

4<sup>th</sup> International Summit on

# GMP, GCP & Quality Control

October 26-28, 2015 Hyderabad, India

## Good Clinical Practice (GCP) and declaration of helsinki

**Pooja Roy**

Vydehi Institute of Medical Sciences and Research Centre, India

The concept of 'good physician' is evident by the Hippocratic Oath (460 BC). In the United States, the first landmark in the regulation of drugs was the Food and Drugs Act of 1906. In 1947, the Nuremberg Code was created as a result of the unethical and horrific experiments carried out during World War II at Nazi war camps by German physicians. However, since 1964, the Declaration of Helsinki has stood as one of the world's most authoritative statements on ethical standards for human research. The Declaration has undergone six major revisions, most recently in October, 2008. For many years the USFDA has required that foreign clinical studies supporting applications for drug licensure comply with the Declaration. However, on Oct 27, 2008, the FDA formally discontinued its reliance on the Declaration and substituted the International Conference on Harmonization's Guideline for Good Clinical Practice (GCP). Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design, conduct, performance, and monitoring, auditing, recording, analyses and reporting of clinical trials. GCP provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are respected and protected. However, several authors have criticized GCP and compared between GCP and the Declaration of Helsinki from time to time. It has been put forward that at a time when the volume of overseas trials is increasing, the FDA's new policy is troubling. Several requirements in latest revision of Declaration of Helsinki have been highlighted which are absent in GCP.

### Biography

Pooja Roy completed her MBBS from Dr. B R Ambedkar Medical College, Bangalore and her MD in Pharmacology from Vydehi Institute of Medical Sciences, Bangalore. Currently she is working as an Assistant Professor in Bangalore. She takes active interest in all spheres of the subject and is actively involved in teaching medical students and has several oral papers and poster presentations to her credit.

[docpooja2001@rediffmail.com](mailto:docpooja2001@rediffmail.com)

Notes: