

International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)

Volume 3, Issue 1, January 2023

## Introduction of Quality Control and Quality Assurance

Savita Dattatreya Sonawne<sup>1</sup>, Bais S. K.<sup>2</sup>, Saurabh Bharatnavale<sup>3</sup>

Fabtech College of Pharmacy, Sangola, Solapur, Maharashtra, India saurabhnavale2001@gamil.com

Abstract: This concise overview discusses many international methods for evaluating the concept of geotaxis. Pharmaceutical impurities, include residual solvents and different organic and inorganic impurities. Due to national and international requirements, it is now obligatory to provide information on a specific pharmaceutical product's impurity profile in addition to its purity profile. These characteristics, the importance of the quality, efficacy, and safety of medicines, as well as the origin, types, and regulation of impurities, are discussed. One of the requirements for the delivery of any nation's healthcare system has been highlighted as the availability of critical medicines of high quality, as subpar medications have the potential to hurt or even kill their users. a chemical environment that is undesirable in a specific medicine, Its safety and effectiveness may be affected, even in incredibly little levels. A pharmaceutical is a dynamic product that, unlike products from other industries, can alter between manufacture and final consumption in terms of colour, consistency, weight, and even chemical identification. Therefore, pharmaceutical product quality has been a worry for people all over the world, and regulatory agencies are now paying close attention to it. Pharmaceutical product impurities are a major source of concern due to their potential for detrimental effects on drug stability and shelf life as well as their intrinsic toxicity in some cases. Impurities in pharmaceutical and drug products are undesirable substances (organic, inorganic, and residual solvents) that arise or are added during formulation, or that remain with the active pharmaceutical ingredients (APIs) during storage. Even with sufficient precaution, organic impurities are the most prevalent contaminants discovered in every API and are not included during the multi-step manufacturing process.

Keywords: Quality Control

## REFERENCES

- [1]. ISO 9000:2005, Clause 3.2.11
- [2]. Smith, Larry (2001). "Shift-Left Testing".
- [3]. "Quality Assurance vs Quality Control Learning Resources ASQ".
- [4]. "ASQ Practical Quality Assurance for Embedded Software".
- [5]. "Define, Measure, Analyze, Improve, Control (DMAIC Approach) ASQ".
- [6]. The Marketing Accountability Standards Board (MASB) endorses this definition as part of its ongoing Common Language in Marketing Project.
- [7]. "Quality Assurance vs Quality Control: Definitions & Differences | ASQ". Asq.org. Retrieved 2020-11-21.
- [8]. Stebbing, L. (1993). Quality Assurance: The Route to Efficiency and Competitiveness (3<sup>rd</sup> ed.). Prentice Hall. P. 300. ISBN 978-0-13-334559-9.
- [9]. Prause, Christian; Bibus, Markus; Dietrich, Carsten; Jobi, Wolfgang (2016). "Software Product Assurance at the German Space Agency". Journal of Software: Evolution and Process. 28 (9): 744–761. Doi:10.1002/smr.1779. S2CID 13230066.
- [10]. Garvin, D.A. (15 October 1984). "What Does "Product Quality" Really Mean?". MIT Sloan Management Review. Massachusetts Institute of Technology. Retrieved 29 November 2017.
- [11]. V^ISO 9000:2005, Clause 3.2.10
- [12]. ft, L.S. (1997). "Chapter 1: Introduction". Fundamentals of Industrial Quality Control. CRC Press. Pp. 1–17.

Copyright to IJARSCT www.ijarsct.co.in

## IJARSCT



International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)

## Volume 3, Issue 1, January 2023

- [13]. Dennis Adsit (9 November 2007). "What the Call Center Industry Can Learn from Manufacturing: Part I" (PDF). National Association of Call Centers. Archived from the original (PDF) on 4 July 2017. Retrieved 21 December 2012.
- [14]. Dennis Adsit (23 November 2007). "What the Call Center Industry Can Learn from Manufacturing: Part II" (PDF). National Association of Call Centers. Archived (PDF) from the original on 9 October 2022. Retrieved 21 December 2012.
- [15]. The Difference Between Quality Assurance vs. Quality Control By Newcastle Systems, on Tue, Nov 06, 2018
- [16]. International Journal of Creative Research Thoughts (IJCRT) www.ijcrt.org
- [17]. Quality assurance book niraliprakashanR. Kashi , bendu
- [18]. Importance and Advantages of Quality Control System
- [19]. https://accountlearning.com > importance-and-advantag...
- [20]. https://www.apexuniversity.co.in/LMS/2020/09/04/role-of-qa-and-gmp-in-pharmaindustry/#:~:text=In%20the%20pharmaceutical%20industry%2C%20quality,its%20research%2C%20develo pment%20and%20manufacturing21
- [21]. https://nscpolteksby.ac.id/ebook/files/Ebook/Hospitality/Production%20and%20Operations%20Management %20(2008)/7.%20Chapter%206%20-%20QUALITY%20CONTROL.pdf
- [22]. Quality Assurance and Quality Control (QA/QC) Kay Abel (Australia) and Michael Gillenwater (USA) AUTHOR OF BACKGROUND PAPER Joe Mangino (USA) Page no 8.16-8.21
- [23]. United States Pharmacopeia 29-National Formulary 24, United States Pharmacopeial Convention, (2006).
- [24]. Guidelines on General Principles of Process Validation, Food and Drug Administration, Maryland, 1984, 4-25.
- [25]. WHO Tech. Report Series 823, Geneva, 1992.
- [26]. Mukherjee, S.K., The Eastern Pharmacist., (1990), XXXIII, (396), 17-21.
- [27]. Kiffer, R.G., J.Pharm. Sci. Tech., (1995), 44, (5), 249.
- [28]. Guidelines on General Principles of Process Validation