

2nd International Summit on **Clinical Pharmacy**

December 02-03, 2014 DoubleTree by Hilton Hotel San Francisco Airport, USA

A unique experience for a Clinical Trials Unit (CTU) of pharmacy: ISO 9001 Certification

Carpenet Helene, Maillan Gaelle and Renon-Carron Francoise
Limoges University Hospital Center, France

For 14 years, the computerization of pharmaceutical management of Clinical Trials and the implementation of a quality system have helped secure the experimental drug use process in Limoges Hospital Center. To further develop “continuous improvement”, the Clinical Trials Unit (CTU) chose to embark on ISO 9001 certification process. This project, initiated in late 2007, has involved the hospital authorities, the CTU staff, the administrative/logistic departments and the cross-functional teams of the pharmacy. Several steps have been necessary: to obtain the management commitment, to appoint a Chief Quality Officer, to train pharmacists to standards, to develop a process mapping, to realize inquiries on “customer needs” (sponsors, investigators), and to define a quality policy. Our unit is the first CTU to be certified in France (certification obtained in October 2010). The scope of certification includes “the planning, the management of biomedical researches and the pharmaceutical production of clinical trial record to the Sponsor”. This certification process allowed to gain external recognition by strengthening the Unit image toward its “customers”, and to identify hot spots during the audits in order to obtain financial and material resources necessary for compliance. In conclusion, this project has brought a valuable dynamic to the team and allowed to anticipate requirements of the April 6, 2011 decree concerning the medication use system quality management. Certification guarantees the CTU expertise, both within our institution and with external customers such as sponsors.

Biography

Helene Carpenet and Gaelle Maillan pursued their PhD in Limoges Hospital Center and graduated in September 2012 and October 2010 respectively. Francoise Renon-Carron is a PhD and Hospital practitioner, Head of the CTU of the Pharmacy since 1992 (and managed over 1400 clinical trials), member of various committees such as Department of Clinical Research and Innovation, Technical Committee of the Clinical Investigation Center Limoges, Clinical Trial working group for the hospital french pharmacists' congress. They have participated in the publication of an article on CTU ISO 9001 Certification in a reputed french journal “Le pharmacien hospitalier et clinicien” and in the redaction of several publications and posters.

Helene.Carpenet@chu-limoges.fr