ISPE 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
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- Outage Planning & Management

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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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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