Agenda

- Introduction
- What is ASME BPE?
- What's New?
- Certification & Requirements
- 2012 BPE & Future: Current Trends & Needs in the BioPharm industry
- How to get involved in ASME BPE?

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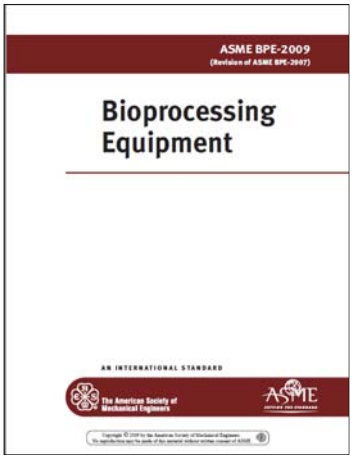
What is ASME BPE?
Why is it Important?

BPE =

Bio**P**rocessing

Equipment

Standard



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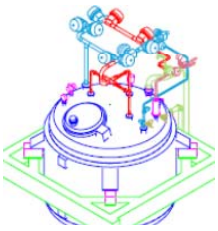
ASME BPE Scope

- To define the requirements of the bioprocessing, pharmaceutical and other industries requiring high levels of hygienic quality
- To standardize subjects of materials, design, fabrication, inspections, testing, and certification



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Voluntary Consensus Standard

- Developed and maintained by a balanced group of experts
- Multiple stages of approval before publication
- Continuously updated to support industry accepted practices
- Corrections and clarifications can be requested by anyone

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Familiar BPE Topics

Dimensions & Tolerances

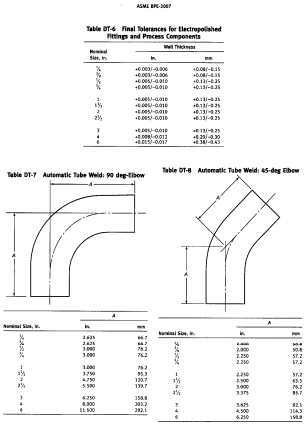

ASME BPE-2007

Table DT-6 Final Tolerances for Electropolished Fittings and Process Components

Nominal Size, in.	Wall Thickness	
	in.	mm
¼	+0.003/−0.006	+0.08/−0.15
⅜	+0.003/−0.006	+0.08/−0.15
½	+0.005/−0.010	+0.13/−0.25
¾	+0.005/−0.010	+0.13/−0.25
1	+0.005/−0.010	+0.13/−0.25
1½	+0.005/−0.010	+0.13/−0.25
2	+0.005/−0.010	+0.13/−0.25
2½	+0.005/−0.010	+0.13/−0.25
3	+0.005/−0.010	+0.13/−0.25
4	+0.008/−0.012	+0.20/−0.30
6	+0.013/−0.017	+0.33/−0.43

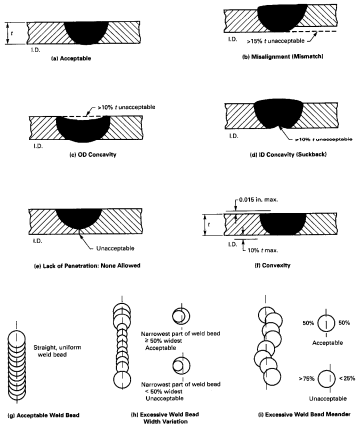
Table DT-7 Automatic Tube Weld: 90 deg-Elbow

Nominal Size, in.	A	
	in.	mm
½	2.625	66.7
¾	2.625	66.7
1	3.000	76.2
1½	3.000	76.2
2	3.750	95.3
2½	4.750	120.7
3	5.500	139.7
4	6.250	158.8
6	8.000	203.2
8	11.500	292.1

Table DT-8 Automatic Tube Weld: 45-deg Elbow

Nominal Size, in.	A	
	in.	mm
½	1.000	25.4
¾	1.000	50.8
1	2.250	57.2
1½	2.250	57.2
2	2.250	57.2
2½	2.500	63.5
3	3.000	76.2
4	3.375	85.7
6	5.625	142.9
8	4.500	114.3
10	6.250	158.8

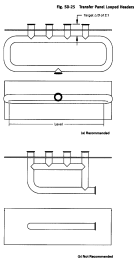
Weld profiles



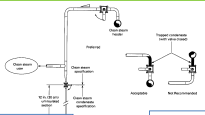
6

Every 2 Years - System & Facility Topics

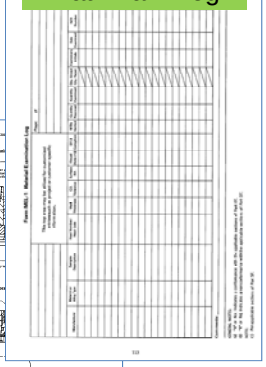
Looped Headers

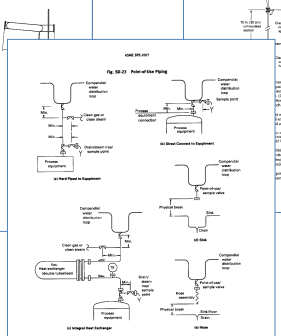


CS POU



Mat Exam Log





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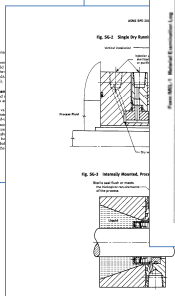

Mech Seals

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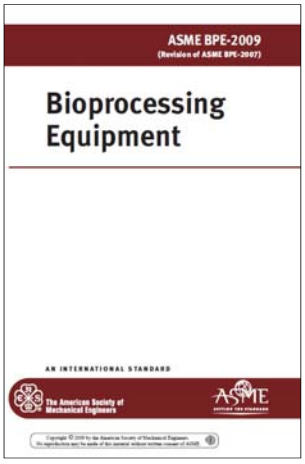
What's New?



- ***The most extensive revision to date is planned with ASME BPE 2012***
- New Process Systems Design Requirements
- All Sections Updated
- Supplier Certification Program
- International editing for clear understanding

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2012 – Content Updates

- Fermentor & Bioreactor Design
- CIP Distribution Systems
- Process Gas System Design
- Steam Sterilizers / Autoclaves
- Hygienic Pump Design
- CIP Skid Design
- Single-Use Product Requirements
- Compendial Water Pump Seals
- Electropolishing & Passivation
- Rouge & Stainless Steel
- Polymer Surface Finishes
- Metallic Materials of Construction
- Corrosion Testing
- Elastomer Performance
- Hygienic Hose Assemblies
- Process Instrumentation
- ASME Certification Program

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ASME BPE Roster

Roster comprises Designers, Fabricators, and Owners with up to 40 years of experience in the BioPharmaceutical Industry. ***Their knowledge at your fingertips in the ASME BPE.3***

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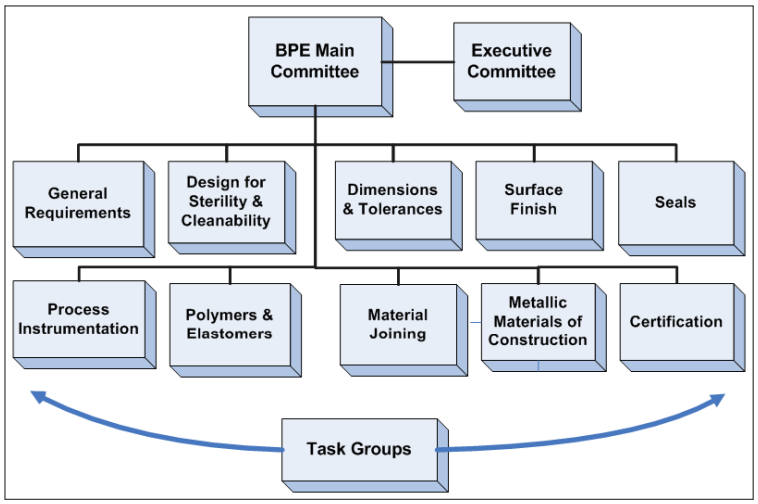
ASME BPE Committee Structure



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BPE Standards Committee (Main Committee)

- Meets 3 times annually to:
  - Review Subcommittee Progress
  - Coordinate Efforts Between Subcommittees
  - Delegates from Europe and Asia vote
  - Liaison Reports with other Organizations

ISPE	ASTM	DIN
P3-A	3-A SSI	EHEDG

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BPE Certification Program (Part CR)

- Certificate of Authorization issued to qualified component suppliers
- ASME BPE Symbol Stamp
- First to be certified: Tubing and fitting manufacturers

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General Requirements (Part GR)

- GR-4 (Inspector Delegates)
  - New section defining the qualifications of personnel involved in inspection of BioProcessing, Pharmaceutical and other systems involving a high degree of bioburden control
- Inspector Delegates (4 levels of qualification):
  - Trainee
  - QID-1
  - QID-2
  - QID-3

Defining the Technology

bioburden

mechanical seal

corrosion

biofilm

rouge

cleanable

passivation

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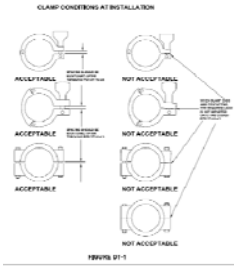
Dimensions & Tolerances (Part DT)



- New Design Criteria for Hygienic Clamps
- New Nominal one inch fitting design
- Reducing the length on eccentric & concentric reducing fittings

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Metallic Materials of Construction (Part MMoC)

- Metallic materials commonly used in hygienic service
  - Testing standards
  - Mechanical & chemical properties
  - Surface finish
  - Fabrication guidelines

16

Material Joining (Part MJ)

- New Content:
  - Use of duplex alloys
  - Sample weld criteria
  - Welding Performance Qualification Requirements

17

Polymers and Elastomers (Part PM)

- Single-Use Components & Assemblies
- Elastomer Performance
- Hose Assemblies
- Surface of Polymers

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Surface Finishes (Part SF)

What's New?

- Acceptance criteria for passivated product contact surfaces
- Section SF-P on Polymer Product Contact Surfaces
- New Non-mandatory Appendices
  - Electropolishing Procedure Qualification
  - Passivation Procedure Qualification
  - Rouge & Stainless Steel (Rouge Remediation)

19

Equipment Seals (Part SG)

What's New?

- Standardized Process Test Conditions for Seal's fitness for use
  - Simulated SIP & CIP conditions
- Application Data Sheet for seal specification
- New section on seals for compendial water pumps

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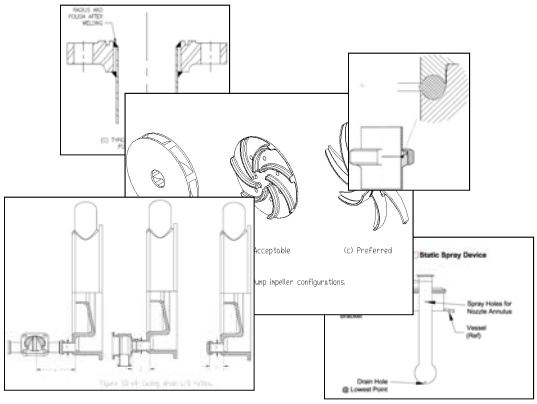
Design for Cleanability and Sterility (Part SD)

- New Design Content
  - Hygienic Pumps
  - Spray Devices
  - Ball Valves
  - O-ring connections
  - Top-entering mixers
  - Steaming for bioburden control
- New Process Systems
  - Bioreactors
  - Autoclaves
  - CIP Distribution
  - Process Gas Systems



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Steam Sterilizers / Autoclaves (SD-4.14)

- Cycle Capabilities
- Materials/Finish
- Elastomers
- Door Design
- Sterile filters
- Loading carts/trays
- Jacket design
- Instrumentation

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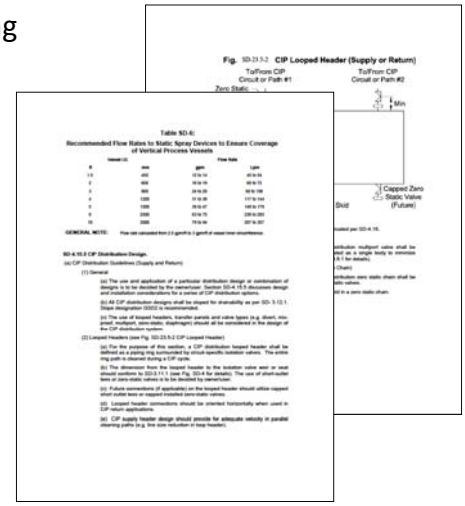
CIP Systems and Design (SD-4.15)

- System Functionality & Operating Capabilities
- CIP Skid Design
- Flow Rate Guidelines
- Guidelines for Cleaning Vessels
- Spray Device Design
- CIP Distribution Design
  - Supply & Return
  - Looped Headers
  - Zero Static Chains
  - Multiport Valves
  - Transfer Panels
  - Swing Elbows & Transfer Spools
  - CIP Return Pumps
  - CIP Return Educators



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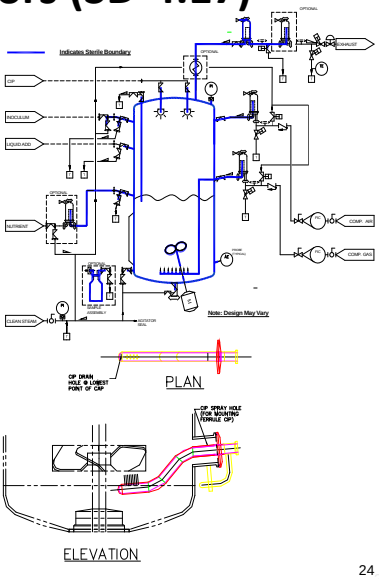
Bioreactors and Fermentors (SD-4.17)

- Vessel Internals
- Sampling System
- Sterile Boundary
- Inlet Gas Assembly
  - Inlet filters
  - Sparger design
- Exhaust Gas Assembly
  - Vent filters
  - Vent heaters & condensers
- Feed lines & Diptubes
- Harvest valves
- Agitators & foambreakers
- CIP/SIP requirements



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Process Gas Distribution Systems (SD-4.18)

- Materials of Construction
- Process Requirements
- Piping Design
- Filtration

" Gas systems are not designed or configured with the intent or provisions to be cleaned, passivated or chemically treated after installation."

SD 4.18(d) BPE 2009

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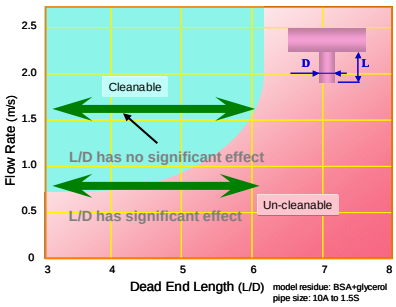
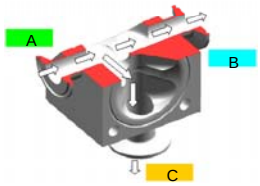
2012 BPE and Future….

- Science-based L/D requirements
- Chromatography & Filtration Systems
- Reorganization





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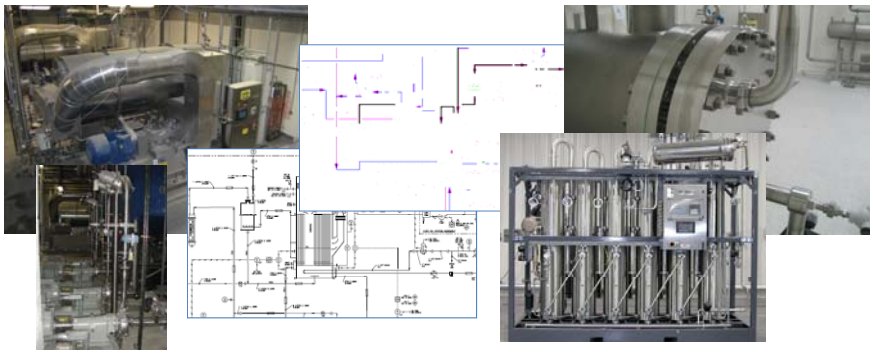
What are the current trends and needs in the BioPharm industry?



How is your ASME BPE addressing those needs?

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Case/Trend #1

Multi-Product, Contract Manufacturing Facilities

Licensed CMO has to be accepted by:

- Several operating companies
- Several regulatory agencies from around the globe
- International Standards are CRITICAL to address this trend

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Case/Trend #2

Better Yields – Higher titers than ever before

- Upstream smaller
- Downstream is new limit to production
- Lean manufacturing
- Green manufacturing
  - Better use of current designs and materials
  - Increased use of single use systems

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Case/Trend #3

Demand for better performing Materials (i.e., Alloys, Thermoplastics, Elastomers)

- 2-5 year life before replacement
- Resistance and compatibility with steam and corrosives
- *Consistent (Repeatable) Material Performance is CRITICAL*
- Expectation that fittings, tubing, valves and components comply with STANDARDS

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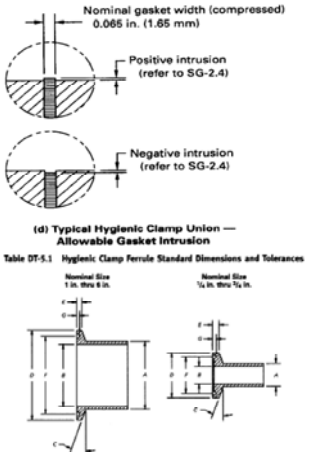
Internationally accepted "*Acceptance Criteria*" is required for all 3 cases/trends



- Science-Based Requirements
- Not too restrictive or expensive
- Consideration for the 5-10 year old system – Not just the "new system" (they are only new for a short time)
- Updated regularly to reflect the current acceptance criteria

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How do I get involved in the ASME BPE?

- Go to a meeting and listen to the Subcommittee Sessions
- Determine where your technical strengths would help
- *Participate* in a Task Group
- Speak up and be an active participant in the Subcommittee Sessions

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Should I become a member?

- If you have the time and interest to be an active participant
- If your company will support your ASME BPE work
- If you want to vote on changes and updates to an international standard

You do not have to become a member to participate in ASME BPE

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Thank you

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