CO-ORGANIZED EVENT

International Conference on

Toxicology and Clinical Pharmacology

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Generic Drugs and Biosimilars

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Quality aspects for medical devices, quality system and certification process

Medical devices (MDs) are nowadays more and more important in the healthcare industry and the related processes for worldwide regulation and certification are a topic of great interest. In particular, the need for regulation harmonization between European Countries (European Regulation), as well as worldwide, is very important both for Regulatory Authorities and for the industry world. A typical process for an MD development and industrialization phase is covered, providing some case studies and taking into consideration all steps from design up to start-up of the production phase and process validation. All these activities are necessary for the product certification process. The aspects related to the Quality System, Production, Validation and Quality Control are emphasized, proposing an integrated approach, which combines the GMP and ISO requirements (e.g., ISO 13485 and ISO 14971), following a Quality Risk Management (ICH Q9) and, where applicable, an integrated Pharmaceutical Quality System (ICH Q10) structure.

Biography

Fabio Geremia has completed his graduation in Pharmaceutical Chemistry. He has worked in Italian and multinational pharmaceutical companies, in Quality and Production field. 10 years ago, he has joined CTP System group, the biggest Italian company of pharmaceuticals, healthcare and life science consultancy, now part of the multinational group Akka Technologies, where he is a Senior Consultant and a Qualified Person Auditor and the Technical Responsible for Process and Quality Business Area, Northern Italy. Since many years, he collaborates with the Italian association AFI for medical devices and borderline products, for the preparation of publications and presentations.

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