PHARMADVICES

Thorough knowledge on good research practices is of paramount importance

Insufficient knowledge of the rules on good research practices is a threat for the safety of patients / volunteers participating in clinical trials and the quality of the data. Applying these rules, preferable in combination with some of the general principles of quality management to the drug development process can diminish or avoid these insufficiencies.

Thorough training of all professionals involved in the conduct of clinical trials

During the last decades the number (inter)national rules and laws increased rapidly. The worldwide introduction of ICH-GCP (1996) was a major step forwards. It was incorporated in national laws (1997: in the Netherlands). Additional, more detailed, regulations and laws followed *e.g.* the WMO in the Netherlands (1999; revised in 2006). More recently a second major piece of regulation became official, when the European Union issued several Directives on clinical trials (2000) and GCP (2005).
Although the picture of rules and regulations is now virtually complete, the awareness among (academic) researchers is in many cases not yet optimal.
Marketing authorization authorities require now a days that studies with investigational new drugs are being performed strictly in line with GCP.
Since 2005 the joint editors of the major medical journals only accept manuscripts on studies performed strictly according to GCP.
So, selling a new medicine and publishing data of clinical trials is now virtually impossible without GCP-adherence, which requires thorough training.

Necessity of thorough training of all professionals involved in the conduct of clinical trials was acknowledged in an early stage by the University of Groningen by creating a chair in "Quality Management in Drug Research and Manufacturing" (1995). Since then Ph. D.- students of this university and those of the Utrecht University systematically follow a 7-day course in Good Research Practices. The course is being organized by Professor JanHasker G. Jonkman under the auspices of the GUIDE-institute. It results in a GCP-certificate.
Prof. Jonkman very much advocates an (inter-)national system of training and examination leading to a standardized and officially recognized GCP-certificate, and recently also took initiatives to this aim.
Since 2006 the course is also open to other professionals involved in drug development who want to upgrade their knowledge on this subject. The next course (the "12-th International Masterclass on Good Research Practices: GCP/GLP") will be held in May 2006. Faculty are a number of distinguished experts from university, government (GCP- and GLP-inspectors; CCMO), industry and CRO's.
The course is being organized in a close cooperation between GUIDE and PharmAdvices.

PharmAdvices is a drug development consultancy company founded in 2005 by Professor Jonkman, an experienced (bio-) medical and pharmaceutical scientist.
During the past 30 years he performed / supervised over 1,000 Phase I and Phase II clinical studies and 1,250 bio-analytical projects both in academia (University of Groningen, the Netherlands; University of Uppsala, Sweden; University of California, San Francisco, USA) and in the governmental environment (Food and Drug Administration, Washington D.C, USA; GCP-Inspection, The Hague, the Netherlands). He also performed research in the CRO-environment. He was founder and was executive director of the independent contract research organisation Pharma Bio-Research (Zuidlaren, the Netherlands) and director at PAREXEL(Berlin, Germany), working in close cooperation with pharmaceutical companies.
Apart from the systematic training of research staff by organizing the masterclass, Prof. Jonkman also wants to transfer his knowledge and experience to the young generation of (bio-)medical researchers by consultancy on an *individual* basis.

His extensive business experience both in setting up new companies as well as managing medium sized commercial organizations proved to be very helpful.
He acts as an individual consultant for all parties in the whole spectrum of the drug development process: the innovating company (often a start-up biotech), the venture capitalist (often not aware of details of benefit and risks of the process) and the authorities. ■

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