cybersecurity in medical devices.

For premarket submissions submitted for cyber devices before October 1, 2023, FDA generally intends not to issue "refuse to accept" (RTA) decisions based solely on information required by section 524B of the FD&C Act. Instead, FDA intends to work collaboratively with sponsors of such premarket submissions as part of the interactive and/or deficiency review process. Beginning October 1, 2023, FDA expects that sponsors of cyber devices will have had sufficient time to prepare premarket submissions that contain information required by section 524B of the FD&C Act, and FDA may RTA premarket submissions that do not. For information about FDA's RTA policy more generally, sponsors of cyber devices should consult FDA's guidance documents.

Read more online

Research Involving Children as Subjects and Not Otherwise Approvable by an IRB: Process for Referrals to FDA and Office for Human Research Protections (OHRP)

30 March 2023 – the FDA published draft guidance on the review of research involving children as subjects for Review Boards, Investigators, and Sponsors. Submit comments by 30 May 2023.

This guidance is intended to assist institutional review boards (IRBs), institutions, investigators, and sponsors in understanding the processes used for review of research involving children as subjects that is not otherwise approvable by an IRB and has been referred to the Food and Drug Administration (FDA) under 21 CFR 50.54, the Office for Human Research Protections (OHRP) under 45 CFR 46.407, or both, for review.

Read more online

Orthopedic Non-Spinal Bone Plates, Screws, and Washers – Premarket Notification (510(k)) Submissions

29 March 2023 – the FDA published draft guidance on the premarket submissions for orthopedic non-spinal bone plates, screws, and washers. Submit comments by 29 May 2023.

This draft guidance document provides recommendations for premarket notification (510(k)) submissions for non-resorbable bone plate, screw, and washer devices. These devices are indicated for orthopedic bone fixation and exclude indications for spinal, mandibular, maxillofacial, cranial, and orbital fracture fixation.

Read more online

Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics

24 March 2023 – the FDA published draft guidance on the pharmacogenomic data submissions. Submit comments by 24 May 2023.

The purpose of this guidance is to provide recommendations to sponsors of anti-cancer drugs or biological products on considerations for designing trials intended to support accelerated approval. The accelerated approval pathway is commonly used for approval of oncology drugs in part due to the serious and life-threatening nature of cancer and because of available surrogate or intermediate clinical endpoints considered reasonably likely to predict clinical benefit.

Read more online

FDA CDER & JHU CERSI Workshop | Addressing Challenges in the Design and Analysis of Rare Disease Clinical Trials: Considerations and Tools

24 March 2023 – the FDA announced a two-day virtual workshop on addressing challenges in the design and analysis of rare disease clinical trials.

On May 2 and 3, 2023, the FDA's Center for Drug Evaluation and Research (CDER) and the Johns Hopkins University's Center of Excellence in Regulatory Science and Innovation (JHU CERSI) will host a jointly sponsored virtual workshop on addressing challenges in the design and analysis of rare disease clinical trials.

Read more online

Electronic Systems, Electronic Records, and Electronic Signatures Webinar

22 March 2023 – the FDA scheduled a webinar to be held on 25 April 2023, on electronic systems, electronic records, and electronic signatures.

As technology advances, the electronic data flow between systems is more efficient and more prevalent. Understanding the evolving uses of electronic records, electronic systems, and electronic signatures in clinical investigations is important. 21 CFR 11 helps ensure the authenticity, integrity, and reliability of data submitted in support of marketing applications or submissions. In this webinar, FDA will present the current thinking regarding 21 CFR 11 and its application to electronic records, electronic systems and electronic signatures during a clinical investigation.

Read more online

Pharmacogenomic Data Submissions

17 March 2023 – the FDA published draft guidance on the pharmacogenomic data submissions. Submit comments by 20 June 2023.

This draft guidance is intended to facilitate progress in the field of pharmacogenomics and the use of pharmacogenomic data in drug development. The document is intended to clarify the contexts in which pharmacogenomic study findings and data must be included in submissions related to investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) based on the FDA's regulations. In addition, this document provides recommendations to sponsors and applicants on the format and content of the pharmacogenomic data submissions.

Read more online

Development of Local Anesthetic Drug Products with Prolonged Duration of Effect

15 March 2023 – the FDA published the draft guidance on the development of local anesthetic drug products. Submit comments by 14 June 2023.

The purpose of this guidance is to assist sponsors that are developing local anesthetic drug products to produce postoperative analgesia for a prolonged duration, for which submission of a new drug application (NDA) through the pathway described in section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) is appropriate.

FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

Read more online

Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers

15 March 2023 – the FDA published draft Q&A guidance on the use of electronic systems, electronic records, and electronic signatures in clinical investigations. Submit comments by 15 May 2023.

This document provides guidance to sponsors, clinical investigators, institutional review boards (IRBs), contract research organizations (CROs), and other interested parties on the use of electronic systems, electronic records, and electronic signatures in clinical investigations of medical products, foods, tobacco products, and new animal drugs.

The guidance provides recommendations regarding the requirements, including the requirements under 21 CFR part 11 (part 11), under which FDA considers electronic systems, electronic records, and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

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Evaluation of Gastric pH-Dependent Drug Interactions with Acid-Reducing Agents (ARAs): Study Design, Data Analysis, and Clinical Implications

10 March 2023 – the FDA published the final guidance on the evaluation of gastric pH-dependent drug interactions with ARAs.

This guidance describes the FDA's recommendations regarding: (1) when clinical DDI studies with ARAs are needed; (2) the design of such clinical DDI studies; (3) how to interpret these study results; and (4) communicating these findings in drug product labeling.

Read more online

Q13 Continuous Manufacturing (CM) of Drug Substances and Drug Products

1 March 2023 – the FDA published the final ICH Q13 guidance on the CM of drug substances and drug products.

This guidance describes scientific and regulatory considerations for the development, implementation, operation, and lifecycle management of continuous manufacturing (CM). Building on existing ICH Quality guidance, this guidance provides clarification on CM concepts and describes scientific approaches and regulatory considerations specific to CM of drug substances and drug products.

Read more online

Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting Viral Pathogens

1 March 2023 – the FDA published draft guidance on the development of monoclonal antibodies. Submit comments by 1 May 2023.

The purpose of this guidance is to provide to sponsors recommendations that assist in the development of monoclonal antibodies (mAbs) and other therapeutic proteins that directly target viral proteins or host cell proteins mediating pathogenic mechanisms of infection. A critical quality control measure for these products is the development and implementation of a potency assay(s) adequate to ensure that each lot is produced consistently with the potency necessary to achieve clinical efficacy and that such potency is maintained over the shelf life of the product. This guidance provides detailed recommendations to drug developers with the goal of helping to ensure that drug developers provide adequate information to assess potency at each stage of a product's life cycle.

Read more online

Crafting an Intended Purpose in the Context of Software as a Medical Device (SaMD)

22 March 2023 – the UK MHRA published guidance on the context of software as a medical device.

This document is aimed at manufacturers of SaMD, including standalone software and apps. The purpose of the document is to explain the benefits of having a clear and accurate intended purpose.

Read more online

The ICH Q9(R1) Introductory Training Presentation Available on the ICH Website

20 March 2023 – the ICH announced the ICH Q9(R1) introductory training presentation is now available on their website.

The ICH Q9(R1) Guideline on Quality Risk Management has reached Step 4 of the ICH Process in January 2023.

Following the adoption of this Guideline, a Step 4 Introductory Training Presentation has been developed by the Q9(R1) Expert Working Group.

Read more online

The ICH S12 Guideline Reaches Step 4 of the ICH Process

17 March 2023 – the ICH announced the ICH S12 Guideline on "Nonclinical Biodistribution Considerations for Gene Therapy Products" reached Step 4 on 14 March 2023.

This Guideline is intended to provide guidance on the conduct of nonclinical biodistribution (BD) studies in the development of gene therapy (GT) products that mediate their effect by the expression (transcription or translation) of transferred genetic materials, and harmonized recommendations to facilitate the development of GT products while avoiding unnecessary use of animals, in accordance with the 3Rs (reduce/refine/replace) principles.

A Step 4 Introductory Training Presentation has been developed by the S12 EWG to summarize the content of the Guideline.

Read more online

Swissmedic Inspects Class I Manufacturers in Switzerland

27 March 2023 – the Swissmedic published the inspection report on 27 medical devices class I manufacturers in Switzerland.

Between August and December 2022, Swissmedic reviewed declarations of conformity, evidence that Swissmedic had been notified of the devices, and post-market surveillance plans and reports in a random sample of 27 manufacturers (approximately 8% of all Swiss

manufacturers identified at the time the data analysis was conducted) to investigate how the new regulation was being implemented regarding otherwise unmonitored devices.

As work progressed, it became apparent that 14% of the manufacturers in the sample were not registered with Swissmedic when the review took place. Initially, it was found that Swissmedic had not been correctly notified of 39% of the Class I medical devices reviewed. The outstanding and incorrect manufacturer and device registrations / notifications were dealt with during the review.

Overall, 70% of the post-market surveillance documentation reviewed, failed to meet legal requirements.

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Swissmedic Technical Update of CPP Order Form and New Version of the CPP Guidance Request

20 March 2023 – the Swissmedic published the updated version of the WHO pharmaceutical product (CPP) order form and the CPP guidance request.

A new version of the CPP order form (BW302_00_004e_FO Order form for a CPP (Certificate of a Pharmaceutical Product)) and the guidance Request CPP (BW302_00_001e_WL_Request_CPP) is effective immediately.

Read more online

ICH Electronic Common Technical Document (eCTD) v4.0

17 March 2023 – the Swissmedic published eCTD v4.0 Step 4 Implementation Package.

eCTD v4.0 is a technical standard relating to the submission of applications for the authorization of medicinal products. The standard – developed by the ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) – is an upgraded version of the currently valid standard eCTD v3.2.2 on which Swissmedic's current eCTD solution is based.

Read more online

Changes to the Guidance Document Product Information for Human Medicinal Products

1 March 2023 – the Swissmedic announced that detailed Information for healthcare professionals and Patient information templates are being withdrawn.

Clarifications from the detailed *Information for Healthcare Professionals and Patient Information* templates have been incorporated into the guidance document *Product Information for Human Medicinal Products*. The two detailed templates will therefore no longer be available. The new version of the guidance document *Product Information for Human Medicinal Products* was published on 1 March 2023.

Read more online

New Mobile Technologies Guidance Document for Human and Veterinary Medicinal Products

1 March 2023 – the Swissmedic published regulations on the use of QR codes on packaging and in medicinal product information.

The new guidance document sets forth regulations on the use of mobile technologies, citing the example of the QR code printed on packaging and in medicinal product information. The new Mobile technologies guidance document and the related form was published on 1 March 2023.

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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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