CURRICULUM VITAE Renald Hennig, M.D., MBA

Professional Experience

Sep 2007 – present

Senior Consultant / Managing Director SCRATCH Pharmacovigilance GmbH

Providing sustainable, effective, and value creating consulting and service in all areas of Pharmacovigilance

« To err is human, to cover up is unforgivable, and to fail to learn is inexcusable. »
Sir Liam Donaldson

Current activities: PV consultancy; Qualified Person for Pharmacovigilance; generating and maintaining a Detailed Description of the PV System (DDPS); setting up and maintaining a SOP system; creation / review of periodic reports (e.g. PSURs); review of safety related documents, including case reports; labelling activities; response to regulatory requests; PV audits; PV due diligence; preparation of regulatory inspections; PV training, including risk case studies; creation / review of Risk Management Plans (RMPs); chairing of drug safety monitoring board.

May 1998 – Aug 2007

Executive Director Pharmacovigilance Novartis Vaccines
(formerly Chiron Vaccines)

Major responsibilities: Ensure reliable international Pharmacovigilance (pre- and postauthorisation) by collecting and assessing all reported drug risks; complete all regulatory, including reporting, requirements related to this task; coordinate measures necessary to avert drug risks, including responsibility for Risk Management Plans.
Fulfil all responsibilities of Qualified Person for Pharmacovigilance.
Manage and develop global Pharmacovigilance team (headcount total 27), incl. cost center responsibility.
Ensure that Novartis Vaccines products are safe for the patient.

Major achievements: Integration of Italian PV group (formerly Biocine; 98) and U.K. group (formerly PowderJect; 03)
Database migration from in-house developed software to Argus Safety (99); incl. upgrades and MedDRA implementation since then
Initiation and successful implementation of necessary international recalls (e.g. Encepur; 99)
Passing of audits, both internal and external (e.g. FDA April 06; Paul-Ehrlich-Institut July 07)
Creation of Risk Management Plans (e.g. Flu Cell Culture vaccine application; June 06)

Earlier professional experience in marketing, training, and nuclear medicine.