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How the different GLP/GMP/GCP guidelines interact Comment les différentes directives BPL/BPF/BPC interagissent entre elles

Abstract

Le développement d'un nouveau médicament doit être mené en se conformant aux exigences de différents ensembles de réglementations (BPL, BPF et BPC). Cette présentation mettra en évidence les principales interactions entre ces réglementations et leurs effets sur le processus qui permet de conduire une nouvelle entité chimique jusqu'à sa commercialisation. Des sujets tels que l'organisation du système qualité, les responsabilités de la gestion de la qualité ainsi que le rôle du Service Assurance Qualité seront notamment abordés. De plus, la présentation étudiera comment un contexte différent peut donner une signification légèrement différente à certains mots. La dernière partie de la présentation permettra de décrire comment des concepts du système qualité valides au 21ème siècle ont des effets sur la modernisation de ces directives.

The development of a new drug has to be carried out fulfilling the requirements of different regulations (GLP, GMP and GMP), this presentation is aimed to compare the basic elements, to highlight similarities and differences, to demonstrate that there are important interactions among them for a new chemical entity no the way to become a new commercial pharmaceutical product.

Some of the aspects addressed by the presentations are:

- Comparison

- *The organization : to describe the rules of the responsible persons specifically requested by each regulation*
- *The Quality Assurance Unit (QAU): to deal with the role and responsibilities assigned by the regulations to the Quality Unit*
- *The responsibility for the Quality System management : to illustrate the responsibilities for the quality system management*
- *Change and deviation management: to assess the meaning of "deviation" within each regulation and to estimate the importance of "changes" for the improvement of the quality level within the organization*
- *Managing analytical activities in GLP and GMP compliance : to define what to do and not to do when the analytical activities for GLP samples are carried out in a GMP lab*

- Interactions

- *When and how GLP and GMP should be followed*
 - ❖ *Using GLP analyses for GMP purposes*
 - ❖ *Using GLP material for GMP purposes*
- *When and how GMP and GCP should have interactions*
 - ❖ *Shipping investigational material*
 - ❖ *Accountability of the investigational material*
 - ❖ *Return and destruction*

The last part of the presentation is dedicated to discuss how the ICH 10 (guideline on Pharmaceutical Quality System) could affect the three regulations so that they can be a step ahead of new challenges coming from the very fast changing environment of the pharmaceutical industry.

Biographie / Biography

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Luciano Gambini a débuté sa carrière professionnelle comme chimiste analytique au Laboratoire de Physique Chimie de Farmitalia Carlo Erba (Milan). Depuis 1992, il a occupé différents postes de direction dans le domaine de la Validation et de l'Assurance Qualité. Il a notamment travaillé sur le site européen de R&D de Pharmacia & Upjohn et a contribué à monter un système qualité de niveau mondial, conforme aux normes BPF, appliqué à la fabrication de nouveaux médicaments de recherche. En travaillant dans un contexte mondial, il a acquis une expérience et une mentalité internationales sur les BPF européennes et aussi celles de la FDA. Il travaille actuellement comme consultant sur les BPF.

Luciano Gambini has begun his professional career as analyst in the Physical Chemical Lab of Farmitalia Carlo Erba and moved, after this experience to the Pharmaceutical Controls Lab of the same Company, in charge of life cycle management of anti-cancer drug formulations, playing an important role in the invention of two novel patented formulations.

Since 1992, when he became the head of the Validation Section, L. Gambini has taken care of the validation of the facilities, utilities and equipment of Pharmaceutical Development (Pharmacia & Upjohn) in Nerviano. After this experience, in 2000 he took the role of manager of the Quality Assurance department involved in the preparation of the investigational medicinal products (in Pharmaceutical Sciences and then in Global R&D QA) of Pharmacia R&D Italy. In this position he played a part in the development of Corporate Quality Standards for IMPs in compliance with the new regulations (Annex 13 and EU Directive 2001/20).

He has terminated his professional career as responsible of the Quality Assurance Group in the Business Unit of Pharmaceutical Sciences of Nerviano Medical Sciences, spin off company from Pfizer.

He works currently as a GMP consultant.