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Chapter 1 : Good manufacturing practice - Wikipedia

CGMP refers to the Current Good Manufacturing Practice regulations enforced by the FDA. CGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and.

Find articles by Bruno G. Reis Find articles by Catarina P. Catarina Pinto Reis, E-mail: This article has been cited by other articles in PMC. Abstract At international and national levels, there are public and private organizations, institutions and regulatory authorities, who work and cooperate between them and with Pharmaceutical Industry, in order to achieve a consensus of the guidelines and laws of the manufacturing of medicinal products for human use. In this way, it is intended to achieve quality, security and effectiveness exceptional levels in the manufacturing of health products. Good Manufacturing Practice aim the promotion of the human health and consequently, to the improvement of quality of life. For achieve the proposed objectives, it is necessary to ensure the applicability of the presented concepts and show the benefits arising from this applicability. GMPs are guidelines which govern the production, distribution and supply of a drug. It is a necessary condition for marketing authorization MA. The aim of this review is to map the regulation, production, distribution and consumption of pharmaceuticals. This is possible through a close cooperation between the several national and international entities, achieving a regulatory harmonization of GMP for medicinal products for human use, as well as a more rigorous monitoring compliance of these, by the competent authorities. Since the middle of the beginning of the last half of the 20th century, all stakeholders in the health and pharmaceutical industry are making efforts in the conception, knowledge and applicability of guidelines for GMP. National and international organizations and institutions International conference on harmonization of technical requirements for registration of pharmaceuticals for human use International Conference on Harmonization is an international organization with the propose of making recommendations and implementing standards of the International Organization for Standardization ISO to achieve greater harmonization in the understanding and application of the guidelines and technical requirements for registration of pharmaceutical products. This organization is the only initiative that brings together the drug regulatory authorities and the pharmaceutical industry in Europe, Japan and the United States. It provides an activity and constructive cooperation in the field of GMP with several objectives such as the implementation, development and maintenance of harmonized GMP standard and quality inspectors systems in the field of drugs, as well as to facilitate cooperation and contacts between the competent authorities, regional and international organizations, increasing mutual confidence between them. All decisions are taken unanimously. Currently is composed of 43 Participants Authorities, most of them from Europe. Ever since, the World Health Assembly has adopted many resolutions requesting the Organization to develop international standards, recommendations and instruments to assure the quality of medicinal products, whether produced and traded nationally or internationally. GMP guidelines published by WHO should be considered as consultative documents and may need some adaption to the specific conditions of each country. The Agency is responsible for the scientific evaluation of medicinal products developed by pharmaceutical companies in the EU. Among the extensive functions assigned, EMA is responsible for emphasizing the development of guidelines, setting standards and contribution to international cooperation activities with authorities outside the EU. By law, a company can only start to market a medicine once it has received a MA. The arrangements allow the exchange of confidential information between the EU and the FDA as part of their regulatory and scientific processes. This includes information on advance drafts of legislation and regulatory guidance documents, as well as non-public information related to ensuring the quality, safety and efficacy of medicinal products for human and veterinary use. A system of MA ensures that all medicinal products are assessed by a competent authority to ensure compliance with contemporary requirements of safety, quality and efficacy. Manufacturing authorizations are required by all pharmaceutical manufacturers in the EU whether the products are sold within or outside of the same. In the field of the medicinal products, the responsibilities of the FDA are

protecting the Public Health by assuring the safety, efficacy and quality of medicinal products, vaccines, biological products and medical devices. This initiative aims to improve the promotion and protection of public health, focusing on three major goals. The first goal is to focus cGMP requirements on potential risks to public health by providing additional attention and resources on aspects of manufacturing. The second goal is to ensure that the establishment and application of medicinal product quality standards do not prevent innovation and the introduction of new manufacturing technologies in the Pharmaceutical Industry. The third goal is to improve the consistency and predictability of the FDA approach and ultimately to ensure quality and safety. This guideline will growth the technological innovation and strengthening of the link between pharmaceutical development and manufacturing activities. The guideline applies to supporting the development and manufacture of substances of Pharmaceutical Industry, Active Pharmaceutical Ingredient and medicinal products, including biotechnology and biological products throughout the life cycle of the product. It is applied in pre-production to verify what will be made meets specifications and requirements and also while manufacturing production. Two principles included in quality assurance are: In order to achieve quality, there must be a system of comprehensive quality assurance and implemented it correctly. This last issue include the management of GMP, quality control and quality risk. Effective coordination and management of human resources are key factors in the proper functioning of any enterprise. To this end, enterprise management has duties and responsibilities in staff recruitment as well as the delegation of tasks. Documentation may exist in several forms paper-based, electronic or photographic media. The objectives of the system of documentation must be to establish, monitor and record all activities with impact on all aspects of the quality of medicinal products. They must comply with the principles of GMP in order to obtain quality products and be in accordance with the relevant manufacturing and MA. Production should be performed and supervised by competent people. All handling of materials and products, such as reception and quarantine, sampling, storage, labeling, dispensing, processing, packaging and distribution should be done in accordance with written procedures or instructions and where necessary, recorded. The independence of quality control from production is considered fundamental to the satisfactory operation of quality control. The introduction of guidance on the Activities Subcontracting is based on the Pharmaceutical Quality System of the ICH Q10 document in order to provide updated guidance on subcontracting activities regulated by GMP, beyond the current scope of operations of the contract manufacture and analysis. The procedures should include procedures for evaluation by the Quality Control Unit. It must be designed to detect any deficiency in the implementation of GMP and to recommend corrective procedures. This guideline is intended to provide guidance regarding GMP for the manufacture of active substances under an appropriate system for managing quality. It is also intended to ensure that active substances meet the requirements for quality and purity that they purport or are represented to possess. These controls are inherent responsibilities of the manufacturer and are governed by other parts of the legislation. All commitments in registration documents must be met. These guidelines apply to the manufacture of active substances for medicinal products for human use and to the manufacture of sterile active substances only up to the point immediately prior to the active substance being rendered sterile. Although the sterilization and aseptic processing of sterile active substances are not covered, those issues should be performed in accordance with the principles and guidelines of GMP, as defined by local authorities, including active substances that are produced using blood or plasma as raw materials, in spite of excluding whole blood and plasma as there are other detailed technical requirements for the collection and testing of blood. It should be noted that these guidelines do not apply to bulk-packaged medicinal products. This type of manufacture must strictly follow methods and preparation processes, carefully established and validated, since the quality assurance, is of particular importance. Unlike conventional medicinal products, which are normally produced and controlled using reproducible chemical and physical techniques, biological products are manufactured through methods that involve biological processes and materials, such as cultivation cells or extraction of material from living organisms. These biological processes may exhibit inherent variability and hence, that the range and nature of the by-products may be variable. The regulatory

procedures necessary for the control of radiopharmaceuticals are determined in large part by the sources of these products and the production methods. The level of risk depends essentially on the types of radiation emitted and the half-lives of radioactive isotopes. It is necessary to pay special attention to the cross contamination, the contaminant of radioactive isotopes and to waste disposal. Due to its short half-life, some radiopharmaceuticals are released and administered to the patients after their production, before completing all quality control tests. Radiopharmaceuticals, PET radiopharmaceuticals, Radioactive Precursors for radiopharmaceutical production and lastly Radionuclide Generators. These medicinal products must be manufactured under conditions that minimize microbial and particulate contaminations. The quality assurance is fundamental for components with valve and to the uniformity of suspensions. In this respect, these guidelines deal with the manufacture of active substances from gases and the manufacture of medicinal gases. The delineation between the manufacture of active substances and the manufacture of medicinal products should be clearly defined in each MA dossier. The manufacture of active substances from gases must comply with the basic requirements for active substances used as starting materials and other guidance when needed. Procedures need to be flexible as the process increases, and it should be appropriate to the stage of development of the product. It is noted that an increase in complexity in manufacturing operations requires a highly effective quality system. Those products are considered to be biological medicinal products due to their specific characteristics and the starting materials include biological substances, such as cells or fluids including blood or plasma of human origin. Furthermore, apply to the starting material e. However, it does not apply to blood components intended for transfusion. The herbal substance should be of suitable quality. A consistent quality assurance of herbal substances requires more detailed information on its agricultural production. Medicinal plants, herbal substances or herbal preparations. This process should be carried out in accordance with written and approved procedures that are appropriate to the sample and the type of control intended to be applied to the sample and the sample material. These systems are a set of software and hardware components, which collectively satisfy certain functionalities. There should be no decrease in product quality, process control or quality assurance, where the quality system is replaced by manual operations. In these requirements, manufacturers identify what validation work needed to prove control of the critical aspects of their particular operations. It also covers cases where the batch had different stages of production or test conducted at different locations or by different manufacturers, and where an intermediate or bulk production batch is divided into more than one finished product batch. Investigational Medicinal Products are also under these guidelines. However, it does not mean that all tests specified should be executed in the finished product before release. According to these guidelines, the implementation of parametric release is in line with the European Pharmacopoeia. These guidelines are not intended to be a barrier to technical innovation. Recommendations are not mandatory for the industry, but the latter should regard them as appropriate. Currently, this agency requires that sterile products meet certain requirements for sterility before release to the market. These guidelines also include guidelines on the collection and retention of samples of medicinal products for parallel import and distribution. Samples are retained in order to meet two objectives: First, to provide a sample for analytical testing; second, to provide a sample of the totally finished product. Samples are divided into two categories: Reference sample and retention sample. It is not intended to create new expectations beyond current requirements. The purpose of this guideline is to provide a systematic approach of quality risk management and serves as a base or resource, independent, supporting other documents relating to the quality of ICH and complements existing quality practices, requirements, standards and guidelines in the scope of Pharmaceutical Industry and regulatory environment, thus remaining optional character. The guidelines also apply to regulatory authorities in the field of pharmaceutical evaluation of the quality of the dossier for MA, GMP inspections and treatment of suspicions of quality defects. It is noticeable a growing involvement by organizations and institutions whether public or private, regulatory authorities and the pharmaceutical industry in the reach of maximum harmonization guidelines of GMP for medicinal products to be applied in each country. To be achieved all these parameters, it is necessary that manufacturers

are aware of the importance of good implementation and management of these guidelines, their responsibilities relating to the manufacture of medicinal products. It is important to have an effective system of Quality Control and Quality Risk Management; the control and inspection of GMP guidelines are key factors for the personnel within the manufacturer and external stakeholders as well as the importance of having an organization and effective management of all human resources and qualified personnel, motivated and responsible.

Chapter 2 : GMP Certification | Good Manufacturing Practice | Supplement Factory UK

What is GMP? GMP refers to the Good Manufacturing Practice Regulations promulgated by the US Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act.

Closed Loop Quality Management: These good manufacturing practice guidelines are enforced by the FDA in order to ensure that life science companies are utilizing systems that assure proper design, monitoring, and control of manufacturing processes and facilities. The good manufacturing practice guidelines are minimum requirements that are flexible enough to allow manufacturers to make decisions based on their individual organizational needs in regards to the best methods of implementing the necessary controls according to scientifically sound processing methods, testing procedures, and design. Can you tell just by looking at a pill if it will work or not when you swallow it? Does it smell like it has spoiled? Good manufacturing practice guidelines exist to help ensure that drug products are safe and that they work as they are supposed to. MasterControl Software Solutions Can Help Your Company Maintain Consistent Compliance with Good Manufacturing Practice Guidelines For more than two decades, MasterControl has provided hundreds of companies around the world with quality management software solutions that help them achieve and maintain compliance with good manufacturing practice guidelines. MasterControl software has been specifically designed to help companies doing business in regulated environments with quality management issues such as: It automates and efficiently manages document control processes to help ensure compliance with FDA 21 CFR Part 11 regulations, ISO quality standards, and other similar regulatory requirements. MasterControl automates the assignment and monitoring of training tasks and grading of online exams to assure compliance with good manufacturing practice guidelines. The software allows sequencing of training courses, so that after a prerequisite course is completed, the next course is automatically launched. The software also provides a group sign-off feature for verifying the training of large groups of employees. Training management can be integrated with the rest of the quality system to ensure implementation of good manufacturing practice guidelines, so that any change to a document or process that warrants new training will automatically invoke training tasks upon approval of the change. An effective corrective and preventive action CAPA software system improves product quality and safety, increases customer satisfaction, and, more importantly, ensures compliance with global standards such as the good manufacturing practice guidelines set forth by the FDA. MasterControl CAPA connects quality events such as nonconformance, deviations, and customer complaints while automating the management of the entire CAPA process, from initiation to investigation and all the way through closure. The system allows a CAPA form to be automatically launched from another form such as a customer complaint in order to streamline the CAPA process and avoid human data entry errors. Quality audits are required on an ongoing basis to help improve product quality and safety and to ensure compliance with good manufacturing practice guidelines. MasterControl enables efficient execution of audits, streamlines the capture and management of findings and responses, facilitates the effective planning and scheduling of audits and resources, and simplifies the reporting on resulting data. These are just a few of the quality management processes that MasterControl software solutions are designed to streamline. For a more comprehensive list of MasterControl offerings, visit the Solutions page on the MasterControl website.

Chapter 3 : Good Manufacturing Practice (GMP) - Pharmaceutical Industry - USA

manufacturing of sterile products and biological products. The inherent flexibility of the cGMP regulations should enable manufacturers to implement a quality system in a form that.

High-level details[edit] Good manufacturing practice guidelines provide guidance for manufacturing, testing, and quality assurance in order to ensure that a manufactured product is safe for human consumption or use. Many countries have legislated that manufacturers follow GMP procedures and create their own GMP guidelines that correspond with their legislation. All guideline follows a few basic principles [2] [6]: Manufacturing facilities must maintain a clean and hygienic manufacturing area. Manufacturing facilities must maintain controlled environmental conditions in order to prevent cross-contamination from adulterants and allergens that may render the product unsafe for human consumption or use. Manufacturing processes must be clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications. Manufacturing processes must be controlled, and any changes to the process must be evaluated. Changes that affect the quality of the drug are validated as necessary. Instructions and procedures must be written in clear and unambiguous language using good documentation practices. Operators must be trained to carry out and document procedures. Records must be made, manually or electronically, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the food or drug was as expected. Deviations must be investigated and documented. Records of manufacture including distribution that enable the complete history of a batch to be traced must be retained in a comprehensible and accessible form. Any distribution of products must minimize any risk to their quality. A system must be in place for recalling any batch from sale or supply. Complaints about marketed products must be examined, the causes of quality defects must be investigated, and appropriate measures must be taken with respect to the defective products and to prevent recurrence. Good manufacturing practices are recommended with the goal of safeguarding the health of consumers and patients as well as producing quality products. In the United States, a food or drug may be deemed "adulterated" if it has passed all of the specifications tests but is found to be manufactured in a facility or condition which violates or does not comply with current good manufacturing guideline. GMP guidelines are not prescriptive instructions on how to manufacture products. They are a series of general principles that must be observed during manufacturing. When a company is setting up its quality program and manufacturing process, there may be many ways it can fulfill GMP requirements. The regulations use the phrase "current good manufacturing practices" CGMP to describe these guidelines. Each of the inspectorates carry out routine GMP inspections to ensure that drug products are produced safely and correctly. Additionally, many countries perform pre-approval inspections PAI for GMP compliance prior to the approval of a new drug for marketing. Courts have held that any time the firm is open for business is a reasonable time for an inspection. Other examples include good guidance practices, and good tissue practices.

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Chapter 4 : GMP news. Good Manufacturing Practice. News & Events

FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations.

Good manufacturing practice 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. 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: Agency role The Agency has a coordinating role for GMP inspections of manufacturing sites for medicines whose marketing authorsation in the EU is submitted through the centralised procedure or as part of a referral procedure. It is involved in: Legal framework and guidance Regulation No. The EU GMP guidelines provide interpretation of these principles and guidelines , supplemented by a series of annexes that modify or augment the detailed guidelines for certain types of product, or provide more specific guidance on a particular topic. Manufacturing authorisation 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. 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 auhtorisation application comply with GMP. For more information, see section 5. Registration of manufacturers of active substances 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. Responsibility for inspections 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 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. It meets at EMA four times a year. The group provides a forum for harmonisation and discussion of common issues, such as: This facilitates cooperation between EU Member States and supports harmonisation and exchange of inspection-related information.

Chapter 5 : GMP, Good Manufacturing Practice, SOP

Good manufacturing practices (GMP) are the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices.

Chapter 6 : GMP Training Free

Good manufacturing practices (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot

be eliminated through testing the final product.

Chapter 7 : Good manufacturing practices for medicinal products for human use

Good Manufacturing Practices (GMP) are the part of quality assurance that ensures that drugs are consistently produced and controlled in such a way to meet the quality standards appropriate to their intended use, as required by the marketing authorization.

Chapter 8 : Guidance Documents â€“ Good Manufacturing Practices - racedaydvl.com

Good Manufacturing Practice (GMP) for Drugs Chapter 1 General Provisions Article 1: These provisions of Good Manufacturing Practice (GMP) for Drugs, in accordance with the Drug Administration Law of the People's Republic of China and the Regulations for Implementation of the Drug Administration Law of the People's Republic of China, are.

Chapter 9 : Good Manufacturing Practice (GMP) Guidelines

manufacturing practice in the manufacture and quality control of medicines and pharmaceutical specialities and was accepted. The revised text was discussed by the WHO Expert Committee on.