WSQMS Homepage Dec 12, 2022

CTIS Training Program Module 07 Updates

8 November 2022 – EMA updated training module 07 of the CTIS step-by-step guide.

Step-by-Step Guide: Management of Roles and Permissions (High-level Administrator Registration), Version 1.3

Management of Roles and Permissions: High Level Admins Roles and Permissions: Sponsors Workspace Roles and Permissions: FAQs

---

Procedural Advice for Orphan Medicinal Product Designation

7 November 2022 – EMA updated guidance on the orphan medicinal product designation for sponsors.

In examining an application for orphan medicinal product designation, the COMP will focus on determining whether the sponsor has established that the designation criteria are met, i.e.:

- the life-threatening or debilitating nature of the condition;
- the medical plausibility of the proposed orphan indication;
- that the prevalence of the condition in the European Union is not more than five in 10,000 or that it is unlikely that marketing the medicinal product in the European Union, without incentives, would generate sufficient return to justify the necessary investment;
- that no satisfactory method of diagnosis prevention or treatment exists, or if such a method exists, that the medicinal product will be of significant benefit to those affected by the condition.

Read the pdf

Anonymization of Protected Personal Data and Assessment of Commercially Confidential Information during the Preparation of

RMPs

4 November 2022 – EMA updated RMP guidance (main body and annexes 4 & 6) for protected personal data and confidential information.

This document aims at giving general guidance to companies on the retention/removal of Protected Personal Data (PPD) and identification of Commercially Confidential Information (CCI). All the changes suggested in this guidance are of editorial nature and should be implemented in the RMP during the scientific review process prior to the Opinion and adoption of the final RMP version.

Read the pdf

European Medicines Agency Pre- and Post-Authorization Procedural Advice for Users of the Centralized Procedure

4 November 2022 – EMA updated guidance on pre- and post-authorization procedural advice for users of the centralized procedure.

European Medicines Agency Pre-Authorization Procedural Advice for Users of the Centralized Procedure

EMA Pre-Auth Procedural Advice EMA Post-Auth Procedural Advice

---

Clinical Trials Information System (CTIS) - Sponsor Handbook

30 November 2022 – EMA published version 3.0 of the CTIS sponsor handbook.

The Handbook addresses key questions on CTIS and provides a compilation and references to key guidance, technical information, recommendations, training materials, and supportive documentation to facilitate the submission and assessment of CTAs and additional information during the lifecycle of a trial.

Read the pdf

Union Guidance on Record Keeping and Archiving of Documents Obtained or Resulting from Pharmacovigilance (PV) Inspections

29 November 2022 – EMA published guidance on record keeping and archiving of documents related to EU PV inspections.

The standardization of records management policies and procedures ensures that appropriate attention and protection is given to all records, and that the evidence and information they contain can be retrieved more efficiently, using standard practices and procedures. This guidance was prepared to standardize best practice in records management by setting the minimum requirements for document retention and record keeping for pharmacovigilance inspections.

Read the pdf

Records of Data Processing Activity (public) Regarding the Processing of Personal Data in the Clinical Trials Information

System (CTIS)

28 November 2022 – EMA published updated guidance on CTIS data processing activities.

The purpose of the CTIS data processing activities is based on the requirements set out in the Clinical Trials Regulation (Regulation (EU) No 536/2014), including the areas of clinical trials, annual safety reports Registration of organizations/CTIS users and management of access permissions.

Read the pdf

ICH Guideline Q3C (R8) on Impurities: Guideline for Residual Solvents

28 November 2022 – EMA updated step 5 of the ICH guideline Q3C(R8) on residual solvents.

The objective of this guideline is to recommend acceptable amounts for residual solvents in pharmaceuticals for the safety of the patient. The guideline recommends use of less toxic solvents and describes levels considered to be toxicologically acceptable for some residual solvents.

Read the pdf

Guidance for Applicants on Simultaneous National Scientific Advice (SNSA) Phase 2 Pilot (from October 2022) – Optimized Process

21 November 2022 – EMA updated the guidance for SNSA phase 2 pilot.

The objective of the concept is to establish a more efficient procedure for applicants who wish to seek advice on the same set of questions and data package from different NCAs. The aim of an SNSA request is to advise the Applicant in a targeted way on the specific questions that are being raised and not to perform a pre-assessment of the complete formal application(s) to which the SNSA request. EMA scientific advice should continue to be used for scientific advice related to the suitability of the proposed clinical development to support a centralized marketing authorization application.

Read the pdf

IRIS Guide to Registration and RPIs

21 November 2022 – EMA published version 2.10 of the preliminary requirements for all IRIS submissions, including substance and research product identifier registration.

This guide has been produced to help new users of IRIS to complete the prerequisite steps before accessing the platform. Most of these steps are independent from the IRIS platform and are similar to those to obtain registration to use other European Medicines Agency (EMA) systems, such as Management Services for Substances, Products, Organization and Referentials (SPOR).

Read the pdf

Annual Report of the Good Clinical Practice (GCP) Inspectors Working Group (IWG) 2021

21 November 2022 – EMA published the annual report of the GCP IWG 2021.

In total, 27 triggered GCP inspections were requested by CHMP and carried out by the inspectorates of the EU/EEA Member States (MSs) in 2021. A total of 286 deficiencies, comprising 24 critical (8,4%), 152 major (53,1%) and 110 minor (38,5%) findings were recorded for the 27 CHMP requested inspections conducted in 2021. This represents an average of 10-11 findings per site inspected. The three top categories of the findings were General, Trial Management and Computer System.

Read the pdf

Reflection Paper on Criteria to be Considered for the Evaluation of New Active Substance (NAS) Status of Biological Substances

18 November 2022 – EMA published draft guidance on criteria for the evaluation of NAS status of biological substances for consultation. Comments may be submitted until 31 May 2023.

This document is intended to reflect the current experience of the Biologics Working Party (BWP) of the Committee for Medicinal Products for Human Use (CHMP), the Committee for Advanced Therapies (CAT), and the Co-ordination Group for Mutual Recognition and Decentralized Procedures-Human (CMDh) on New Active Substance (NAS) in the context of scientific advice and assessment of Marketing Authorization Applications (MAA). It applies to all types of procedures for submission of a MAA, i.e. Centralized Procedure (CP), Mutual Recognition Procedure (MRP)/Decentralized Procedure (DCP) and purely national procedures for biological and biotechnology-derived medicinal products for human use.

Read the pdf

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

10 November 2022 – FDA published draft guidance on Q5A(R2) viral safety evaluation of biotechnology products. Submit comments by 14 January 2023.

This guideline concerns the testing and evaluation of the viral safety of biotechnology products, and it outlines what data should be submitted in marketing application and registration packages for those products.

Read more online

Sameness Evaluations in an ANDA — Active Ingredients

8 November 2022 – FDA published draft guidance on sameness evaluations in an ANDA. Submit comments by 8 January 2023.

This guidance is intended to assist applicants preparing an abbreviated new drug application (ANDA) by providing recommendations on demonstrating sameness between the active ingredient in a proposed generic drug product and its reference listed drug (RLD) as required

under section 505(j)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)(2)(A)(ii)) and FDA's regulations in § 314.94(a)(5) (21 CFR 314.94(a)(5)).

Read more online

M10 Bioanalytical Method Validation and Study Sample Analysis

4 November 2022 – FDA published the final guidance on M10 bioanalytical method validation and study sample analysis.

The guidance provides recommendations for method validation for bioanalytical assays for nonclinical and clinical studies that generate data to support regulatory submissions, including the procedures and processes for chromatographic and ligand-binding assays that are used to measure the parent and active metabolites of drugs administered in nonclinical and clinical subjects.

Read more online

Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial

4 November 2022 – FDA published final guidance for studies that evaluate multiple versions of a cellular or gene therapy product.

The purpose of this guidance is to provide recommendations to sponsors interested in studying multiple versions of a cellular or gene therapy product in an early-phase clinical trial for a single disease.

Read more online

Cross Labeling Oncology Drugs in Combination Regimens

2 November 2022 – FDA published final guidance on cross labeling oncology drugs for industry.

This guidance is to describe FDA's current recommendations about including relevant information in labeling for oncology drugs approved for use in a combination regimen, including important considerations for cross labeling of these drugs.

Read more online

S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals

2 November 2022 – FDA published S1B(R1) as an addendum to the current ICH S1 guidance for industry.

This Addendum applies to all pharmaceuticals that need carcinogenicity testing as described in ICH S1A. This Addendum expands the evaluation process for assessing human carcinogenic risk of pharmaceuticals by introducing an additional approach that is not described in the original ICH S1B.

Read more online

Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers

1 November 2022 – FDA published draft Q&A guidance on expanded access to investigational drugs for treatment use. Submit comments by 3 January 2023.

FDA issued guidance providing recommendations in a question-and-answer format, addressing the most frequently asked questions. The updates include additional recommendations related to IRB review, informed consent, and new requirements established by the Cures Act and FDARA related to sponsors making their policies for evaluating and responding to expanded access requests (i.e., expanded access policy) public and readily available.

Read more online

Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - Small Entity Compliance Guide

1 November 2022 – FDA published the final Small Entity Compliance guidance on HCT/Ps regulations.

The FDA has prepared this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). It is intended to help small entity establishments that manufacture human cells, tissues, or cellular or tissue-based products (HCT/Ps) better understand the comprehensive regulatory framework for HCT/Ps, set forth in Title 21 of the Code of Federal Regulations, part 1271 (21 CFR 1271). Section 21 CFR 1271.3 provides definitions for important terms used in 21 CFR 1271.

Read more online

Enforcement Policy Regarding Investigational New Drug (IND) Requirements for Use of Fecal Microbiota for Transplantation (FMT) to Treat Clostridium difficile Infection Not Responsive to Standard Therapies

28 November 2022 – FDA published its policy on IND requirements for FMT use.

The FDA is informing members of the medical and scientific community and other interested persons of the policy regarding the investigational new drug application (IND) requirements for the use of fecal microbiota for transplantation (FMT) to treat Clostridioides difficile (C. difficile) infection not responding to standard therapies. At this time, FDA intends to exercise enforcement discretion with respect to such requirements under limited circumstances as described in section II of this guidance.

Read more online

Access Consortium Good Manufacturing Practice (GMP) Statement

15 November 2022 – MHRA published access consortium statement on GMP inspections reliance and recognition.

The Access Consortium was formed in 2007 by 'like-minded' regulatory authorities to promote greater regulatory collaboration and alignment of regulatory requirements. The Consortium was initially formed by the regulatory authorities from Australia (Therapeutic Goods Administration), Canada (Health Canada), Singapore (Health Sciences Authority), and Switzerland (Swissmedic). More recently, the United Kingdom's Medicines and Healthcare products Regulatory Agency joined the Consortium. Its goal is to maximize international cooperation, reduce duplication, and increase each agency's capacity to ensure consumers have timely access to high quality, safe and effective therapeutic products.

Read more online

Return to International GMP Inspections

8 November 2022 – MHRA Inspectorate published the blog on return to international GMP inspections.

Since April 2022, GMP Inspectors have been taking part in a pilot program to evaluate a potential return to international onsite GMP inspections. Inspectors will work with sites to ensure that inspections can be performed with appropriate mitigations in place to reduce the risk of COVID-19 transmission.

Read more online

European Commission (EC) Decision Reliance Procedure (ECDRP)

18 November 2022 – MHRA updated guidance on the EC decision reliance procedure.

On 30 September 2022 the ECDRP announced it will continue to be available until 31 December 2023, an extension of 12 months. Therefore the text "For a period of 2 years from 1 January 2021" was amended to "For a period of 3 years from 1 January 2023".

Read more online

Borderline Products: How to Tell if Your Product is a Medical Device and Which Risk Class Applies

16 November 2022 – MHRA updated guidance on medical device borderline products.

A new section 'Risk classification of medical devices' was added.

Read more online

MHRA Process for Approving Manufacturing Authorizations or API Registrations in Relation to Unlicensed Cannabis-Based Products for Medicinal Use (CBPMs)

16 November 2022 – MHRA Inspectorate published the blog on MHRA process for approving unlicensed CBPMs.

Several companies have contacted the MHRA regarding cannabis-based products for medicinal use. This blog provides information on what authorizations are required in order to manufacture within this sector of the pharmaceutical industry.

Read more online

Issue of Export Certificates (Free Sales Certificates) for Medical Devices

8 November 2022 – Swissmedic announced the adaptation of the export certificates ordering process for medical devices beginning 1 January 2023.

Swissmedic issues FSC export certificates to manufacturers and authorized representatives based in Switzerland, provided that they submit the required documentation with the relevant order form. They can submit orders via the eGov portal with the help of the information on the website, such as guidelines, order forms, FAQs, video, etc.

Read more online

Changes to the Guidance Document Variations TAM HMV4

4 November 2022 – Swissmedic announced an extended reporting time limit of 60 days that applies to variations without assessment.

The reporting time limit for variations without assessment has been extended at the request of marketing authorization holders: instead of the previous 30 days, a reporting time limit of 60 days now applies.

The revised Guidance document Variations TAM HMV4 is valid with effect from 1 November 2022.

Read more online

Public Consultation on ICH Guidelines M11 "Clinical electronic Structured Harmonized Protocol (CeSHarP)" and Q5A(R2) "Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin"

28 November 2022 – Swissmedic launched the public consultation on ICH guidelines M11 and Q5A(R2), with a deadline for comments of 26 February 2023 and 10 February 2023, respectively.

Stakeholders are invited to comment on ICH Guideline M11 "Clinical electronic Structured Harmonized Protocol (CeSHarP)" andICH Guideline Q5A(R2) "Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin" until 26 February and 10 February 2023, respectively.

ICH Guideline M11 ICH Guideline Q5A(R2)

Regulatory Guidelines for Laboratory Developed Tests (LDTs)

24 November 2022 – Singapore Health Sciences Authority (HSA) issued revision one of its regulatory guidelines for LDTs.

This document provides guidance and clarity in assisting clinical laboratories on understanding the regulatory requirements applicable to Laboratory Developed Tests (LDTs) under the Health Products Act 2007 (HPA) and Health Products (Medical Devices) Regulations 2010 (HP (MD) Regulations).

Guidelines will be effective beginning March 2023.

Read the pdf

NMPA Announcement on Putting into Use the Electronic Certificates of Documentation for Export of APIs to EU and Certificate of a Pharmaceutical Product

31 October 2022 – NMPA announced putting into use the electronic certificates of Documentation for Export of APIs to EU and Certificate of a Pharmaceutical Product (No. 95, 2022).

As part of the efforts to implement the major decisions and plans of the Communist Party of China Central Committee and the State Council on deepening the reforms to separate operating permits from business licenses, in order to further improve the business environment, stimulate the vitality of market entities, optimize the service capacity for "internet + drug supervision" of the National Medical Products Administration (NMPA), and provide drug export enterprises with more efficient and convenient administrative services, it is decided that the electronic certificates of the Documentation for Export of APIs to EU and Certificate of a Pharmaceutical Product will be officially put into use from Dec 1, 2022.

Read more online

Interested in a Partnership with Widler & Schiemann AG?

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.

Contact us:

Widler & Schiemann AG
St Alban Ring 245
CH 4052 Basel, Switzerland
Phone:+41 41 558 9193
E-mail:info@wsqms.com