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Nota di contenuto	Guidelines for Process Safety in Bioprocess Manufacturing Facilities; CONTENTS; List of Tables; List of Figures; Items on the Web Accompanying This Book; Acknowledgements; Preface; 1 INTRODUCTION; 1.1 Bioprocess Engineering Information Transfer and Management Practices; 1.2 The Need for Bioprocess Safely Management Systems; 1.2.2 Bioprocessing Incidents and Releases; 1.3 Our Target Audience; 1.4 How to use this Guideline; 2 AN OVERVIEW OF THE BIOPROCESSING INDUSTRY; 2.1 Bioprocessing's History; 2.1.1 Bioprocessing's Historical Advancement; 2.1.1.1 Microbiological Advancements 2.1.1.2 Food Science and Food Process Technology Advancements2. 1.1.3 Genetic Advancements; 2.1.1.4 Future Bioprocessing Developments; 2.2 Industrial Applications; 2.2.1 Processes; 2.2.2 Products; 2.3 The Bioprocess Lifecycle; 2.3.1 Discovery; 2.3.2 Development Phase: Laboratory and Pilot Plant; 2.3.3 Scale-up Phase; 2.3.4 Upstream Operations and Downstream Operations; 2.3.4.1 Inoculation / Seed and Production Biosafety Containment and Production Risk; 2.3.4.2 Fermentation / Cell Culture; 2.3.4.3 Scale of

Manufacturing; 2.3.5 General Biosafety Recommendations for Large Scale Work
2.3.5.1 Facility Design2.3.5.2 Equipment Design; 2.3.5.3 Cleaning, Inactivation, and Sterilization; 2.3.5.4 Maintenance; 2.3.5.5 Air and Gas Emissions; 2.3.5.6 Waste Handling; 2.3.5.7 Accidental Release; 2.3.6 Product Safety Information; 2.3.6.1 Product Handling; 2.3.6.2 Material Disposal; 2.3.6.3 Disposable Process Technology; 2.3.7 Outsourced Manufacturing Concerns; 3 BIOPROCESSING SAFETY MANAGEMENT PRACTICES; 3.1 Sample Approach; 3.1.2 Develop and Document a System to Manage Bioprocess Safety Hazards; 3.1.3 Appoint a Biological Safety Officer; 3.1.4 Collect Bioprocess Hazard Information 3.1.5 Identify Bioprocess Safety Hazards3.1.5.1 Point of Decision; 3.1.6 Assess Bioprocess Safety Risks and Assign Bioprocess Safety Hazard Level; 3.1.7 Identify Bioprocess Controls and Risk Management Options; 3.1.8 Document Bioprocess Safety Hazard Risks and Management Decisions; 3.1.9 Communicate and Train on Bioprocess Safety Hazards; 3.1.10 Investigate & Learn from Bioprocess Incidents; 3.1.11 Review, Audit, Manage Change, and Improve Hazard Management Practices and Program; 3.2 Existing Management Systems; 3.2.1 Product Stewardship for Bioproducts
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4.1 Key Considerations for Assessing Risk to Manage Bioprocess Safety

Sommario/riassunto

"This book helps advance process safety in a key area of interest. Currently, no literature exists which is solely dedicated to process safety for the bioprocessing industry. There are texts, guidelines, and standards on biosafety at the laboratory level and for industrial hygiene, but no guidelines for large-scale production facilities. In fact, biosafety is largely defined as a field that promotes safe laboratory practices, procedures and use of containment equipment and facilities. Additionally, biomedical engineers, biologists, or other professionals without chemical engineering training or knowledge of inherently safe design are designing many of these facilities"--