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ICH Q_{10}: Pharmaceutical quality system

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ICH Q_{10} describes one comprehensive model for an effective pharmaceutical quality system that is based on International Organization for Standardization (ISO) quality concepts, includes applicable good manufacturing practice (GMP) regulations and complements ICH Q_8 "Pharmaceutical Development" and ICH Q9 "Quality Risk Management". It aims to promote a paradigm shift from discrete GMP compliance procedures at each stage of the product life cycle to a comprehensive quality systems approach over the life cycle of the product. It demonstrates industry and regulatory commitment to robust quality systems and technical innovation and enhance assurance of consistent availability of medicines around the world. It's guidance applies to the systems supporting the development and manufacture of pharmaceutical drug substances and drug products, including biotechnology and biological products. The elements of ICH Q10 should be applied in a manner that is appropriate and proportionate to each of the product life cycle stages, recognizing the differences among and the different goals of each stage.

The key objectives are to

- Achieve product realization
- Establish and maintain a state of quality control
- Facilitate continual improvement.

Biography

Sandeep Kanna is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. He has completed his B.Pharm from Narasaraopet Institute of Pharmaceutical Sciences, Narasaraopet, Andhra Pradesh, India during the year 2011. Presently he is pursuing M.Pharm in Pharmaceutics. His present interests are in Novel Drug Delivery Systems and Nanoparticulation.

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Hatch-Waxman act: The law behind generic drugs in US

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The Hatch-Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act, 1984 created a new era in the pharmaceutical industry by laying down consolidated provisions for the approval of less costly bioequivalent generic version of the branded drugs in US. The Federal Food Drugs and Cosmetics Act, 1938 was amended in a significant way through the Hatch–Waxman Act and a streamlined regulatory submission process for the approval of generic drugs known as Abbreviated New Drug Application (ANDA) was introduced. Title I of Hatch-Waxman Act sets forth the contents of ANDA. Under this Act a generic drug manufacturer is allowed to conduct drug testing for the regulatory submission even before the expiry of the innovator's patent. The Hatch–Waxman Act rewards the first generic manufacturer who challenges one or more patents associated with the innovator's product in the form of 180-day market exclusivity. Title II of Hatch-Waxman Act contains provisions for extending the term of pharmaceutical patents to compensate the delays in regulatory approvals of drug products. In 2003, The Medicare Prescription Drug, Improvement and Modernization Act implemented major changes to the Hatch–Waxman Act. Among the most noteworthy changes, the Act provides for new causes of action for the generic applicant, outlines events that trigger the generic applicant's 180-day market exclusivity and restricts branded drug manufacturers to one 30-month stay per product to resolve infringement disputes.

Biography

Mr. Saurabh Sharma is presently pursuing M. Pharmacy in Pharmaceutical Management & Regulatory Affairs branch at Lachoo Memorial College of Science & Technology, Pharmacy Wing, Jodhpur, India