

The importance of good manufacturing practices in pharmaceutical regulatory compliance.

Jacques McCarthy*

Department of Pharmaceutical Sciences, University of Perugia, Perugia, Italy

Abstract

Pharmaceutical Regulatory, also referred to as Pharma Regulatory, is a provider of expert clinical and regulatory support of all phases of global drug development. They support clinical and regulatory activities in the USA, European Union, as well as the emerging markets of Asia Pacific, Latin America, and Central and Eastern Europe. This includes regulatory support of: new chemical entity development, clinical trials, marketed products, generics, OTC products, medical devices, as well as regulatory activities related to mergers and acquisitions.

Keywords: Good manufacturing practices, Pharmaceutical regulatory compliance, Food and drug administration, Marketing authorization.

Introduction

Developing a new drug is a complex process that involves extensive research, testing, and regulatory approvals. The drug development and approval process is governed by several regulatory bodies, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). These regulatory agencies ensure that drugs are safe and effective for human use. In this article, we will discuss the regulatory considerations for drug development and approval [1].

Preclinical development

The preclinical development stage is the first step in the drug development process. It involves laboratory testing of the drug in animals to evaluate its safety and effectiveness. The results of these tests are submitted to regulatory agencies as part of the drug approval process.

During preclinical development, the drug must undergo extensive safety testing to determine its potential for toxicity, as well as its pharmacokinetic properties. Pharmacokinetics is the study of how the body processes a drug. This includes how the drug is absorbed, distributed, metabolized, and eliminated by the body. Pharmacokinetic data is critical for determining the appropriate dose and dosing schedule for the drug [2].

Clinical development

Once the drug has passed preclinical testing, it can move on to clinical trials. Clinical trials are conducted in humans to evaluate the safety and efficacy of the drug. Clinical trials are typically divided into three phases:

Phase 1 trials involve a small number of healthy volunteers and are designed to evaluate the safety and pharmacokinetics of the drug [3].

Phase 2 trials involve a larger group of patients with the disease the drug is intended to treat. These trials are designed to evaluate the efficacy of the drug and determine the appropriate dose.

Phase 3 trials involve a larger group of patients and are designed to confirm the safety and efficacy of the drug.

The results of clinical trials are submitted to regulatory agencies as part of the drug approval process. Regulatory agencies evaluate the data to determine if the drug is safe and effective for human use [4].

Once a drug has completed clinical trials, it can be submitted for regulatory approval. The approval process can take several years and involves extensive review by regulatory agencies.

Regulatory approval

In the United States, the FDA is responsible for approving drugs for human use. The FDA reviews the data from preclinical and clinical trials to determine if the drug is safe and effective. If the drug is approved, the FDA will issue a New Drug Application (NDA) or a Biologics License Application (BLA) depending on the type of drug.

In the European Union, the EMA is responsible for approving drugs for human use. The EMA also reviews the data from preclinical and clinical trials to determine if the drug is safe and effective. If the drug is approved, the EMA will issue a Marketing Authorization (MA) [5].

*Correspondence to: Jacques McCarthy, Department of Pharmaceutical Sciences, University of Perugia, Perugia, Italy, E-mail: mccarthy@jacques.it

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Post-marketing surveillance

Once a drug has been approved for human use, it is subject to post-marketing surveillance. Post-marketing surveillance is the process of monitoring the safety and efficacy of a drug after it has been approved for use. This includes monitoring for adverse events and conducting additional studies if necessary.

Conclusion

Drug development and approval is a complex process that involves extensive research, testing, and regulatory approvals. The regulatory considerations for drug development and approval are critical to ensuring that drugs are safe and effective for human use. Preclinical development, clinical development, regulatory approval, and post-marketing surveillance are all important stages in the drug development process. It is essential to follow the guidelines set forth by regulatory agencies to ensure that drugs are safe and effective for human use.

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