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PV requirements in non ICH regions

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PV requirements in the ICH region are well established and implemented. However, in countries that do not belong to these regions, the PV regulations are not as well formulated. However the legal requirement for MAHs to perform PV activities exists. Compliance to these requirements by MAHs is considerably complicated by the fact that these countries do not have the necessary infrastructure to support PV activities imposed upon MAHs by these regulations. This presentation focuses on the PV requirements of some of these regions with special focus on non EU Europe, Central America and South East Asia.

Biography

Shoba Rajagopal has done her MBBS from Trichur Medical College and MD in Anaesthesiology. Currently she is working as head pharmacovigilance & medical affairs at Norwich Clinical Services, Bangalore. Previously she worked as Head biostudies at Lotus Labs Pvt. Ltd. and was in-charge of all clinical studies in the 350 bedded CRO. She was Principal investigator in several BA/BE, phase 1 and 2 studies. She is founder member of Bangalore's first Independent Ethics committee. She is member of the Data Safety Monitoring Board of 2 phase 1 vaccine trials.

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