

Table of Contents

Introduction: Getting Started with CABP.....	3
Overview of the CABP Credential	3
Steps to Becoming a CABP	5
Study Tips from Others	13
Online Resources.....	14
Domain 1: Biotherapies in the Patient Care Ecosystem	15
Objectives	15
Key Terms.....	17
Overview	17
Walk-Through of Domain 1 Objectives	18
References	36
Domain 2: Biotherapies Science and Ethics.....	41
Objectives	41
Key Terms.....	42
Overview	45
Key Concepts in Biotherapies: Science	45
Walk-Through of Domain 2 Objectives: Science.....	47
Key Concepts in Biotherapies: Ethics	61
Walk-Through of Domain 2 Objectives: Ethics.....	63
Conclusion	64
References	64
Domain 3: Operations and Equipment	69
Objectives	69
Key Terms.....	71
Overview	73
Facility Requirements	74
Safety	77
Collection of Cellular Material	80
Cellular Product Processing	84
Storage.....	91
Testing Cellular Products	94
Cellular Product Distribution and Monitoring	95
Transportation and Shipping.....	95
Documentation and Records	97
Equipment Management	98
Laboratory Equipment Validation	99
Quality Assurance	103

Supply Chain Management	106
References	107
Domain 4: Biotherapies Development Lifecycle	109
Objectives	109
Key Terms.....	111
Overview.....	112
Background.....	112
Walk-Through of Domain 4 Objectives	117
Conclusion	154
References	154
Domain 5: Manufacturing Biotherapies	157
Objectives	157
Key Terms.....	159
Overview.....	161
Key Aspects of Manufacturing Biotherapies.....	161
How to Study for Domain 5 of the CABP Exam	165
Walk-Through of Domain 5 Objectives.....	166
Conclusion	195
References	196
Domain 6: Quality Systems	201
Objectives	201
Key Terms.....	203
Overview.....	206
Part I: Quality Guidelines and Oversight	206
Part II: Quality Management System Elements	210
Part III: Quality Assurance Tools, Statistical Analysis, and Manufacturing Optimization.....	241
References	261
Domain 7: The Regulatory Environment.....	265
Objectives	265
Key Terms.....	266
Overview.....	267
The Biotherapies Regulatory Environment.....	268
Walk-Through of Domain 7 Objectives.....	272
Conclusion	290
References	291
Appendices	295
Appendix A. CABP Self-Assessment Tool	295
Appendix B. CABP Study Group Planner	302
Appendix C. Study Plan Tool.....	304
Appendix D. AABB Resources in Biotherapies	306