Roberta J. Smithey

Roberta Smithey serves as a key board member with over 30 years experience in clinical research and product development. Roberta's extensive sponsor experience ranges from large multinationals to start ups, which allows her to bring a strong sponsorship perspective to the board.

Roberta has been the Director of Regulatory Affairs at a startup biotech where she was responsible for all aspects related to Regulatory global operations and submissions. She has 25 years experience related to the planning, implementation, and process of completing global regulatory submissions. She provides expertise on CTD and eCTD formats, risk management, and post submission activities. She has been directly involved in most major submissions made by Eli Lilly and Company during her tenure there. As a member of the original Lilly regulatory component, Roberta established the first centralized submission team. Her expertise in clinical trials also spans protocol development, CRF design, data capture and edits, as well as authoring integrated documents and labels for submissions.

Roberta is a graduate of the University of Indianapolis.

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