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Research and Development in Pharmacy & Life Sciences Abstract

Applications of Quality by Design (QbD) in formulation development

Devendra Ridhurkar
Neurax Pharmaceuticals, Spain

Abstract:

The main objective of pharmaceutical development is to design a quality product and its manufacturing process to consistently deliver the intended performance of the product. Pharmaceutical industry realized that Quality by Design (QbD) principles, when implemented, lead to a successful product development, subsequent prompt regulatory approval, reduce exhaustive validation burden, and significantly reduce postapproval changes and also helps to build a quality in all pharmaceutical products. Hence the application of QbD in pharmaceutical product development is now a thrust area for the regulatory authorities and the pharmaceutical industry. International Conference on Harmonization and United States Food and Drug Administration (USFDA) emphasized the principles and applications of QbD in pharmaceutical development in their guidance for the industry. Target product quality profile, critical quality attributes, risk assessments, design space, control strategy, product lifecycle management, and continual improvement are the key elements of QbD. Throughout designing and development of a product with QbD, it is essential to define desire product performance profile Target product profile (TPP), Target product Quality profile(TPQP) and identify Critical quality attributed (CQA) leads to recognize the impact of raw material,Critical material attributes (CMA), Critical process parameter (CPP), on the CQA's and identification and source of variability.

Biography:

Dr. Ridhurkar works as an Expert Scientist at Neurax Pharm., Barcelona. He is responsible for development of a value-added complex formulations. He has over 13 years of experience and was associated with various reputed pharmaceutical companies like Egis, Hungary, Dr. Reddys, India. He is expert in using platform technologies like hot melt extrusion, nanotechnology, and cyclodextrin complexation. He obtained his M. Pharm, Ph.D. degree in Pharmaceutics from IIT, Varanasi, India. He is a member of editorial board for various pharmaceutical journals and has earned to his credit over 8 peer-reviewed papers in reputed international and national journals and 5 patents to his credit. He has been associated with various pharmaceutical bodies in India and American Association of Pharmaceutical Scientists. He is a member of programme advisory committee for Pharma Connect Congress, Hungary and has attended and delivered seminars and presentations at various national and international conferences.

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