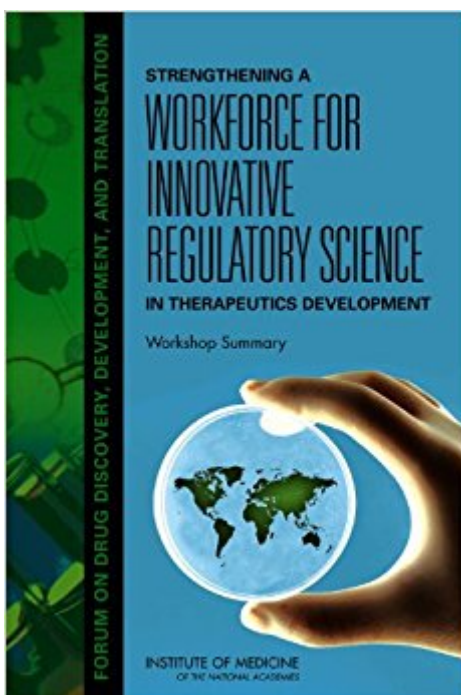


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Strengthening A Workforce For Innovative Regulatory Science In Therapeutics Development: Workshop Summary



Synopsis

The development and application of regulatory science - which FDA has defined as the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products - calls for a well-trained, scientifically engaged, and motivated workforce. FDA faces challenges in retaining regulatory scientists and providing them with opportunities for professional development. In the private sector, advancement of innovative regulatory science in drug development has not always been clearly defined, well coordinated, or connected to the needs of the agency. As a follow-up to a 2010 workshop, the IOM held a workshop on September 20-21, 2011, to provide a format for establishing a specific agenda to implement the vision and principles relating to a regulatory science workforce and disciplinary infrastructure as discussed in the 2010 workshop.

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