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Good Clinical Practice Guide Gary L. Chadwick, David G. Forster, Cynthia M. Gates, Jamie Gault, JoAnn Giannone, Diane Paul, Deborah Rosenbaum, Carmen Wantowski, Jaime Arango, Karen Arts, Paul Braunschweiger, Karen Hansen, 2012-09-17

The Good Clinical Practice GCP Guide is a logical extension of the CITI Program's web based Good Clinical Practice GCP training and is based on the CITI Program's recognized content It is intended to serve as a quick reference guide for GCP using Drugs and Biologics as well as Devices

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standards and recommendations that apply to thousands of highly specific tasks processes and roles in the conduct of clinical research Interpreting and implementing GCP standards continue to represent challenges for pharmaceutical biotechnology and medical device industries This publication sets out to systematically collect catalog and answer the most important emerging and difficult questions regarding the interpretation and implementation of GCP standards today This text s question and answer format address a vast array of these questions some of which have persisted for many years without definitive answers and some of which have emerged in response to new clinical trials or regulatory related developments

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