CONTENTS

Foreword		(ix)
Preface Acknowledgement		(xiii) (xv)
List of Figures and Tab	ales	(xvii)
About the Authors	nc3	(xxi)
Abbreviations		(xxiii)
Chapter 1: OVERV	IEW OF QbD	
1.1	Introduction	1
1.2	History of QbD	4
1.3	Regulatory Aspects of QbD	6
1.4	Pharmaceutical Quality by Testing	9
1.5	Elements of QbD	11
1.6	Benefits of QbD	18
1.7	Current State of QbD	20
	References	22
Chapter 2: ASPEC	TS OF QbD TO PRODUCT DEVELOPM	ENT
2.1	Introduction	24
2.2	Quality Target Product Profile (QTPP)	25
2.3	Critical Quality Attributes (CQAs)	28
2.4	Critical Process Parameters	33
2.5	Risk Assessment (Linking Material Attributes and Process Parameters to Drug Product CQA's) 36
2.6	Design Space	43
2.7	Control Strategy	45
2.8	Product Lifecycle Management and	48
	Continual Improvement	48
	References	56
Chapter 3: ASPEC	TS OF QbD TO ANALYTICAL METHOD)
3.1	Introduction	57
3.2	Types of Analytical Procedures considered for Validation of AQbD	59

(vi)	Contents		
	3.3	Implementation of Analytical QbD	61
		References	65
Chap	ter 4: DOE, P	AT AND RTRT	
	4.1	Design of Experiment (DOE)	67
	4.2	Process Cnalytical Vechniques (PAT)	78
	4.3	Real Time Release Testing (RTRT)	85
		References	88
Chap	ter 5: QUEST	ION BASED REVIEW (QbR)	
	5.1	Introduction	89
	5.2	QbR Development	90
	5.3	QbR Questions - Drug Substance	93
	5.4	QbR Questions - Drug Product	95
		References	98
Chap	ter 6: QbD A	S AN ALTERNATIVE APPROACH TO	
	PROCE	ESS VALIDATION	
	6.1	Introduction	99
	6.2	Process Design	100
	6.3	Process Qualification	105
	6.4	Continued Process Verification	106
		References	106
Chap	ter 7: IMPLE	MENTATION OF QbD IN	
	PRODU	CT DEVELOPMENT (CASE STUDIES)	
	7.1	Introduction	107
	7.2	Implementation of QbD in Tablet Formulation	107
	7.3	Implementation of QbD in Pellet Formulation	114
	7.4	Implementation of QbD in Emulsion Formulation	121
	7.5	Implementation of QbD in Powder Formulation	126
	7.6	Implementation of QbD in Liposomes	130
		References	139

Chapter 8: IMPLE	MENTATION OF QbD IN	
ANALY	TICAL METHODS (CASE STUDIES)	
8.1	Introduction	142
8.2	Implementation of QbD in Chromatographic Techniques	142
8.3	Implementation of QbD in Dissolution Studies	149
	References	156
Glossary of Terms		15;
Index		165