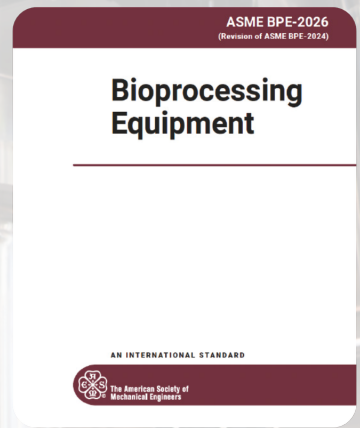


ASME BPE-2026

Bioprocessing Equipment

Updated guidance for high-purity systems, single-use technologies, and certified bioprocessing equipment.



ASME BPE-2026 provides the bioprocessing, pharmaceutical, and personal-care industries with a globally recognized standard for designing, fabricating, inspecting, testing, and certifying equipment used in hygienic and high-purity production environments.

With stronger single-use requirements, updated integrity testing expectations, and enhanced documentation guidance, BPE-2026 helps organizations strengthen contamination control, improve audit readiness, and support safer, more consistent bioprocessing equipment and systems.

What's included in this Standard:

- Updated requirements for hygienic design and high-purity equipment used in bioprocessing and pharmaceutical production
- Expanded guidance for single-use process components, single-use instrumentation, and joining methods
- New and expanded leak and integrity testing methods, including formalized Maximum Allowable Leakage Limit, or MALL
- Dual-marking pathway for BPVC U-Stamp holders pursuing BPE certification
- Updated acceptance criteria for metallic and polymeric product-contact surfaces
- Stronger documentation, change-notification, Certificate of Conformance, and record-retention expectations
- Enhanced guidance for cleanability, drain-ability, material compatibility, passivation, electropolishing, and hygienic instrumentation installation

BPE-2026 is especially relevant for organizations operating in regulated, high-purity production environments where contamination control, supplier quality, documentation, equipment qualification, and audit readiness are critical to product quality and patient safety.

Intended for those who have direct or indirect responsibilities in the areas of:

Bioprocessing equipment design, facility engineering, process engineering, quality assurance, validation, contamination control, supplier qualification, procurement, pressure vessel and tank fabrication, hygienic instrumentation, component manufacturing, inspection, certification, documentation control, cleanroom operations, and regulated manufacturing compliance.

Relevant industries include:

Biopharmaceutical manufacturing, pharmaceutical preparations, biologics production, vaccine manufacturing, cell and gene therapy, advanced therapies, personal-care manufacturing, medical equipment and supplies, industrial machinery and equipment, high-purity process equipment, commercial biological research, and hygienic component manufacturing.



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