

Contents

1	Introduction to Competitive Intelligence.....	1
1	Definition	1
2	Introduction: Why Perform CI?	2
	Reference	3
3	Regulatory Guidance, Advisory Committee Meetings, and Case Examples	3
3.1	Regulatory Guidance	3
3.2	Advisory Committee Meetings	4
4	Case Examples	5
4.1	Case Example I: Cardiovascular Risk.....	5
4.1.1	Introduction	5
4.1.2	QT Prolongation as a Cardiac Safety Biomarker	7
4.1.3	Regulatory History of Formalized Cardiac Safety Assessment	7
4.1.4	Regulatory History of Formalized Cardiovascular Safety Assessment for Antidiabetic Drugs for T2DM...	10
4.1.5	FDA's December 2008 Guidance for Industry	12
4.1.6	Continued Discussion in the Literature of the Cardiovascular Safety of Avandia and Actos	13
4.1.7	July 2010 FDA Advisory Committees' Meeting on Avandia	14
4.1.8	EMA's January 2010 Draft Guidance.....	14
4.1.9	Potential Ramifications for Future Global Development of Antidiabetic Drugs for T2DM	14
4.1.10	Summary	15
	References.....	15
4.2	Case Example II: Patient-Centric Services	16
4.2.1	Introduction	16
4.2.2	Privacy Challenges of Launching an Integrated PCS Platform.....	19

4.2.3	Remote Patient Monitoring	20
4.2.4	Regulatory Implications and Challenges	20
4.2.5	HIPAA	21
4.2.6	HITECH	21
4.2.7	Social Media and HIPAA	22
4.2.8	510(k) Classification	22
4.2.9	Health and Wellness Programs	23
4.2.10	REMS Programs	23
4.2.11	Latest FDA Regulations for Mobile Medical Applications	24
4.2.12	Regulatory Overlap	25
4.2.13	Summary	26
	References	26
4.3	Case Example III: Biosimilars	26
4.3.1	EU Biosimilar Status	27
4.3.2	Approved Biosimilars in the EU	28
4.3.3	Status of FOBs in America	29
4.3.4	Interchangeability	30
4.3.5	Exclusivity	30
4.3.6	Approved Biosimilars in the USA	31
4.3.7	Summary	32
4.3.8	Chemistry, Manufacturing & Controls (CMC) Concerns for Biosimilars	32
4.3.9	Efficacy Comparisons, Preclinical Safety, Pharmacokinetics, and Clinical Studies for Biosimilars	35
4.3.10	Summary	37
	References	37
2	Overall Perspective of Due Diligence	
	Investigations and Processes	39
1	Experience of Risk-Based Transactions	39
2	The Process of Due Diligence	40
3	Outcomes of Due Diligence	41
	Reference	41
3	The Regulatory Functional Review: Primary Roles	43
1	Introduction	43
2	Transaction Types	44
3	Time Commitment	44
	Reference	44
4	Output and Expectations	44

4 The On-Site Due Diligence/Data Room Meeting and Interactions with Other Functional Area Experts	47
1 Preparation	47
2 The Virtual Data Room	49
2.1 Types of Electronic Databases	49
2.2 Internet-Based Data Rooms	50
2.3 Advantages	50
2.4 Potential Disadvantages of VDRs	51
3 Summary	52
Reference	53
4 The On-Site Data Room Meeting	53
5 Requests of the Potential Partner	54
6 FDA Correspondence	54
7 Preclinical Information	55
Reference	55
8 Chemistry Manufacturing Controls Information	55
9 Clinical Information	56
10 Commercial Information	57
11 Secondary Research	60
12 Primary Market Research	61
5 Intellectual Property	65
1 Introduction	65
2 Patent Exclusivity	66
3 The IP Due Diligence Process	67
4 Initial Due Diligence and Role of the Regulatory Affairs Professional	69
5 Role of the Patent Attorney	69
6 Role of the Chemistry Manufacturing Controls Expert	70
7 Contractual Protection	70
8 Regulatory Exclusivity: The US Drug Price Competition and Patent Restoration Act	70
9 Case Study	73
10 Summary	74
References	74
6 The Final Report	75
Reference	75
7 Competitive Intelligence Summary	77
About the Author	79
Index	81