

Understanding facility validation for GMP compliance

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In the past decade, many far-reaching changes have taken place in the application of cGMP regulations relating to the pharmaceutical industry. Continuous quality improvement thus is ingrained in the cGMP concept. The design, construction, commissioning, and validation of pharmaceutical facilities play very important role in the risk mitigation of product Quality and Safety. Among the six GMP systems of US FDA requirements for facility system are particularly important for pharmaceutical companies to understand and implement this GMP requirement therefore constructing new facilities and reconstructing the existing ones both require the compliance with the GMP. Facility qualification (a part of validation that proves and documents that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results), and validation (establishing documented evidence that provides a high degree of assurance that the manufacturing processes, including buildings, systems, and equipment consistently produce the desired results according to predetermined specifications and quality attributes) activities will establish and provide documentary evidence that the facility suitable for the intended use for manufacturing, testing, storage meeting GMP requirements.

Biography

J.Ramniwas has total more than 21 years of experience of working in various Pharmaceutical industries. At present he is the chief executive officer at Sai Pharma Solutions Inc. located at Vadodara, India which is a gateway to the Regulatory Affairs, Quality and cGMP compliance. His experience includes Regulatory Affairs, Analytical Development and Validations, Quality, Establishment of Quality Systems, Regulatory and GMP trainings, Qualifications and Validations of Facilities, Equipments and Utilities, GMP Documentation, Auditing, Regulatory Submissions, Hosting customer and Regulatory Audits, Risk Management and Compliance to Global Regulatory requirements. His articles pertaining to Regulatory Affairs and cGMP compliance issues have been published by many leading pharmaceutical magazines. He is one of the renowned international speaker on GMP and Regulatory Issues.

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Innovations in developments of gastro retentive drug delivery systems

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The oral route is the most promising route of drug delivery. Effective oral drug delivery may depend upon gastric emptying process, GI transit & residence time, drug release from DF and site of absorption of drug. Conventional oral dosage forms possess several physiological limitations like variable gastric emptying, variable GI transit & shorter residence time, incomplete drug release from the DF in stomach. It may lead to incomplete & non uniform absorption of the drugs having absorption window in upper part of GIT as once the DF passes down the absorption site, the remaining quantity goes unabsorbed. Hence, a beneficial DDS would be one which exhibits the ability to control & prolong the gastric emptying time and can deliver drug in maximum conc. at the absorption site (i.e. upper part of the small intestine). Pharma world is focusing towards such drugs which require site specificity. Gastro Retentive Drug Delivery System (GRDDS) is one of the site specific deliveries for the delivery of drugs either in stomach or intestine. This can be obtained by retaining dosage form into stomach and drug is released in controlled manner to specific site either in stomach, duodenum or/and intestine.

Biography

L.D. Patel is presently Director & Professor at C. U. Shah College of Pharmacy & Research, Wadhwan -363030, Dist.: Surendranagar (Gujarat, India). Dr. Patel has passed B.Pharm., M.Pharm. and Ph.D. in Pharmacy from the world reputed L. M. College of Pharmacy, Ahmedabad, Gujarat. He served at L. M. College of Pharmacy as senior faculty and P.G. Guide in Pharmaceutics. Dr. Patel was Founder Principal & Professor of C. U. Shah College of Pharmacy & Research, Wadhwan. Dr. Patel was also Founder Dean & Professor of Faculty of Pharmacy, Dharmsinh Desai University, Nadiad, Gujarat. He is a member of BOG, Academic Advisory Committee, Standing Committee, and BOS of various organizations. He is an expert to AICTE and Pharmacy Council of India. He is recognized Ph.D. guide in Pharmaceutics in various universities. He has more than 100 research publications in national and international journals. His research interest is in the area of Development of Novel Drug Delivery Systems (NDDS), Patent and Trade marks, Computer & Software Statistical Applications, Direct Compression Formulation & Technology, Dissolution Enhancement, Sustained Release Dosage forms and Transdermal Dosage forms, Artificial neural networks (ANNs) and applications, and Nanotechnology applications.

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