Compliance Monitor (CM) Overview and Application Process

On 29 April 2022 the UK MHRA published guidance on the CM overview and application process.

From April 2022, the MHRA will be running a pilot scheme to monitor companies that fail to comply with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) and will be referred to the Inspection Action Group (IAG) after an inspection has resulted in a compliance escalation process being initiated.

Read more online

ICH E8(R1) General Considerations for Clinical Studies

On 28 April 2022 the ICH announced that Step 4 - Introductory Training Presentation – is available on the ICH website.

This document has been signed off as Step 4 document (6 October 2021) to be implemented by the ICH Regulatory Members. This document was developed based on a Concept Paper (14 November 2017) and Business Plan (14 November 2017).

Read the pdf

Providing Submissions in Electronic Format — Postmarketing Safety Reports

On 27 April 2022 the FDA published the final guidance on electronic submissions of postmarketing safety reports for industry.

This guidance is one in a series of guidance documents intended to assist industry when making certain regulatory submissions in electronic format to FDA's Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). This guidance provides general information on the electronic submission of postmarketing safety reports under the following provisions:

- 21 CFR 314.80 and 314.98 (regarding products with approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs), respectively, including combination products or drug constituent parts with approved NDAs or ANDAs
- 21 CFR 600.80 (regarding products with approved biologics license applications (BLAs), including combination products or biological product constituent parts with approved BLAs)
- 21 CFR part 4, subpart B (requiring additional reports for combination products with approved NDAs, ANDAs, or BLAs)
- 21 CFR 310.305 (regarding prescription drug products marketed for human use without approved NDAs or ANDAs, including prescription drug products that are compounded by facilities registered as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b))
- 21 CFR 329.100 and section 760 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379aa) (regarding nonprescription drug products marketed for human use without approved NDAs or ANDAs)

Read more online

Drug Products, Including Biological Products, that Contain Nanomaterials

On 21 April 2022 the FDA published the final guidance for industry on drug products with nanomaterials.

Nanotechnology can be used in a broad array of FDA-regulated products, such as human drug products, including those that are biological products. Nanotechnology may be used to create drug products in which nanomaterials (as explained in section II of this document), serve a variety of functions, as active ingredients or inactive ingredients, including carriers loaded with an active ingredient. The inclusion of such materials may result in product attributes that differ from those of products that do not contain such materials, and thus may merit particular examination. This document provides guidance on the development of human drug products, including those that are biological products, in which a nanomaterial is present in the finished dosage form.

Read more online

Refuse to Accept Policy for 510(k)s

On 21 April 2022 the FDA published the final guidance for industry and FDA staff.

The purpose of this document is to explain the procedures and criteria FDA intends to use in assessing whether a premarket notification (510(k)) submission meets a minimum threshold of acceptability and should be accepted for substantive review. Focusing FDA's review resources on complete submissions will provide a more efficient approach to ensuring that safe and effective medical devices reach patients as quickly as possible.

Read more online

PRAC Strategy on Measuring the Impact of Pharmacovigilance Activities

On 21 April 2022 the EMA issued PV guidance revision 2 on the Pharmacovigilance Risk Assessment Committee (PRAC) strategy.

The PRAC strategy has closed this gap with a concept for systematically measuring patient-relevant health outcomes of major regulatory interventions, shifting the focus of pharmacovigilance to those activities and regulatory tools that make a difference in daily healthcare.

The latest revision integrates the achievements over a five-year period since its launch, in the following four key activity areas:

- effectiveness evaluation of risk-minimization measures;
- effectiveness of pharmacovigilance processes;
- enablers of effective pharmacovigilance and stakeholder engagement;
- analytical methods for impact research.

The revised strategy also includes:

- new information on how to prioritize and carry out impact research;
- a review of industry-sponsored post-authorization safety studies evaluating the effectiveness of risk-minimization process improvements.

Read the pdf

Compilation of Union Procedures on Inspections and Exchange of Information

On 20 April 2022 the EMA published the compilation of union procedures on inspections and exchange of information.

The Compilation of Union Procedures on Inspections and Exchange of Information (hereafter referred to as 'Compilation'), formerly known as the Compilation of Community Procedures on Administrative Collaboration and Harmonization of Inspections, is a tool for facilitating co-operation between the GMP and GDP inspectorates of the Member States and a means of achieving harmonization. The procedures within it provide the basis for national procedures that form part of the national GMP inspectorates' quality systems. These quality systems are based on a framework laid down in one of the documents of the Compilation. In July 2010 documents connected with Good Distribution Practice (GDP) inspections started to be added to the Compilation.

The Compilation has two parts; procedures within the Part I and other documents (e.g. interpretation documents and forms used by regulators) within the Part II.

Read the pdf

2021 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission

On 20 April 2022 the EMA published the 2021 EudraVigilance annual report (1 Jan to 31 Jan 2021).

EudraVigilance, the European database of suspected adverse drug reaction (ADR) reports, is the tool that the European Medicines Agency (EMA) and national competent authorities (NCAs) use for monitoring the safety of all authorized medicines in the EU as well as medicines studied in clinical trials. Timely detection and assessment of safety signals from sources such as EudraVigilance complements the benefit-risk evaluation of medicinal products via assessment of periodic safety update reports (PSURs) and risk management plans (RMPs) by the Pharmacovigilance Risk Assessment Committee (PRAC).

The database currently holds over 22.3 million individual case safety reports (ICSRs) relating to 12.9 million unique suspected adverse drug reaction case reports1 and is one of the largest pharmacovigilance databases in the world. It has undergone significant development in recent years, and this has delivered enhanced functionalities allowing for a better support of pharmacovigilance activities and the protection of public health.

Read the pdf

Overview of Comments Received on ICH Guideline Q9 (R1) on Quality Risk Management

On 20 April 2022 the EMA published comments on ICH guideline Q9(R1) on quality risk management.

Comments will be sent to the ICH Q9(R1) EWG for consideration in the context of Step 3 of the ICH process.

Read the pdf

Annual Report of the Good Manufacturing and Distribution Practice Inspectors Working Group 2021

On 20 April 2022 the EMA published annual report of the GMP/GDP Inspectors Working Group (IWG).

The GMP/GDP IWG focuses on harmonization and coordination of GMP and GDP related activities at EU level and maintains close cooperation with international partner authorities. This annual report is set out in line with the format and objectives of the 2021–2023 three-year work plan.

Read the pdf

NMPA Guidelines for Pharmacovigilance Inspection

On 15 April 2022 the Chinese NMPA published the announcement of distributing the PV inspection guidelines (NMPA [2022] No. 17).

These guidelines are applicable to the inspections conducted by the drug regulatory authorities at or above the provincial level on the pharmacovigilance activities carried out by the drug marketing authorization holders themselves or entrusted by the holders; drug registration applicants who have been approved to conduct drug clinical trials should conduct pharmacovigilance inspections. Combined with drug safety characteristics and

clinical trial safety information report and risk assessment, start pharmacovigilance inspection during clinical trial or before marketing authorization, and the specific implementation can refer to this guideline.

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WSQMS Homepage May 16, 2022

Benefit-Risk Considerations for Product Quality Assessments

On 10 May 2022 the FDA published the draft guidance for industry. Comments may be submitted until 10 July 2022.

This guidance describes the benefit-risk principles applied by FDA when conducting product quality-related assessments of chemistry, manufacturing, and controls (CMC) information submitted for FDA assessment as part of original new drug applications (NDAs) under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), original biologics license applications (BLAs) under section 351 of the Public Health Service Act (PHS Act), or supplements to such applications, in addition to other information (e.g., inspectional findings) available to FDA during its assessment.

Read more online

Compliance Monitor Process (Part 2) – CM Role and Application Process

On 10 May 2022 the UK MHRA Inspectorate published the second part of the compliance monitor process.

As outlined in the first part of this blog, the MHRA is starting a pilot in April 2022 whereby Compliance Monitors (CM) will supervise the completion of an agreed Compliance Protocol (CP) for eligible Inspection Action Group (IAG) cases. It is common for companies that are at IAG to employ consultants to assist with remediation activities. The pilot for the compliance monitor process will establish a framework for the CM to carry out the remediation work but also report on progress to the MHRA. This second blog provides details on the CM role and application process.

Read more online

Guidelines on MedDRA Coding for Drug Marketing Authorization Holders

On 6 May 2022 the Chinese NMPA issued the MedDRA coding guidelines for the MAHs.

The purpose of this guideline is to guide the drug marketing authorization holders (hereinafter referred to as "holders") in China to use MedDRA coding-related medical terms in the work related to post-marketing adverse reaction reporting. Other reporting entities may refer to the ideas and suggestions provided in this guide.

Read more online

Updated Good Clinical Practice (GCP) Inspection Procedures

On 5 May 2022 the EMA announced the updates of the guidance on GCP inspection procedures.

These Annexes cover updates to the following Procedures for Conducting GCP Inspection Requested by the Committee for Medicinal Products for Human Use (CHMP):

- Annex I: Investigator Site
- Annex II: Clinical Laboratories
- Annex IV: Sponsor and Contract Research Organizations (CRO)
- Annex VI: Record Keeping and Archiving of Documents
- Annex VII: Bioanalytical Part, Pharmacokinetic and Statistical Analyses of Bioequivalence Trials

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Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program

On 5 May 2022 the FDA published the draft guidance for industry and FDA staff. Comments may be submitted until 5 July 2022.

The FDA's Center for Devices and Radiological Health (CDRH) is issuing this draft guidance to describe its policy regarding FDA's participation in the Voluntary Improvement Program (VIP). The VIP is a voluntary program facilitated through the Medical Device Innovation Consortium (MDIC) that evaluates the capability and performance of a medical device manufacturer's practices using third-party appraisals, and is intended to guide improvement to enhance the quality of devices. The VIP builds on the framework piloted through FDA's 2018 Case for Quality Voluntary Medical Device Manufacturing and Product Quality Pilot Program (CfQ Pilot Program) and incorporates some of the successes and learnings from the pilot. This voluntary program is currently only available to eligible manufacturers of medical devices regulated by CDRH and whose marketing applications are reviewed under the applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (including under sections 510(k), 513, 515, and 520).

Read more online

Clinical Pharmacology Considerations for Human Radiolabeled

Mass Balance Studies

On 5 May 2022 the FDA published the draft guidance for industry. Comments may be submitted until 4 August 2022.

This guidance describes the FDA's recommendations regarding clinical pharmacology considerations for conducting human radiolabeled mass balance studies of investigational drugs, including: (1) deciding whether and when to conduct the study, (2) designing the study, and (3) reporting results. This guidance does not cover animal mass balance studies, safety testing of drug metabolites, or recommendations for selecting the radioactive dose.

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Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised)

On 4 May 2022 the FDA published the final guidance for industry and FDA staff.

FDA is issuing this guidance to provide a policy to help address current manufacturing limitations or supply chain issues due to disruptions caused by the COVID-19 public health emergency.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of HHS on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).

Read more online

ICH Guideline Q3D (R2) on Elemental Impurities

On 3 May 2022 the EMA published step 5 of the revised ICH guideline Q3D (R2) on elemental impurities.

This guideline presents a process to assess and control elemental impurities in the drug product using the principles of risk management as described in ICH Q9. This process provides a platform for developing a risk-based control strategy to limit elemental impurities in the drug product.

Read the pdf

Use of Circulating Tumor DNA for Early-Stage Solid Tumor Drug Development

On 2 May 2022 the FDA announced the availability of the draft guidance for industry.

This draft guidance is intended to help sponsors planning to use circulating cell-free plasma derived tumor deoxyribonucleic acid (ctDNA) as a biomarker in cancer clinical trials conducted under an investigational new drug application (IND) and/or to support marketing approval of drugs and biological products for treating solid tumor malignancies in the early-stage setting.

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Risklick Provides Clinical Trial Educational Programs

The Clinical Trial Academy Essential Program provided by Risklick is aimed to address the difficulties in developing an ideal clinical trial protocol.

The clinical trial educational programs are designed for clinical research professionals, Startups, Principal investigators, Sponsor Investigators, Project managers, Study coordinators, Research fellows and Students in academia and industry.

The Risklick Academy offers knowledge-sharing interactive programs to design, develop and optimize clinical study protocols that follow international guidelines, using state-of-the art methodology and novel technologies.

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