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Perspectives on Drug and Device Development and Registration: FDA Engagement

Abstract: The FDA and Sponsor (industry, academia) share a common objective of bringing safe, effective and high quality medical products to patients and physicians. The purpose of the seminar is to provide perspectives on FDA engagement that could facilitate the bridging of CMU research & entrepreneurship to commercial availability. The presentation will provide an overview of FDA Fundamentals on drug and device review classification, evolution and communication of standards, core elements of assessment, global considerations and opportunities for expediting development and review. A discussion of FDA Innovation will cover topics of ‘big data’ for decision making, patient preference, precision medicine, mobile medical apps, and payor/reimbursement Concurrent with FDA regulations, the Sponsor’s approach to regulatory strategy will discuss product development and commercialization considerations, regulatory plan and building FDA partnership. Case Studies will present specific examples and learnings related to pharmaceutical, biotechnology, startup and digital medicine products. The seminar will conclude with a discussion of resources for continued learning and FDA engagement.