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Peggy J Berry

Synergy Consulting LLC, USA

Good clinical practices

Good clinical practices continue to be a major focus of Regulatory Agencies to ensure the consistency and reliability of data and the protection of human subjects. This presentation will review specific GCP requirements for sponsors, investigators, and IRBs. Providing practical guidance and successful implementation strategies, as well as oversight strategies for vendors, contractors, and clinical study sites. We will also examine evolving practices in GCPs, including electronic case report forms, patient diaries, and consent forms, risk-based monitoring, and effective project management. Examples and case studies will provide scenario-based learning for monitors, auditors and other study management personnel. Suggestions for effectively training and managing monitors, investigators and study staff will also be provided.

Biography

Peggy J Berry, MBA, RAC, is the President & CEO at Synergy Consulting, where she provides consulting services to companies in all aspects of drug development. She also provides group and one-on-one training in drug development, regulatory affairs and project management topics. Prior to founding Synergy Consulting in 2015, she was Vice President of Regulatory Affairs at Insmed where she was responsible for the development and implementation of global regulatory strategies and the management and oversight of the Regulatory Affairs department. Prior to Insmed, she was Vice President of Regulatory Affairs and Quality at Amarin. She has also held a variety of senior level positions at Dyax (now Shire), MGI Pharma (now Eisai), AstraZeneca, and Dey Pharma (now Mylan). She has also held Regulatory Affairs roles within two clinical contract research organizations (ILEX Oncology and Cato Research Ltd) and has worked in review divisions at the FDA. In addition, she consults for a number of companies in the regulatory and quality area, conducts a number of training courses, and is active in the Regulatory Affairs Professionals Society. She is the Editor of the 2010 book "*Choosing the Right Regulatory Career*" (RAPS, MD) and author of the 2011 book "*Communication & Negotiation*" (RAPS, MD).

734berry@gmail.com