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Standard Guide for Biopharmaceutical Facilities Architectural Design Considerations¹

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1. Scope

1.1 This guide covers architectural design considerations for buildings and facilities used in the biological processing industry to make drugs, chemicals, and other products.

1.2 These designs are intended to meet current good manufacturing practices (cGMP) criteria and guidelines published by the U.S. Food and Drug Administration (FDA) for processes and products manufactured under CFR Title 21.

1.3 While the guidelines described are general in nature, they are not expected to apply to all of the possible biotechnical processes used in the industry today. Accordingly, the user of this guide must exercise good engineering judgment in specific design applications to select the proper guidelines that apply.

1.4 In addition to the cGMP guidelines provided herein, other regulations and guides should be considered that are promulgated by other federal agencies such as the Occupational Safety and Health Administration (OSHA), the U.S. Environmental Protection Agency (EPA), the U.S. Drug Administration (USDA), the National Institute of Health (NIH), and so forth.

1.5 While the buildings will be designed to meet specific functional requirements and comply with local zoning ordinances, building codes, handicapped employee standards, and so forth, these considerations are not included in this guide.

1.6 The values stated in SI units are to be regarded as the standard.

1.7 *This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 Code of Federal Regulations:

CFR Title 21, Parts 58, 210, 211, 212, 606, 809, 820²

¹ This guide is under the jurisdiction of ASTM Committee E-48 on Biotechnology and is the direct responsibility of Subcommittee E48.01 on Materials for Biotechnology.

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² Available from Standardization Documents Order Desk, Bldg. 4, Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

2.2 Other Document:

NIH Guidelines, Containment Area Designations³

3. Terminology

3.1 Definition:

3.1.1 *cGMP*—abbreviation for current good manufacturing practices as defined in CFR Title 21, Parts 210 and 211.

4. Significance and Use

4.1 This guide is intended for use in designing laboratory, pilot plant, commercial production buildings that will use processes involving living organisms to produce products. These products are also manufactured under the FDA and other federal agency regulations.

4.2 These guidelines include the layout of facilities, design of containment areas, ventilation and air quality, personnel areas, special processing hazards, controlled environment areas, and other items.

4.3 This guide is for use by engineers, architects, and owners of biopharmaceutical manufacturing facilities to consider the special factors in laying out the facilities to meet cGMP requirements and other good engineering principles.

4.4 By using these guidelines along with other design criteria required by a variety of regulatory agencies, a validation effort can be achieved more easily to meet agency requirements and obtain operating permits.

4.5 This guide is intended to provide general guidelines for consideration and application in a variety of plant operations and processes in which the designers can make specific decisions concerning the exact architectural design features to use.

5. Summary of Guide

5.1 This guide provides architectural design principles to consider when applying federal regulations to biopharmaceutical plant facilities construction and functions. Check lists for specific plant operation activity areas presented with criteria for their design and layout considerations. Environmental considerations are also included for aseptic and special laminar

³ Available from National Institutes of Health, (NIH), 9000 Rockville Pike, Bethesda, MD 20892.