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Good Automated Manufacturing Practices: A master control process for manufacturing in pharmaceutical industry

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GAMP is largely about automated system validation. Its main objective is to achieve good compliance by building upon existing industrial good manufacturing practices in an effective and efficient manner. Good Automated Manufacturing Practices (GAMP) is both a technical subcommittee of the International Society for Pharmaceutical Engineering (ISPE) and a set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry. The core principle of GAMP is that "quality cannot be tested into a batch of product but must be built into each stage of the manufacturing process". As a result, GAMP covers all aspects of production starting from processing of the raw materials, facility and equipment to training and hygiene of personnel. In October 2014, Irish tech company Data works Ltd. described it as such. It is a formal process of thorough testing, logical, and documentation process steps that validate clients' required specifications. The process begins with a user requirements specification for the machine, from which a functional requirement and a design specification are created. These documents then form the basis for the traceability matrix and for the formal testing of internal acceptance, factory acceptance, site acceptance, operational & performance acceptance. Categorizing software is used to support the approach to validation based on the difficulty and individuality of the computerized system. It also includes duplication of activities (e.g. by fully integrating engineering and computer system activities so that they are performed only once). GAMP practice guide include in Validation of R & D Systems, Quality Risk of Equipment & Product, etc.

Biography

Swapneel H. Bagal has completed his Bachelor in Pharmacy at the age of 22 years from Hon. Shri Babanrao Pachpute Vichardhara Trust's Group of Institutions College of Pharmacy and currently pursuing Master in Pharmacy in the same Institute. He has published more than 10 papers in reputed journals and has been serving as a lifetime membership of Association of Pharmaceutical Teachers in India (APTI)..

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Page 107