IJARSCT



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

Volume 3, Issue 1, February 2023

Q. A. and Q. C. Documentation and Regulatory Authorities of Indian Pharmaceutical

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Abstract: The notion of documentation is significantly more important in the pharmaceutical sector, as it helps to comprehend product quality standards, safety requirements, etc. In a nutshell, the document communicates the finished result. There are several guidelines, including GLP, GMP, and cGMP, to preserve product quality. The industry's Q.A. and Q.C. departments inspect and guarantee that the final Bach product meets criteria. Even though ICH is a reputable institution, it does not maintain global harmonisation. I attempted to introduce some of the documentation needed for such a body that should be kept on file by the maker organisation for emergency situations in this review piece. Additionally, the idea of IPQC (In Process Quality Control) verifies that quality is maintained throughout the production process, from the raw materials to the finished product. Several regulatory organisations that create and uphold the professionalism of our pharmacy profession were introduced in this article. Various papers, including BMR, MFR, SOPs, a quality audit plan, and reports are included in this article. Common Technical Document and Electronic Common Technical Documentation submission materials for regulators were examined. The discovery and development of drugs, the introduction of clinical trials, investigational new drug applications, new drug applications, the SUPAC approach, and the many stages involved in product registration to the CDSCO and USFDA are also crucial.

Keywords: Documentation

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 DOI: 10.48175/568
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IJARSCT



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

Volume 3, Issue 1, February 2023

DOI: 10.48175/568

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