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REVIEW

Historical incidents leading to the evolution of good manufacturing practice

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Abstract The concept of good manufacturing practice (GMP) is not new; its roots are very old. The incidents that gave birth to the concept of GMP are summarized in this article. The journey from the FDA toward GMP is highlighted in chronological order. These regulations are mandatory for pharmaceutical industries in order to manufacture quality products.

Keywords GMP · FDA · WHO

Introduction

Good manufacturing practice (GMP) refers to an international set of regulations devised for implementation in the drug/pharmaceutical industries to assure the quality, effectiveness, and safety of drugs/pharmaceutical products. It is a matter of building in quality rather than testing quality. It is a system devised to ensure 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 by testing the final product. The main risks include unexpected contamination of products causing damage to health or even leading to death, incorrect labeling that could lead to patients' receiving the wrong medicine, and, last but not least, insufficient or excess active ingredient that contributes to ineffective treatment and adverse effects [1–8].

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GMP requirements

The objectives of GMP are to guarantee quality and patient protection. This should mean that a product of assured quality, purity, potency, and safety is produced. The manufacturer will also have a permanent record, indicating that every product has passed through a similar protocol without taking any aspect for granted [2, 3, 6, 8].

The elements that encompass GMP are: a quality-management system, personnel (qualified, trained, and supervised), premises and equipment (location, design, construction, and maintenance), documentation (complete history of each batch and standard operating procedures for each activity), production (manufacturing operations), quality control (sampling, specifications, testing, release procedures), contract manufacture and analysis (agreed and controlled), complaints and product recall (complaints must be reviewed and documented), and self inspection (conducted in order to monitor implementation of and compliance with the principles of GMP) [2, 3, 6–8].

History

From the very beginning of civilization people have been concerned about the quality and safety of food and medicine. In 1202, King John of England proclaimed the first English food law, the Assize of Bread, which prohibited adulteration of bread with ingredients such as ground peas or beans [9].

The Biological Control Act (1902), first introduced in the USA (for regulation of biological products) was introduced after more than a dozen children died from a diphtheria antitoxin that was contaminated with live tetanus bacilli. This act demanded testing of products for purity and strength, and inspections of manufacturers and sellers of biological products [10].

The original Food and Drug Act launched in 1906 made it illegal to sell contaminated (adulterated) food or meat and demanded truthful labeling [11]. The US Pharmacopoeia and National Formulary was recognized in the same year as setting official standards for the strength, quality, and purity of drugs. The law included provisions against "misbranding". A drug was considered misbranded [12] if it contained alcohol, morphine, opium, cocaine, or any of several other potentially dangerous or addictive drugs or if its label failed to indicate the quantity or proportion of such drugs. The law pertained only to labeling, not to advertising [13–15].

After the introduction of sulfa drugs in 1935, a well established pharmaceutical company Massengill included diethylene glycol (a poisonous solvent) as constituent in the oral elixir of sulfanilamide, leading to death of 107 people, many of them children. In 1938, The Food, Drug, and Cosmetic Act insisted companies prove their products were safe before marketing them, in order to extend control to cosmetics and therapeutic devices, providing that safe tolerances be set for unavoidable poisonous substances and authorizing standards of identity, quality, and fill of container for foods [16].

In 1941, nearly 300 people died after taking sulfathiazole tablets contaminated with phenobarbital, manufactured by Winthrop Chemical Company, New York. The FDA's investigation into Winthrop's sulfathiazole production revealed manufacturing deficiencies in the plant and serious irregularities in the firm's attempt to recall the contaminated tablets. This incident prompted the FDA to revise manufacturing and quality-control requirements throughout the industry, an approach that became the basis for production control standards for all pharmaceuticals leading to what would later be called GMP [17]. The phrase "Good Manufacturing Practice" first appeared officially in the 1962 amendment to the US Food, Drug and Cosmetic Act [18–20].

The first draft of World Health Organization (WHO) on GMP was prepared at the request of the twentieth World Health Assembly in 1967 by a group of consultants. It was subsequently submitted and accepted by the twenty-first World Health Assembly under the title "Draft requirements for good manufacturing practice in the manufacture and quality control of drugs and pharmaceutical specialties". The text was further reproduced with some revisions in 1968 by a WHO expert committee and then in 1971 in the second edition of the International Pharmacopoeia [21].

Enforcement of legislation to ensure the quality of drugs is, by itself, not sufficient. It is really the responsibility of the manufacturer to ensure that quality products are marketed. While good control is required to assure the quality of pharmaceutical products, it must be realized that the ultimate aim of quality control is attainment of perfection in the manufacturing process. Quality control is to assure the professional user or ultimate consumer that every batch of a product conforms to quality standards, fulfils the label claim, and meets all legal requirements. Quality control alone, despite essentially encompassing all scientific checks, is not sufficient to achieve all the aims, though indisputably it is a vital function. There must also be a total dedication to building quality and reliability into every product. This dedication is best reflected by the adoption of GMP [1–8].

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