

*Biopharmaceutical Contract Manufacturing 2017:
Growing Markets, Capacities, and Innovations*

Table of Contents

Presented by

HighTech Business Decisions

3150 Almaden Expressway, Suite 222, San Jose, CA 95118

Tel: (408) 978-1035 Fax: (408) 978-8925

www.hightechdecisions.com

May 2017

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

TABLE OF CONTENTS

| | | |
|-------------------|--|-------------|
| Chapter 1: | EXECUTIVE SUMMARY | |
| | 1.1 Introduction | 1-1 |
| | 1.2 Market Overview | 1-2 |
| | 1.2.1 Introduction | 1-2 |
| | 1.2.2 Industry Drivers | 1-3 |
| | 1.2.3 Market Size | 1-5 |
| | 1.3 Summary of Customer Needs | 1-7 |
| | 1.3.1 Products | 1-7 |
| | 1.3.2 Outsourcing Budgets | 1-9 |
| | 1.3.3 Change in CMO Pricing | 1-10 |
| | 1.3.4 CMO Response to Capacity Shortfall | 1-11 |
| | 1.3.5 Industry Trends and Observations | 1-13 |
| | 1.4 Summary of Contractors' Capabilities | 1-15 |
| | 1.4.1 Annual Revenue Ranges | 1-15 |
| | 1.4.2 Technology Capabilities | 1-16 |
| | 1.4.3 Capacity | 1-17 |
| | 1.4.4 Expectations for the Future of the Industry | 1-19 |
| <hr/> | | |
| Chapter 2: | METHODOLOGY, DEFINITIONS, AND ACRONYMS | |
| | 2.1 Research Objectives | 2-1 |
| | 2.2 Research Methodology | 2-2 |
| | 2.3 Definition of Biopharmaceutical Manufacturing | 2-3 |
| | 2.4 Box-and-Whiskers Plot Definition | 2-4 |
| | 2.5 Acronyms | 2-4 |
| <hr/> | | |
| Chapter 3: | BIOPHARMACEUTICAL CONTRACT MANUFACTURING: MARKET OVERVIEW | |
| | 3.1 Introduction | 3-1 |
| | 3.2 Suppliers: The Contract Biomanufacturers | 3-2 |
| | 3.2.1 Types of Contract Biomanufacturing Companies | 3-2 |
| | 3.2.2 Major Players: Contract Biomanufacturing Companies | 3-4 |
| | 3.2.3 Organizational Changes in the Industry | 3-6 |
| | 3.2.4 Technologies and Services | 3-7 |
| | 3.2.5 Contract Biomanufacturers' Capacities | 3-8 |
| | 3.2.6 Contractor Revenues | 3-12 |

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

TABLE OF CONTENTS (continued)

| | | |
|-------------------|--|-------------|
| Chapter 3: | 3.3 The Customers: Pharmaceutical and Biotechnology Companies | 3-13 |
| | <i>3.3.1 Respondents' Biopharmaceuticals by Phase</i> | 3-13 |
| | <i>3.3.2 Outsourced Biomanufacturing</i> | 3-14 |
| | <i>3.3.3 Examples of Contractors Used by Client Companies</i> | 3-15 |
| | <i>3.3.4 Customers' Future Outsourcing Expectations</i> | 3-16 |
| | <i>3.3.5 In-House Capacity Expansion</i> | 3-18 |
| | <i>3.3.6 Outsource Requirements</i> | 3-19 |
| | 3.4 Industry Drivers | 3-23 |
| | <i>3.4.1 Supply and Demand</i> | 3-23 |
| | 3.5 Market Size | 3-28 |
| | <i>3.5.1 Estimates of Market Size Based on Contractor Revenues</i> | 3-28 |
| | <i>3.5.2 Market Size by Technology and Service Categories</i> | 3-28 |
| | 3.6 Market Growth Forecasts | 3-30 |
| | 3.7 Trends in the Biopharmaceutical Contract Mfg. Market | 3-33 |
| | <i>3.7.1 Industry Opportunities and Challenges</i> | 3-33 |
| | <i>3.7.2 Overall Industry Trends</i> | 3-34 |
| <hr/> | | |
| Chapter 4: | PHARMACEUTICAL AND BIOTECHNOLOGY COMPANIES: CLIENT ANALYSIS | |
| | 4.1 Introduction | 4-1 |
| | <i>4.1.1 Study Participants</i> | 4-1 |
| | <i>4.1.2 Respondents' Titles and Experience</i> | 4-3 |
| | <i>4.1.3 Locations and Sites</i> | 4-4 |
| | <i>4.1.4 Respondents' Biopharmaceutical Products on the Market</i> | 4-7 |
| | <i>4.1.5 Respondents' Preclinical Products</i> | 4-8 |
| | <i>4.1.6 Respondents' Clinical and Commercial Products</i> | 4-11 |
| | <i>4.1.7 Respondents' Outsourced Products</i> | 4-14 |
| | 4.2 Biomanufacturing Needs | 4-20 |
| | <i>4.2.1 Current and Forecasted Tank Size Requirements</i> | 4-21 |
| | <i>4.2.2 Number of Outsourced Batches</i> | 4-24 |
| | <i>4.2.3 Current and Forecasted Outsourced Demand</i> | 4-27 |
| | <i>4.2.4 Future Production Technology Requirements</i> | 4-29 |
| | <i>4.2.5 New Molecules Entering Clinical Pipeline</i> | 4-32 |
| | 4.3 Biomanufacturing Strategies | 4-33 |
| | <i>4.3.1 Outsource versus In-House Decision</i> | 4-33 |
| | <i>4.3.2 Deviation from Outsourcing Strategy</i> | 4-39 |
| | <i>4.3.3 When Decision is Made to Expand Internal Capacity</i> | 4-45 |
| | <i>4.3.4 Estimate of Future Outsourcing Requirements</i> | 4-49 |

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

TABLE OF CONTENTS (continued)

| | | |
|-------------------|--|--------------|
| Chapter 4: | 4.4 Outsourcing Biomanufacturing | 4-57 |
| | 4.4.1 <i>Outsourcing vs. In-House Manufacturing Spending</i> | 4-57 |
| | 4.4.2 <i>Current and Anticipated Needs for Outsourced Services</i> | 4-61 |
| | 4.4.3 <i>Change in CMO Pricing</i> | 4-65 |
| | 4.4.4 <i>External Funding</i> | 4-69 |
| | 4.4.5 <i>CMO Response to Capacity Shortfall</i> | 4-72 |
| | 4.4.6 <i>China Market Strategy</i> | 4-78 |
| | 4.4.7 <i>Use of China CMO for Export Purposes</i> | 4-84 |
| | 4.4.8 <i>New Services Sought in a Contractor</i> | 4-90 |
| | 4.4.9 <i>Companion Diagnostics</i> | 4-94 |
| | 4.5 Manufacturing Technologies | 4-99 |
| | 4.5.1 <i>Current Expression Levels</i> | 4-99 |
| | 4.5.2 <i>Projects Requiring Continuous Manufacturing</i> | 4-102 |
| | 4.5.3 <i>Molecules Requiring Continuous Manufacturing</i> | 4-107 |
| | 4.5.4 <i>Range of Bioreactor Scale</i> | 4-111 |
| | 4.5.5 <i>Biggest Challenges to Innovative Biomanufacturing</i> | 4-114 |
| | 4.5.6 <i>New Technologies for Complex Molecules</i> | 4-126 |
| | 4.6 Contractor Selection | 4-131 |
| | 4.6.1 <i>Essential Characteristics Sought in a Contractor</i> | 4-131 |
| | 4.6.2 <i>Commercial-Phase CMO Differentiation</i> | 4-135 |
| | 4.6.3 <i>Change in Commercial-Phase CMO Differentiation</i> | 4-140 |
| | 4.6.4 <i>Clinical-Phase CMO Differentiation</i> | 4-144 |
| | 4.6.5 <i>Consideration of CMO New in the Industry</i> | 4-149 |
| | 4.6.6 <i>Importance for Services to be Co-Located</i> | 4-155 |
| | 4.6.7 <i>Services Difficult to Find</i> | 4-162 |
| | 4.7 Contractor Relationships | 4-167 |
| | 4.7.1 <i>Favorite Contractors</i> | 4-167 |
| | 4.7.2 <i>Top CMOs for Operational Excellence, Price and Overall Reputation</i> | 4-174 |
| | 4.7.3 <i>Number of CMOs Utilized</i> | 4-175 |
| | 4.8 Outsource Spending | 4-180 |
| | 4.8.1 <i>Outsourcing Budgets</i> | 4-180 |
| | 4.8.2 <i>Outsourcing Budgets by Technology</i> | 4-182 |
| | 4.8.3 <i>Outsourcing Budgets by Service</i> | 4-182 |
| | 4.9 Future Trends and Expectations | 4-185 |
| | 4.9.1 <i>Microbial Fermentation Trends</i> | 4-185 |
| | 4.9.2 <i>Challenges for Biomanufacturing</i> | 4-188 |
| | 4.9.3 <i>Long-Term Industry and Market Trends</i> | 4-195 |
| | 4.9.4 <i>Future of Biopharmaceutical Contract Manufacturing</i> | 4-202 |

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

TABLE OF CONTENTS (continued)

Chapter 5: BIOPHARMACEUTICAL CONTRACT MANUFACTURERS

| | |
|---|-------------|
| 5.1 Introduction | 5-1 |
| 5.1.1 <i>Study Participants</i> | 5-1 |
| 5.1.2 <i>Types of Suppliers</i> | 5-2 |
| 5.1.3 <i>Locations</i> | 5-6 |
| 5.1.4 <i>Regulatory Inspections and Status</i> | 5-8 |
| 5.1.5 <i>Acquisitions and Organizational Changes</i> | 5-9 |
| 5.1.6 <i>Revenues</i> | 5-11 |
| 5.2 Technologies and Capacities Offered | 5-14 |
| 5.2.1 <i>Number of cGMP Phase III and Commercial Products</i> | 5-14 |
| 5.2.2 <i>Production Technologies</i> | 5-15 |
| 5.2.3 <i>Business Mix by Service Category</i> | 5-19 |
| 5.2.4 <i>Contract Manufacturers' Current Capacities</i> | 5-24 |
| 5.2.5 <i>Contract Manufacturers' Expansion Plans</i> | 5-29 |
| 5.3 Manufacturing Technologies | 5-33 |
| 5.3.1 <i>Expression Yields and Batch Success Rates</i> | 5-33 |
| 5.3.2 <i>Number of Batches Run per Tank</i> | 5-34 |
| 5.3.3 <i>Investment in Technology Over Past Five Years</i> | 5-36 |
| 5.3.4 <i>Investment Plans: Next Five Years</i> | 5-39 |
| 5.3.5 <i>Expression Technologies for Non-Standard Format Antibodies</i> | 5-42 |
| 5.3.6 <i>Production Scale</i> | 5-45 |
| 5.3.7 <i>Single-Use Capacity Mix</i> | 5-48 |
| 5.3.8 <i>Importance of Drug Substance and Drug Product Capability</i> | 5-49 |
| 5.3.9 <i>Biosimilar Projects</i> | 5-54 |
| 5.3.10 <i>Biosimilar Strategy</i> | 5-57 |
| 5.4 Marketing | 5-59 |
| 5.4.1 <i>Request-for-Proposals Received</i> | 5-59 |
| 5.4.2 <i>Request-for-Proposals Requiring Single-Use vs. Stainless Steel Bioreactors</i> | 5-61 |
| 5.4.3 <i>Request-for-Proposals Outside Standard Platform</i> | 5-63 |
| 5.4.4 <i>Request-for-Proposals Leading to Contract</i> | 5-65 |
| 5.4.5 <i>Revenue Spent on Research and Development</i> | 5-67 |
| 5.4.6 <i>Metrics Used to Benchmark Business Performance</i> | 5-69 |
| 5.4.7 <i>How to Measure Customer Satisfaction</i> | 5-71 |

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

TABLE OF CONTENTS (continued)

| | | |
|-------------------|---|-------------|
| Chapter 5: | 5.5 Customer Relationship | 5-75 |
| | 5.5.1 <i>Clients Served</i> | 5-75 |
| | 5.5.2 <i>Bookings</i> | 5-76 |
| | 5.5.3 <i>Offerings to Clients to Help Manage Schedule or Capacity</i> | 5-79 |
| | 5.5.4 <i>Differentiation from Other CMOs</i> | 5-82 |
| | 5.5.5 <i>Contractor vs. Client Relationship Changes</i> | 5-85 |
| | 5.5.6 <i>Characteristics of the Customer Base</i> | 5-88 |
| | 5.5.7 <i>Portion of Business by World Regions</i> | 5-91 |
| | 5.6 Industry and Future Trends | 5-94 |
| | 5.6.1 <i>Observation of Change in Demand for Outsourcing Services</i> | 5-95 |
| | 5.6.2 <i>Expectation of Industry Growth</i> | 5-98 |
| | 5.6.3 <i>Price Changes for Biopharmaceutical Production</i> | 5-100 |
| | 5.6.4 <i>Regulatory Challenges</i> | 5-104 |
| | 5.6.5 <i>Changes and Trends for the Future of the Biopharmaceutical Contract Manufacturing Industry</i> | 5-107 |

Appendix A: Write-Ups of Interviews with 41 Pharmaceutical and Biotechnology Company BioManufacturing Directors Worldwide, Unnamed and Edited for Confidentiality

Appendix B: Directory of Biopharmaceutical Contract Manufacturers

Appendix C: Interview Guide for Pharmaceutical and Biotechnology Company Respondents

Appendix D: Interview Guide for Biopharmaceutical Contract Manufacturers

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

LIST OF TABLES

Chapter 1

| | | |
|-------|---|------|
| 1.3-1 | Observed CMO Response to Capacity Shortfall | 1-12 |
| 1.3-2 | Willingness to Accept Implemented CMO Changes | 1-13 |
| 1.3-3 | User' Opinions on Future of the Industry | 1-14 |
| 1.4-1 | Future Trends Noted by CMO Respondents | 1-19 |

Chapter 2

| | | |
|-------|-----------------------|-----|
| 2.2-1 | Market Research Steps | 2-2 |
| 2.5-1 | List of Acronyms | 2-4 |

Chapter 3

| | | |
|-------|---|------|
| 3.2-1 | CMOs Preferred by Respondents | 3-4 |
| 3.2-2 | Examples of Changes or Events in the CMO Industry: Past Two Years | 3-6 |
| 3.2-3 | Industry Revenue Mix by Technology Categories | 3-7 |
| 3.2-4 | Biopharmaceutical Contract Manufacturing Industry Capacity Estimates | 3-9 |
| 3.2-5 | Examples of New Capacity for Biopharmaceutical Contract Manufacturing | 3-11 |
| 3.3-1 | Examples of Contract Biomanufacturers and their Client Companies | 3-15 |
| 3.3-2 | Examples of Pharmaceutical/Biotechnology Companies Building Capacity | 3-18 |
| 3.3-3 | Outsourced Volumes by Technology | 3-19 |
| 3.3-4 | Estimates of Needs for Outsourced Volumes for the Worldwide Industry | 3-22 |
| 3.4-1 | Outsourced Manufacturing Capacity vs. Needs: Mammalian Cell Culture | 3-24 |
| 3.4-2 | Outsourced Manufacturing Capacity vs. Needs: Microbial Fermentation | 3-26 |
| 3.5-1 | Worldwide 2016 Market Size for Contract Biomanufacturing: Revenues | 3-28 |
| 3.5-2 | 2016 Market Size by Technology Category: US\$ | 3-29 |
| 3.5-3 | 2016 Market Size by Service Category: US\$ | 3-30 |
| 3.6-1 | Worldwide 2017 Market Size for Contract Biomanufacturing | 3-31 |
| 3.7-1 | Major Biopharmaceutical Contract Manufacturing Industry Trends | 3-35 |

Chapter 4

| | | |
|--------|---|------|
| 4.1-1 | Respondent Pharmaceutical and Biotechnology Companies | 4-2 |
| 4.1-2 | Respondents' Titles by Segment | 4-3 |
| 4.1-3 | Respondent Locations | 4-4 |
| 4.1-4 | Respondents' Bulk Biopharmaceutical Manufacturing Sites | 4-5 |
| 4.1-5 | Respondents' Fill-and-Finish Biopharmaceutical Manufacturing Sites | 4-6 |
| 4.1-6 | Respondents' Preclinical Products | 4-8 |
| 4.1-7 | Respondents' Preclinical Products Requiring Outsourcing | 4-10 |
| 4.1-8 | Number of Products Produced Using Mammalian Cell Culture | 4-11 |
| 4.1-9 | Number of Products Produced Using Microbial Fermentation | 4-11 |
| 4.1-10 | Types of Respondents' Products by Production Technology | 4-14 |
| 4.1-11 | Outsourced Products by Phase by Year | 4-16 |
| 4.1-12 | Number of Products Outsourced by Tank Size Needs in 2017: Mammalian Cell Culture | 4-18 |
| 4.1-13 | Number of Products Outsourced by Tank Size Needs in 2017: Microbial Fermentation | 4-19 |

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

LIST OF TABLES (continued)

Chapter 4

| | | |
|--------|--|-------|
| 4.2-1 | Tank Size Distribution for Outsourced Products: Mammalian Cell Culture | 4-21 |
| 4.2-2 | Tank Size Distribution for Outsourced Products: Microbial Fermentation | 4-23 |
| 4.2-3 | Outsource Batches per Project: Mammalian Cell Culture | 4-24 |
| 4.2-4 | Outsource Batches per Project: Microbial Fermentation | 4-26 |
| 4.2-5 | Outsource Demand by Phase: Mammalian Cell Culture | 4-27 |
| 4.2-6 | Outsource Demand by Phase: Microbial Fermentation | 4-28 |
| 4.2-7 | Expected Changes in Technologies Used | 4-31 |
| 4.2-8 | Molecule Class Mix Entering Clinical Pipeline | 4-33 |
| 4.3-1 | Drivers for Companies Who Outsource 100% GMP Manufacturing | 4-35 |
| 4.3-2 | Drivers for Companies Who Outsource Some GMP Manufacturing | 4-36 |
| 4.3-3 | Deviation from Outsourcing Strategy | 4-41 |
| 4.3-4 | Decision Points to Add Internal Capacity | 4-45 |
| 4.3-5 | Considerations for Estimating Future Outsourcing Requirements | 4-49 |
| 4.3-6 | Future Outsourcing Trends | 4-50 |
| 4.4-1 | Spending Mix by Production Source and Technology | 4-59 |
| 4.4-2 | Services Currently Outsourced | 4-62 |
| 4.4-3 | Services To Be Outsourced | 4-63 |
| 4.4-4 | No Plans to Outsource Services | 4-64 |
| 4.4-5 | Change in Outsourced Service by Number of Products | 4-65 |
| 4.4-6 | Reasons for Pricing Change for CMO Biopharmaceutical Services | 4-66 |
| 4.4-7 | External Funding Observations | 4-70 |
| 4.4-8 | Observed CMO Response to Capacity Shortfall | 4-73 |
| 4.4-9 | Willingness to Accept Implemented CMO Changes | 4-74 |
| 4.4-10 | China Market Strategy and Drivers | 4-80 |
| 4.4-11 | Considerations for Use of Chinese CMO for Export Purposes | 4-85 |
| 4.4-12 | New CMO Services Sought | 4-90 |
| 4.4-13 | Companion Diagnostics by Segment | 4-95 |
| 4.5-1 | Expression Levels Reported by Respondents in Grams per Liter | 4-101 |
| 4.5-2 | Expression Levels Reported for Mammalian mAb Products | 4-102 |
| 4.5-3 | Summary of Comments Related to the Use of Continuous Manufacturing | 4-103 |
| 4.5-4 | Required Bioreactor Scales in Liters | 4-111 |
| 4.5-5 | Innovative Biomanufacturing: Challenges and Actions | 4-115 |
| 4.5-6 | Development of Manufacturing Technologies for Complex Molecules | 4-127 |
| 4.6-1 | Essential Characteristics for Choosing a CMO | 4-132 |
| 4.6-2 | Weighted Characteristics by Respondent Segment | 4-134 |
| 4.6-3 | Main Differentiators Among Commercial-Phase CMOs | 4-136 |
| 4.6-4 | Observations Regarding Contract Manufacturing Industry Changes | 4-142 |
| 4.6-5 | Main Differentiators Among Clinical-Phase CMOs | 4-145 |
| 4.6-6 | Criteria for Using a New CMO without Manufacturing History | 4-150 |
| 4.6-7 | Reasons for Importance Rating of Service Co-Location | 4-157 |
| 4.6-8 | Services Difficult to Find | 4-162 |
| 4.7-1 | Contract Manufacturers Preferred by Respondents | 4-167 |
| 4.7-2 | Top CMOs for Operational Excellence, Price and Overall Reputation | 4-174 |
| 4.7-3 | Reasons for Change in Number of CMOs Utilized | 4-176 |

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

LIST OF TABLES (continued)

Chapter 4

| | | |
|-------|---|-------|
| 4.8-1 | Expenditures on Outsourcing of Biopharmaceutical Production | 4-181 |
| 4.8-2 | Spending Mix by Technology: 2017 and 2019 | 4-182 |
| 4.8-3 | Weighted Averages: Outsourcing Budget by Services in 2017 | 4-183 |
| 4.8-4 | Weighted Averages: Outsourcing Budget by Services in 2019 | 4-183 |
| 4.9-1 | Microbial Fermentation Trends | 4-186 |
| 4.9-2 | Capacity Constraints and Challenges | 4-190 |
| 4.9-3 | Near-Term Challenges for the Biopharmaceutical Manufacturing Industry | 4-190 |
| 4.9-4 | Future Trends in Biopharmaceutical Manufacturing | 4-196 |
| 4.9-5 | Future Expectations of the Biopharmaceutical Manufacturing Industry | 4-204 |

Chapter 5

| | | |
|-------|--|------|
| 5.1-1 | Respondents from Companies Offering Contract Biomanufacturing Services | 5-1 |
| 5.1-2 | Types of Biopharmaceutical Contract Manufacturing Organizations | 5-4 |
| 5.1-3 | Contract Biomanufacturers: Headquarter Locations | 5-7 |
| 5.1-4 | Examples of Company Changes in Contract Biomanufacturing | 5-10 |
| 5.1-5 | Organization Changes Over Last Two Years | 5-11 |
| 5.1-6 | Contract Biomanufacturers' Revenue in 2016 (US\$) | 5-12 |
| 5.2-1 | Phase III and Commercial cGMP Products Manufactured | 5-14 |
| 5.2-2 | Business Mix by Production Technology and Year | 5-16 |
| 5.2-3 | Business Mix by Production Technology and Respondent Segment: 2017 | 5-17 |
| 5.2-4 | Business Mix by Service and Production Category and Year | 5-20 |
| 5.2-5 | Business Mix by Service and Production Category by Respondent Segment | 5-21 |
| 5.2-6 | Mammalian Cell Culture Capacity at 17 Respondents' Facilities in 2017 | 5-25 |
| 5.2-7 | Microbial Fermentation Capacity at 14 Respondents' Facilities in 2017 | 5-28 |
| 5.2-8 | New Capacity Expected: 2017 to 2022 | 5-31 |
| 5.3-1 | Contractor Yields and Success Rates | 5-33 |
| 5.3-2 | Number of Batches Run per Tank | 5-35 |
| 5.3-3 | Investment in Technology Over Past Five Years | 5-36 |
| 5.3-4 | Investment in New Technology | 5-40 |
| 5.3-5 | Expected Bioreactor Scale in Demand | 5-45 |
| 5.3-6 | Percentage of Single-Use Technologies at Respondent Sites | 5-48 |
| 5.3-7 | Advantage of Drug Substance and Drug Product Capability | 5-50 |
| 5.3-8 | Biosimilar Strategies | 5-58 |
| 5.4-1 | Number of RFPs Received per Month | 5-59 |
| 5.4-2 | Percent of RFPs Split by Stage of Project | 5-60 |
| 5.4-3 | Percent of RFPs Split by Bioreactor Type | 5-62 |
| 5.4-4 | RFPs Received Not Within Standard Platform | 5-64 |
| 5.4-5 | RFP Success Rate | 5-65 |
| 5.4-6 | Areas of Investment | 5-68 |
| 5.4-7 | Benchmarking Metrics | 5-70 |
| 5.4-8 | How Customer Satisfaction is Measured | 5-72 |

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

LIST OF TABLES (continued)

Chapter 5

| | | |
|--------|---|-------|
| 5.5-1 | Number of Clients in 2016 | 5-75 |
| 5.5-2 | Offerings to Clients to Manage Schedule | 5-80 |
| 5.5-3 | Factors CMOs' Clients Use to Differentiate Them | 5-82 |
| 5.5-4 | Observed Contractor and Client Relationship Changes | 5-85 |
| 5.5-5 | Business Mix by Customer Base by Respondent Segment | 5-88 |
| 5.5-6 | Simple and Weighted Business Mix by Customer Base | 5-89 |
| 5.5-7 | Types of Customers Served and Number of Products | 5-90 |
| 5.5-8 | Average Percentage of International Clients | 5-91 |
| 5.5-9 | Business Mix by World Region by Respondent Segment | 5-92 |
| 5.5-10 | Simple and Weighted Business Mix by World Region | 5-93 |
| 5.6-1 | Observations for Demand Increase Over Last 12 Months | 5-96 |
| 5.6-2 | Average Expectations of Growth: Next Twelve Months | 5-98 |
| 5.6-3 | Average Expectations of Growth: Next Three Years | 5-99 |
| 5.6-4 | Areas Impacted by Price Pressures | 5-102 |
| 5.6-5 | Regulatory Challenges | 5-104 |
| 5.6-6 | Industry Prospects and Trends Noted by Contractor Respondents | 5-108 |

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

LIST OF FIGURES

Chapter 1

| | | |
|-------|---|------|
| 1.2-A | Outsourcing Demand vs. Contract Biomanufacturers' Capacity: Mammalian | 1-4 |
| 1.2-B | Outsourcing Demand vs. Contract Biomanufacturers' Capacity: Microbial | 1-5 |
| 1.2-C | Worldwide Biopharmaceutical Contract Manufacturing Market Forecast | 1-7 |
| 1.3-A | Respondents' Biopharmaceutical Products by Phase and Technology | 1-8 |
| 1.3-B | Respondents' Preclinical Products | 1-9 |
| 1.3-C | Respondents' Expected Change in Biopharmaceutical Outsourcing Budgets | 1-9 |
| 1.3-D | Price Change for CMO Biopharmaceutical Services | 1-11 |
| 1.4-A | Contract Biomanufacturers' Annual Revenue Ranges in 2016 | 1-16 |
| 1.4-B | Technology Comparisons: Weighted Business Mix in 2017 | 1-17 |
| 1.4-C | Worldwide Biopharmaceutical Contract Manufacturing Industry Capacity | 1-18 |

Chapter 2

| | | |
|-------|--------------------------------------|-----|
| 2.4-A | Explanation of Box-and-Whiskers Plot | 2-4 |
|-------|--------------------------------------|-----|

Chapter 3

| | | |
|-------|---|------|
| 3.2-A | Worldwide Biopharmaceutical Contract Manufacturing Industry Capacity | 3-10 |
| 3.2-B | Biopharmaceutical CMO Average Revenue in 2016 | 3-12 |
| 3.3-A | Respondents' Biopharmaceutical Products by Phase | 3-13 |
| 3.3-B | Production Source Mix | 3-14 |
| 3.3-C | Outsourced Products by Phase in 2017 | 3-15 |
| 3.3-D | Outsourced Production Spending by Respondent Segment | 3-17 |
| 3.3-E | Outsourced Products by Phase by Year | 3-20 |
| 3.3-F | Trends Indicated by Number of Products Outsourced or to be Outsourced | 3-21 |
| 3.4-A | Outsourcing Demand versus Contract Capacity: 2017 to 2022: Mammalian | 3-24 |
| 3.4-B | Outsourcing Demand versus Contract Capacity: 2017 to 2022: Microbial | 3-27 |
| 3.6-A | Worldwide Biopharmaceutical Contract Manufacturing Market Forecast | 3-33 |

Chapter 4

| | | |
|-------|--|------|
| 4.1-A | Respondent Segment by Number of Biomanufacturing Sites | 4-5 |
| 4.1-B | Summary of Respondents' Bulk and Fill-and-Finish Biopharmaceutical Manufacturing Sites | 4-6 |
| 4.1-C | Number of Biopharmaceutical Products on the Market | 4-7 |
| 4.1-D | Respondents' Preclinical Products | 4-8 |
| 4.1-E | Respondents' Preclinical Products Requiring Outsourcing | 4-9 |
| 4.1-F | Change in Number of Preclinical Products Requiring Outsourcing | 4-10 |
| 4.1-G | Respondents' Biopharmaceutical Products by Phase and Technology | 4-12 |
| 4.1-H | Respondents' Biopharmaceutical Product Mix by Phase | 4-12 |
| 4.1-I | Respondents' Biopharmaceutical Products by Technology and Company Type | 4-13 |
| 4.1-J | Respondents' Biopharmaceutical Products Sourcing Mix | 4-15 |
| 4.1-K | Outsourced Products by Phase in 2017 | 4-15 |
| 4.1-L | Outsourced Products by Phase by Year | 4-17 |

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

LIST OF FIGURES (continued)

Chapter 4

| | | |
|-------|---|-------|
| 4.1-M | Tanks Sizes Required for Outsourced Mammalian Cell Culture Products | 4-19 |
| 4.1-N | Tanks Sizes Required for Outsourced Microbial Fermentation Products | 4-20 |
| 4.2-A | Tanks Size Mix for Outsourced Products: Mammalian Cell Culture | 4-22 |
| 4.2-B | Tanks Size Mix for Outsourced Products: Microbial Fermentation | 4-23 |
| 4.2-C | Outsource Batches per Project: Mammalian Cell Culture | 4-25 |
| 4.2-D | Outsource Batches per Project: Microbial Fermentation | 4-26 |
| 4.2-E | Summation of Outsourced Volumes Required by Respondents | 4-29 |
| 4.2-F | Technology Usage Patterns Top 6 Mentions | 4-30 |
| 4.2-G | Molecule Class Mix Entering Clinical Pipeline | 4-32 |
| 4.3-A | Respondents' Outsourcing Strategies | 4-34 |
| 4.3-B | Deviation from Outsourcing Strategy | 4-40 |
| 4.3-C | Decision Time Frame in Advance of Capacity Expansion | 4-46 |
| 4.4-A | Outsourced Production Spending by Respondent Segment | 4-58 |
| 4.4-B | Outsourced Spending Mix by Technology: 2017 | 4-60 |
| 4.4-C | Expected Changes in Outsourced Spending | 4-61 |
| 4.4-D | Price Change for CMO Biopharmaceutical Services | 4-66 |
| 4.4-E | Distribution of Price Increase for CMO Biopharmaceutical Services | 4-67 |
| 4.4-F | Observed Change in External Funding | 4-70 |
| 4.4-G | China Market Strategy | 4-79 |
| 4.4-H | China Market Strategy—Local Manufacturing vs. Import Path | 4-80 |
| 4.4-I | Use of Chinese CMO for Export Purposes | 4-85 |
| 4.4-J | Developing Companion Diagnostics | 4-95 |
| 4.5-A | Mammalian Cell Culture Titrers | 4-100 |
| 4.5-B | Microbial Fermentation Yields | 4-100 |
| 4.5-C | Future Projects Requiring Continuous Manufacturing | 4-103 |
| 4.5-D | Molecules Requiring Continuous Manufacturing | 4-107 |
| 4.5-E | Mammalian Cell Culture Bioreactor Scale—Commercial Phase | 4-112 |
| 4.5-F | Mammalian Cell Culture Bioreactor Scale—Clinical Phase | 4-112 |
| 4.5-G | Microbial Fermentation Bioreactor Scale—Commercial Phase | 4-113 |
| 4.5-H | Microbial Fermentation Bioreactor Scale—Clinical Phase | 4-113 |
| 4.5-I | Major Areas that Present Challenges to Innovative Biomanufacturing | 4-114 |
| 4.5-J | Availability of Technology for Development and Manufacture of Complex Molecules | 4-126 |
| 4.6-A | Top Criteria for Selecting a CMO | 4-133 |
| 4.6-B | Top 5 Weighted Characteristics by Respondent Segment | 4-135 |
| 4.6-C | Changes in Main Differentiators that Set Commercial-Phase CMOs Apart | 4-141 |
| 4.6-D | Importance for CMO to Have All Services Co-Located | 4-155 |
| 4.6-E | Importance for CMO to Have All Services Co-Located by Respondent Segment | 4-156 |
| 4.7-A | Change in Number of CMOs Utilized | 4-176 |
| 4.8-A | Respondents' Expected Change in Outsourcing Budgets: 2017 to 2019 | 4-181 |
| 4.8-B | Weighted Averages: Outsourcing Budget by Services: 2017 and 2019 | 4-184 |
| 4.9-A | Microbial Fermentation Trends | 4-185 |
| 4.9-B | Challenges for Biomanufacturing | 4-189 |
| 4.9-C | Opinion on Future Success of Biopharmaceutical Manufacturing | 4-203 |

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

LIST OF FIGURES (continued)

Chapter 5

| | | |
|-------|--|------|
| 5.1-A | Length of Time in CMO Business | 5-5 |
| 5.1-B | Number of CMO Respondent Sites | 5-6 |
| 5.1-C | Number of FDA or EMA Inspections | 5-8 |
| 5.1-D | Inspections Associated with New or Approved BLA | 5-9 |
| 5.1-E | Contract Biomanufacturers' Annual Revenue Ranges in 2016 | 5-12 |
| 5.1-F | Contract Biomanufacturers' Expected Revenue Change: 2016 to 2017 | 5-13 |
| 5.2-A | Average Number of Phase III and Commercial Products | 5-15 |
| 5.2-B | Technology Comparisons: Business Mix by Respondent Segment: 2017 | 5-17 |
| 5.2-C | Technology Comparisons: Weighted Business Mix: 2017 | 5-18 |
| 5.2-D | Service Category Comparisons: Business Mix by Respondent Segment | 5-22 |
| 5.2-E | Production Category Comparisons: Business Mix by Respondent Segment | 5-22 |
| 5.2-F | Weighted Business Mix by Service and Production Category: 2017 | 5-23 |
| 5.2-G | Mammalian Cell Culture Capacity Utilization Rates: 2017/2019 | 5-26 |
| 5.2-H | Microbial Fermentation Capacity Utilization Rates: 2017/2019 | 5-29 |
| 5.2-I | Additional Mammalian Cell Culture Capacity by Year | 5-30 |
| 5.2-J | Additional Microbial Fermentation Capacity by Year | 5-30 |
| 5.2-K | Summary of Current and Future Capacity at Surveyed Contractor Facilities | 5-32 |
| 5.3-A | Expression Yields by Technology and Respondent Segment | 5-34 |
| 5.3-B | Average Number of Batches Run per Tank | 5-35 |
| 5.3-C | Expression Technology Implementation for Non-Standard Format Antibodies | 5-43 |
| 5.3-D | Distribution of Scale for Mammalian Cell Culture: Clinical Phase | 5-46 |
| 5.3-E | Distribution of Scale for Mammalian Cell Culture: Commercial Phase | 5-46 |
| 5.3-F | Distribution of Scale for Microbial Fermentation: Clinical Phase | 5-47 |
| 5.3-G | Distribution of Scale for Microbial Fermentation: Commercial Phase | 5-47 |
| 5.3-H | Distribution of Single-Use Technologies by Respondent Type | 5-48 |
| 5.3-I | Importance of Drug Substance and Drug Product Capability | 5-49 |
| 5.3-J | Change in Importance of Drug Substance and Drug Product Capability | 5-50 |
| 5.3-K | Percent of Business Related to Biosimilar Projects | 5-55 |
| 5.3-L | Change in Percentage of Business for Biosimilar Projects | 5-56 |
| 5.3-M | Biosimilar Strategy | 5-57 |
| 5.4-A | Average Number of RFPs Received per Month | 5-60 |
| 5.4-B | Percent of Respondents Whose RFPs Specify Requirements | 5-61 |
| 5.4-C | RFP Success Rate | 5-66 |
| 5.4-D | Percent of Revenue Invested in R&D | 5-67 |
| 5.4-E | Change in R&D Investment from 2016 | 5-68 |
| 5.4-F | Customer Loyalty Survey Implementation | 5-72 |
| 5.5-A | Distribution of Number of Clients Served in 2016 | 5-76 |
| 5.5-B | Percent of Respondents Fully Booked in 2016 | 5-77 |
| 5.5-C | Production Technology Fully Booked in 2016 | 5-77 |
| 5.5-D | Length of Time Manufacturing Plant Booked Out | 5-78 |
| 5.5-E | Business Mix by Customer Base by Respondent Segment | 5-89 |
| 5.5-F | Simple and Weighted Business Mix by Customer Base Comparison | 5-90 |

Biopharmaceutical Contract Manufacturing 2017: Growing Markets, Capacities, and Innovations

LIST OF FIGURES (continued)

Chapter 5

| | | |
|-------|--|-------|
| 5.5-G | Business Mix by World Region by Customer Segment | 5-92 |
| 5.5-H | Simple and Weighted Business Mix by World Region Comparison | 5-94 |
| 5.6-A | Change in Demand for Outsourced Services Over Last 12 Months | 5-95 |
| 5.6-B | Expectations of Industry Growth: Twelve Months and Three Years | 5-99 |
| 5.6-C | Price Expectations in 2017 | 5-101 |
| 5.6-D | Distribution of Expected Price Change | 5-101 |