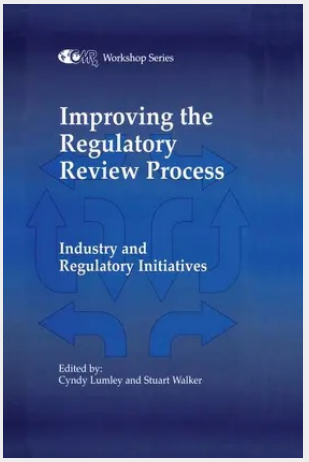
Lumley / Walker

Improving the Regulatory Review Process

Industry and Regulatory Initiatives



Regulatory review is the last major development hurdle that must be passed by a new medicine before it reaches the market. At a time when pharmaceutical companies are reviewing their R&D strategies, and attempting to reduce drug development times, it is extremely important that the review process is made as efficient as possible. The 11th CMR Workshop, held in September 1995, provided the opportunity for regulatory authority and industry personnel from Europe, North America, Australia and Japan to openly discuss views and exchange experiences on the subject of improving the review process. The proceedings of this meeting provide a comprehensive overview of the current review process around the world. The contributors describe the present situation and highlight company strategies and regulatory initiatives to improve the review process. This volume also summarises the suggestions that were developed by the participants, covering many facets of this process, including the quality and size of the dossier, dialogue, submission strategies, feedback and the response to questions.

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