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### The importance of developing and managing a well-defined regulatory strategy

A comprehensive regulatory strategy exemplifies expectations, and clarity for the entire project plan from early development to commercialization. In addition, it enables the identification of potential impediments, and creates a systematic guide for the progression of the project. Early regulatory guidance is an invaluable tool for long-term project projections, and to meet defined deliverables, and goals.

Regulatory strategy incorporates the development plan, outstanding issues, background information, applicable regulatory guidance's, and recommendations for implementation. Ultimately, a regulatory strategic plan is a reflection of the corporate culture, and commitment to manufacture safe and efficacious, quality products. Following a well-designed strategic plan could result in significant savings with revenue and time, and minimizes risk for the manufacturer.

#### Biography

Chitra Edwin is the Director, Regulatory and Quality Affairs, Cleveland HeartLab, Cleveland, OH. She held management positions at Chiron Corporation (currently Novartis) and MassBiologics. She is an Adjunct Associate Professor of Pharmaceutical Sciences, College of Pharmacy, University of Cincinnati, Cincinnati, OH. She founded Biotechnology Consulting Solutions, Ltd. in 2006. She obtained her Ph.D. from the University of Minnesota, followed by post-doctoral training at the Harvard Medical School and the Dana Farber Cancer Institute. She has Regulatory Affairs board certification (RAC), and is a Review Board member of Opus Institutional Review Board (IRB).

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