Benefit-risk appraisal of medicines: a systematic approach to decision-making

Establishes the background and criteria required to assess benefit and risk, and reviews current practices by regulatory authorities and the pharmaceutical industry.

Benefit-risk assessment is at the center of the approval process for every new medicine. The ability to assess the risks of a new medicine accurately and to balance these against the benefits the medicine could bring is critical for every regulatory authority and pharmaceutical company. Despite this there are very few tried and tested evaluative models currently available.

The authors of this book have developed a new, pioneering tool for the assessment of benefits and risks for new medicines in development. This model utilizes a multi-criteria decision analysis which involves selecting, scoring and weighting key benefit and risk attributes and leads to an overall appraisal of benefits and risks of medicines. This book outlines the development and evaluation of the model and analyses the implications of its implementation.

It covers the entire process from the discovery of new medicines to their marketing and is ideal for all those who work in the pharmaceutical industry and regulatory authorities, as well as post-graduate students of pharmaceutical medicine and clinical pharmacology.