Outsourcing R&D in the Pharmaceutical Industry

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**From Conceptualisation to
Implementation of the
Strategic Sourcing Process**

Dr. Bianca Piachaud

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List of Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
CRO	Clinical Research Organisation
DNA	Deoxyribonucleic Acid
ECU	European Currency Unit
EU	European Union
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GNP	Gross National Product
HGP	Human Genome Project
HMO	Health Maintenance Organisation
NCE	New Chemical Entity
NDA	New Drug Application
NHS	National Health Service
OECD	Organisation for Economic Co-operation and Development
OTC	Over-the-Counter
PBM	Pharmaceutical Benefit Manager
PD	Pharmacodynamic
PEDC	Pharmaceutical Economic Development Council
PK	Pharmacokinetic
PLA	Product Licence Application
POM	Prescription-only-Medicine
PPRS	Pharmaceutical Price Regulation Scheme
R&D	Research & Development
RCT	Randomised Clinical Trial
SLA	Service Level Agreement
UK	United Kingdom
UNCTC	United Nations Centre on Transnational Co-operation
USA	United States of America

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Preface

The pharmaceutical industry is passing through a very challenging period in its evolution with the traditional approaches to conducting pharmaceutical research and development being increasingly challenged. Successful pharmaceutical organisations have recognised the need to effectively leverage resources and so have come to rely on the wealth of expertise provided by specialist external suppliers. This practice of contracting to external organisations the services and tasks normally performed by internal departments has now become commonplace across the pharmaceutical sector. Essentially, the two most important motives for outsourcing R&D is the need to access sources of innovation in pharmaceutical research, and to reduce the excessive costs of conducting the many activities associated with the R&D process. Yet despite its growing occurrence, the outsourcing phenomenon represents a radical departure from the traditionally held philosophy of the large pharmaceutical firms, which were established with a view to maintaining superiority in as many areas of the R&D process as possible. However, this book demonstrates that if pharmaceutical firms are to successfully reap the benefits of a strategic sourcing partnership, then a fundamental change to traditional ways of thinking must also take place if it is to complement the changes that are made to how R&D is managed.

Although much of existing literature on collaborative R&D has focussed on the dynamics of alliances, joint ventures and licensing agreements between large and small firms, the academic community has failed to examine the nature of outsourcing in relation to the pharmaceutical firm. This book therefore examines the strategic aspects of outsourcing in relation to the pharmaceutical firm. Through this analysis, a 'Strategic Sourcing Model' is developed with the aim of providing a holistic view to external sourcing, from conceptualisation through to implementation and management of the outsourcing arrangement.