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Good manufacturing practice (GMP): An overview

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Good Manufacturing Practice (GMP) is a set of regulations, codes, and guidelines for the manufacture of drug substances and drug products, medical devices, *in vivo* and *in vitro* diagnostic products, and foods. The term GMP is recognized worldwide for the control and management of manufacturing and quality control testing of pharmaceutical products. GMPs is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing Authorization or product specification. GMP is concerned with both production and quality control. Both industry and regulatory practices will need to be informed by the best techniques of risk assessment and management. "Pharmaceutical cGMPs for the 21st Century" is intended to jump-start progress into this future. The last few years has seen the FDA steer industry further in the direction of a Quality-by-Design (QbD) approach, and away from the Quality-by-Testing (QbT) approach traditionally taken by the pharmaceuticals sector. This move has largely been lauded by business as a sensible move likely to ensure consistent quality of the end product. Quality objective can be achieved only through careful planning and implementation of QA system and practical implementation of GMP. The effective implementation of GMP requires extensive care and knowledge about the different components of GMP that should be incorporated form the inception of the manufacturing building and product development till the production.

Biography

Firoj A Tamboli is pursuing PhD in Pharmacy from Shivaji University, Kolhapur. He is working as Assistant Professor at Bharati Vidyapeeth College of Pharmacy, Kolhapur. He has more than 15 years of teaching and research experience. He has published number of papers in reputed national and international journals and has been Member of APTI.

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