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## Good Manufacturing Practices: The Gap within

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Good manufacturing practice (GMP) is a standard system which ensures that products are consistently produced and controlled according to quality standards as per FDA. GMP is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing of final product. The main risks involved are contamination of products which may lead to death, incorrect labels on containers. GMP covers all aspects of production; from the starting materials, raw materials, premises, surroundings and equipment to the training and personal hygiene of staff. Many countries have formulated their own requirements for GMP based on WHO GMP. GAMP is Good Automated Manufacturing Product and the first meeting was conducted in UK, it is basically the guide for validation of automated systems for pharmaceutical manufacturing and has been published since 1995. It originally means advising suppliers of pharmaceutical manufacturing equipment what was needed in terms of their compliance. GAMP focussed on increased efficiency and productivity. GAMP has helped individual to understand the requirements of prospective validation and suppliers ensure that systems are developed according to good system and ensures that it works. The cGMP regulations for drugs are those containing minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product and other drug material. FDA inspectors determine whether the company has the necessary facilities, well equipped instruments and skills to manufacture the new drug for which it has applied for approval to FDA. Decisions regarding compliance with cGMP regulations are based upon inspection of the facilities, sample analyses, and compliance history of the firm. GCP is defined as a standard for the design, conduct, performance, and monitoring, auditing, recording, analysis and reporting of clinical trials or studies. GCP compliance provides public assurance that the rights, safety, liberty and well-being of human subjects involved in research are protected. The aim of GCP is to protect the rights of human beings, welfare of the individuals (patients) participating in the research work and to comply with the standards of the clinical research as per guidelines. Some of the ethical foundations of clinical research are: 1) Nuremberg code; 2) Declaration of Helsinki etc. The objective of this ICH GCP guidance is to provide a standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. The goal of an audit is to express an opinion on the person, organization, system, management etc. in question, under evaluation based on work done on a test basis. Any pharmaceutical company that makes medications today must be able to prove that it does so with absolute reliability, under optimal secure conditions, and with extreme uniformity and according to standards to allow for exact reproduction of the medications. Pharmaceutical auditing expertise includes writing and review of validation policies, guidelines and Standard Operating Procedures (SOP) from installation qualification to operation qualification, design qualification to performance qualification.

## Biography

The author is research fellow at Masters of Pharmacy from NDMVPs College of Pharmacy (Govt. College). The author has 4 review and 1 research articles credit to her account. She is an Active student member of Indian Pharmaceutical Association (IPA), Mumbai working as Student and Media Press Co-ordinator of Placement Cell under Pune University. Bagged first prize at National Pharmacy Week conducted under Pune University for Industrial Problem Solving Competition.

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