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Evolution of quality assurance in pharmaceutical industry

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Abstract

It is brief review of History of Quality control, Timeline of evolution of quality assurance in pharmacy field, GMP guidelines and current trends. Quality assurance is a term used in systematic process of determining whether a product or service meets specified requirements. Quality assurance also involves establishing and maintaining quality management systems to continually improve processes and prevent defects or deviations. Overall, a Quality assurance plays a critical role in safeguarding public health and maintaining the integrity. The main functions are to provide consumer satisfaction. This article reviews the evolution of quality assurance practices within the pharmaceutical sector, tracing the historical development of quality control measures and examining the pivotal shift towards TQM methodologies. Quality management of pharmaceutical products was started with production premises based on the principle of Good Manufacturing Practices (GMP) and Food and Drug Administration (FDA) regulating bodies. And this aspect includes the quality, efficacy and safety of pharmaceuticals, including the sources like (impurities- residual solvents and various inorganic and organic impurities in pharmaceuticals.).And these Quality controls has policy to control many critical points starting from raw materials, in - process check, equipment, production, packaging material, packing of finished goods till dispatch. Key aspects such as regulatory compliance, technological advancements, and cultural shifts within organizations are analyzed to understand the driving forces behind this evolution. Insights from case studies and industry trends provide valuable perspectives on the current landscape of quality assurance in the pharmaceutical industry, offering practical recommendations for optimizing quality processes and ensuring product integrity and patient safety.

Keywords: Quality control; Quality assurance; Total quality management; Good manufacturing practices; Food and drug administration

1. Introduction

Quality assurance in pharmaceutical industry has come a long way. From days when drugs were compounded in the dispensary by pharmacist with no provision to assure the quality of the end product, to current day, with provisions of inprocess inspection, digital records and automations in drug testing, efficient supply chains, stringent etc. This article aims to outline the important events in this leap, from medieval era to now and further rules and inspections into the future.

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2. History of quality

Quality has been defined as fitness for use, conformance to requirements, and the pursuit of excellence. Even though the concept of quality has existed from early times, the study and definition of quality have been given prominence only in the last century[1].

2.1. 1920s

- Some of the first seeds of quality management were planted as the principles of scientific management through U.S. industry.
- Businesses clearly separated the processes of planning and carrying out the plan, and union opposition arose as workers were deprived of a voice in the conditions and functions of their work.
- The Hawthorne experiments in the late 1920s showed how worker productivity could be impacted by participation.

2.2. 1930s

- Walter Shewhart developed the methods for statistical analysis and control of quality

2.3. 1950s

- W. Edwards Deming taught methods for statistical analysis and control of quality to Japanese engineers and executives. This can be considered the origin of TQM.
- Joseph M. Juran taught the concepts of controlling quality and managerial breakthrough.
- Armand V. Feigenbaum's book *Total Quality Control*, a forerunner for the present understanding of TQM, was published.
- Philip B. Crosby's promotion of zero defects paved the way for quality improvement in many companies

2.4. 1968

- The Japanese named their approach to total quality "companywide quality control." It is around this time that the term quality management system arises.
- Kaoru Ishikawa's synthesis of the philosophy contributed to Japan's ascendancy as a quality leader[1].

2.5. 2004

- There has been a growing awareness for the significances of the quality of the pharmceuticl product.
- Many articles were written to demonstrate the special nature of the product –customer relationship of medicine[12]

2.6. Today

- TQS is the name for the philosophy of a broad and systemic approach to managing organizational quality.
- Quality standards such as the ISO 9000 series and quality award programs such as the Deming Prize and the Malcolm Baldrige National Quality Award specify principles and processes Quality that comprise TQM.
- TQM as a term to describe an organization's quality policy and procedure has fallen out of favor as international standards for quality management have been developed. Please see our series of pages on quality management systems for more information [1].

3. Timeline of evolution of in pharmacy quality assurance field

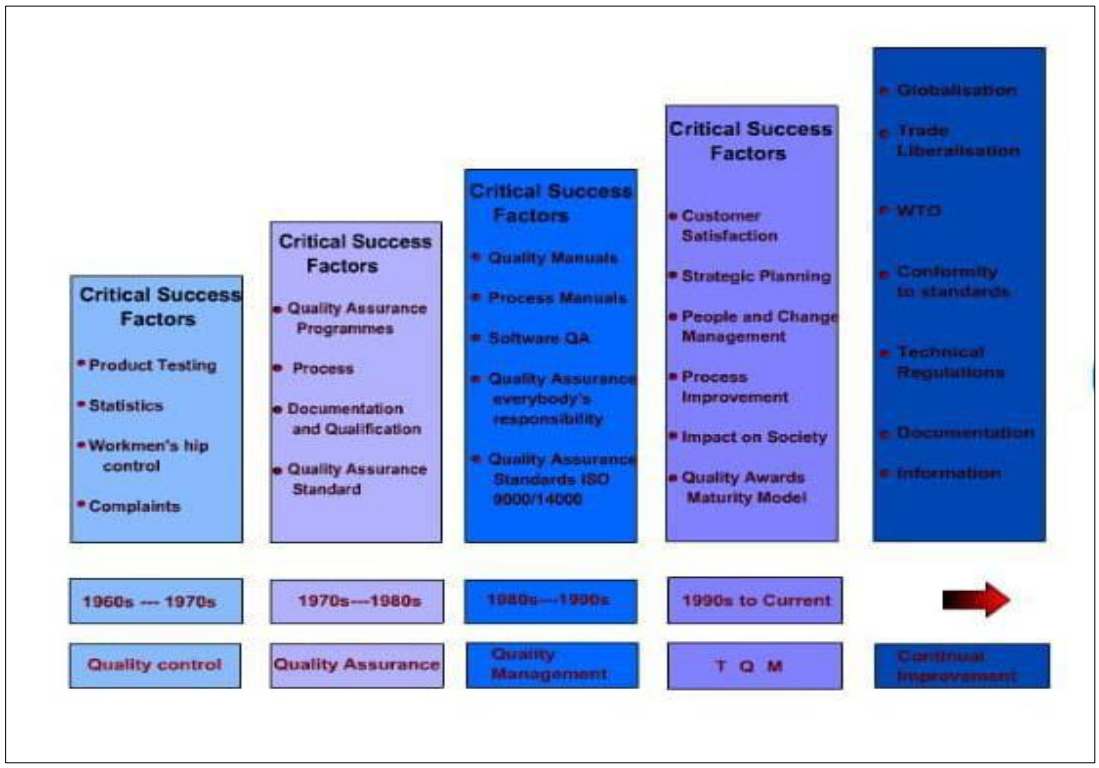

Figure 1 The evolution and scope of quality control and quality assurance[13]

3.1. The early days

The concept of QA in pharma dates back to when pharmacists would visually inspect and test product concoctions [2]. This era was characterized by a lack of standardized processes and guidelines, where the emphasis was on individual skill and integrity. The 19th and early 20th centuries saw the rise inspection [2].

3.2. The 20th century

This was the time when quality standards in pharmacy made a breakthrough with the introduction of quality and safety guidelines, quality standards being introduced in various national and international pharmacopeias, adoption of GMPs by majority countries etc.

3.2.1. The International Pharmacopoeia, Second Edition

The second edition of International pharmacopeia in the year 1967 incorporated specifications for the Quality Control of Pharmaceutical Preparations [3]. Owing to the development of new analytical techniques such as infrared spectroscopy, chromatography (column, paper and thin-layer), non-aqueous titration and radioactivity, the Second Edition incorporated numerous alterations and constituted a revision of the First Edition [3]. The selection of monographs and appendices was based largely on the availability, at the time of preparation, of specifications intended for publication in national pharmacopoeias and in other volumes of specifications for pharmaceutical quality control [3]. Specifications for 162 pharmaceutical preparations not included in the First Edition were introduced in the Second Edition, while 114 monographs were deleted, based on feedback from the First Edition [3]. New analytical methods were also added [3]. The specifications and methods in the monographs were tested in a number of national pharmacopoeial and pharmaceutical quality control laboratories, in pharmaceutical manufacturers' laboratories and at various pharmacopoeial institutes [3].

3.2.2. GMP guidelines

GMPs by WHO

The first WHO draft text on GMP was adopted in 1968 [4]. 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 [4]. A supplementary annex on biological medicinal products was adopted by the Expert Committee on Biological Standardization (ECBS) in 1991 and established 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 [4].

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 [4]. The WHO GMP continues to be used as a basis for the WHO Certification Scheme and prequalification of vaccines for procurement by UN agencies [4].

GMPs by FDA

The 1960s Thalidomide was marketed in Europe as a sleeping pill and to treat morning sickness [5]. When regulatory agencies gave permission to sell the drug for that indication, they had no knowledge of its serious side effects [5]. It turned out to be teratogenic [5]. It caused serious deformities in developing fetuses [5]. Children whose mothers took thalidomide in the first trimester were born with severely deformed arms and legs. An estimated 10,000 cases of infant deformities in Europe were linked to thalidomide use. The product was not allowed on the market in the United States [5]. The drug reviewer responsible for the thalidomide application in the United States was Frances Kelsey [5]. In 1962 President Kennedy awarded her the President's Distinguished Federal Civilian Service Award, the highest honor a government employee may earn as a civilian [5]. Thalidomide galvanized public opinion [5]. Two legislators, Kefauver and Harris, pushed more stringent legislation through Congress that required companies to test not only to ensure that products were safe, but that they were efficacious for their intended uses [5]. Regulating clinical trials, the amendments required drugs to be tested in animals before people [5]. They made investigators responsible for supervising drugs under study [5]. Manufacturers were expected to inform participants if a drug was being used for investigational purposes and to obtain their consent before testing it on them. Drugs had to be shown to work before going on the market [5]. Manufacturers were required to report unexpected harm (adverse events). FDA was given authority to regulate advertising of prescription drugs [5]. And in 1963, the first GMPs for finished pharmaceuticals were made final [5]. In 1969, FDA established CGMPs in the Code of Federal Regulations (CFR) (21 CFR Part 110) [5].

3.2.3. ISO 9000 and 14000-

In 1987, ISO published its first quality management standard. Standards in the ISO 9000 family have gone on to become some of the most well-known and bestselling standards [6].

In 1996, ISO launched its environmental management system standard, ISO 14001 [6]. The standard provides tools for companies and organizations to help them identify and control their environmental impact [6].

3.2.4. ICH Guidelines

Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development [7]. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner [7]. Harmonisation is achieved through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts working side-by-side [7]. Key to the success of this process is the commitment of the ICH regulators to implement the final Guidelines [7].

3.3. Current trends

3.3.1. Personalized Medicine

Pharmaceutical manufacturers will work hand-in-hand with physicians to develop a hyper-personalized approach to medicine. This shift in manufacturing will inevitably lead to smaller production runs, forcing manufacturers to develop an agile approach to development [9].

3.3.2. Digitization and Automation

Digitally enabled labs achieve at least 80 percent paperless operations [10]. *They* use advanced real-time data analytics and ongoing process verification to track trends, prevent deviations or out-of-specifications, and optimize scheduling [10].

Finally, automation is another promising pharmaceutical manufacturing trend that organizations will pursue this year [9]. In fact, according to recent studies, robots will soon handle 34% of pharmaceutical packing operations in North America [9]. Moreover, an increasing number of manufacturers are using robotics to assist with drug development, including screening, anti-counterfeiting, and various manufacturing processes [9]

3.3.3. Artificial Intelligence

An increasing number of pharmaceutical manufacturers will utilize powerful artificial intelligence capabilities to enhance research and development in the creation of new drugs [9]. Additionally, artificial intelligence will improve production processes by increasing quality control, reducing human intervention, and eliminating waste [9].

3.3.4. Sustainability

Mounting pressure from international organizations and increased dialogue surrounding localization and environmental responsibility highlight the industry's necessary shift to sustainability [8].QMS strategies aimed towards reducing waste energy, resources and time are the need of the time.

4. Conclusion

Even though pharma industry has achieved the milestone from quality control to total quality management, this is true for only a few developed countries.

It was reported –'deaths of children from acute kidney injury beginning in July 2022 in Gambia, followed by cases in Indonesia and Uzbekistan linked to over-the-counter cough syrups containing either diethylene glycol or ethylene glycol. Citing "unacceptable levels" of toxins in the products, the WHO sought information about the specific raw materials used by six manufacturers in India and Indonesia to produce medicines linked to the deaths' [11]. Such unfortunate incidents show the dark but true reality of quality control of drug products in developing countries. Quality assurance in such places is yet to reach the standards of developed countries and this cannot go on for longer as human lives matter wherever, irrespective of the countries that they belong to.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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