

WHITEPAPER

THE ASME BPE STANDARD IN BIOPHARMACEUTICAL MANUFACTURING – WHAT REALLY MATTERS





Pharmaceutical production and biotechnology – industries with special hygiene requirements

Biotech production is a growing industry. Driven by the increasing number of innovative biopharmaceuticals and new cell and gene therapies, the demands on biotechnological plant engineering are also rising. Pharmaceutical companies demand absolute hygiene, precision, and reliability from the equipment and components used. Anyone who wants to be among the first suppliers must provide installations that are tailored to the specific needs of pharmaceutical and biotechnological processes and meet strict quality standards.

But what exactly are the process engineering units involved? And what requirements do equipment and plant manufacturers face?

The following are used, for example

- **Bioreactors for the cultivating of microorganisms and cells**
- **Separators, filter and chromatography systems for separation and purification**
- **Preparation systems for the production of culture media and buffer solutions**
- **CIP/SIP systems for cleaning and sterilizing the equipment**
- **Piping systems for transporting media and products**
- **Storage and distribution systems for raw materials and products**

National and international authorities and committees keep a close eye on the production of critical biopharmaceuticals and subject the industry to strict regulations. Plant and equipment manufacturers in the pharmaceutical and biotechnology sectors are confronted with a variety of guidelines and standards designed to ensure high standards of hygiene,

safety, and consistent quality. At the heart of this are the GMP (Good Manufacturing Practice) requirements, which broadly define the requirements for the manufacture, processing, testing, packaging, and storage of medicinal products. These are monitored by the FDA in the USA and the EMA in Europe. Both issue detailed guidelines that are harmonized in parts but also differ in some respects. In order for plants and equipment to comply with the GMP standard, they must meet the high requirements set out here in terms of materials, surface finish, hygienic design, geometry, and documentation.

Compliance with the ASME BPE standard is therefore essential for plant manufacturers in order to achieve these goals. Dockweiler AG / AS (Dockweiler ASIA) is ASME BPE certified and offers a comprehensive portfolio of pipes and fittings manufactured in accordance with ASME BPE. By using these products, plant manufacturers can be sure that they meet their customers' GMP requirements.



Image: Dockweiler

The ASME BPE Standard: A Guide for Industry Experts

The ASME-BPE has a long tradition. Essentially, it deals with the design and manufacture of plants, apparatus, and components used in pharmaceuticals and biotechnology.

Since its introduction in 1997 by the American Society of Mechanical Engineers, the standard has been revised every two years and becomes effective six weeks after approval. Dockweiler experts also participate in the committee, ensuring that Dockweiler components are always manufactured according to the latest findings.

The standard applies to

- **All components that come into contact with the product, raw materials, or intermediate products;**
- **Critical systems such as water for injection (WFI), clean steam, filtration and storage;**
- **Tube systems for hygienic processes.**

Key components of the ASME BPE standard

The ASME BPE standard specifies requirements for materials and material testing, design for sterilizability, surface requirements, documentation, and traceability. By specifying the use of high-quality, corrosion-resistant materials and designs that ensure easy cleaning and sterilization, the ASME BPE standard guarantees high hygiene standards. In addition, surface roughness requirements are specified to minimize contamination risks, and detailed documentation and traceability of materials and processes are required.

Image: Dockweiler



This is what it entails in detail

- **Material requirements:** Components must be made of biocompatible, corrosion-resistant materials (e.g., 316L stainless steel, approved polymers, elastomers) that comply with defined ASTM/ASME standards to ensure purity and durability.
- **Various specifications for surface roughness** (defined Ra max values, e.g., SF1 = 0.51 µm / SF4 = 0.38 µm), surface treatment (e.g., mechanically polished SF1 - SF3; electropolished SF4 - SF6) and other surface acceptance criteria (e.g., scratches, indentations, etc.).
- **Design for cleanability and sterilizability:** The geometry of the equipment must avoid dead spaces, gaps, and accumulations in low-lying areas. The design must support both CIP (clean-in-place) and SIP (steam-in-place) processes without compromising structural integrity.
- **Dimension and compatibility standards:** Tubes, fittings, valves, and connectors comply with specified nominal dimensions, wall thicknesses, and tolerances to ensure compatibility between different manufacturers and easy assembly/disassembly.
- **Welding and manufacturing requirements:** Welding processes (often orbital welding) must produce smooth, fully welded joints without gaps. The acceptability of discoloration is assessed using the ASME BPE tables MJ-8.4-2 / MJ-8.4-3, and heat treatment after welding may be required in some circumstances. There are also additional tables for acceptance criteria for visual inspection of welds (e.g., porosity, inclusions, slag points, etc.).
- **Validation, documentation, and traceability:** Each component requires detailed documentation (material certificates, manufacturing documents), unique identification, and traceability from raw material to final installation in order to comply with legal requirements.

In the 2024 revised standard, the committee members have additionally included the topics of TOC (Total Organic Carbon) and single use:

- **Expansion of the certification program for static polymer seals (quality system certificate) and metal valves (approval certificate)**
- **Inclusion of austenitic stainless steels in accordance with JIS specifications, e.g. SUS316L**
- **Inclusion of super duplex UNS S32750 (2507) / 1.4410**
- **Inclusion of welding consumables/consumable inserts UNS No6686 for welding super austenitic stainless steels**
- **Pressure ratings for metallic fittings manufactured in accordance with DT-4.1**
- **Specific tolerances for welded pipe ends (DT-7.2)**
- **88° and 92° elbows as new DT components**
- **Additional dimensions for large reducing tees**
- **Revised design and dimensions of automatic pipe welding caps**
- **Separation of requirements for multi-use and single-use systems, equipment and components**
- **New structure with three categories:**
Basic requirements, multi-use applications, and single-use applications

Advantages of ASME BPE compliance

Compliance with the ASME BPE standard ensures adherence to international regulations. For manufacturers of biopharmaceutical equipment, this means the certainty of manufacturing in accordance with GMP and FDA requirements.

And there is another plus: plant and equipment manufacturers who consistently apply the ASME BPE guidelines can often achieve higher production efficiency, reduce development and manufacturing costs, and increase quality and safety.

For biopharmaceutical plant and process equipment manufacturers who use ASME BPE-compliant tubes and fittings, this offers several strategic and practical advantages for their projects:

Advantage	Project benefits
Securing hygiene standards	Product-contact surfaces meet defined roughness and material requirements → minimizes contamination risks
Regulatory compliance	Complies with international standards and regulatory requirements (e.g., FDA, EMA) → fewer audit complaints
Planning and financial security	Consistent dimensions and tolerances facilitate design and procurement → less rework, on-time commissioning
Compatibility & interchangeability	Components from different suppliers fit together seamlessly → flexible supply chains
Longer lifetime of the plant	High corrosion and chemical resistance → reduced downtime and maintenance costs
Process optimization	Improved CIP/SIP cleanability → fast restart times and higher plant availability
International market opportunities	Use in global projects without adaptation to regional hygiene requirements → competitive advantage in tenders

Additional practical benefits: Equipment manufacturers who use ASME BPE-certified pipe components can offer projects directly on an international scale, saving time in planning and avoiding costly changes shortly before acceptance.





Why ASME-BPE is not always ASME-BPE

In addition to German and European premium suppliers, there are around 20 globally certified manufacturers of tubing components – most of which are based in Asia. This appears to be an advantage for buyers, as it gives them more suppliers to choose from. However, it is also becoming increasingly difficult for individuals to separate the wheat from the chaff, as the specifications are very similar. As a result, hygiene-critical piping components are becoming largely interchangeable commodities that differ only in price. ASME-BPE certification is also in danger of losing its significance. Increasingly, the American Society of Mechanical Engineers stamp on piping components is not a guarantee of high product quality, but merely formal proof of an existing quality management system. This is mainly because, according to the American Society of Mechanical Engineers website, the primary focus is on “certification of the quality management system for organizations that manufacture components and equipment for bioprocessing within the scope of the ASME BPE standard ‘Bioprocessing Equipment’.” In plain language, this means that the manufacturer submits its quality management manual and it is assessed to determine whether it meets the requirements of the current ASME BPE edition. Later, an ASME survey team checks the QMS documentation and its implementation on site. All of this is a snapshot and no guarantee of lasting process discipline, manufacturing consistency, traceability, and adherence to deadlines.

"When you buy from us, you are not just buying to standard – you are getting the highest, reproducible level of quality, documented and ready for delivery."

Dr. Lydia Fehlberg, Product Manager

But this is precisely what is crucial in a regulated environment. Quality deviations, missing documentation, or fitting inaccuracies can quickly turn a supposed price advantage into the opposite and make GMP systems many times more expensive.

What do plant manufacturers need to consider with focus on GMP?

- **Material selection:** Selecting the right materials for installation components is crucial to ensure that they meet pharmaceutical standards and do not have a negative impact on product quality.
- **Surface qualities:** The surfaces of the systems must be easy to clean in order to ensure compliance with hygiene regulations.
- **Hygienic design:** It is particularly important to have a hygienic design, especially when manufacturing sterile products, in order to prevent contamination.
- **Geometries:** The shape and design of the system components can affect product quality and must therefore be carefully considered.
- **Documentation:** Comprehensive documentation of the plant design is required to demonstrate compliance with GMP requirements.

For premium manufacturers, the quality management manual is not just a document, but a living experience of quality. This is another reason why premium manufacturers are characterized by an understanding of quality that goes far beyond the minimum standards set by ASME-BPE. The quality system integrates quality, environmental, and safety management (ISO 9001, 14001), and internal controls ensure that all production steps are checked multiple times.

Dockweiler, for example, applies up to 50 quality assurance steps per component. In production, the premium supplier relies on seamless quality control—from material testing to final acceptance, the “path” of the goods is seamlessly documented in SAP:

- **Visual inspection, dimensional inspection, endoscopy, dye penetration testing, delta ferrite measurement, microscopy, micro sections, surface analysis (XPS) ...**
- **Non-destructive material testing and corrosion testing under real conditions**
- **Documentation of every step in a digitized QM system, traceable at any time**

These measures not only ensure quality, but also create trust and transparency—crucial for customers in regulated GMP markets.

Original instead of commodity

It is therefore worthwhile for purchasers to take a close look. Premium manufacturers fully comply with ASME BPE specifications: the plant manufacturer does not take any risks with deviations that could later lead to audit complaints.

Complete documentation packages (material certificates, welding reports, test reports) facilitate GMP compliance and complaint management. Another advantage is that customers have direct access to engineering expertise, e.g., for special solutions, material selection, or surface treatment.

Premium manufacturers invest in R&D, e.g., for optimized geometries, new materials, or improved welding technology and surface processes that increase efficiency and hygiene.

In addition, companies such as Dockweiler, which have decades of tradition in the market, guarantee continuity and a secure supply of spare parts for years to come.

High level of manufacturing expertise among premium manufacturers

70 Years of Dockweiler: a commitment to quality with a long-term guarantee

- 1. Measurable premium surfaces:** Ra values and topography are maintained and documented with test reports – across the entire supply chain.
- 2. Traceability back to the raw material:** Each batch and each component is clearly marked; complete 3.1 certificates, measurement and cleaning records are included.
- 3. In-house production of critical processes:** Polishing, cleaning, and packaging are carried out in-house → reproducible quality without external interfaces.
- 4. Stricter tolerances than the standard:** Perfect fit ensures reduced assembly effort and faster commissioning.
- 5. Validated CIP/SIP cleanability:** Practically tested surfaces reduce qualification effort and create greater process reliability.
- 6. Audit-proof documentation:** Structured documentation packages facilitate GMP approvals and minimize queries from QA or authorities.
- 7. First-hand technical advice:** Customers get direct access to application expertise and special solutions without any workarounds.
- 8. Predictable delivery times & high availability:** Warehousing in Europe and Asia protects projects against delays.
- 9. Long-term continuity:** Dockweiler stands for consistent quality over many years – ideal for spare parts strategies in validated plants.
- 10. Proven lifecycle advantage:** Fewer non-conformities, less downtime and reduced batch risks lower overall costs over the lifecycle.

Welding properties and subsequent processability of pipeline components are key factors for plant engineers in ensuring efficient production processes that help keep costs under control. The manufacturing processes used for T-pieces, elbows, and other workpieces are crucial in this regard. The basis for this is homogeneous materials whose corrosion behavior and welding properties meet high standards. Dockweiler therefore uses only high-quality primary melts sourced from selected and audited suppliers. The materials are verified batch by batch as soon as they arrive, rather than simply checking the tool results, as is often the case. Material characterization and surface analysis are carried out in our own laboratory.

The surface of the pipe components is particularly critical in terms of hygiene. Electropolishing is the key to hygienic, passivated and reproducibly clean surfaces. Unlike many of its competitors, Dockweiler carries out this process entirely in-house, giving it full control over this critical manufacturing step, which also ensures high corrosion resis-



tance of the components. In-house electropolishing also means no dependence on subcontractors, no loss of quality due to transport and no loss of information for validation.

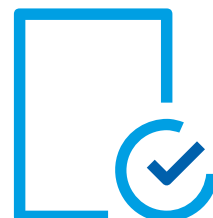
Overall, all these measures not only ensure the quality of the piping components, but also create trust and transparency – crucial for customers in regulated markets.

Conclusion: A Dockweiler elbow or tee is not a commodity product, but a verifiably validatable process component – which makes all the difference in a GMP-regulated environment.

Brief profile of Dockweiler

Dockweiler AG is one of the world's leading suppliers of stainless steel tube systems for technical gases and sensitive liquids. Our products, such as tubes, fittings, connections, and customized solutions, are used for media supply in the future-oriented industries of micro-

electronics (semiconductor industry), life sciences (pharmaceuticals and biotechnology), and new energy (photovoltaics and plasma fusion). For many decades, we have been supporting our customers with our expertise as a supplier to high-tech industries.



Checklist ASME BPE conformity

Inspection point	What to look for	Verification/ test method
☐ 1. Material certificate	Material in accordance with ASME BPE (e.g., 316L, specified heat treatment)	3.1 Material certificate, analysis values
☐ 2. Surface quality	Ra value $\leq 0.51 \mu\text{m}^*$ (or project-specific in accordance with ASME BPE chapter).	Measurement report, surface inspection report
☐ 3. Weld seams	Consistent, burr-free internal contour; welding process and qualifications documented	Endoscope photos, WPS/PQR verification
☐ 4. Dimensional accuracy	Compliance with dimensional and shape tolerances according to ASME BPE	Measurement report, gauge inspection
☐ 5. Cleaning & packaging	Free of particles, oil, grease; hygienic final packaging	Visual inspection, cleaning report
☐ 6. CIP/SIP capability	Material and design suitable for cleaning and sterilization processes	Project specification, ASME BPE reference
☐ 7. Marking	Manufacturer/batch identification without compromising hygiene	Visual inspection, documentation check
☐ 8. Traceability	Complete documentation from raw material to finished component	Certificate folder, checklists
☐ 9. Scope of documentation	Complete, structured delivery of all test and manufacturing certificates	Check of delivery documents
☐ 10. Standard reference	Clear reference to ASME BPE version in the offer/delivery note	Contract and documentation review

*This Ra value applies to SF1.

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