



Guide

Biopharmaceutical Process Development and Manufacturing



TECHNOLOGY FOR PRODUCTION, FINANCIAL, QUALITY AND COMPLIANCE SUCCESS



- Process Characterization / Design of Experiments (DOE)
- Site-to-Site Tech Transfer
- Scale-Up Tech Transfer
- Automation IT (Integration & IV&V)
- Verification, Commissioning & Qualification
- Process Validation
- FDA/EMA/SFDA Compliance Consulting
- Reliability & Asset Performance Management
- Owner's Project Management
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- Operational Excellence
- Outage Planning & Management

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Guide

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Disclaimer:

This Guide focuses on the development and the process approaches and practices involved in providing cost effective, regulated manufacturing of biopharmaceutical products in a timely manner that meet their intended use. ISPE cannot ensure and does not warrant that a system managed in accordance with this Guide will be acceptable to regulatory authorities. Further, this Guide does not replace the need for hiring professional engineers or technicians.

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Preface

The development and scaling up of processes is a cornerstone of success for the biopharmaceutical industry in making safe and effective medicinal products. These processes are required to meet cGMP regulations wherever products are marketed, while remaining in compliance with all other governing codes, laws, guidelines, and regulations.

This Guide focuses on the development and the process approaches and practices involved in providing cost effective, regulated manufacturing of biopharmaceutical products in a timely manner that meet their intended use. It is intended to be used by industry for the design, development and scaling up to regular production, all leading to processes meeting the requirements from FDA, EMA, MHLW, WHO, PMDA or other health authorities.

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Table of Contents

1	Introduction	9
1.1	Background.....	9
1.2	Purpose.....	9
1.3	Scope.....	10
1.4	Key Concepts.....	11
1.5	Structure	12
2	Regulatory Considerations for Biopharmaceutical Process Development and Manufacturing.....	13
2.1	Introduction	13
2.2	Regulatory Organizations	14
2.3	Specific GMP Regulatory Requirements for Non-US Markets and Non-US Manufacturing Locations.....	18
2.4	Relationship to ICH Guidance Documents	23
2.5	Regulatory Considerations Across the Product Life Cycle.....	23
2.6	Differences Between the EU and FDA Approaches to Risk.....	27
3	Biopharmaceutical Processes, General	29
3.1	Introduction	29
3.2	Stages of Biopharmaceutical Product Development.....	31
3.3	Overview of the Regulatory Implications of Quality by Design and Quality Risk Management	39
3.4	Stability	43
4	Upstream Unit Operations	45
4.1	Cell Line Development.....	45
4.2	Cell Bank Preparation, Validation, and Maintenance.....	49
4.3	Fermentation and Cell Culture.....	52
4.4	Media Systems	57
4.5	Clarification and Recovery.....	58
5	Downstream Processing Unit Operations	63
5.1	Overview of Downstream Processing	63
5.2	Filtration in Downstream Processing	66
5.3	Chromatography Operations.....	70
5.4	Viral Clearance	71
5.5	Biopharmaceutical and Vaccine Conjugation.....	76
5.6	Bulk Formulation and Filling.....	77
5.7	Buffer Preparation and Storage	79
5.8	Special Topics	80
6	Scale-Up and Technology Transfer	87
6.1	Introduction	87
6.2	Scale-Up General Considerations	87
6.3	Upstream Scale-Up.....	88
6.4	Primary Recovery	90
6.5	Chromatography	91
6.6	Ultrafiltration/Diafiltration (UF/DF).....	91
6.7	Technology Transfer.....	92

7	Process Support and Utility Systems	103
7.1	Introduction	103
7.2	Regulatory Guidance	103
7.3	Materials of Construction	104
7.4	System Layout and Routing.....	106
7.5	Specific Service Considerations	106
7.6	Pharmaceutical Water.....	106
7.7	Pharmaceutical Steam.....	110
7.8	Equipment Cleaning.....	110
7.9	Process and Utility Gases.....	113
7.10	Process Temperature Control Systems	113
7.11	Cryogenics and Process Cooling.....	114
7.12	Process Bio-Waste Handling	114
7.13	Drains and Waste Collection.....	115
7.14	Potable Water Systems	115
7.15	Vacuum Systems	115
7.16	Electrical Services.....	116
8	Process Impact on Facilities	117
8.1	Introduction	117
8.2	Process Considerations.....	117
8.3	Application of Risk Assessment to Facility Design.....	124
8.4	Impact of Operational Philosophy and Process Definition on Facility Design.....	124
8.5	The Impact of Closed System Process Design on Facility Design	129
8.6	Automation and Control Philosophy Impacts on Facility Design.....	129
8.7	Pilot Plant Items for Consideration.....	130
9	Appendix 1 – Non-US Manufacturing and Non-FDA Regulated Market Requirements.....	135
9.1	Introduction	136
9.2	Occupational Health and Safety Regulatory Organizations and Standards	136
9.3	Environmental Regulatory Organizations and Standards	139
9.4	Specific GMP Regulatory Requirements for Non-US Markets and Non-US Manufacturing Locations....	140
9.5	Residual DNA.....	143
9.6	Drug Development and Clinical Trials.....	144
9.7	Specific Safety Requirements for Non-US Manufacturing Locations.....	145
9.8	Environmental Aspects Specifically Related to Biopharmaceutical Processing.....	145
9.9	Particular Engineering Items Affecting Bio-Equipment and Process Systems Design	145
9.10	General Commentary on Specific Environmental Health and Safety Issues	146
10	Appendix 2 – Equations	149
10.1	Growth Curve Equation for Batch Fermentations	150
10.2	Design Equations for a Fermentation System	153
11	Appendix 3 – Detailed Information.....	155
11.1	Bacterial and Mammalian Cell Types.....	156
11.2	Stirred Tank Reactor Scale-Up	156
11.3	Cell Disruption.....	161
11.4	Homogenization	162
11.5	Centrifugation.....	166
11.6	Filtration	171
11.7	Chromatography Operations.....	184

12	Appendix 4 – References	197
13	Appendix 5 – Glossary	207
	13.1 Acronyms and Abbreviations	208
	13.2 Definitions	214



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1 Introduction

1.1 Background

The development and scaling up of processes is a cornerstone of success for the biopharmaceutical industry in making safe and effective medicinal products. These processes are required to meet cGMP regulations wherever products are marketed, while remaining in compliance with all other governing codes, laws, guidelines, and regulations.

There is a high focus on process understanding both from regulators and from the industry. A better process understanding is required under the currently much discussed concepts, e.g., quality risk management or quality by design, as outlined in respective ICH documents.

1.2 Purpose

This Guide focuses on the development and the process approaches and practices involved in providing cost effective, regulated manufacturing of biopharmaceutical products in a timely manner that meet their intended use. It is intended to be used by industry for the design, development and scaling up to regular production, all leading to processes meeting the requirements from the following:

- World Health Organization (WHO)
- European Medicines Agency (EMA)
- Food and Drug Administration (FDA) (US)
- Japan Ministry of Health, Labour, and Welfare (MHLW) (Japan)
- Pharmaceuticals Medical Devices Agency (PMDA) (Japan)
- Other health authorities

The Guide is intended to be in alignment with ICH guidance including:

- ICH Q3 [1]
- ICH Q4 [2]
- ICH Q5 [3]
- ICH Q6 [4]
- ICH Q7 [5]
- ICH Q8 [6]
- ICH Q9 [7]
- Applicable parts of ICH Q10 [8] and ICH Q11 [9]
- Associated international standards, regulations, and guidance documents