

Regulatory requirements of drug products for human use in EU & Turkey

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A regulatory process is known as drug approval process which allows a person /organization /sponsor /innovator to launch a drug in the market. In general, a drug approval process consisted of various stages: application to conduct clinical trials, conducting clinical trials, application to marketing authorization of drug and post-marketing studies. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate the marketing of the drugs.

The aim of this presentation is to understand European and Turkish regulatory environment including critical regulatory updates of medicinal product for human use. For this purpose, licensing of drug products in EU and Turkey is discussed according to:

1. Types of marketing authorization applications in EU and Turkey (full & abridged applications)
2. Assessing the regulatory requirements (applicants, steps in drug approval process, application format, language in application files)
3. Understanding procedures (centralized, national, mutual recognition & decentralized)
4. Current GMP audit decisions for import drugs in Turkey (effects on marketing authorization process & strategies to overcome these hurdles)
5. General requirements for the Common technical document (CTD) (full & abridged applications)

Biography

Figen Kabadas is a Regulatory Affairs Consultant at Harmonic Pharma, France, with experience in regulatory affairs, R&D, clinical trials and product development phases of human pharmaceutical products to name just a few. She holds an M.Sc. in "In Silico Drug Design" from Paris 7 Diderot - Strasbourg University. She was also involved in studies at Università Degli Studi di Milano in Milan. Besides various pharmaceutical companies, she also worked as regulatory affairs manager & trainer at Academy Anatolia. She's been living in France since 2010 and she's currently doing another master's degree in Regulatory Affairs and Management from IPIL (Institut de Pharmacie Industrielle de Lyon) and EMLYON Management School.

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