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Quality by design: Generic versus brand drug development, delays in review of drug applications at FDA, regulatory problems and solutions

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Quality by Design (QbD) has brought a great sense and discipline to drug product development, for both branded and generic drug products. One ought to keep the design parameters and scope of QbD in proper perspective while applying it to generic drug development. In quest to circumvent patents protecting brand drug products, generic drug development has taken on a whole different path and in many cases it is getting closer to brand drug formulation development. Some of the generic drug products bear little resemblance to brand drug product formulations. This topic will be discussed with examples. A lack of full appreciation for QbD and making short cuts in the developmental process in order to catch a certain date to submit drug applications often make it difficult for reviewers to process drug applications in a timely manner. Review of a generic drug application, ANDA, should essentially be on "auto-pilot" and should really not take more than 6-9 months of review time. Getting refuse to file (RTF) letters for ANDAs leaves a lot to desire in terms of quality of drug development and documentation. Yet as we all know, many applicants receive RTF letters from the FDA, there is tremendous back log, and the review times are lengthy. It can take as much as 36 months to get an ANDA reviewed and approved. Some key reasons of such back logs and lengthy review times and ways to improve will be discussed. Some common GMP problems will be highlighted and discussed.

Biography

Charan R. Behl completed his B. Pharm (Hons) from BITS, Pilani, India. He received his M.S. in Pharm. Chem. from Duquesne University, Pittsburgh, PA; Ph.D. in Pharm Sciences from the University of Michigan, Ann Arbor, MI followed by three years of post-doctoral research at the same university. He worked for about 14 years at Roche in Nutley, NJ where he worked on difficult to develop drugs via various routes of administration including the oral/enteral, intranasal, topical, and transdermal routes. He worked for about six years at Nastech Pharma in Long Island, NY where he focused on nasal drug product development. He spent about five years at Elite Pharma focusing on drug development in pain management area making narcotics formulations abuse deterred. For the past about four years, he is involved in drug product development via collaborations with different companies and groups. He is working on both generic and branded drug products developing oral controlled release, intranasal, topical, and transdermal products. He has been invited to make presentations at many national and international conferences and has coauthored over 200 scientific articles, chapters, and abstracts. His patent portfolio includes over 30 patents issued, in review, and in preparation. He is a fellow of the American Association of Pharmaceutical Scientists.

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