Who gmp guidelines 2018

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GOOD MANUFACTURING PRACTICES(GMP) GUIDELINES

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- GENERAL PROVISIONS
  1.BUILDING&FACILITIES

US FDA; 21 CFR Part 211 - 211.68

- Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product
- If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained

Calibration, inspection, routine checks
written program
Calibration records

GMP Guidelines

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- EU Guidelines to Good Manufacturing Practice – Medicinal Products for Human and Veterinary Use

  Part 1: Basic Requirements for Medicinal Products

  Annex 1: Manufacture of Sterile Medicinal Products
- PIC/S – Pharmaceutical Inspection Co-operation Scheme A cooperative arrangement between health authorities of different nations intended to improve the GMP standards and facilitate international harmonisation of GMP standards

  PIC/S GMP Guide is harmonised with EU GMP Guide

  Plus additional non-mandatory guidance documents (cGMP)

ECOLAB

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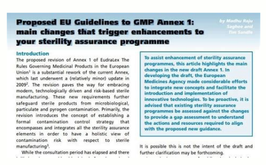
Proposed EU Guidelines to GMP Annex 1: main changes that trigger enhancements to your sterility assurance programme

by Madhu Raja Engineer and Pet Healthy

Introduction

The proposed revision of Annex 1 of Eudralex The Rules Governing Medicinal Products in the European Union' is a substantial rework of the current Annex, which last underwent a (relatively minor) update in 2009'. The revision paves the way for embracing modern technologies and methods in sterile product manufacturing. These new requirements further safeguard sterile products from microbiological, particulate and pyrogen contamination. Primarily, the revision introduces the concept of establishing a formal contamination control strategy that encompasses and integrates all the sterility assurance elements in order to have a holistic view of contamination risk with respect to sterile manufacturing.

While the consultation period has elapsed and there

To assist enhancement of sterility assurance programmes, we have identified the main changes in the new draft Annex 1. In developing the draft, the European Medicines Agency made considerable efforts to integrate new concepts and facilitate the introduction and implementation of innovative technologies. To be proactive, it is suggested that sterility assurance programmes be assessed against the changes to provide a gap assessment to understand the actions and resources required to align with the proposed new guidance.

It is possible this is not the intent of the draft and further clarification may be forthcoming.

Importance of medicine vigilance. Importance of good manufacturing practice. Full meaning of gmp. Meaning of gmp.

Good Manufacturing Practices (GMP, also referred to as 'cGMP' or 'current Good Manufacturing Practice') is the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.GMP defines quality measures for both production and quality control and defines general measures to ensure that processes necessary for production and testing are clearly defined, validated, reviewed, and documented, and that the personnel, premises and materials are suitable for the production of pharmaceuticals and biologicals including vaccines. GMP also has legal components, covering responsibilities for distribution, contract manufacturing and testing, and responses to product defects and complaints. Specific GMP requirements relevant to classes of products such as sterile pharmaceuticals or biological medicinal products are provided in a series of annexes to the general GMP requirements.GMP guidanceThe first WHO draft text on GMP was adopted in 1968. In 1969, when the World Health Assembly recommended the first version of the WHO Certification Scheme on the quality of pharmaceutical products moving in the global market, it accepted the WHO GMP as an integral part of the Scheme. A supplementary annex on biological medicinal products was adopted by the Expert Committee on Biological Standardization (ECBS) in 1991 and establishes the general approach to the quality control of biological medicines that include products such as vaccines, blood and blood products, antigens, cell and tissue therapies, biopharmaceutical products, and others.More than 100 countries have incorporated the WHO GMP provisions into their national medicines laws, and many more countries have adopted its provisions and approach in defining their own national GMP requirements. The WHO GMP continues to be used as a basis for the WHO Certification Scheme and prequalification of vaccines for procurement by UN agencies.Written standardsWHO good manufacturing practices for biological products, Annex 2, TRS No 999. Replacement of Annex 1 of WHO Technical Report Series, No. 822 This content applies to human and veterinary medicines.Good manufacturing practice (GMP) describes the minimum standard that a medicines manufacturer must meet in their production processes. The European Medicines Agency (EMA) coordinates inspections to verify compliance with these standards and plays a key role in harmonising GMP activities at European Union (EU) level.Any manufacturer of medicines intended for the EU market, no matter where in the world it is located, must comply with GMP.GMP requires that medicines: The Agency has a coordinating role for GMP inspections of manufacturing sites for medicines whose marketing authorisation in the EU is submitted through the centralised procedure or as part of a referral procedure.The Agency also plays a key role in coordinating and harmonising GMP activities at an EU level. It is involved in:coordinating the preparation of new and revised guidance on GMP;ensuring common interpretation of EU GMP requirements and related technical issues;developing EU-wide procedures on GMP inspections and related activities;facilitating cooperation between Member States for inspections of manufacturers in third countries.Marketing authorisation holders and applicants need to use EMA's IRIS system to communicate with EMA on GMP inspections requested by the Agency’s scientific committees.Using IRIS for GMP inspections improves efficiency by harmonising and automating processes and re-using master data held by EMA. It also simplifies retrieving and reporting data.More information on the use of EMA's IRIS system: Manufacturers and importers located in the European Economic Area (EEA) must hold an authorisation issued by the national competent authority of the Member State where they carry out these activities.They must comply with EU GMP to obtain a manufacturing or import authorisation. They can ensure that they meet all their legal obligations by following the EU GMP guidelines.Importers are responsible to ensure that the third country manufacturer they are importing from comply with GMP.Marketing authorisation applicants are responsible to ensure that the proposed manufacturing sites included in the marketing authorisation application comply with GMP. For more information, see section 5.2 Inspections of the Pre-authorisation guidance. Manufacturers of active substances intended for the manufacture of human medicines for the EU market must register with the national competent authority of the Member State where they are located.Active substance manufacturers must comply with GMP. In addition, the manufacturer of the finished product is obliged to ensure that the active substances they use have been manufactured in compliance with GMP.Importers of active substances intended for the EU market are also required to register. In addition, each consignment needs to be accompanied by a confirmation by the competent authority of the country where it is produced that it conforms to GMP standards equivalent to those in the EU, unless a waiver applies. In the EU, national competent authorities are responsible for inspecting manufacturing sites located within their own territories.Manufacturing sites outside the EU are inspected by the national competent authority of the Member State where the EU importer is located, unless a mutual recognition agreement (MRA) is in place between the EU and the country concerned. If an MRA applies, the authorities mutually rely on each other's inspections.If products are imported directly into more than one Member State from a manufacturing site outside the EU, there may be more than one national competent authority responsible for inspecting it. EMA facilitates cooperation between the authorities concerned in supervising the site.EU competent authorities plan routine inspections following a risk-based approach, or if there is suspicion of non-compliance. EudraGMDP is a publicly accessible EU database which contains manufacturing and import authorisations, registration of active substance manufacturers, GMP certificates and non-compliance statements.After inspecting a manufacturing site, EU competent authorities issue a GMP certificate or a non-compliance statement, which is entered in the EudraGMDP database. EMA maintains a compilation of GMP and good distribution practice (GDP) inspection-related procedures and forms agreed by all Member States. This facilitates cooperation between EU Member States and supports harmonisation and exchange of inspection-related information.It covers the basis for national procedures that form part of the national inspectorates' quality systems: For products derived from blood or blood plasma, EMA is responsible for coordinating inspections of the blood establishments in which collection, testing, processing, storage and distribution is carried out under the PMF certification procedure.For more information on the PMF certification procedure, see Plasma master files.Vaccine antigen master file (VAMF) inspectionsEMA is responsible for coordinating inspections of vaccine antigen manufacturing sites under the VAMF certification procedure.For more information on the VAMF certification procedure, see Vaccine antigens. The EU has signed mutual recognition agreements on GMP inspections with regulatory authorities outside the EU. This allows EU authorities and their counterparts to:rely on each other's GMP inspections;waive batch testing of products on entry into their territories;share information on inspections and quality defects.The scope of each agreement differs. FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The approval process for new and generic drug marketing applications includes a review of the manufacturer's compliance with the CGMPs. FDA assessors and investigators determine whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market. Code of Federal Regulations (CFR). FDA's portion of the CFR is in Title 21, which interprets the Federal Food, Drug and Cosmetic Act and related statutes, including the Public Health Service Act. The pharmaceutical or drug quality-related regulations appear in several parts of Title 21, including sections in parts 1-99, 200-299, 300-499, 600-799, and 800-1299. The regulations enable a common understanding of the regulatory process by describing the requirements to be followed by drug manufacturers, applicants, and FDA. 21 CFR Part 314 For FDA approval to market a new drug. 21 CFR Part 210. Current Good Manufacturing Practice in Manufacturing Processing, packing, or Holding of Drugs. 21 CFR Part 211. Current Good Manufacturing Practice for Finished Pharmaceuticals. 21 CFR Part 212. Current Good Manufacturing Practice for Positron Emission Tomography Drugs. 21 CFR Part 600. Biological Products: General. The following pages provide more information with respect to regulations for particular product types and manufacturing considerations: Contact for Further Information: CDER-OPQ-Inquiries@fda.hhs.gov Report a problem or mistake on this page You will not receive a reply. For enquiries, contact us. Date modified: 2020-08-28 Production covers all operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product. Good manufacturing practice (GMP) is that part of a quality management system to ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. GMP is aimed primarily at diminishing the risks inherent in any pharmaceutical production; which may broadly be categorized into two groups: (1) cross-contamination/mix-ups and (2) false labelling. Above all, manufacturers must not place patients at risk due to inadequate safety, quality or efficacy. For this reason, risk assessment has come to play an important role in WHO quality assurance guidelines.

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