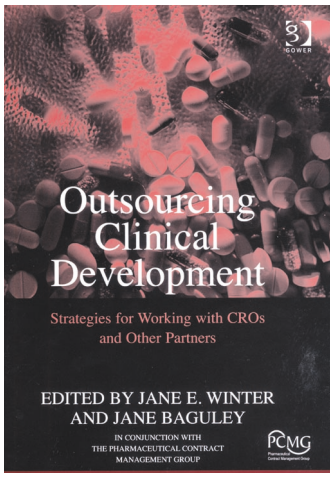
# reviews

## OUTSOURCING

### Outsourcing Clinical Development

Edited by Jane E Winter and Jane Baguely
Published by Gower, 2006
e146, US$185
ISBN 0-566-08686-7
(www.gowerpub.com)




I WISH I'd had a copy of this book three years ago when I was asked by my employer to be the European representative on our global outsourcing network responsible for devising and implementing the company's policy on outsourcing. Although I was familiar with what I now know is called tactical outsourcing, this book summarises and clarifies much of what I was to learn in the ensuing years.

As with all specialities, outsourcing has begun to evolve its own form of jargon, which to the uninitiated can seem complex and daunting. This book takes the reader carefully through the stages and elements of outsourcing and examines the different forms of commercial relationship that can be established between sponsor and vendor. And while it can can be read from cover to cover, it also serves as a useful reference, if needed, to help understand a particular aspect of the outsourcing process.

Chapters two through to seven explain the process of contracting and the options that are available, while chapters eight and nine give valuable insight into how to best manage the relationship between CRO and sponsor once a project has been outsourced. The book offers advice and comment for different organisations from small biotech to large multinational pharmaceutical companies. I like the way that some aspects of the outsourcing process are placed in a wider commercial context and some of the chapters provide a useful and concise summary of business issues such as contracts, negotiation skills and performance management.

The authors suggest that the pharmaceutical industry will benefit from more strategic relationships with CROs, so I was disappointed that this book did not address the role that clinical development can play in developing a franchise. This is becoming more and more important, especially in local affiliate organisations, as the possibilities for direct selling become less and less. Sadly this book does not discuss how this element of clinical research should be built in to an outsourcing agreement and how CROs can support their clients in building the foundations for new drug launches, an element of the relationship which could offer significant advantages to both sides.

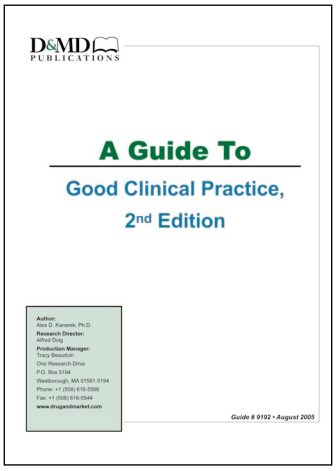
Any clinical research group involved in outsourcing should have a copy of this book on their shelves and any one new to the field would do well to read this useful and informative book.

*Paul Chester, Special Projects Leader, Novo Nordisk, UK*

## GCP

### A Guide to Good Clinical Practice, 2nd Edition

Edited by Dr Alex Kanarek
Published by D&MD Publications, 2005
e323, US$395
ISBN 1-57936-337-7
(www.drugandmarket.com)




THIS book takes on the ambitious task of explaining clinical research regulatory requirements in the US, Canada, the EU and Japan. Theoretically, the reader could skip the explanatory material in chapters one to ten and just read the 207 pages of regulations and guidelines in chapter 14. However, that exercise in masochism is unnecessary because Dr Kanarek distils the essence of the regulations into a coherent narrative using straightforward prose.

His narrative relies primarily on the US Code of Federal Regulations and differences in other jurisdictions are mentioned from time to time. For example, in Japan, the investigator must sign and seal each case report form as it is completed, before submission to the study sponsor.

Chapter three presents each region's regulatory sources. Interestingly, US 21 CFR 54 (financial disclosure by clinical investigators) has no counterpart in other regulatory regions.

Although the author quotes specific regulations, there are relatively few of the detailed citations that close readers might find useful for clarification or further exploration.

As well as discussing the GCP-related duties and responsibilities of the sponsor, the clinical investigator and the IRB/EC, the book includes chapters on the following topics:

- Internal regulations governing GCP
- Elements of GCP compliance
- The Investigator's brochure
- The clinical trial protocol
- Essential documents for trial conduct
- Internal and external monitoring and inspections
- Checklists and forms for monitoring and audits.

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