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This book explains how managers and supervisor can provide direction whether or not they have been given clear direction themselves. The second role is to communicate expectations. The chapter explain how to identify behaviours that lead to resultts and how to measure performance. The next role is to equip people with skills, information, and tools so they can succeed. This book deals with all these relevant chapters.

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This book proposes and investigates a universal framework, and accompanying documentation system, to facilitate and catalogue benefit-risk decisions; a valuable addition to the benefit-risk toolbox. Over the past decade, pharmaceutical companies and regulatory agencies have been reviewing the benefit-risk assessment of medicines with a view to developing a structured, systematic, standardized approach. Examining the evaluation of such an approach by several mature regulatory authorities ensures that the reader gains a unique insight into the ongoing debate in this area. The field of benefit-risk assessment continues to evolve at a rapid pace due to political and societal pressure, as is reflected in the recent FDA PUDFA agreement as well as in the EMA 2015 Roadmap. Rather than provide a comprehensive snap-shot of this constantly changing environment, this book evaluates selected current approaches to benefit-risk assessment. The strengths and weaknesses of publicly available documents in communicating benefit-risk decisions to stakeholders are reviewed and these evaluations are used to inform development of a prospective framework that could be used to harmonise procedures globally.

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