



2007 Edition ASME BPE Standard

Presentation & Review

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Presented For

***CHINA-PHARM 2008
Beijing, China PRC***



ASME BPE-2007
(Revision of ASME BPE-2005)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD



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ASME Bioprocessing Equipment Standard

Or

ASME BPE

2007 Edition



Introduction 简介

- **The standard was started in 1988 with a small task group at the ASME Annual meeting**

此标准于1988年的ASME年会中确定由一组小团队开始筹建工作

- **ASME BPE Standard is a worldwide standard for the Biopharmaceutical, Personal Care, API industries and other hygienic industries**

ASME BPE是一个在生物制药、个人保健、原料药工业和其他有除菌要求的行业

Why Develop a Standard?

标准产生的背景

- **The lack of applicable industry standards for biopharmaceutical in 1988**

在1988还从来没有适合生物制药工业的标准

- **Industry demands for higher quality associated with hygienic process systems and sterilization needs**

考虑到卫生工艺系统和除菌的要求，需要更严格的标准来进行规范

- **First ASME BPE Standard was issued in 1997, the fastest standard published in the history of ASME**

最早的ASME BPE标准于1997年出版，这是在ASME历史上从讨论到出版经历时间最短的标准

Why American Society of Mechanical Engineers(ASME) ?

美国机械工程师协会（ASME）存在的目的和作用



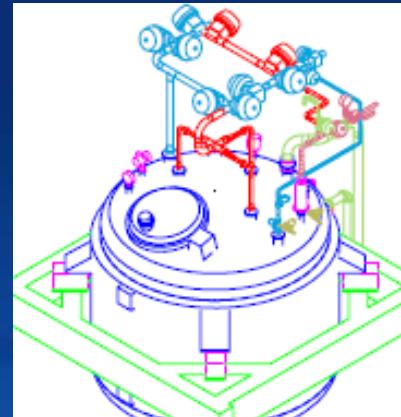
- **History of Establishing Codes and Standards**
制定标准代码的历史
- **Started in 1800's with Boiler Code**
从19世纪初开始制定锅炉代码
- **International Reputation for Acceptable Standards**
现行标准中有全球的声望
- **Great need for mechanical engineers in industry**
机械工程师强烈的需求



ASME BPE Scope ASME BPE使用范围

This Standard deals with the requirements of the bioprocessing, pharmaceutical, and personal care product industries as well as other applications with relatively high levels of hygienic requirements, covering directly or indirectly the subjects of materials, design, fabrication, welding inspections, testing, and certifications.

此标准主要用于生物制药、保健产品和其他对卫生和除菌有特殊要求的工业中，直接或间接的涵盖了这些工业系统中对材料、设计、构造、焊接检验、测试和相关认证的相关要求。



BPE Standards Committee BPE标准委员会

Voluntary Consensus Standard

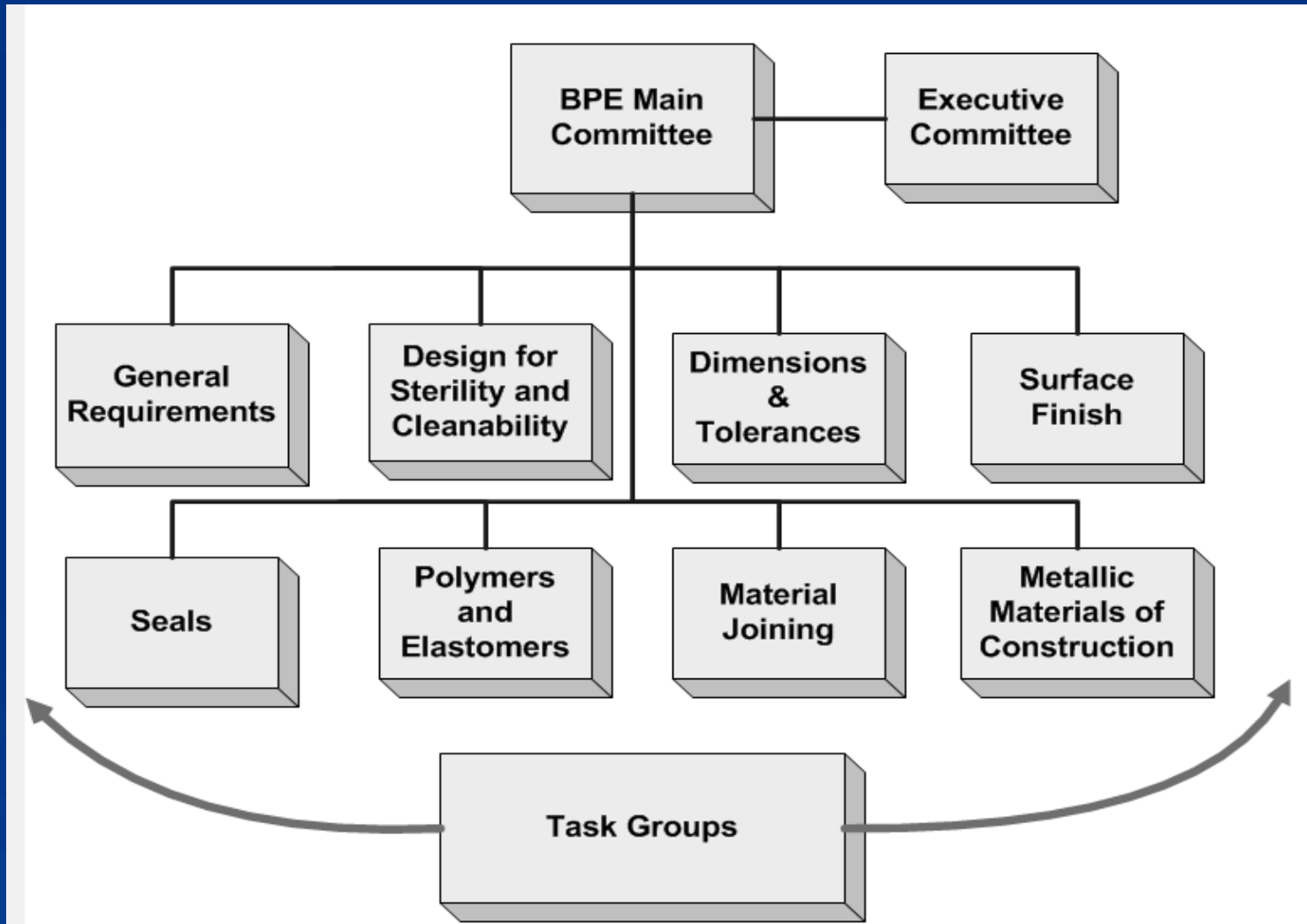
非强制性平衡的标准

- **Developed and maintained by a balanced group of experts**
由相互制约平衡的一组专家发展和维护
- **Multiple stages of approval before publication**
出版前我层次的讨论和认定
- **Continuously updated to support industry accepted practices**
跟据生产实践，保持持续及时的更新
- **Corrections and clarifications can be requested by anyone**
每个人都可以提出改正和澄清的要求

BPE Standards Committee BPE标准委员会

- **Balanced standards committee is established with volunteers from the following Industry segments:**
- 制衡的委员会委员由分别来自以下各行业的志愿者组成
 - **Industry Users (Biopharmaceutical Manufacturers)**
使用者（生物制药产品生产商）
 - **Designer/Constructors (Engineering Firms)**
设计/构造者（工程公司）
 - **Manufacturers (Equipment Vendors)** 制造者（相关设备生产商）
 - **Material Manufacturers (Tubing & Fitting Mfrs.)**
材料制造者（管路和管件生产商）
 - **General Interest (Consultants, Inspectors, etc.)**
其他关联者（咨询者，检测者等）
 - **Insurance / Regulatory (FDA)** 保证/调整（FDA）

ASME BPE Main Committee ASME 主委员会



5 Stages in Approval Process for BPE

BPE标准形成的五个步骤

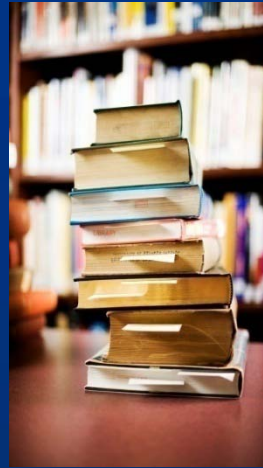
- **ASME BPE Subcommittee development**
ASME 分委员会提出
- **ASME BPE Main Committee**
BPE 主委员会讨论
- **ANSI Public Review** **ANSI** 公众审核
- **ASME Board on Pressure Technology Codes & Standards**
ASME 压力标准董事会批准
- **ANSI Board of Standards Review** **ANSI** 董事审核
- **Next ASME BPE publication** 由ASME BPE 出版

Above stages could take 18-24 months depending on issue date
根据不同的递交日期，以上这些过程要历时18—24个月的时间

BPE Subcommittee General Requirements

BPE一般要求分委会 Part **GR**

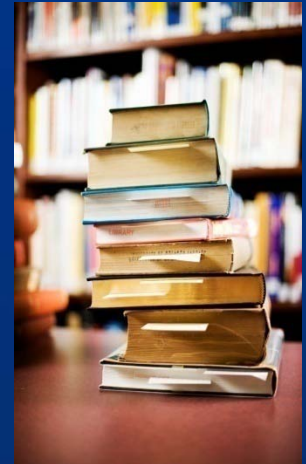
- **This subcommittee coordinates and reviews the drafts produced by all subcommittees**
此分会编辑和修改其他各个分委会提交的各种草案
- **It is responsible for developing a lexicon of terms encompassing all the different parts of the standard**
负责把语言组织修改成标准里的通用语言
- **Coordinates and reviews all terms and definitions for the standard**
审核和定义标准里的每一条款



BPE Subcommittee General Requirements

BPE一般要求分委会 Part **GR**

- **Provides the standard's introduction**
提供标准的介绍
- **This subcommittee covers the general requirements applicable to the standard**
涵盖此标准的一般应用要求
- **Covers references to all standards applicable to ASME BPE Standards**
涵盖ASME BPE引用的所他其他标准
- **Is responsible for the BPE Standard's index**
负责BPE标准的索引查找工作



BPE Subcommittee on Design for Sterility

除菌设计分会 Part **SD**

- **This subcommittee develops criteria for BPE equipment and systems to establish industry requirements for cleanability, Sterility, and Aseptic Processing**

此分会制定在**BPE** 设备和系统中对可清洁性，可除菌性，和防腐性的要求

- **Establishes design guidelines applicable to bioprocessing equipment, components, assemblies and systems**

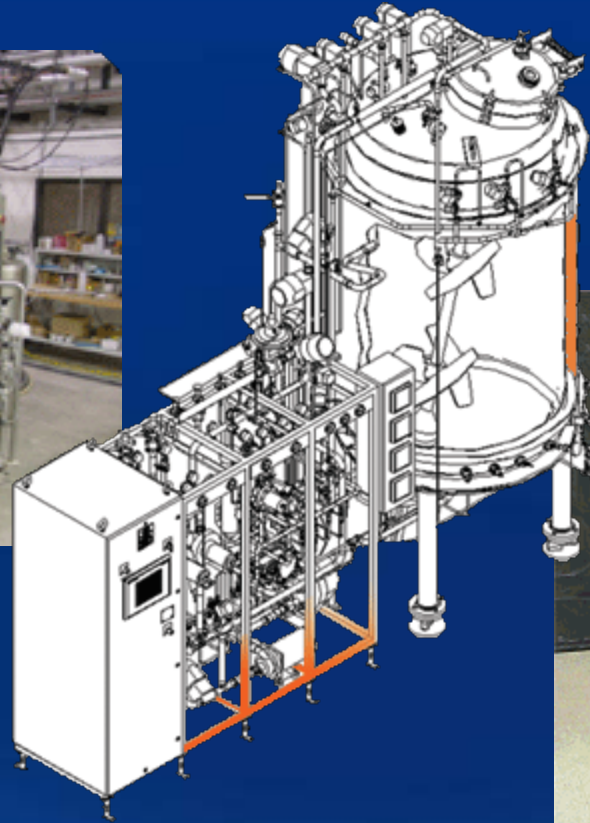
确定生物制药工艺，设备，组件，装配线和整个系统的设计指导方针

除菌设计分会 Part *SD*



BPE Subcommittee on Design for Sterility

除菌设计分会 Part **SD**



BPE Subcommittee on Design for Sterility

除菌设计分会 Part **SD**

- **The BPE SD part is not intended to limit new and possibly better designs**
BPE SD分会并不是有意限制新的和可能的更好设计
- **The BPE SD part covers “new construction” and should not be used to the acceptability of existing equipment**
BPE SD分会使用了“新的构造”，但此“新的构造”不应成为已经存在设备的接受标准
- **The new 2007 BPE part SD had 21 changes from the 2005 edition**
2007年版 SD部分与2005年版相比较有21处修改

BPE Subcommittee on Dimensions & Tolerances

尺寸和公差分会 Part *DT*

- **This subcommittee is responsible for establishing requirements for the overall dimensions, tolerances, pressure ratings, marking and packaging of all BPE fittings, tube and process components**

此分会主要制定针对所有卫生管路和管件的尺寸、压力等级公差大小、标识和包装的要求。

- **All fittings are standardized and are nominal OD tube conforming to BPE part DT**

所有的管件在归定了标准的外径



- **Tube standards for BPE were developed with ASTM A-270 as a supplemental S2 addition**

BPE中对管子的标准是在ASTM A-270的标准上加上附件S2发展而成的



BPE Subcommittee on Dimensions & Tolerances

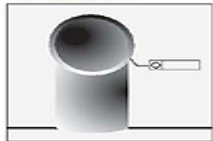
尺寸和公差分会 Part *DT*

○ Dimensions & Tolerances:

Dimensions as specified in ASME BPE Part DT.

Nominal OD Size	½"	¾"	1"	1½"	2"	2½"	3"	4"	6"
O.D. Tolerance	±.005	±.005	±.005	±.008	±.008	±.010	±.010	±.015	±.030
Nominal Wall Thickness	.065	.065	.065	.065	.065	.065	.065	.083	.109
Wall Thickness Tolerance before EP	+.005 - .008	+.005 - .008	+.005 - .008	+.005 - .008	+.005 - .008	+.005 - .008	+.005 - .008	+.008 - .010	+.015 - .015
Wall Thickness Tolerance after EP	+.005 - .010	+.005 - .010	+.005 - .010	+.005 - .010	+.005 - .010	+.005 - .010	+.005 - .010	+.008 - .012	+.015 - .017
Control Length (C)	.750	.750	.750	.750	.750	.750	.750	.750	.750
Tangent Length (T)	1.500	1.500	1.500	1.500	1.500	1.500	1.750	2.000	2.500
Squareness Face to Tangent (B)	.005	.005	.008	.008	.008	.010	.016	.016	.030
Off Angle (O)	.014	.018	.025	.034	.043	.054	.068	.086	.135
Off Plane (P)	±.030	±.030	±.030	±.050	±.050	±.050	±.050	±.060	±.060

•Roundness



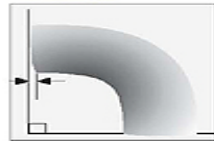
•Wall Thickness



•Squareness Face to Tangent



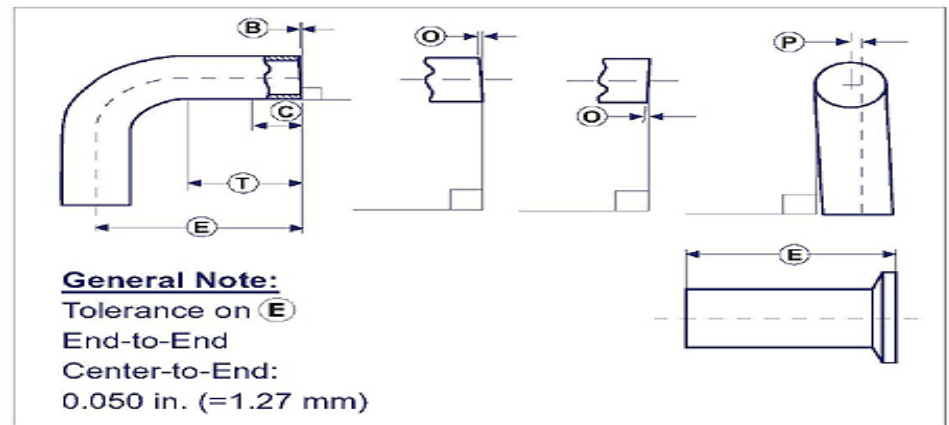
•Off Angle



•Off Plane



•Height



Required ASME BPE fitting inspections

BPE Subcommittee on Dimensions & Tolerances

尺寸和公差分会 Part **DT**

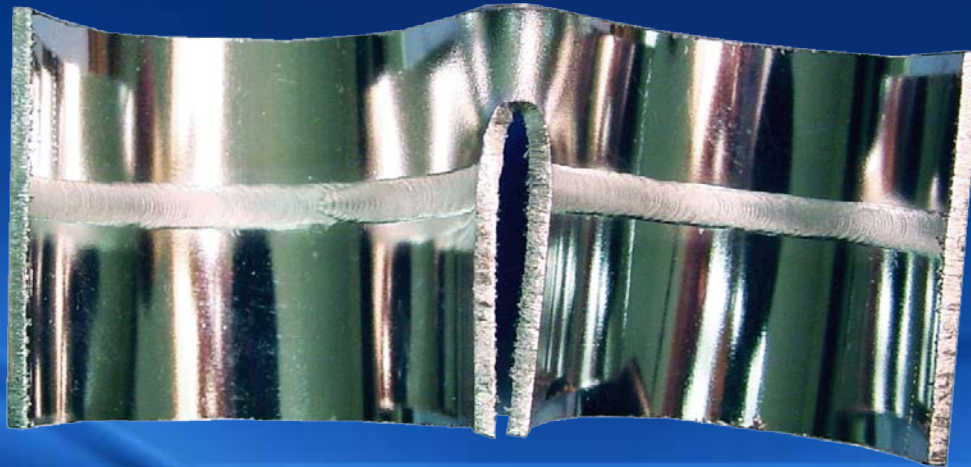
- **The dimensions in metric units are conversions from U.S. customary units, and are listed for reference only**
尺寸被转化为公制的单位供使用都参考。
- **The new 2007 BPE part DT had 18 changes from the 2005 edition**
新的2007版标准相对于2005版，这部分共有18处修改



BPE Subcommittee on Material Joining

材料连接分会 Part *MJ*

- **MJ Subcommittee establishes requirements for material joining (welding) associated with BPE equipment**
MJ分会制定BPE设备上材料连接（焊接）的要求
- **It develops requirements for orbital and manual welding, weld acceptance / rejection criteria, fit up, concavity and weld geometry**
制定轨道焊和人工焊的接受/拒绝标准，焊缝的平整、凹度、焊道形状、焊接工序和执行的条件
- **Develops weld procedures and performance qualifications**
制定新的焊接工序和认定新的操作资格



材料连接分会 Part MJ

- **welder's ID number**
焊接者操作代码



BPE Subcommittee on Material Joining

材料连接分会 Part *MJ*

- The new 2007 BPE part MJ had 16 changes from the 2005 edition

新2007版BPE标准相对于2005版在材料连接（部分）有16处修改



BPE Subcommittee on Surface Finish

表面处理分会 Part **SF**

- **SF establishes surface finish Ra designations that can be qualified and inspected**
此分会组建表面处理状态**Ra**单位，可被检测与核定
- **SF developed finish requirements that will enhance efficient cleaning and sterilizing procedures**
制定出表面处理要求以加强在进程中清洁和除菌的效果
- **SF Developed acceptance criteria for mechanical and electro polished surfaces**
此分会制定出经机械抛光和经电抛光后接受的标准

BPE Subcommittee on Surface Finish

表面处理分会 Part **SF**



Part SF covers product contact surfaces only
此部分只涵盖与产品接触的表面状态

BPE Subcommittee on Surface Finish

表面处理分会 Part **SF**

- **This part shall be referenced when specifying surface finishes for specific systems including, but not limited to vessels and distribution piping system components**

当有特别的生产系统对表面状态有要求时，要参这一部分，特别的生产系统包括但不限于容器、配管系统及相关的零部件

- **Change in surface finish codes developed for 2007 edition, SF0 through SF6**
2007版改变了表面状态代码，从SF0到SF6

- **The new 2007 BPE part SF had 11 changes / deletions from the 2005 edition**
新的2007版BPE表面处理部分对比2005版有11处修改/删除

BPE Subcommittee on Equipment Seals

设备密封分会 Part **SG**

- **SG subcommittee establishes design and material requirements for various mechanical seals and gaskets used in BPE equipment**
此分会确定BPE设备中不同机械密封和垫圈的设计和材料的要求
- **Included but not limited to pumps, valves, rotating and reciprocating equipment, pressure vessels and hygienic process piping**
包括但不限于泵体、阀门、旋转和往复设备、压力容器和卫生管路系统
- **Develop seal classes defining the level of integrity for a given service**
对现有的服务确定密封级别，定义密封等级



BPE Subcommittee on Equipment Seals

设备密封分会 Part **SG**

- **Seals are defined as those elements that create or maintain process boundaries between system components / subassemblies in order to ensure system integrity in a validated process.**

密封被定义为为保证在一个有效使用进程中造成或保持 各部件间边缘的元件



- **The new 2007 BPE part SG had 6 changes / deletions from the 2005 edition**
新的**2007**版**BPE**密封部分对比**2005**版有**6**处修改/删除

BPE Subcommittee on Polymer Based Materials

聚合物基材料分会 Part *PM*

- **SG subcommittee establishes requirements that are applicable to polymer based materials used within bioprocess systems and components**
此分会确定在生物制药系统和零部件中聚合物基材料的使用要求
- **Polymer based materials include thermoplastics and thermosetting materials in both virgin and composite forms**
聚合物基材料包括加工和未加工过的热塑性和热硬化性材料，
- **The objective of this part is to describe and outline accepted practices for the use of polymer based materials for clean and sterile bioprocess applications**
此部分的目的是描述在清洁和除菌生物工艺实践中聚合物机材的应用

BPE Subcommittee on Metallic Materials

金属材料分会 Part *MM* (2009)

- **Metallic Materials subcommittee establishes requirements for selection of acceptable metallic materials in hygienic process applications**
此分会确定在除菌进程中金属材料的使用要求
- **MM will additionally list all mechanical and physical properties for these alloys**
这部分还将列出所有合金的机械和物理性能
- **Alloys being considered are, ALX6N, Hastalloy, DIN, BN and ISO versions of 316 / 316L**
合金主要考虑的是ALX6N, Hastalloy, DIN, BN 和ISO 标准中的316/316L

Certification 认证

- **Under development, timeline 2009 edition**

正在更新 计划2009年出版

- **Purpose 目的**

Establish a certification and accreditation program for suppliers of products (components and equipment) and services to ASME BPE end users.

为ASME BPE的最终用户提供一个对产品(零部件和设备)供货商的认证和鉴定程序

- **Modeled after ASME-RTP-1 Standard's Accreditation Program**

以ASME-PTP-1标准的鉴定程序为样本

Certification 认证/ Accreditation 鉴定

➤ Discussions include 讨论的内容包括:

- Accrediting manufacturers of fittings and tubing. Eventually will include vessels manufacturers, **skid manufacturers**, etc.

管子和管件制造商的认定。最后会加上容器制造商、**skid manufactures**等制造商。

- Develop audit checklist for specific areas of accreditation.

对特殊部位的鉴定做审查记录

- Enforcement 强制性
- Application requirements 申请的要求

International Participation 国际上的发展

European Subcommittee 欧州分会

- **Established in 2003** 于2003年成立
- **Developed to address European Philosophies and Methods of Design and Installations Practices**
从事于按欧州的体系和方法来确定设计和按装规范
- **Coordinate / Communicate with US Subcommittees**
与美国分保证联系与合作
- **Number one challenge is addressing harmonization : DIN vs. BN vs. EHEG vs. ISO vs. CE**
相似的标准有：DIN、BN、EHEG、ISO和CE
- **Asian membership – Delegate Program (Japan group now active)**
亚州顾员—代理/表体制（目前日本团队已经在开展工作）

We want YOU! 我们需要你的参与!



Future of BPE BPE的明天

- **Next Edition, ASME BPE 2009**
scheduled to be published by February 2009
下一个版本，ASME BPE 2009计划于2009年2月份出版
- **Scope expanded to include** 使作范围将包括：
 - **Personal Care Products** 个人保健产品
- **Challenges** 挑战：
 - **Worldwide Recognition & Acceptance**
世界范围内的认可与接受
- **Certification / Accreditation** 认证/鉴定
 - **Program in place by 2009 edition**
相关程序将在2009年版使用

ASME BPE Membership ASME BPE 成员资格

- **All members are volunteers**

所有的成员均是志愿者

- **Membership on ASME Committees require a commitment from both prospective member and financial guarantee from their employer**

ASME委员资格的取得必需是自愿和得到他们雇主财务上的承诺

- **Members are appointed to the committee for a term of 5 years attending 3 meetings per calendar year**

会员会被任命5年的期限，并参加自然年3次的会议

- **Meeting locations are decided on by the Main committee**

会议的地点由主委员会确定

BPE Future Meetings BPE将要召开的会议

- January 19 - 22, 2009, Caribe Hilton
San Juan, Puerto Rico, USA Territory
2009年1月19—22日，波多黎哥 圣湖安
- May 25-29, 2009, Crowne Plaza Hotel,
Dublin, Ireland
2009年5月25—29日，爱尔兰 都柏林
- October 5-9, 2009 Radisson Boston Hotel, ***Boston. MA, USA***
2009年10月5—9日，美国 波士顿
- January 18-21, 2010 Rio Mar Beach Resort
San Juan, Puerto Rico
2010年1月18—21日，波多黎哥 圣湖安
- May/June 2010 – Europe (not decided)
London or Amsterdam
2010年5月/1月，欧州（未确定）伦敦或阿姆斯特丹

ASME BPE 2007 Standard

Ordering Information 标准订购信息

<http://catalog.asme.org/home.cfm?CATEGORY=CS&TaxonomyItemID=2968&ProductFormat=DigitalBook>

BPE - 2005 Bioprocessing Equipment

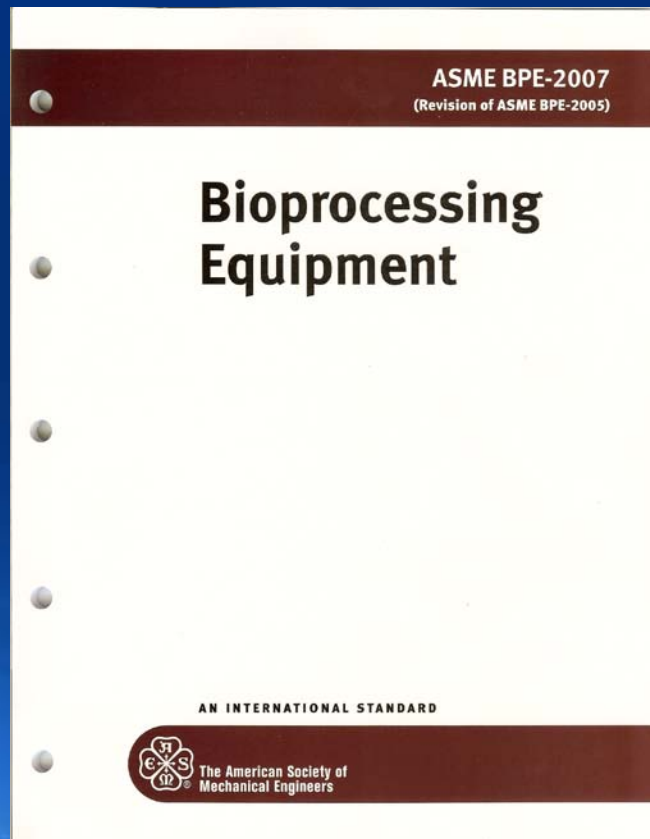


The ASME BPE Standard standardizes specifications for the design, manufacture, installation, inspection and acceptance of equipment used in the pharmaceutical and biologic products industries.

List Price: \$205.00

Format: **Buy Print** or **Buy PDF**

No. of pages: 128



BPE wants questions / suggestions
BPE期待你的提问和建议

Thanks for your attention today!
非常感谢您今天的参与！

