Available online on 15 Dec, 2024 at https://ijdra.com/index.php/journal

International Journal of Drug Regulatory Affairs

Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with RAPS & Delhi Pharmaceutical Sciences & Research University

Review Article **Open Access**

Comparison of GMP for Drugs in EU, US, Canada, WHO and Australia

Akshda Patil, Medha Devidas Kuchal, Prasanthi D.*

Department of Regulatory Affairs, G. Pulla Reddy college of pharmacy, Osmania University, Mehdipatnam-500028, Hyderabad, Telangana, India

Abstract

Good Manufacturing Practices (GMP) are essential for ensuring the safety, quality, and efficacy of pharmaceutical products. GMP covers all aspects of production, including personnel training, equipment maintenance, and facility sanitation. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. This article provides a comparative analysis of GMP regulations across five key regions: the European Union (EU), United States (US), World Health Organization (WHO), Canada, and Australia. The regulations and guidelines followed by EU, US, WHO, Canada, and Australia are mentioned in this article. By identifying both the convergences and divergences in these guidelines, the study highlights how regional practices address the challenges of drug safety and efficacy in a globalized market, ultimately contributing to improved public health outcomes.

Keywords: Good Manufacturing Practices; GMP regulations; Quality assurance; Drug efficacy; Regulatory compliance; Production standards; Quality control; Risk management; WHO

Article Info: Received 19 Nov 2024; Review Completed 11 Dec 2024; Accepted 15 Dec 2024

Cite this article as:
Patil A, Kuchal MD, Prasanthi D. Comparison of GMP for Drugs in EU, US, Canada, WHO and Australia. Int. J. Drug Reg. Affairs [Internet]. 2024 Dec15 [cited 2024 Dec 15]; 12(4):82-91. Available from: http://ijdra.com/index.php/journal/article/view/724

DOI: https://doi.org/10.22270/ijdra.v12i4.724
*Corresponding author

1. Introduction

The pharmaceutical industry includes the manufacture of compounds and medicines intended for human or veterinary use. Pharmaceutical manufacturing can be divided into primary pharmaceutical manufacturing, related to the production of chemical compounds of therapeutic value (active pharmaceutical ingredients (APIs)), and secondary pharmaceutical manufacturing, which produces medicines by a suitable formulation of API(s) and appropriate excipients in a final product (e.g., tablets) (1) Pharmaceutical manufacturing follows a series of steps defined in the manufacturing process to produce medicines. This process is developed in the Research and Development (R&D), scaled up to the commercial manufacturing, approved by the Food and Drug Administration (FDA) and other health authorities in a country before implementing them in a manufacture plant. The manufacturing process is static and every production batch needs to follow the process exactly the way it's defined and all the steps need to be completed. The process documentation for every production batch needs to be completed in real-time as various steps in the process are done-Good Manufacturing Practice (GMP) ensures documented evidence is completed during the operation and not as an afterthought. (2)

2. Good Manufacturing Practice

Good Manufacturing Practice, or GMP for short, is a system that makes sure that manufactured commodities like food, cosmetics, and pharmaceuticals are regularly produced and controlled in accordance with pre-determined quality standards. By putting GMP into practice, one can reduce waste and losses while avoiding recalls, penalties, and jail time. All things considered, it shields the business and the customer from unfavourable food safety incidents. (3)

It is intended to reduce any production-related risks associated with pharmaceuticals that cannot be eradicated by testing the finished product. The primary hazards include: unexpected product contamination that might lead to harm to health or even death; inaccurate labelling on containers that could result in patients receiving the wrong medication; and an excessive or insufficient amount of active ingredient that could cause side effects or ineffective therapy.

GMP addresses every facet of manufacturing. For any process that has the potential to impact the final product's quality, written, comprehensive procedures are necessary. Every time a product is manufactured, there needs to be mechanisms in place to offer recorded evidence that the right processes are regularly followed at every stage of the production process. Numerous

nations have developed their own GMP regulations based on WHO GMP. (4)

GMPs inspect and cover every aspect of the production process to protect against risks including adulteration, misbranding, and cross-contamination, which can have disastrous consequences for products. Some areas that can influence safety and quality of products that GMP guideline and regulation address are the following:

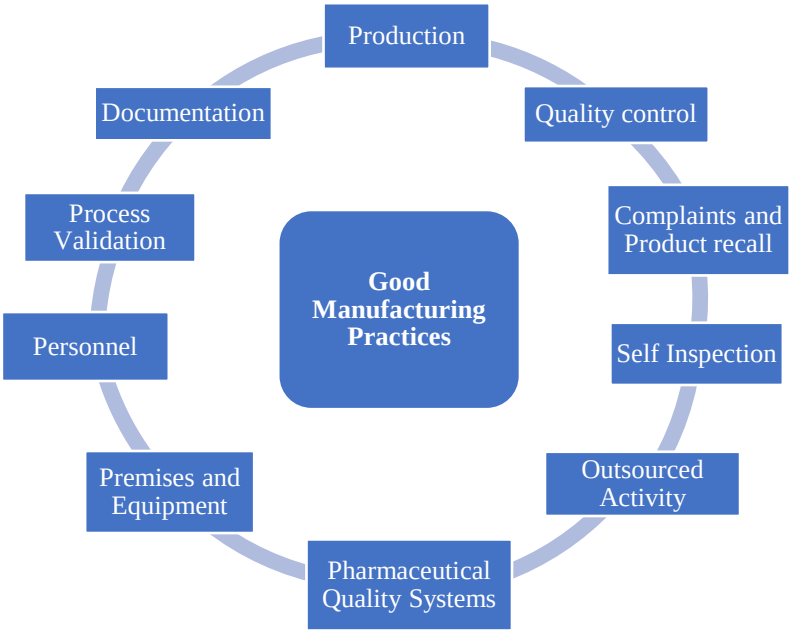

Figure 1. GMP guidelines

3. Importance of GMP in the Healthcare Industry

3.1 Patient Safety

The safety of patients is the first priority in the healthcare sector. In order to limit the potential of patient injury, GMP is essential in ensuring that healthcare products are made under stringent quality standards. Manufacturers can lessen the possibility of contamination, mistakes, and variations that can jeopardize the security and effectiveness of medical products by putting GMP rules into practice. Following GMP guidelines aids in recognizing and reducing manufacturing process risks, guaranteeing that only secure and efficient products are supplied to patients.

3.2 Product Quality Assurance

In the healthcare sector, GMP is crucial for preserving consistent product quality. By following the GMP rules, firms can build solid quality control systems and procedures throughout the manufacturing process. This entails thorough batch records, in-process controls, and rigorous testing of raw materials to guarantee that the final products fulfill predefined requirements and quality standards. GMP guarantees that medical supplies are reliable, efficient, and free from defects, giving patients and healthcare providers trust.

3.3 Compliance with Regulatory Requirements

To protect public health, the healthcare industry is subject to stringent regulatory oversight. Good manufacturing practice (GMP) regulations set minimum standards for the manufacturing, quality control, and documentation of healthcare products. Regulatory agencies worldwide enforce GMP regulations and conduct inspections to verify manufacturers' adherence to these standards. Following GMP guidelines not only ensures product safety and quality but also reduces the risk of regulatory non-compliance and the associated penalties or sanctions.

3.4 Risk Mitigation

There are inherent hazards associated with manufacturing healthcare products, including cross-contamination, contamination, and product deviations. A methodical strategy to identifying, evaluating, and reducing these risks is offered by GMP. Manufacturers can create reliable processes for risk assessment, process validation, and corrective action by putting GMP rules into practice. The necessity of continual monitoring, change control, and continuous improvement is also emphasized by GMP in order to reduce risks related to patient safety and product quality.

3.5 Maintaining Public Trust

The public's trust in the security and effectiveness of medical supplies is essential to the healthcare sector. Maintaining this confidence is made possible by adhering to GMP standards, which guarantee that products are produced under strict quality control procedures. A dedication to product quality, safety, and legal compliance is shown by GMP. It also promotes transparency through adequate documentation, traceability and accountability in the production process. Manufacturers can establish and preserve public trust by

adhering to GMP guidelines, which is essential for the prosperity and standing of the healthcare sector as a whole.

In conclusion, GMP is of utmost importance in the healthcare industry. It ensures patient safety, maintains product quality assurance, facilitates compliance with regulatory requirements, mitigates risks, and fosters public trust. Adhering to GMP guidelines is critical for healthcare product manufacturers to deliver safe, effective, and high-quality products that meet regulatory standards and inspire confidence among healthcare professionals and the general public. (5)

4. Guidelines

Many nations have passed laws requiring manufacturers of pharmaceuticals and medical devices to develop their own GMP criteria in accordance with such laws. The fundamental tenets of GMP guidelines are to produce high-quality medications, medical devices, or active pharmaceutical goods while simultaneously protecting patient health. The 1960s saw the formalisation of GMP, which is now in use in more than 100 nations, from Zimbabwe to Afghanistan. These consist of the following examples.

4.1 Pharmaceutical Inspection Convention (PIC) Guide to GMP for pharmaceutical products - Australia, Austria, Belgium, Canada, Italy, Latvia, Liechtenstein, Denmark, Finland, France, Hungary, Ireland, Malaysia, The Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Spain, Sweden, Switzerland, and the United Kingdom.

4.2 Association of South-East Asia Nations (ASEAN):

General guidelines Brunei Darussalaam, Indonesia, Lao People's Democratic Republic (Lao PDR), Malaysia, Cambodia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.

4.3 European Economic Community (EEC): Guide to GMP for medicinal products Austria, Belgium, Denmark, Ireland, Italy, Luxembourg, The Netherlands, Finland, France, Germany, Greece, Portugal, Spain, Sweden, and the United Kingdom. (6)

5. WHO prequalification

A service provided by the WHO, known as WHO prequalification of medicines, assesses the quality, safety, and effectiveness of medications. Initially, in 2001, the focus was on medications for malaria, tuberculosis, and Human Immunodeficiency Virus (HIV). This was expanded in 2006 to include items and medications for reproductive health, and it was expanded once more in 2008 to include zinc prequalification for the treatment of acute diarrhoea in children. 316 medications for priority diseases were listed on the WHO List of Prequalified Medicinal Products as of the end of 2012.

International procurement agencies buy medications worth billions of US dollars annually to be distributed in nations with inadequate resources. The goal of prequalification is to provide these organisations with a large selection of high-quality medications that they may buy in bulk.

5.1 Prequalification consists of five components:

a. Invitation

Companies are invited to submit an expression of interest (EOI) for product review by United Nations International Drug Purchase Facility (UNITAID), United Nations Programme on HIV/AIDS (UNAIDS), United Nations International Children's Emergency Fund (UNICEF), and the WHO Prequalification of Medicines Programme (PQP). Prequalification is only available for products that are listed in an EOI. One or more of the following three factors determine whether a medication is included in an EOI:

- It is recommended for use by a current WHO treatment guideline;
- it is listed on the WHO Model List of Essential Medicines;
- an application for its addition to the Model List has been submitted to the relevant WHO Expert Committee for assessment, and it is likely to meet the criteria for inclusion (based on public health need, comparative effectiveness, safety, and cost-effectiveness).

b. Dossier submission

A thorough collection of information regarding the product's effectiveness, safety, and quality is supplied by the manufacturer and is submitted for review. This comprises:

- information about the stability of the final pharmaceutical product;
- data regarding the purity of all substances used in its manufacture;
- Consider the outcomes of clinical trials carried out on healthy volunteers for bio-equivalency testing, unless excluded.

c. Assessment

Each piece of data is assessed by a group of assessors. WHO personnel and specialists from national regulatory agencies across the globe are on assessment teams.

d. Inspection

A group of inspectors confirms that WHO good manufacturing practices are followed at the production facilities for the pharmaceutical product's active ingredient(s) and final pharmaceutical product. They also confirm that the submitted product complies with WHO good laboratory and clinical practice for any contract research organisation that carried out clinical trials related to it.

e. Decision

The product is added to the WHO list of prequalified medical products if it is determined to fit the requirements and the related production site(s) and contract research organization(s) comply with WHO standards.

If all the information submitted is accurate and shows that the medication satisfies all the requirements, the WHO prequalification of medicines process can be completed in as little as three months. However, as the maker must provide the required data for re-evaluation, the procedure may take much longer if the data are insufficient.

PQP periodically re-inspects prequalified product manufacturing locations to make sure that the items still match WHO criteria. Additionally, it assesses modifications (referred to as "variations") made to the specifications, production procedures, and quality assurance of items that have been prequalified, as well as random. (7)

6. WHO GMP

The Good Manufacturing Practices (GMP) guidelines are globally acknowledged standards that the World Health Organisation (WHO) adheres to in order to guarantee the safety and quality of pharmaceutical products. These rules are made to make sure that goods are consistently made and monitored in accordance with quality standards suitable for the purposes for which they are intended. More than 100 countries have incorporated WHO GMP provisions into their national laws. (8)

Annexures to the overall GMP standards provide specific GMP criteria for various product types, such as biological medicinal items or sterile pharmaceuticals.

Annex 1: Manufacture of sterile Medicinal Products, **Annex 2:** Manufacture of Biological Medicinal Products, **Annex 3:** Manufacture of Radiopharmaceuticals, **Annex 4:** Manufacture of Veterinary Medicinal Products, **Annex 5:** Manufacture of Herbal Medicinal Products, **Annex 6:** Manufacture of Medicinal gases, **Annex 7:** Manufacture of Active Pharmaceutical Ingredients (API), **Annex 8:** Manufacture of Investigational Medicinal Products for Clinical Trials in Humans

7. EU GMP

The European Union's (EU) regulatory framework for pharmaceutical products is managed by the European Medicines Agency (EMA). Comprehensive Good Manufacturing Practices rules for medicinal products intended for human and veterinary use have been established by the European Union. These rules offer comprehensive specifications for the production and quality control of pharmaceutical products, covering elements like personnel, documentation, distribution, quality control and facility design.

In the European Union, Good Manufacturing Practice (GMP) regulations are governed by several key directives and regulations. Here are the main ones:

Directive 2001/83/EC: This directive relates to medicinal products for human use and lays down the principles and guidelines of GMP, **Directive (EU) 2017/1572:** This supplements Directive 2001/83/EC and provides additional guidelines for GMP for medicinal products for human use, **Regulation No. 1252/2014:** This regulation applies to active substances for human use, **Directive 91/412/EEC:** This directive applies to veterinary medicinal products, **Regulation (EU) 2019/6:** This regulation also pertains to veterinary medicinal products. (9)

8. US GMP

In the United States, the Food and Drug Administration (FDA) is responsible for enforcing GMP requirements. The FDA established the Current Good Manufacturing Practice (cGMP) regulations, which set forth the minimal standards for the production, handling, storage, and packaging of pharmaceutical goods. The cGMP regulations cover various aspects such as facility design, personnel qualifications, equipment maintenance, quality control, documentation, and labelling. The pharmaceutical or drug quality-related regulations appear in several parts of Title 21

21 Code of Federal Regulations (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. (10)

9. CANADA GMP

In Canada, Health Canada is responsible for regulating pharmaceutical products. Health Canada has implemented Good Manufacturing Practices (GMP) regulations that ensure the safety, quality, and efficacy of pharmaceuticals. These regulations cover areas such as facility design and maintenance, personnel training, documentation, quality control, and product testing.

Guidance on Drug Establishment Licenses (GUI-0002), Guidance: How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080), Risk classification guide for drug good manufacturing practices observations (GUI-0023), Good Manufacturing Practices (GMP) for Active Pharmaceutical Ingredients (API) - (GUI-0104), **Annex 1** to the Good manufacturing practices guide – Manufacture of sterile drugs (GUI-0119). (11)

Table 1. Comparisons of various GMP Parameters in EU, USA, Canada, WHO, Australia (12-17)

S.No.	Parameters	EU GMP	USA GMP	CANADA GMP	WHO GMP	AUSTRALIA GMP
1.	**Regulatory authority**	**EMA** (European Medicinal Agency and **NCA** (National Competent Authorities) **Regulations:** Eudralex Volume IV (Rules governing medicinal products in the EU) **Binding Force:** Regulation have binding legal force in every Member State (MS) **Inspections:** Conducted by National Competent Authorities (NCA) and EMA (European medicines agency). **Collaboration:** MRA (mutual recognition agreement) in place for some products.	**USFDA** (United States Food and Drug Administration) **Regulations:** Detailed in Title 21 of the Code of Federal Regulations (CFR). **Binding Force:** Legally binding. **Inspection:** Conducted by the FDA. **Collaboration:** No mutual Recognition Agreement (MRA) with the EU.	**Health Canada** **Binding Force:** Binding legal force. **Inspections:** Health Canada. **Collaboration:** MRA with the EU for medicinal products and GMP compliance certification.	**Guidelines:** WHO provides guidelines for GMP **Binding Force:** No legally binding **Collaboration:** Collaboration globally on health standards	**TGA** (Therapeutic Goods Administration) **Binding Force:** Binding legal force. **Inspections:** Therapeutic Goods Administration (TGA) **Collaboration:** Collaborates with international agencies
2.	**Quality Risk Management**	**Greater Emphasis on Quality Risk Management:** The EU (European Union) GMPs place a greater emphasis on quality risk management **Binding Force:** Regulations have binding legal force in every Member State (MS) and require systematic risk management **Collaboration:** European Medicines Agency (EMA) collaborates with Member States and European Economic Area Countries	**Emphasis on Risk Management:** The US GMP's emphasis risk management but provide more flexibility in implementing risk- based approaches. **Systematic approach:** Manufacturers are required to have a systematic approach to identify, assess, and control risks associated with manufacturing processes.	Similar to EU, with emphasis on risk management. Health Canada conducts inspections and emphasizes risk - based approaches.	Provides guidelines for GMP (Good Manufacturing Practice) , but not legally binding. Collaborates globally on health standards, including risk management.	Similar to EU and Canada. TGA focuses on risk management in GMP requirements.
3.	**Documentation and Record Keeping**	**GMP Documents:** European authorities explicitly ask to exclude any GMP documents **Approach:** Trust-based approach, with selective data presentation. **Active Substance Master File (ASMF):** Utilized instead of Drug Master File (DMF)	**GMP Documents:** The US quality module explicitly contains GMP and batch record documents. **Approach:** The FDA requires raw data and GMP documents, examining critical aspects. **Drug Master File (DMF):** Several types of DMFs exists, including active substance, colourants, flavours, excipients and more.	Similar to the EU emphasising risk management. GMP documents are not explicitly required in CMC sections.	Provides guidelines for GMP, but not legally binding. Collaborates globally on health standards, including documentation practices.	Similar to EU and Canada. Streamline regulatory requirement, including no requirement for an Investigational New Drug (IND)

S.No.	Parameters	EU GMP	USA GMP	CANADA GMP	WHO GMP	AUSTRALIA GMP
4.	**Process Validation**	EU GMP requires formal process validation protocol with predefined acceptance criteria. Aligned with ICH Q8, Q9 and Q10 guidelines.	The FDA emphasizes science and risk- based approach to process validation. No specific mandate for a formal process validation protocol.	Health Canada provides guidance on process validation on drug manufacturing. The **lifecycle approach** is emphasized, including data from batch processing, packaging records, process control charts, maintenance logs, personnel changes, process capability studies, and finished product data.	The WHO GMP's focus on quality risk management (QRM) and process validation. They emphasize **global standards** for over 100 countries.	The Therapeutic Goods Administration (TGA) emphasizes a lifecycle approach. Process validation includes data from batch processing, packaging records, process control charts, maintenance logs, personal changes, process capability studies, and finish product data.
5.	**Quality Management System (QMS)**	**Medical product directive (EU):** Directive 2001/83/EC Outlines the pharmaceuticals quality system requirements. **European medical device regulations (MDR):** Relevant for medical device used with medical products. **EMA Guideline:** Provide quality requirement for medicinal products used with medical devices. **ICH Guidelines:** Q8 (pharmaceutical development), Q9 (quality risk management) and Q10 (pharmaceutical quality system) are applicable	**21 CFR PART 4:** Addresses combination products. **21 CFR PART 862-892:** Devices Regulations. **21 CFR PART 820:** Quality System Regulation (QMSR) for medical devices. **ICH Guidelines:** similar to the EU	**Health Canada:** Follows GMP requirements similar to the EU and US.	**WHO GMP Guidelines:** Provide global standards for pharmaceutical manufacturing.	**Therapeutic Goods Administration (TGA):** Adheres to GMP principles.
6.	**Annual Product Quality Review (APQR)**	**Objective:** The EU PQR concentrates on the quality system and process to demonstrate consistent production of high-quality products. **Scope:** It covers a greater number of items and areas for review compared to US product Annual Review (PAR) or ICH Q7 PQR	**Requirement:** Annual Product Reviews have been mandatory under US GMPs for pharmaceutical products since 1978. **Focus:** The US PAR emphasizes product quality and consistency.	Health Canada includes APQR requirements.	Provides GMP guidelines globally.	Australia GMP also emphasizes APQR, aligning with international standards.

S.No.	Parameters	EU GMP	USA GMP	CANADA GMP	WHO GMP	AUSTRALIA GMP
		Inclusions: The EU PQR expands the review to include quality systems and registration commitments.	**Comparison:** The US PAR (Product Annual Report) is most streamlined compared to comprehensive EU PQR (Product Quality Review).			
7.	**Inspection and Audit**	The EU and US have implemented a mutual recognition agreement (MRA) for inspection of manufacturing sites for certain human medicines. EU inspector rely on their own inspection and those conducted by US FDA, avoiding duplicative work. The EU focuses on quality systems and processes to ensure consistent production of high- quality products.	The FDA monitors drug on the market to ensure they meet safety and quality requirements. The US PQR (Product Quality Review) concentrates on a quality of the product itself, without expensive coverage of quality systems.	Health Canada conducts drug inspection to ensure compliance with GMP. Like the EU. Canada emphasises quality system and process consistency.	WHO GMP guidelines apply globally. Inspections assess both quality system and product quality.	Australia follows GMP guidelines similar to EU and US.
8.	**Product specific guidelines**	The EU Provides specific guidelines for generic drug development, including bioequivalence studies and therapeutic equivalence assessments. These guidelines ensure that generic drugs are therapeutically equivalent to specific reference drugs.	The FDA publishes product-specific guidance for generic drugs, describing agency's current thinking on how to develop generic drug products equivalent to specific reference listed drug.	Health Canada provides guidance on developing generic drug, emphasizing bioequivalence studies and therapeutic equivalence. The Canadian regulatory framework aligns with international standards.	WHO guidelines apply globally and cover various aspects of drug development, including generics. These guidelines ensures consistency and quality across different regions.	Australia follows similar principles to the EU and US in terms of generic drug development. Specific guidelines address bioequivalence and therapeutic equivalence assessment
9.	**Inspection and Certification**	**Mutual recognition agreement (MRA):** The EU and US have implemented MRA for inspections of manufacturing sites for certain human medicines. These allows authorities on both sides to rely on each other's inspection results, avoiding duplicate work. **Evidence:** Robust evidence supports comparable procedures for GMP inspection in the EU and the US.	**Regulatory Framework:** The FDA monitors drug on the market to ensure safety and quality. The data dashboard provides detailed information on inspection, compliance, recalls and import actions. **Focus:** FDA inspection focus on compliance with Title 21 CFR (Code of Federal Regulations).	**Canada-Australia MRA:** Canada and Australia have a Mutual Recognition Agreement specifically for mutual recognition of medicinal product GMP inspections and certification.	WHO GMP guidelines apply globally. Inspection assess both quality systems and product quality.	Same as that of Canada GMP

S.No.	Parameters	EU GMP	USA GMP	CANADA GMP	WHO GMP	AUSTRALIA GMP
		Batch Testing waivers: Qualified person in EU pharmaceutical companies no longer need to duplicate quality control for products manufactured in and imported from the us. **Expansion:** The MRA aims to expand to veterinary medicines, human vaccines, and plasma-derived medicinal products.	**Style:** Differences exist in inspection approach and style compared to EU inspection.			
10.	**Drug labelling requirement**	Drug name, dosage form and strength. Active ingredients and their quantities. Direction for use. Warning and precaution. Manufacturers name and lot number. Unique identifier (for serialization)	Drug name, dosage form and strength. Active ingredients and their quantities. Direction for use. Warning and precaution. Manufacturers name and address. Expiry date and lot number.	Drug name, dosage form and strength. Active ingredients and their quantities. Direction for use. Warning and precaution. Manufacturers name and address. Expiry date and lot number. Bilingual labelling (English and French)	Drug name, dosage form and strength. Active ingredients and their quantities. Direction for use. Warning and precaution. Manufacturers name and address. Expiry date and lot number.	Drug name, dosage form and strength. Active ingredients and their quantities. Direction for use. Warning and precaution. Manufacturers name and address. Expiry date and lot number.
11.	**Packaging requirement**	**Tamper-Evident packaging:** Required for certain drugs. **Child-Resistant packaging:** Required for certain drugs. **Labelling:** Must include all required information and a unique identifier for serialization. **Container Closure System:** Must protect the drug from contamination and degradation.	**Tamper-Evident packaging:** Required for certain (OTC) drugs. **Child-Resistant packaging:** Required for certain drugs **Labelling:** Must include all required information. **Container Closure System:** Must protect the drug from contamination and degradation.	**Tamper-Evident packaging:** Required for certain drugs. **Child-Resistant packaging:** Required for certain drugs. **Labelling:** Must be bilingual (English and French) and include all required information. **Container Closure System:** Must ensure the integrity and quality of the drug.	**Tamper-Evident packaging:** Recommended for certain drugs. **Child-Resistant packaging:** Recommended for certain drugs **Labelling:** Must include all required information. **Container Closure System:** Must protect the drug from contamination and degradation	**Tamper-Evident packaging:** Required for certain drugs. **Child-Resistant packaging:** Required for certain drugs. **Labelling:** Must include all required information. **Container Closure System:** Must ensure the integrity and quality of the drug.

Annex 2 to the Current Edition of the Good Manufacturing Practices Guidelines – Schedule D Drugs, Biological Drugs (GUI-0027), **Annex 3a** to the Current Edition of the Good Manufacturing Practices Guidelines – Schedule C Drugs (GUI-0026), **Annex 3b** to the Good Manufacturing Practices Guidelines – Positron Emitting Radio-pharmaceuticals (PER's) (GUI-0071), **Annex 4** to the Current Edition of the Good Manufacturing Practices Guidelines – Veterinary Drugs (GUI-0012), **Annex 7** to the Good manufacturing practices guide – Selected non-prescription drugs (GUI-0066), **Annex 11 –** PIC/S Annex 11: Computerized Systems, **Annex 13** to the Current Edition of the Good Manufacturing Practices Guidelines – Drugs Used in Clinical Trials (GUI-0036), **Annex 17 –** PIC/S Annex 17: Guidance on Parametric Release, Good manufacturing practices for medical gases (GUI-0031). (11)

10. AUSTRALIA GMP

Australia's Therapeutic Goods Administration (TGA) is in charge of regulating medications. The TGA created the Code of Good Manufacturing Practice for Medicinal Products, which describes the specifications for the production, quality assurance, and distribution of medications. The code addresses things like personnel, documentation, quality control, facilities, equipment, and product release. There are twenty annexes to the two halves of the guide.

10.1 Guide to Good Manufacturing Practice for Medicinal Products - Part I

Pharmaceutical Quality System, Personnel, Premises and equipment, Documentation, Production, Quality control, Outsourced activities, Complaints and product recall, Self – inspection

10.2 Guide to Good Manufacturing Practice for Medicinal Products – Part II

Introduction, Quality management, Personnel, Buildings and facilities, Process equipment, Documentation and records, Materials management, Production and in-process controls, Packaging and identification labelling of APIs and intermediates, Storage and distribution, Laboratory controls, Validation, Change control, Rejection and re-use of materials, Complaints and recalls, Contract manufacturers (including laboratories), Agents, brokers, traders, distributors, re-packers and re-labellers, Specific guidance for APIs manufactured by cell culture / fermentation, APIs for use in clinical trials, Glossary.

Guide to Good Manufacturing Practice for Medicinal Products – Annexes

The Australia GMP guide for medicinal products contains the different annexures which are being addressed in detail - Manufacture of sterile medicinal products, Manufacture of advanced therapy medicinal products for human use, Manufacture of biological medicinal substances and products for human use, Manufacture of radiopharmaceuticals, Manufacture of veterinary medicinal products other than immunologicals [This Annex is not adopted by the TGA], Manufacture of immunological veterinary medical products [This Annex is not adopted by the TGA], Manufacture of medicinal gases, Manufacture of herbal medicinal products, Sampling of starting and packaging materials, Manufacture of liquids, creams and ointments, Manufacture of pressurized metered dose aerosol preparations for inhalation, Computerized systems, Use of ionizing radiation in the manufacture of medicinal products, Manufacture of investigational medicinal products, Manufacture of products derived from human blood or human plasma [This Annex is not adopted by the TGA], Qualification and validation, Authorized person and batch release, Real time release testing and parametric release, GMP guide for active pharmaceutical ingredients [This Annex no longer exists], Reference and retention samples, Quality risk management and glossary.

The table 1 defines the different parameters concerning the GMP requirements of drugs in different countries.

11. Conclusion

A set of rules known as "good manufacturing practices" is intended to guarantee that products are consistently manufactured and controlled in accordance with quality standards. GMP essentially guarantees that goods are high-quality, safe, and effective, which promotes customer trust and legal compliance. Every region has its own unique set of rules and regulations. Agreements on mutual recognition are in place in some areas to speed up the GMP clearance procedure. Strong quality management systems are emphasised in every region; keeping thorough records is essential for adhering to all regulations; and frequent audits and inspections are required to guarantee compliance.

Acknowledgements

We would like to express our sincere gratitude to IJDRA Journal for publishing our work.

Financial Disclosure statement:

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

Reference

1. Menezes JC, Ferreira AP, Rodrigues LO, Brás LP, Alves TP. Chemometrics role within the PAT context: examples from primary pharmaceutical manufacturing [Internet]. Elsevier; 2009 [cited 2024 Oct 24]; p. 313-355. Available from: doi:10.1016/B978-044452701-1.00012-0
2. Kamal Biswas. The Pharmaceutical Value Chain-An Introduction. Capter 2. [Internet]. Science direct; 2014 [cited 2024 Oct 24]; p. 9-65. Available from: doi: 10.1016/B978-0-12-407662-4.00002-7
3. Jona Tarlengco. GMP: Good Manufacturing Practices [Internet]. Jona Tarlengco; 2024 Jul 26 [cited 2024 Oct 24]. Available from: https://safetyculture.com/topics/gmp/

4. Medicines: Good manufacturing practices [Internet]. WHO; 2015 Nov 20 [cited 2024 Oct 24]. Available from: https://www.who.int/news-room/questions-and-answers/item/medicines-good-manufacturing-processes
5. Sharma A, Gamta V, Luthra G. The Importance of Good Manufacturing Practices (GMP) in the Healthcare Industry. Journal of Pharmaceutical Research International. 2023 Jul 10;35(18):75-90. [cited 2024 Oct 24]. Available from: https://journaljpri.com/index.php/JPRI/article/view/7394/14768
6. Chaudhri, Vikash & Yadav, Vijay & Verma, Praveen Kumar & Singh, Amit. A Review on Good Manufacturing Practice (GMP) for Medicinal Products. [Internet]. Researchgate; 2022 [cited 2024 October 23]. Available from: https://www.researchgate.net/publication/366047170_A_Review_on_Good_Manufacturing_Practice_GMP_for_Medicinal_Products
7. Prequalification of medicines by WHO [Internet]. WHO; 2013 Jan 31 [cited 2024 Oct 25]. Available from: https://www.who.int/news-room/fact-sheets/detail/prequalification-of-medicines-by-who
8. Health Products Policy and Standards [Internet]. WHO; [cited 2024 Oct 25]. Available from: https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/norms-and-standards-for-pharmaceuticals/guidelines/production
9. Good manufacturing practice [Internet]. European Union (EU); 2024 [cited 2024 Oct 25]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice
10. Current Good Manufacturing Practice (CGMP) Regulations [Internet]. USFDA; 2023 Dec 29 [cited 2024 Oct 26] Available from: https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations
11. Good manufacturing practices guide for drug products (GUI-0001)-Summary [Internet]. Canada: Government of Canada; 2020 Jul 01 [cited 2024 Oct 26] Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-0001.html
12. PIC/S Guide to GMP for medicinal products – version 16 [Internet]. Australia: Therapeutic Goods Administration; 2024 Mar 01 [cited 2024 Oct 26] Available from: https://www.tga.gov.au/resources/publication/publications/pics-guide-gmp-medicinal-products-version-16
13. Alexandre De Freire. Understanding the main differences between the Certification of EU-GMP (Good Manufacturing Practice) and other regions of the Globe [Internet]. Linkedin: Alexandre De Freire; 2024 Jun 18 [cited 2024 Oct 27] Available from: https://www.linkedin.com/pulse/understanding-main-differences-between-certification-eu-gmp-ny3ce
14. EU vs US GMPs: Key differences [Internet]. Linkedin: Bioboston Consulting; 2023 Jun 29 [cited 2024 Oct 27] Available from: https://www.linkedin.com/pulse/eu-vs-us-gmps-key-differences-biobostonconsulting#:~:text=The%20EU%20GMPs%20require%20manufacturers,specific%20requirement%20for%20a%20PQS
15. John G. Grazal and David S. Earl. EU and FDA GMP Regulations: Overview and Comparison [Internet]. John Wiley & Sons, Ltd.; 2024 Nov 22 [cited 2024 Oct 27] Available from: https://onlinelibrary.wiley.com/doi/pdf/10.1002/%28SICI%2910991786%28199706%292%3A2%3C55%3A%3AAID-QAJ35%3E3.0.CO%3B2-X
16. GMP regulations in different countries | Comprehensive Overview [Internet]. US: GxP Cellators; 2023 [cited 2024 Oct 28] Available from: https://gxpcellators.com/gmp-regulations-in-different-countries-comprehensive-overview/
17. EU and US GMPs | Understanding the Similarities and Differences [Internet]. 2024 Mar 15 [cited 2024 Oct 28] Available from: https://pharmadigests.com/eu-and-us-gmps-understanding-the-similarities-and-differences/