

Regulatory science: An emerging new scientific discipline

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Abstract

Regulatory Science is an emerging scientific discipline that provides scientific support including tools to make policy and regulatory decisions. In this paper we review historical views on the nature of regulatory science and provide a description of key tools including Best Available Science and Metrics for Evaluation of Regulatory Science Information derived from it. We address key elements of independent peer review and independent scientific assessment and briefly discuss other tools used in regulatory science. Finally, we address the three phases of regulatory science and use the examples of a drug vioxx to demonstrate the practical aspects of the three phases.

Key words

Best Available Science (BAS), scientific metrics, Universal Scientific Principles (USP), evolving science, vioxx

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