Biopharmaceutical Contract Manufacturing:
Best Practices Pricing Study 2016

Presented by

HighTech Business Decisions
3150 Almaden Expressway, Suite 222  San Jose, California  95118
Tel: (408) 978-1035  Fax: (408) 978-8925
www.HighTechDecisions.com

August 2016
## TABLE OF CONTENTS

### Chapter 1: EXECUTIVE SUMMARY

1.1 Introduction .................................................. 1-1
1.2 Participants’ Locations ........................................ 1-2
1.3 Industry Pricing Trends ........................................ 1-3
   1.3.1 Recent Industry Pricing Changes .................. 1-3
   1.3.2 Changes in CMO Pricing in Next Two Years ...... 1-4
1.4 Outsourcing Strategies and Contractor Selection ........ 1-6
   1.4.1 Users’ Outsourcing Strategies ..................... 1-6
   1.4.2 Importance of Price in Decision-Making Process .. 1-7
   1.4.3 Technical Support Expected from CMO ............ 1-9
   1.4.4 Use of China CMO for Chinese Market .......... 1-12
1.5 Contractors’ Business Strategies and Customer Types ...... 1-13
   1.5.1 Contractors’ Client Segments ....................... 1-13
   1.5.2 Importance of Price in Clients’ Decision-Making Process 1-15
   1.5.3 Provisions for Inflation in Contracts .............. 1-16
   1.5.4 CMOs’ Management of Development Risk .......... 1-18
1.6 Contract Agreement: Expectations and Preferences ........ 1-19
   1.6.1 Preferred Pricing Models ......................... 1-19
   1.6.2 Premium Paid for Earliest Capacity Availability ... 1-21
   1.6.3 Typical Pricing Model for Development Services .. 1-26
1.7 Prices Paid and Prices Charged ............................ 1-27
   1.7.1 Contractors’ Pricing Models ....................... 1-27
   1.7.2 Pricing: Per-Batch, Per-Week, and Per-Gram .... 1-30
1.8 Improving Contract Agreements and Solving Problems ...... 1-36
   1.8.1 Users’ Perspective: Negotiation Challenges ...... 1-36
   1.8.2 Contractors’ Perspective: Negotiation Challenges 1-38
   1.8.3 Contractors’ Cancellation Fees for GMP Runs .... 1-39
   1.8.4 Users’ Tolerance of CMO Rescheduling .......... 1-40
   1.8.5 Final Observations .................................. 1-42

### 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 ......................... 2-3
2.5 Acronyms ...................................................... 2-4
## TABLE OF CONTENTS (continued)

### Chapter 3: INDUSTRY PRICING TRENDS

#### 3.1 Introduction

- **3.1.1 Participants’ Locations and Job Titles** 3-1
- **3.1.2 Approved Biopharmaceutical Products on Market** 3-3
- **3.1.3 Number of Biopharmaceuticals in Clinical Trials** 3-4
- **3.1.4 Product Produced in CMO Facility Licensed for Commercial Production** 3-6

#### 3.2 Industry Pricing Trends

- **3.2.1 Recent Industry Price Changes** 3-7
- **3.2.2 Changes in CMO Pricing in the Next Two Years** 3-9
- **3.2.3 Services Where Prices Have Changed the Most** 3-14
- **3.2.4 Key Factors Affecting Manufacturing Costs** 3-17

#### 3.3 Profit Margins

- **3.3.1 Contractors’ Target Gross Profit Margins** 3-20

### Chapter 4: OUTSOURCING STRATEGIES/CONTRACTOR SELECTION

#### 4.1 Outsourcing Strategies

- **4.1.1 Manufacturing Budgets: In-House versus Outsourced** 4-1
- **4.1.2 Outsourcing Budgets: Process Development versus Manufacturing** 4-4
- **4.1.3 Users’ Outsourcing Strategies** 4-7
- **4.1.4 Users’ Future Changes to Outsourcing Strategy** 4-11

#### 4.2 Contractor Relationships

- **4.2.1 Users’ Current Contractors** 4-15
- **4.2.2 Plans for New or Different Contractors** 4-16

#### 4.3 Contractor Selection

- **4.3.1 Initial Contact with Contractors** 4-21
- **4.3.2 Number of CMOs Contacted for Proposals for Project** 4-25
- **4.3.3 Decision Maker for CMO Selection** 4-27
- **4.3.4 Importance of Price in Decision-Making Process** 4-33
- **4.3.5 Outsourcing of Mammalian Cell-Line Development** 4-38
- **4.3.6 Technical Support Expected from CMO** 4-41
- **4.3.7 Co-Work Opportunities with CMO** 4-48
- **4.3.8 Consideration of Low Base Price with Bonuses Tied to Targets** 4-52

#### 4.4 Contractor Location

- **4.4.1 Geographic Location Impact on CMO Selection** 4-57
- **4.4.2 Consideration of Asia-Based CMO** 4-61
- **4.4.3 Use of China CMO for Chinese Market** 4-66
TABLE OF CONTENTS (continued)

Chapter 4: Technology and Service Trends 4-71
4.5.1 Use of Proprietary Expression Systems 4-71
4.5.2 Preferred Payment Model for Proprietary Expression Systems 4-77
4.5.3 Inclusion of Engineering Runs in GMP Production Price 4-80
4.5.4 Changes in Product Portfolio and New Technologies Needed 4-81

Chapter 5: CONTRACTORS’ BUSINESS STRATEGIES/CUSTOMER TYPES 5-1
5.1 Business Strategies 5-1
5.1.1 CMO Focus or Business Strategy 5-1
5.1.2 Importance of Price in Clients’ Decision-Making Process 5-4
5.1.3 Provisions for Inflation in Contracts 5-9
5.1.4 CMOs’ Management of Development Risk 5-11
5.2 Customer Base 5-15
5.2.1 Fee-for-Service versus Partnership Contracts 5-15
5.2.2 Domestic versus International Clients 5-16
5.2.3 Contractors’ Client Segments 5-17
5.3 Technology and Service Trends 5-19
5.3.1 Inclusion of Engineering Runs in GMP Production 5-19
5.3.2 Number of Runs in a Campaign 5-21
5.3.3 Provisions for Raw and Consumable Materials 5-24
5.3.4 Material Pass-Through Costs 5-26
5.3.5 Charging for Product Support/Project Management 5-29
5.3.6 Electronic Documentation 5-31

Chapter 6: CONTRACT AGREEMENT: EXPECTATIONS/PREFERENCES 6-1
6.1 Users’ Expectations of Pricing Models 6-1
6.1.1 Expectations of Core Charges: Users versus Contractors 6-1
6.1.2 Preferred Pricing Models 6-3
6.1.3 Services Users are Willing to Pay a Premium for Speed 6-5
6.1.4 Mammalian Cell-Line Development Pricing and Time Expectation 6-11
6.1.5 Markups of CMO Purchased Materials 6-13
6.1.6 Users’ Management of Development Risk 6-17

**TABLE OF CONTENTS (continued)**

## Chapter 6: Contractors’ Pricing Practices and Preferences
- 6.2.1 Services Clients Willing to Pay Premium for Speed 6-25
- 6.2.2 Typical Pricing Model for Development Services 6-29
- 6.2.3 Charging for Pre-Production Services 6-32
- 6.2.4 Typical Charge for IND Submission Services 6-33
- 6.2.5 Long-Term Supply Agreement with Clients 6-36
- 6.2.6 Price Reduction Provisions from Process Improvements 6-39

## Chapter 7: PRICES PAID AND PRICES CHARGED
- 7.1 Process Development Prices 7-1
  - 7.1.1 Process Development Prices and Time Estimates: Mammalian 7-1
  - 7.1.2 Process Development Prices and Time Estimates: Microbial 7-3
  - 7.1.3 FTE Rates for Process Development 7-5
- 7.2 FTE Rates 7-7
- 7.3 Contractors’ Pricing Models 7-14
- 7.4 Contractors’ Short-Term versus Long-Term Rates 7-16
  - 7.4.1 Contractors’ Batch Pricing: Single versus Multiple Batches 7-17
  - 7.4.2 Contractors’ Batch Pricing: Stainless Steel versus Single-Use 7-20
  - 7.4.3 Batch Pricing: Microbial Refolding 7-21
- 7.5 Pricing: Per-Batch, Per-Week, and Per-Gram 7-22
  - 7.5.1 Per-Batch Pricing: Contractor versus User Averages 7-23
  - 7.5.2 Time-in-Facility Pricing: Contractor versus User Averages 7-26
  - 7.5.3 Price-Per-Gram: Contractor versus User Averages 7-28
- 7.6 Special Analysis: Price Per-Gram 2016 versus 2013 7-30
- 7.7 Special Analysis: Price Per-Batch or Per-Week, Per-Liter 7-33
- 7.8 Typical Charges for Additional Services 7-37
  - 7.8.1 Typical Charges for Mammalian Cell Culture Services 7-38
  - 7.8.2 Typical Charges for Microbial Fermentation Services 7-44
# Chapter 8: Improving Contract Agreements and Final Observations

## 8.1 Contract Negotiations for Production
- **8.1.1 Users’ Perspective: Negotiation Challenges**
- **8.1.2 Contractors’ Perspective: Negotiation Challenges**

## 8.2 Users’ Perspective: Preparing for Problems
- **8.2.1 Users’ Experience with Cancellation Fees for GMP Runs**
- **8.2.2 Users’ Cancellation Fees for Development/Non-GMP Batches**
- **8.2.3 Users’ Frequency of Change Orders**

## 8.3 Contractors’ Perspectives: Preparing for Problems
- **8.3.1 Contractors’ Reservation Fees For GMP Runs**
- **8.3.2 Contractors’ Reservation Fees for Development/Non-GMP Batches**
- **8.3.3 Contractors’ Cancellation Fees for GMP Runs**
- **8.3.4 Contractors’ Cancellation Fees for Development/Non-GMP Batches**
- **8.3.5 Flexibility in Rescheduling Manufacturing Campaigns**
- **8.3.6 Users’ Tolerance of CMO Rescheduling**

## 8.4 Final Observations
- **8.4.1 Concerns Regarding Capital Expenditures or Supply Capability**
- **8.4.2 Changes in Commercial Contract Terms Due to Capacity Concerns**
- **8.4.3 Commoditization of Biopharmaceutical Manufacturing**
- **8.4.4 Market Challenges: CMOs**
- **8.4.5 Users’ Perspective: Other Observations**
- **8.4.6 Contractors’ Perspective: Other Observations**

LIST OF TABLES

Chapter 1

1.3-1 Reasons for Changes in CMO Pricing in the Next Two Years 1-5
1.4-1 Important Factors in Decision-Making Process Besides Price 1-9
1.4-2 Reasons for Needing Technical Support from a CMO 1-11
1.4-3 Reasons for Needing/Not Needing Regulatory Support from a CMO 1-11
1.4-4 Circumstances for Using China CMO for Chinese Market 1-13
1.5-1 Contractors’ Client Base by Segment 1-14
1.5-2 Strategies for Managing Development Risk: CMOs 1-18
1.6-1 Pricing Models Preferred by Users by Percentage 1-19
1.6-2 Pricing Models Preferred by Users by Product Phase 1-21
1.6-3 Services Users are Willing to Pay Premium for Speed 1-23
1.6-4 Payment of Premium for Speed or Earliest Available Capacity 1-24
1.6-5 Additional Areas Where Premium Might be Paid 1-25
1.7-1 Contractor Preferred Pricing Models by Project Phase 1-29
1.8-1 Users’ Perspective: Challenges in Contract Negotiations 1-37
1.8-2 Contractors’ Perspective: Challenges in Contract Negotiations 1-38
1.8-3 Comparison of Contractor and User Cancellation Fees for GMP Runs 1-40
1.8-4 Observations of Clients’ Tolerance of CMO Rescheduling 1-41
1.8-5 Additional User Observations about Pricing and Contract Agreements 1-43
1.8-6 Additional Contractor Observations about Pricing and Contract Agreements 1-44

Chapter 2

2.2-1 Market Research Steps 2-2
2.5-1 Acronyms 2-4

Chapter 3

3.1-1 Titles of Respondents Listed Alphabetically 3-2
3.2-1 Reasons for Changes in CMO Pricing in the Next Two Years 3-10
3.2-2 Services Where Prices Have Changed the Most 3-15
3.2-3 Factors Affecting Manufacturing Costs: CMOs 3-17
3.3-1 Contractors’ Target Gross Profit Margins 3-21

Chapter 4

4.2-1 Contract Manufacturers Used by Respondents 4-15
4.2-2 Contract Manufacturers Being Considered by Respondents 4-17
4.2-3 Reasons Why a New or Different CMO is Being Considered 4-18
4.3-1 Final Decision Maker for CMO Selection 4-27
4.3-2 Change in Decision Maker for CMO Selection as Project Progresses 4-29
4.3-3 Important Factors in Decision-Making Process Besides Price 4-35
4.3-4 Important Factors in Outsourcing Mammalian Cell-Line Development 4-39
4.3-5 Reasons for Needing Technical Support from a CMO 4-43
4.3-6 Reasons for Needing/Not Needing Regulatory Support from a CMO 4-44
4.3-7 Types of Business Arrangements in Co-Working with CMO 4-50
4.3-8 Concerns to be Addressed Before Proceeding 4-54
## LIST OF TABLES

### Chapter 4

<table>
<thead>
<tr>
<th>Table</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.4-1</td>
<td>Reasons for Importance of Geographic Location in CMO Selection</td>
<td>4-58</td>
</tr>
<tr>
<td>4.4-2</td>
<td>Reasons for Not Considering an Asia-Based CMO</td>
<td>4-63</td>
</tr>
<tr>
<td>4.4-3</td>
<td>Circumstances for Using China CMO for Chinese Market</td>
<td>4-67</td>
</tr>
<tr>
<td>4.5-1</td>
<td>Expression Systems Used by Respondents</td>
<td>4-72</td>
</tr>
<tr>
<td>4.5-2</td>
<td>Reasons for Use of Expression Systems</td>
<td>4-73</td>
</tr>
<tr>
<td>4.5-3</td>
<td>New Technologies Needed at CMOs</td>
<td>4-83</td>
</tr>
</tbody>
</table>

### Chapter 5

<table>
<thead>
<tr>
<th>Table</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1-1</td>
<td>CMOs’ Additional Services Strategies</td>
<td>5-2</td>
</tr>
<tr>
<td>5.1-2</td>
<td>Strategies for Managing Development Risk: CMOs</td>
<td>5-12</td>
</tr>
<tr>
<td>5.2-1</td>
<td>Percentage of Clients: Fee-for-Service versus Partnership Contracts</td>
<td>5-15</td>
</tr>
<tr>
<td>5.2-2</td>
<td>Contractors’ Client Base by Segment</td>
<td>5-18</td>
</tr>
<tr>
<td>5.3-1</td>
<td>Pass-Through Cost Payment Terms</td>
<td>5-27</td>
</tr>
</tbody>
</table>

### Chapter 6

<table>
<thead>
<tr>
<th>Table</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1-1</td>
<td>Pricing Models Preferred by Users by Percentage</td>
<td>6-3</td>
</tr>
<tr>
<td>6.1-2</td>
<td>Pricing Models Preferred by Users by Product Phase</td>
<td>6-5</td>
</tr>
<tr>
<td>6.1-3</td>
<td>Services Users are Willing to Pay Premium for Speed</td>
<td>6-7</td>
</tr>
<tr>
<td>6.1-4</td>
<td>Strategies for Managing Development Risk: Users</td>
<td>6-18</td>
</tr>
<tr>
<td>6.2-1</td>
<td>Payment of Premium for Speed or Earliest Capacity Availability</td>
<td>6-25</td>
</tr>
<tr>
<td>6.2-2</td>
<td>Additional Areas Where Premium Might be Paid</td>
<td>6-26</td>
</tr>
<tr>
<td>6.2-3</td>
<td>Attributes of Long-Term Agreements</td>
<td>6-37</td>
</tr>
</tbody>
</table>

### Chapter 7

<table>
<thead>
<tr>
<th>Table</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.3-1</td>
<td>Contractors’ Preferred Pricing Models by Project Phase</td>
<td>7-15</td>
</tr>
<tr>
<td>7.5-1</td>
<td>Average Number of Batches Per Project By Tank Size</td>
<td>7-22</td>
</tr>
<tr>
<td>7.5-2</td>
<td>Average Number of Weeks Per Project By Tank Size</td>
<td>7-23</td>
</tr>
<tr>
<td>7.5-3</td>
<td>Average Number of Grams Per Project By Tank Size</td>
<td>7-23</td>
</tr>
<tr>
<td>7.6-1</td>
<td>Number of Users’ Products Included in the Analysis</td>
<td>7-30</td>
</tr>
<tr>
<td>7.8-1</td>
<td>Prices Paid or Charged for Additional Services: Mammalian Cell Culture</td>
<td>7-42</td>
</tr>
<tr>
<td>7.8-2</td>
<td>Prices Paid or Charged for Additional Services: Microbial Fermentation</td>
<td>7-47</td>
</tr>
</tbody>
</table>

### Chapter 8

<table>
<thead>
<tr>
<th>Table</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.1-1</td>
<td>Users’ Perspective: Challenges in Contract Negotiations</td>
<td>8-2</td>
</tr>
<tr>
<td>8.1-2</td>
<td>Contractors’ Perspective: Challenges in Contract Negotiations</td>
<td>8-6</td>
</tr>
<tr>
<td>8.2-1</td>
<td>Types and Amounts of Cancellation Fees for Development Services or Non-GMP Batches</td>
<td>8-12</td>
</tr>
<tr>
<td>8.2-2</td>
<td>Users’ Payment of Change Orders</td>
<td>8-16</td>
</tr>
</tbody>
</table>
## LIST OF TABLES (continued)

### Chapter 8

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.3-1</td>
<td>Reservation Fee Arrangements for Development Services or Non-GMP Batches</td>
<td>8-23</td>
</tr>
<tr>
<td>8.3-2</td>
<td>Comparison of Contractor and User Cancellation Fees</td>
<td>8-26</td>
</tr>
<tr>
<td>8.3-3</td>
<td>Cancellation Fees for Development Services or Non-GMP Batches</td>
<td>8-27</td>
</tr>
<tr>
<td>8.3-4</td>
<td>Rescheduling Offerings for Manufacturing Campaigns</td>
<td>8-29</td>
</tr>
<tr>
<td>8.3-5</td>
<td>Observations of Clients’ Tolerance for CMO Rescheduling</td>
<td>8-32</td>
</tr>
<tr>
<td>8.4-1</td>
<td>Concerns Regarding Capital Expenditures or Supply Capabilities</td>
<td>8-36</td>
</tr>
<tr>
<td>8.4-2</td>
<td>Types of Changes in Commercial Contract Terms</td>
<td>8-42</td>
</tr>
<tr>
<td>8.4-3</td>
<td>Areas of Commoditization</td>
<td>8-45</td>
</tr>
<tr>
<td>8.4-4</td>
<td>Barriers to Commoditization</td>
<td>8-45</td>
</tr>
<tr>
<td>8.4-5</td>
<td>Future Market Challenges for Biopharmaceutical Contract Manufacturing</td>
<td>8-50</td>
</tr>
<tr>
<td>8.4-6</td>
<td>Additional User Observations about Pricing and Contract Agreements</td>
<td>8-54</td>
</tr>
<tr>
<td>8.4-7</td>
<td>Additional Contractor Observations about Pricing and Contract Agreements</td>
<td>8-56</td>
</tr>
</tbody>
</table>
LIST OF FIGURES

Chapter 1

1.2-A Locations of Study Participants 1-3
1.3-A Opinions Regarding Price Changes in the Past Two Years 1-4
1.3-B Changes in CMO Pricing in the Next Two Years 1-5
1.4-A Summary of Outsourcing Strategies 1-7
1.4-B Rating of Importance of Price in Decision-Making Process 1-8
1.4-C Importance of Price for Commercial Supply 1-8
1.4-D Technical Support Expected from a CMO 1-10
1.4-E Regulatory Support Expected from a CMO 1-10
1.4-F Interest in Using China CMO for Chinese Market 1-12
1.5-A Contractors’ Client Base by Segment 1-14
1.5-B Rating of Importance of Price in Clients’ Decision-Making Process 1-15
1.5-C Comparison of CMO and User Rating of Importance of Price in Decision-Making 1-16
1.5-D Provisions for Inflation in Contracts 1-17
1.6-A Pricing Models Preferred by Users 1-20
1.6-B Willingness to Pay Premium for Speed or Earliest Capacity Availability 1-22
1.6-C Distribution of Average Premium for Speed or Earliest Capacity Availability 1-22
1.6-D Distribution of Expected Premium for Speed or Earliest Capacity Availability 1-25
1.6-E Comparison of Premium for Speed or Earliest Capacity Availability 1-26
1.6-F Contractors’ Pricing Model for Development Services 1-27
1.7-A Contractors: Primary Pricing Models 1-28
1.7-B Contractor Preferred Pricing Models by Project Phase 1-29
1.7-C Per-Batch Pricing: Average Prices Charged and Paid: Mammalian 1-31
1.7-D Per-Batch Pricing: Average Prices Charged and Paid: Microbial 1-32
1.7-E Time-in-Facility Pricing: Average Prices Charged and Paid: Mammalian 1-33
1.7-F Time-in-Facility Pricing: Average Prices Charged and Paid: Microbial 1-34
1.7-G Per-Gram Pricing: Fee Per Gram by Project Volumes: Mammalian 1-35
1.7-H Per-Gram Pricing: Fee Per Gram by Project Volumes: Microbial 1-36
1.8-A Contractors’ Cancellation Fees for GMP Runs 1-39
1.8-B Users’ Tolerance of CMO Rescheduling 1-41

Chapter 2

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

Chapter 3

3.1-A Locations of Study Participants 3-2
3.1-B Respondents with Biopharmaceutical Products on the Market 3-4
3.1-C Respondents with Biopharmaceuticals in Clinical Trials 3-5
3.1-D Number of Biopharmaceuticals in Clinical Trials 3-5
3.1-E Product Produced in CMO Facility Licensed for Commercial Production 3-6
3.2-A Opinions Regarding Price Changes in the Past Two Years 3-8
3.2-B Changes in CMO Pricing in the Next Two Years 3-10
3.3-A Contractors’ Target Gross Profit Margins by Phase: 2016 and 2019 3-22
Chapter 4

4.1-A Outsource versus In-House Manufacturing 4-1
4.1-B Manufacturing Budgets: Outsourced versus In-House 4-2
4.1-C Percentage of Budget Spent on Outsourcing 4-3
4.1-D Change in Proportion of Manufacturing Budget for Outsourced Production 4-4
4.1-E Outsourcing Budgets: Process Development versus Manufacturing 4-5
4.1-F Level of Outsource Spending for Process Development and Manufacturing 4-6
4.1-G Change in Outsourcing Spending for Process Development and Manufacturing 4-7
4.1-H Summary of Outsourcing Strategies 4-8
4.1-I Future Changes in Outsourcing Strategy 4-12
4.2-A Plan to Use New or Different CMO 4-17
4.3-A Initial Discussions with Contractors 4-22
4.3-B Number of CMOs that Users Seek Proposals From 4-25
4.3-C Change in Decision Maker for CMO Selection as Project Progresses 4-29
4.3-D Rating of Importance of Price in Decision-Making Process 4-34
4.3-E Importance of Price for Commercial Supply 4-34
4.3-F Technical Support Expected from a CMO 4-42
4.3-G Regulatory Support Expected from a CMO 4-42
4.3-H Interest in Co-Work Opportunities with CMO 4-49
4.3-I Consideration of Low Base Price with Bonuses Tied to Target 4-53
4.4-A Effect of Geographic Location on CMO Selection 4-57
4.4-B Willingness to Use an Asia-Based CMO 4-62
4.4-C Interest in Using China CMO for Chinese Market 4-67
4.5-A Use of Expression Systems 4-71
4.5-B Preferred Payment Model for Proprietary Expression Systems 4-77
4.5-C Changing Product Portfolio 4-82
4.5-D New Technologies Needed at CMO 4-82

Chapter 5

5.1-A Phase-Based Business Focus 5-1
5.1-B Rating of Importance of Price in Clients’ Decision-Making Process 5-5
5.1-C Comparison of CMO and User Rating of Importance of Price in Decision-Making 5-6
5.1-D Provisions for Inflation in Contracts 5-9
5.2-A Fee-for-Service versus Partnership Contracts 5-16
5.2-B Percent of Clients Located in Same Country as Contractor’s Facility 5-17
5.2-C Contractors’ Client Base by Segment 5-18
5.3-A Treatment and Charging of Engineering Runs 5-19
5.3-B Average Number of Runs in a Campaign 5-21
5.3-C Engineering Runs Included in Campaign 5-22
5.3-D Provisions for Raw and Consumable Materials 5-24
5.3-E Average Markup Charge for Pass-Through Costs 5-27
5.3-F Charging for Product Support/Project Management 5-30
5.3-G Implementation of Electronic Documentation 5-32

LIST OF FIGURES (continued)

Chapter 6

6.1-A Services Types Expected to Be Included in Batch Pricing 6-2
6.1-B Services Types Expected to Not Be Included in Batch Pricing 6-2
6.1-C Pricing Models Preferred by Users 6-4
6.1-D Willingness to Pay Premium for Speed or Earliest Capacity Availability 6-6
6.1-E Distribution of Average Premium for Speed or Earliest Capacity Availability 6-6
6.1-F Pricing Distribution for Mammalian Cell-Line Development 6-11
6.1-G Time Frame Distribution for Mammalian Cell-Line Development 6-12
6.1-H Clients’ CMO Charging Markups for Purchased Materials 6-14
6.1-I Distribution of Users’ Material Markups Charged by Their CMO 6-15
6.1-J Comparison of CMO Markups Charged for Purchased Materials 6-15
6.1-K Management of Development Risk Comparison: Users versus CMOs 6-19
6.2-A Distribution of Expected Premium for Speed or Earliest Capacity Availability 6-26
6.2-B Comparison of Premium for Speed or Earliest Capacity Availability 6-27
6.2-C Contractors’ Pricing Model for Development Services 6-30
6.2-D Charging for Pre-Production Services 6-32
6.2-E Provide IND Submission Service 6-34
6.2-F How IND Services are Charged 6-34
6.2-G Long-Term Contracts with Clients 6-37
6.2-H Price Reduction Provisions from Process Improvements 6-40

Chapter 7

7.1-B Estimates of Process Development Hours: Mammalian Process 7-3
7.1-C Estimates of Process Development Cost: Microbial Process 7-4
7.1-D Estimates of Process Development Hours: Microbial Process 7-5
7.1-E Annual FTE Rates for Process Development 7-6
7.1-F FTE Rates for Process Development: Users’ Expectations versus Experience 7-7
7.2-A Annual FTE Rates for Manufacturing Staff 7-8
7.2-B Annual FTE Rates for QC Staff 7-8
7.2-C Annual FTE Rates for Project Management Staff 7-9
7.2-D Annual FTE Rates for Regulatory Support Staff 7-9
7.2-E Annual FTE Rates for Analytic Development Staff 7-10
7.2-F FTE Rates for Management Staff: Users’ Expectations versus Experience 7-11
7.2-G FTE Rates for QC Staff: Users’ Expectations versus Experience 7-12
7.2-H FTE Rates for Project Management: Users’ Expectations versus Experience 7-12
7.2-I FTE Rates for Regulatory Support: Users’ Expectations versus Experience 7-13
7.2-J FTE Rates for Analytic Development: Users’ Expectations versus Experience 7-13
7.3-A Contractors: Primary Pricing Models 7-14
7.3-B Contractors’ Preferred Pricing Models by Project Phase 7-16
7.4-A Batch Pricing: Average CMO Rates Per Batch or Run: Mammalian Single Batch versus Multiple Batches 7-18
7.4-B Batch Pricing: Average CMO Rates Per Batch or Run: Microbial Single Batch versus Multiple Batches 7-19
7.4-C Batch Pricing: Average CMO Rates Per Batch: Mammalian Stainless Steel versus Single-Use 7-20
### LIST OF FIGURES (continued)

**Chapter 7**

<table>
<thead>
<tr>
<th>Figure</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.4-D</td>
<td>Batch Pricing: Average Rates Per Batch: Microbial No Refolding versus Refolding</td>
<td>7-21</td>
</tr>
<tr>
<td>7.5-A</td>
<td>Per-Batch Pricing: Average Prices Charged and Paid: Mammalian</td>
<td>7-24</td>
</tr>
<tr>
<td>7.5-B</td>
<td>Per-Batch Pricing: Average Prices Charged and Paid: Microbial</td>
<td>7-25</td>
</tr>
<tr>
<td>7.5-C</td>
<td>Time-in-Facility Pricing: Average Prices Charged and Paid: Mammalian</td>
<td>7-26</td>
</tr>
<tr>
<td>7.5-D</td>
<td>Time-in-Facility Pricing: Average Prices Charged and Paid: Microbial</td>
<td>7-27</td>
</tr>
<tr>
<td>7.5-E</td>
<td>Per-Gram Pricing: Average Prices Charged and Paid: Mammalian</td>
<td>7-28</td>
</tr>
<tr>
<td>7.5-F</td>
<td>Per-Gram Pricing: Average Prices Charged and Paid: Microbial</td>
<td>7-29</td>
</tr>
<tr>
<td>7.6-A</td>
<td>Per-Gram Pricing: Fee per Gram by Project Volumes: Mammalian</td>
<td>7-32</td>
</tr>
<tr>
<td>7.6-B</td>
<td>Per-Gram Pricing: Fee per Gram by Project Volumes: Microbial</td>
<td>7-33</td>
</tr>
<tr>
<td>7.7-A</td>
<td>Per-Batch Pricing: Fee per Batch per Liter by Tank Size</td>
<td>7-34</td>
</tr>
<tr>
<td>7.7-B</td>
<td>Time-in-Facility Pricing: Fee per Batch per Liter by Tank Size</td>
<td>7-35</td>
</tr>
<tr>
<td>7.7-C</td>
<td>Explanation of Box-and-Whiskers Plot</td>
<td>7-36</td>
</tr>
<tr>
<td>7.7-D</td>
<td>Box-and-Whiskers Plot: Per-Batch Pricing: Mammalian Cell Culture</td>
<td>7-36</td>
</tr>
<tr>
<td>7.7-E</td>
<td>Box-and-Whiskers Plot: Per-Batch Pricing: Microbial Fermentation</td>
<td>7-37</td>
</tr>
<tr>
<td>7.8-A</td>
<td>Average Price Paid by Users for Additional Services: Mammalian-1</td>
<td>7-38</td>
</tr>
<tr>
<td>7.8-B</td>
<td>Average Price Paid by Users for Additional Services: Mammalian-2</td>
<td>7-39</td>
</tr>
<tr>
<td>7.8-C</td>
<td>Average Price Paid by Users for Additional Services: Mammalian-3</td>
<td>7-39</td>
</tr>
<tr>
<td>7.8-D</td>
<td>Average Price Paid by Users for Additional Services: Mammalian-4</td>
<td>7-40</td>
</tr>
<tr>
<td>7.8-E</td>
<td>Average Price Charged by CMOs for Additional Services: Mammalian-1</td>
<td>7-40</td>
</tr>
<tr>
<td>7.8-F</td>
<td>Average Price Charged by CMOs for Additional Services: Mammalian-2</td>
<td>7-41</td>
</tr>
<tr>
<td>7.8-G</td>
<td>Average Price Charged by CMOs for Additional Services: Mammalian-3</td>
<td>7-41</td>
</tr>
<tr>
<td>7.8-H</td>
<td>Average Price Paid by Users for Additional Services: Microbial-1</td>
<td>7-44</td>
</tr>
<tr>
<td>7.8-I</td>
<td>Average Price Paid by Users for Additional Services: Microbial-2</td>
<td>7-45</td>
</tr>
<tr>
<td>7.8-J</td>
<td>Average Price Paid by Users for Additional Services: Microbial-3</td>
<td>7-45</td>
</tr>
<tr>
<td>7.8-K</td>
<td>Average Price Charged by CMOs for Additional Services: Microbial-1</td>
<td>7-46</td>
</tr>
<tr>
<td>7.8-L</td>
<td>Average Price Charged by CMOs for Additional Services: Microbial-2</td>
<td>7-46</td>
</tr>
<tr>
<td>7.8-M</td>
<td>Average Price Charged by CMOs for Additional Services: Microbial-3</td>
<td>7-47</td>
</tr>
</tbody>
</table>

**Chapter 8**

<table>
<thead>
<tr>
<th>Figure</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.2-A</td>
<td>Cancellation Fees Paid by Users for GMP Runs</td>
<td>8-9</td>
</tr>
<tr>
<td>8.2-B</td>
<td>Cancellation Fees for Development Services or Non-GMP Batches</td>
<td>8-11</td>
</tr>
<tr>
<td>8.2-C</td>
<td>Users’ Change Orders</td>
<td>8-15</td>
</tr>
<tr>
<td>8.2-D</td>
<td>Users’ Frequency of Change Orders</td>
<td>8-15</td>
</tr>
<tr>
<td>8.3-A</td>
<td>Distribution of Average Reservation Fees for GMP Runs Charged by CMOs</td>
<td>8-20</td>
</tr>
<tr>
<td>8.3-B</td>
<td>Charging of Reservation Fees for GMP Runs</td>
<td>8-20</td>
</tr>
<tr>
<td>8.3-C</td>
<td>Time Slot Guarantee and When Reservation Fee is Paid</td>
<td>8-21</td>
</tr>
<tr>
<td>8.3-D</td>
<td>Reservation Fee Differences Between GMP Runs and Development Services</td>
<td>8-23</td>
</tr>
<tr>
<td>8.3-E</td>
<td>Contractors’ Cancellation Fees for GMP Runs</td>
<td>8-25</td>
</tr>
<tr>
<td>8.3-F</td>
<td>Charging of Cancellation Fees for Development Services or Non-GMP Batches</td>
<td>8-27</td>
</tr>
<tr>
<td>8.3-G</td>
<td>Users’ Tolerance of CMO Rescheduling</td>
<td>8-31</td>
</tr>
<tr>
<td>8.4-A</td>
<td>Concerns Regarding Capital Expenditures or Supply Capability</td>
<td>8-35</td>
</tr>
<tr>
<td>8.4-B</td>
<td>Change in Commercial Contract Terms</td>
<td>8-42</td>
</tr>
<tr>
<td>8.4-C</td>
<td>Commoditization in the Biopharmaceutical Manufacturing Industry</td>
<td>8-44</td>
</tr>
</tbody>
</table>