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ASME STANDARDS & CERTIFICATION

Bioprocessing Equipment (BPE) Committee

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Bioprocessing Equipment (BPE) Committee

The ASME Bioprocessing Equipment (BPE) Committee was formed in 1990 to promulgate an ASME standard intended for design, materials, construction, inspection, and testing of equipment for use in the biopharmaceutical industry.

Membership on ASME committees requires a commitment from both members and their employers. In addition to travel and attendance commitments, members must be prepared to devote time to committee ballots and correspondence. Members are appointed to subcommittees for a term of five years, during which time they will be required to attend three meetings per year. Meeting locations are decided upon by the Standards Committee.

All Task Group, Subcommittee, and Standards Committee meetings are open to the public.

The following subcommittees report to the BPE Standards Committee:

a) Subcommittee on Certification Requirements

This subcommittee provides requirements for the certification of organizations providing components in accordance with this standard. It also provides requirements for the authorization of organizations to mark with the ASME Certification Mark.

b) Subcommittee on Material Joining

This subcommittee establishes requirements for the joining of metallic materials associated with BPE equipment where high purity and process control is essential. It develops requirements for joining methods, weld acceptance/rejection criteria, fit-up, concavity and weld geometry, examination, inspection, testing, and procedures and performance qualifications.

c) Subcommittee on Surface Finish

This subcommittee's primary emphasis is on the selection of appropriate material (metallic and polymeric) and its related product contact surface finish that will enhance efficient cleaning and sterilizing procedures. The requirements it develops address potential cleanliness, sterility and purity problems.

d) Subcommittee on Sealing Components

This subcommittee establishes requirements for sealing components of seals, valves, and fittings used in the bioprocessing industry. These sealing components create or maintain process boundaries between system components and/or subassemblies to ensure process system integrity.

e) Subcommittee on Dimensions and Tolerances

This subcommittee is responsible for establishing requirements for overall dimensions, tolerances, and all supplementary conditions for process components that ensure fit-up and compatibility. It reviews existing national and international standards and incorporates them as required.

Additionally, the subcommittee works to standardize hygienic fitting dimensions, develop marking procedures for identity, and develop workable standard tolerances for exacting fit-up.

f) Subcommittee on Systems Design

This subcommittee develops design criteria for bioprocessing equipment, components, assemblies, and systems to establish industry requirements for efficient cleanability and bioburden control in bioprocessing systems.

g) Subcommittee on General Requirements and Editorial Review

This subcommittee coordinates the drafts produced by the other subcommittees. It is responsible for developing a lexicon of terms encompassing all the different parts of the standard.

h) Subcommittee on Polymers and Other Nonmetallic Materials

This subcommittee establishes requirements that are applicable to and unique to the use of polymer and other nonmetallic materials used in bioprocessing equipment, components (single-use and multi-use) assemblies, and bioprocessing systems. Polymer-based materials include thermoplastics and thermosetting materials in both virgin and composite forms.

i) Subcommittee on Metallic Materials

This subcommittee's primary emphasis is on the selection of acceptable metallic materials for use in hygienic service and definition of mechanical and physical properties, testing procedures, and other attributes for these materials. Additionally, it defines a method by which other metallic materials may be submitted for consideration.

j) Subcommittee on Process Instrumentation

This subcommittee establishes requirements applicable to the proper design, installation, and use of process instrumentation in hygienic systems. It addresses any process instrumentation and associated integrally mounted components in direct contact with the product, raw materials, or product intermediates.