

Contents

1.0	Introduction	1
1.1	Review of the challenges facing the pharma industry	2
1.1.1	Globalisation and emerging markets	3
1.1.2	Declining R&D productivity and innovation	4
1.1.3	Personalised medicine and the growth of the speciality sector	6
1.1.4	The need to reduce sales and marketing expense	7
1.1.5	Increasing generic competition	9
1.1.6	Cost containment and the increased use of cost benefit analysis	10
1.1.7	Changes in the manufacture of drugs	11
1.2	The Virtual Pharma business model	12
1.3	Potential pitfalls of a virtual pharma model	13
1.4	Implementation of a virtual pharma model	15
2.0	Virtual Discovery Research	18
2.1	The drug discovery process	19
2.2	Key advantages of a virtual drug discovery model	21
2.2.1	Access to a wide range of drug discovery expertise and technologies	22
2.2.2	Reduced capital expenditure	23
2.2.3	Greater operational and financial flexibility	23
2.2.4	A more efficient R&D process	24
2.2.5	Reduced organisational complexity and bureaucracy	24
2.3	Key disadvantages and risks of a virtual drug discovery model	25
2.3.1	Potential for loss of control	25
2.3.2	Over-dependence on the service provider	26
2.3.3	Potential for decline in quality	27
2.3.4	Higher transactional costs	27
2.3.5	Reduced opportunity to develop internal expertise	28
2.3.6	Potential for breaches of confidentiality	29
2.4	Implementation challenges of a virtual drug discovery model	29
2.4.1	Choosing the right service provider	31
2.4.2	Getting the right agreement in place	32
2.4.3	Managing relationships	34
2.4.4	Keeping control	35

2.4.5	Monitoring quality	37
3.0	Virtual Drug Development	38
3.1	Advantages of a virtual drug development model	42
3.1.1	Accelerate the development process	42
3.1.2	Benefit from greater depth and breadth of development expertise	44
3.1.3	Conduct clinical research in lower cost countries	45
3.2	Key disadvantages and risks of a virtual drug development model	47
3.3	Implementation challenges of a virtual drug development model	50
3.3.1	Choosing the right service provider	50
3.3.2	Getting the right agreement in place	52
3.3.3	Determine clear study specifications and endpoints – and future plans	53
3.3.4	Managing relationships	54
3.3.5	Assessing the cost-benefit trade-off	56
3.3.6	Working with CROs in emerging markets	57
4.0	Virtual Manufacturing	62
4.1	Advantages of a virtual drug manufacturing model	67
4.1.1	Gain access to capacity with low upfront investment	67
4.1.2	Reduce the operational and financial risk of manufacturing	68
4.1.3	Gain access to cutting-edge manufacturing expertise and technology	69
4.1.4	Benefit from financial and operational flexibility	70
4.1.5	Benefit from low-cost manufacturing in emerging countries	70
4.2	Disadvantages and risks of a virtual drug manufacturing model	72
4.2.1	Loss of control	73
4.2.2	Potential for breaches of confidentiality	73
4.2.3	Risks of outsourcing manufacturing to emerging markets	74
4.2.4	Potential shortfalls in biologics manufacturing capacity	74
4.3	Implementation challenges of a virtual drug manufacturing model	75
4.3.1	Choosing the right service provider	76
4.3.2	Getting the right agreement in place	77
4.3.3	Invest resources in managing relationships	78
4.3.4	Internal manufacturing expertise is desirable	79
5.0	Virtual Sales and Marketing	80
5.1	Advantages of a virtual sales model	83
5.1.1	Cost and efficiency savings	83

5.1.2	Increase flexibility to adapt to changing market conditions	84
5.1.3	Retain control and maximise returns	85
5.2	Disadvantages of a virtual sales model	86
5.2.1	Potential for loss of control of product message and branding	86
5.2.2	Risk of breaches of confidentiality of proprietary information	87
5.3	Implementation challenges of a virtual sales model	87
5.3.1	Choosing the right service provider	88
5.3.2	Getting the right agreement in place	89
5.3.3	Handing over to the CSO	89
5.3.4	Managing relationships	90
6.0	References	92

Case Studies

J&J's Deal with NICE.....	11
Virtual Pharma Companies.....	17
GSK's Centres of Excellence for Drug Discovery.....	37
The Drug Development Process.....	40
Eli Lilly.....	58
VDDI Pharmaceuticals.....	59
Protodigm / Fulcrum.....	60
The Medicines Company.....	60
CROs in Emerging Markets.....	61
AstraZeneca.....	64
Pfizer.....	64
Overview of Drug Manufacturing.....	65
Lonza in Singapore.....	72
The Contract Sales Industry.....	82
ProStrakan and NovaQuest.....	91