The BPE 2012 Edition & “Project 2012”
Requirements & Resources for Bioprocess Systems Design

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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?
What is ASME BPE?  
Why is it Important?

BPE =  
BioProcessing  
Equipment  
Standard

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
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

Familiar BPE Topics

**Dimensions & Tolerances**

**Weld profiles**
Every 2 Years - System & Facility Topics

- Looped Headers
- CS POU
- Mat Exam Log
- WFI POU
- Mech Seals

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
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

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
BPE Standards Committee (Main Committee)

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

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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

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
Dimensions & Tolerances (Part DT)

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

Metallic Materials of Construction (Part MMoC)

- Metallic materials commonly used in hygienic service
  - Testing standards
  - Mechanical & chemical properties
  - Surface finish
  - Fabrication guidelines
Material Joining (Part MJ)

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

Polymers and Elastomers (Part PM)

- Single-Use Components & Assemblies
- Elastomer Performance
- Hose Assemblies
- Surface of Polymers
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
  o Electropolishing Procedure Qualification
  o Passivation Procedure Qualification
  o Rouge & Stainless Steel (Rouge Remediation)

Equipment Seals (Part SG)

What’s New?
• Standardized Process Test Conditions for Seal’s fitness for use
  o Simulated SIP & CIP conditions
• Application Data Sheet for seal specification
• New section on seals for compendial water pumps
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

Steam Sterilizers / Autoclaves (SD-4.14)

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

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
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

2012 BPE and Future....

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

L/D has significant effect
L/D has no significant effect
Cleanable
Un-cleanable

Dead End Length (L/D) vs. Flow Rate (m/s)

Pipe size: 10A to 1.5S

Flow Rate (m/s)

0.5 1.0 1.5 2.0 2.5

L/D has significant effect
L/D has no significant effect
Cleanable
Un-cleanable

Dead End Length (L/D)

3 4 5 6 7 8
What are the current trends and needs in the BioPharm industry?

How is your ASME BPE addressing those needs?

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
Case/Trend #2
Better Yields – Higher titers than ever before
• Upstream smaller
• Downstream is new limit to production
• Lean manufacturing
• Green manufacturing
  o Better use of current designs and materials
  o Increased use of single use systems

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
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

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
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

Thank you

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