BPSA Quality Test Matrices 2023 Update

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Agenda

- Project Review
- Changes
- Path Forward

Objective

- Update the BPSA Quality Test Matrices (Last updated in 2015)
  - Add new standards and references
  - Remove obsolete standards and references
  - Prioritize tests to:
    - Required
    - Recommended
    - To Be Considered
- Complete for rollout with BPSA Summit in ~~July~~ **August** 2023

Project

- Gather community input from BPSA members and the industry in general.
- Survey.
- Combine information in in 5-6 teams-3-4 online meetings
  - Test Categories and/or
  - Component Categories
- Present to other teams at a face to face.
- Refine information in 5-6 teams-2-3 online meetings
- SAB approval
- Board approval
- Presentation to Membership-**Today**

Team Members

Jim Sanford
Paul Priebe
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Russell Darley
Nicole Hunter
Charlie Zhang
Robert "Bob" Huffman
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QTM History

- Purpose: "help guide users when making their selections and (to) facilitate qualification, validation and use of Single-Use products"

- Most accurate, up-to-date and emergent information

QTM History

- 2007-Initial
- 2015-Last Update
- 2023-Current Update

2015

Test Categories

A. Physical
B. Functional
C. Biological
D. Chemical
E. Regulatory
F. Sterilization/Sanitization

Component Categories

1. Chromatography
2. Connectors, Valves and Retainers
3. Containers and Film
4. Sensors
5. Tubing
6. Filters

2023

Test Categories

A. Physical
B. Functional
C. Biological
D. Chemical
E. Regulatory
F. Sterilization/Sanitization

Component Categories

1. Chromatography
2. Connectors, Valves and Retainers
3. Containers and Film
4. Sensors
5. Tubing
6. Filters
7. **Single-Use Assemblies**

2023 Changes

- Single-Use Assembly Sheet added
- Tests added
- Manufacturer defined methods
- Tests deleted
- Links Updated
- Component Categories added to Test Sheets
- Alphabetical Listings
- BPSA color scheme

A. Physical Tests

- Updates
- Integrity
- Shelf life added

A. PHYSICAL TESTS				COMPONE		
TEST TYPE	*GENERAL DESCRIPTION*	*TEST REFERENCES*	*TEST ARTICLE*	1 Chromatography	2 Connectors Valves Retainers	Con
Integrity (Leak) Test	Hydrostatic Pressure Test (Shell/Seat Test)	ASTM E 3251-20	Final Article		ASTM E 3251-20	
	Standard Test Method for Physical Integrity Testing of Single-Use Systems. Confirmation of integrity for components and assemblies at a given temperature. This includes pressure testing under operating conditions and at elevated pressures.	ASTM E3244-20	Final Article	ASTM E3244-20	ASTM E3244-20	ASTM
		ASTM E515-22				ASTM
		ASTM D4991-99				ASTM
		ASTM E 3251-20		ASTM E 3251-20	ASTM E 3251-20	ASTM
		ASTM E3336-22		ASTM E3336-22	ASTM E3336-22	ASTM
	Junction Testing (barbed fittings) Single-use assembly junction connections should be qualified by the supplier to ensure they meet performance criteria as stated in their specification. The supplier shall have an established testing program to substantiate performance of the mechanical connection. The testing should reference at least one of the following: (a) Pressure Testing (b) Leak Testing (c) Tracer Gas Testing	Manufacturer Defined Method	Final Article			
	Hydrostatic leak testing	Manufacturer Defined Method	Final Article	Manufacturer Defined Method	Manufacturer Defined Method	Manufa
		ASMTM E1003-13 (2022)				ASMT

A. Physical Tests

A. PHYSICAL TESTS				COMPONENT CATEGORY APPLICABLE TO THIS TEST						
TEST TYPE	*GENERAL DESCRIPTION*	*TEST REFERENCES*	*TEST ARTICLE*	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors	5 Tubing	6 Filters	7 Single-Use Assemblies
Chamber Integrity/Seal Integrity-Peel	Used to measure manufactured product and seal barrier performance of a variety of package types and forms, as well as seal and/or closure types.	ASTM E3244-20	Container			ASTM E3244-20				*
	Performed to ensure that functional strength requirements are met.	ASTM F88-F88M &/or Manufacturer Defined Method Risk Assessment	Container			ASTM F88-F88M &/or Manufacturer Defined Method Risk Assessment				
	Microbial ingress test of single-use systems	ASTM F 3251-20	Container			ASTM F 3251-20				
	Physical integrity of single-use systems	ASTM E3336-22	Container			ASTM E3336-22				
	Used to measure manufactured product and seal barrier performance of a variety of package types and forms, as well as seal and/or closure types.	Manufacturer Defined Method	Packaging							Manufacturer Defined Method
Compression Set Test	Compression set measures the residual deformation after compressive loading under specified conditions.	ASTM D395	Cured raw material test plaque					ASTM D395		*
		ISO 815						ISO 815		
Durometer (Hardness)	A measurement of the hardness of a material.	ASTM D2240	Cured raw material test plaque					ASTM D2240		*
		ISO 868						ISO 868		
Elongation	A measure of a material ductility. Elastic modulus or modulus of elasticity is a measure of a material's tendency to deform when a force is applied. (Modulus at 100%, 200%)	ASTM D412	Cured raw material test plaque OR Final Article					ASTM D412		*
		ISO 37						ISO 37		
Integrity (Leak) Test	Hydrostatic Pressure Test (Shell/Seat Test)	ASTM F 3251-20	Final Article		ASTM F 3251-20					
	Standard Test Method for Physical Integrity Testing of Single-Use Systems. Confirmation of integrity for components and assemblies at a given temperature. This includes pressure testing under operating conditions and at elevated pressures.	ASTM E3244-20	Final Article	ASTM E3244-20	ASTM E3244-20	ASTM E3244-20	ASTM E3244-20	ASTM E3244-20	ASTM E3244-20	ASTM E3244-20
		ASTM E515-22				ASTM E515-22				
		ASTM D4991-99				ASTM D4991-99				
		ASTM F 3251-20		ASTM F 3251-20	ASTM F 3251-20	ASTM F 3251-20	ASTM F 3251-20	ASTM F 3251-20	ASTM F 3251-20	ASTM F 3251-20
		ASTM E3336-22		ASTM E3336-22	ASTM E3336-22	ASTM E3336-22	ASTM E3336-22	ASTM E3336-22	ASTM E3336-22	ASTM E3336-22
	Junction Testing (barbed fittings) Single-use assembly junction connections should be qualified by the supplier to ensure they meet performance criteria as stated in their specification. The supplier shall have an established testing program to substantiate performance of the mechanical connection. The testing should reference at least one of the following: (a) Pressure Testing (b) Leak Testing (c) Tracer Gas Testing	Manufacturer Defined Method	Final Article							Manufacturer Defined Method
	Hydrostatic leak testing	Manufacturer Defined Method	Final Article	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	
		ASMTM E1003-13 (2022)				ASMTM E1003-13 (2022)				
O_2 and CO_2 Permeability	Determines the steady-state rate of transmission of O_2 or CO_2 gases through material.	ASTM D3985 - 05(2010)e1	Film			ASTM D3985 - 05(2010)e1				*
		ASTM F1927-20				ASTM F1927-20				
		ASTM F2476				ASTM F2476				
Pressure Burst Test	Characterization of device with regard to operating pressure and behavior under elevated pressure conditions at a given temperature; typically including determination of burst pressure under static pressure.	18869-2017	Final Article	18869-2017						*
		ASTM D1599-18		ASTM D1599-18	ASTM D1599-18		ASTM D1599-18	ASTM D1599-18	ASTM D1599-18	
		Manufacturer Defined Method		Manufacturer Defined Method	Manufacturer Defined Method		Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	
		ISO1402:2071		ISO 1402	ISO 1402		ISO 1402	ISO 1402	ISO 1402	
		EN 12266-1			EN 12266-1			EN 12266-1	EN 12266-1	
		ISO 7241-2			ISO 7241-2		ISO 7241-2	ISO 7241-2	ISO 7241-2	
Puncture Resistance	Puncture resistance testing predicts the durability of the film while in use. Films with high puncture resistance correspond with materials that can absorb the energy of an impact by both resistance to deformation and increased elongation. Puncture resistance, measured in energy units, evaluates the film strength and extensibility properties. Puncture resistance is similar to tensile toughness.	ASTM D7192-20	Film			ASTM D7192-20				*
		(FTMS) 101C- Method 2065.1				(FTMS) 101C- Method 2065.1				
Shelf Life	Demonstrates functional performance at end of manufacturer-specified shelf life (typically does not test to failure).	Manufacturer Defined Method	Container			Manufacturer Defined Method				*
Specific Gravity	Density relative to water.	ASTM D792	Cured raw material test plaque OR Final Article					ASTM D792		*
		ISO 1187						ISO 1187		
Tear Resistance	Tear strength measures the resistance to propagation of a rip or tear once the rip has been initiated.	ASTM D624-00	Film/Cured raw material test plaque or Final Article					ASTM D624-00		*
		ASTM D1938-19				ASTM D1938-19		ASTM D1938-19		
		ISO 34						ISO 34		
Tensile Strength	Determines resistance of loading on a jointed union/connection/fitting.	ASTM D882-18	Final Article			ASTM D882-18		ASTM D882-18		
		Manufacturer Defined Method			Manufacturer Defined Method					Manufacturer Defined Method
		ISO 37						ISO 37		
Thickness & Liquid Contamination	Film thickness and materials composition to be defined.	ASTM D1777	Film			ASTM D1777				*
Visual Observation Testing	List of potential visual observations regarded as defects vs cosmetic imperfections. Observations should consider secondary packaging materials that may contribute to visual observations, as well as the installation state of the bio container at the time such inspections would typically be performed.	Manufacturer Defined Method	Container			Manufacturer Defined Method				*
Water Vapor Transmission Rate	(WVTR) The rate at which water vapor will permeate through solid material over a specified time period	ASTM F1249-20	Film			ASTM F1249-20		ASTM F1249-20		*

* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section 1-6 for subassembly recommendations

B. Functional Tests

- Updates
- Additions
  - General Functionality
  - Weldability
  - Pump Life

B. FUNCTIONAL TESTS				
TEST TYPE	*GENERAL DESCRIPTION*	*TEST REFERENCES*	*TEST ARTICLE*	1 Chromatography
Accelerated or Real Time Aging (Shelf Life)	Accelerated and/or real time studies to determine the effects, if any, due to the passage of time and environmental effects on the properties of product, and on the sterile integrity of packages and the physical properties of their component packaging materials.	Manufacturer Defined Method ASTM F1980-21	Final Article	Manufacturer Defined Method ASTM F1980-21
Accuracy/Calibration	Verification that the sensor meets the published accuracy specification, or if applicable, is properly calibrated	Manufacturer Defined Method	Final Article	
Adsorbent Capacity	Static (equilibrium) and/or dynamic binding capacity of the adsorbent, determined for contacting an adsorbing substance and the adsorbent (typically gel or membrane) under specific buffer conditions.	Manufacturer Defined Method	Raw Material and/or Final Article	Manufacturer Defined Method
Bacterial Retention Test (Sterilizing Grade Filters)	Bacterial challenge and effluent sterility test based on standard methodology.	ASTM F838-05	Final Article	

B. Functional Tests
General Functionality

- The Manufacturer/user shall establish that the Single-Use components, SUS assemblies, and SUS systems are designed for integrity and functionality, appropriately. These considerations should be maintained during installation and ensured throughout the use of the item based on scientific product and process understanding for both SUS manufacturing and end user requirement. Qualification of design, manufacturing, testing and distribution should be conducted by the suppliers of Single-Use components and assemblies with a planned and structured verification approach being applied throughout the system life cycle to deliver reliability of performance.
- Critical aspects of the SUS are typically functions, features, abilities, performance, and characteristics necessary for the manufacturing process and use, that ensure consistent product quality and patient safety.

B. Functional Tests

B. FUNCTIONAL TESTS				COMPONENT CATEGORY APPLICABLE TO THIS TEST						
TEST TYPE	*GENERAL DESCRIPTION*	*TEST REFERENCES*	*TEST ARTICLE*	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors	5 Tubing	6 Filters	7 Single-Use Assemblies
Accelerated or Real Time Aging (Shelf Life)	Accelerated and/or real time studies to determine the effects, if any, due to the passage of time and environmental effects on the properties of product, and on the sterile integrity of packages and the physical properties of their component packaging materials.	Manufacturer Defined Method ASTM F1980-21	Final Article	Manufacturer Defined Method ASTM F1980-21	Manufacturer Defined Method ASTM F1980-21	Manufacturer Defined Method ASTM F1980-21	Manufacturer Defined Method ASTM F1980-21	Manufacturer Defined Method ASTM F1980-21	Manufacturer Defined Method ASTM F1980-21	Manufacturer Defined Method ASTM F1980-21
Accuracy/Calibration	Verification that the sensor meets the published accuracy specification, or if applicable, is properly calibrated	Manufacturer Defined Method	Final Article				Manufacturer Defined Method			*
Adsorbent Capacity	Static (equilibrium) and/or dynamic binding capacity of the adsorbent, determined for contacting an adsorbing substance and the adsorbent (typically gel or membrane) under specific buffer conditions.	Manufacturer Defined Method	Raw Material and/or Final Article	Manufacturer Defined Method						*
Bacterial Retention Test (Sterilizing Grade Filters)	Bacterial challenge and effluent sterility test based on standard methodology.	ASTM F838-05	Final Article						ASTM F838-05	*
Break at Cold Temperature Test	Determines cold crack temperature of plastic film.	ISO 8570	Film			ISO 8570				*
Cell Growth	Cell Culture Growth Assessment of Single-Use Material	ASTM E3231 Manufacturer Defined Method	Container/Films Container/Films			ASTM E3231 Manufacturer Defined Method				*
Chromatographic Efficiency Test (HETP test)	Characterization of separation efficiency, typically performed on chromatography columns	Manufacturer Defined Method	Final Article	Manufacturer Defined Method						*
Dart Drop	Test method covers the determination of the energy as part of mechanical properties that causes plastic film to fail under specified conditions of impact of a free-falling dart.	ASTM D1709-15	Film			ASTM D1709-15				*
Filter Integrity Test	Confirms the membrane integrity (no defects, holes etc.) at given conditions of pressure/temperature.	Manufacturer Defined Method	Final Article	Manufacturer Defined Method					Manufacturer Defined Method	*
Gelbo	Determines the flex resistance of materials by the formation of pinholes.	ASTM F392-93	Film			ASTM F392-93				*
General Functionality Fit for Intended Use	The Manufacturer/user shall establish that the Single-Use components, SUS assemblies, and SUS systems are designed for integrity and functionality, appropriately. These considerations should be maintained during installation and ensured throughout the use of the item based on scientific product and process understanding for both SUS manufacturing and end user requirement. Qualification of design, manufacturing, testing and distribution should be conducted by the suppliers of Single-Use components and assemblies with a planned and structured verification approach being applied throughout the system life cycle to deliver reliability of performance. Critical aspects of the SUS are typically functions, features, abilities, performance, and characteristics necessary for the manufacturing process and use, that ensure consistent product quality and patient safety.	Manufacturer Defined Method ASTM 3051	Final Article	Manufacturer Defined Method ASTM 3051	Manufacturer Defined Method ASTM 3051	Manufacturer Defined Method ASTM 3051	Manufacturer Defined Method ASTM 3051	Manufacturer Defined Method ASTM 3051	Manufacturer Defined Method ASTM 3051	Manufacturer Defined Method ASTM 3051
	Min./Max Temperature	ASME BPE SD 2.4.1.2		ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2
Glass Transition Temperature	Determines the glass transition temperature (Tg) of materials. The Tg is the temperature where the polymer goes from a hard, rigid state to a rubber-like, flexible state.	ASTM E1640-13 ASTM D3418 - 12e1	Film			ASTM E1640-13 ASTM D3418 - 12e1				*
Haze and Transmittance	Evaluation of specific light transmitting and wide-angle-light-scattering properties of materials.	ASTM D1003-13	Film			ASTM D1003-13				*
Kink Resistance Bend Radius	The terms *bend radius* and *kink resistance* are used interchangeably to describe the change in the ability of a fluid to flow through the tubing when the tubing is bent.	Manufacturer Defined Method (supplier-specific)	Final Article					Manufacturer Defined Method (supplier-specific)		*
Low Temperature Brittleness	Determines the temperature at which plastics and elastomers exhibit brittle failure.	ASTM D1790-14 ASTM D747	Film			ASTM D1790-14 ASTM D747				*
Microbial Ingress Soil Test	Identification of external bacteria's ability to breach a seal and ingress into a sterile flow path.	Manufacturer Defined Method ANSI/AAMI BF7	Final Article		Manufacturer Defined Method ANSI/AAMI BF7					*
Package Testing Transportation Shipping Integrity	Qualify that product packaging will protect the product during shipping. Standard practice for performance testing of shipping containers and systems to provide a uniform basis of evaluating, in a laboratory, the ability of shipping units to withstand the distribution environment.	ASTM D4169-14 ASTM D4728-06 DIN ISO 2872 ISTA 2A ISTA 3A ISTA 3B ISTA 3E	Final Article	ASTM D4169-14 ASTM D4728-06 DIN ISO 2872 ISTA 2A ISTA 3A ISTA 3B ISTA 3E	ASTM D4169-14 ASTM D4728-06 DIN ISO 2872 ISTA 2A ISTA 3A ISTA 3B ISTA 3E	ASTM D4169-14 ASTM D4728-06 DIN ISO 2872 ISTA 2A ISTA 3A ISTA 3B ISTA 3E	ASTM D4169-14 ASTM D4728-06 DIN ISO 2872 ISTA 2A ISTA 3A ISTA 3B ISTA 3E	ASTM D4169-14 ASTM D4728-06 DIN ISO 2872 ISTA 2A ISTA 3A ISTA 3B ISTA 3E	ASTM D4169-14 ASTM D4728-06 DIN ISO 2872 ISTA 2A ISTA 3A ISTA 3B ISTA 3E	ASTM D4169-14 ASTM D4728-06 DIN ISO 2872 ISTA 2A ISTA 3A ISTA 3B ISTA 3E
Particulate Matter	Evaluates and quantifies the presence of particulates (visible and/or sub-visible) in or on a sample.	BPSA Recommendations for Testing, Evaluation, and Control of Particulates from Single-Use Processing Equipment USP <788> ANSI/AAMI BF7	Final Article		BPSA Recommendations for Testing, Evaluation, and Control of Particulates from Single-Use Processing Equipment USP <788> ANSI/AAMI BF7	BPSA Recommendations for Testing, Evaluation, and Control of Particulates from Single-Use Processing Equipment USP <788> ANSI/AAMI BF7	BPSA Recommendations for Testing, Evaluation, and Control of Particulates from Single-Use Processing Equipment USP <788> ANSI/AAMI BF7	BPSA Recommendations for Testing, Evaluation, and Control of Particulates from Single-Use Processing Equipment USP <788> ANSI/AAMI BF7	BPSA Recommendations for Testing, Evaluation, and Control of Particulates from Single-Use Processing Equipment USP <788> ANSI/AAMI BF7	BPSA Recommendations for Testing, Evaluation, and Control of Particulates from Single-Use Processing Equipment USP <788> ANSI/AAMI BF7
	Practice for Extraction of Particulate Matter from the Surfaces of Single-Use Components and Assemblies Designed for Use in Biopharmaceutical Manufacturing	ASTM E3230-20			ASTM E3230-20	ASTM E3230-20	ASTM E3230-20	ASTM E3230-20	ASTM E3230-20	ASTM E3230-20
Plastic Containers Qualification of Parenteral Ophthalmic - Aqueous Solutions	Tests of plastic materials for use as containers for drug solutions. Tests ensure that the plastics do not change/degrade under conditions of normal use. They look for changes in physical characteristics, pH, or other changes associated with light, or chemicals.	ASTM E3231	Containers/Films			ASTM E3231				*
Product Conditioning	Characterization and Qualification of recommended conditions for conditioning the product, primarily prior to use. This can involve the removal (wash out) of storage solutions; or the wetting of a device.	Manufacturer Defined Method	Final Article	Manufacturer Defined Method						*
Pump Life	Evaluates the ability and duration tubing can withstand pumping.	Manufacturer Defined Method	Final Article					Manufacturer Defined Method		*
Separation Test	Characterization of separation performance and scalability of the sorbent/membranes when packed into the device (column or capsules).	Manufacturer Defined Method	Final Article	Manufacturer Defined Method						*
Water Flow Rate Pressure Drop Test	Measures flow through the device. Pressure-flow testing is applied to determine the pressure loss over the device as a function of liquid flow rate. Data depends on the properties of the liquid and temperature. Typically, pressure drop for water at room temperature is included for reference.	ISO 7241-2 ISO 3968 Manufacturer Defined Method ISO 815 ISO 37	Final Article	Manufacturer Defined Method ISO 815 ISO 37	ISO 3968 Manufacturer Defined Method		ISO 7241-2 ISO 3968 Manufacturer Defined Method	ISO 7241-2 ISO 3968 Manufacturer Defined Method	ISO 7241-2 ISO 3968 Manufacturer Defined Method	*
	Flow coefficient C_v	IEC60534-2-3 DIN EN 1267	Final Article		IEC60534-2-3 DIN EN 1267					
Weldability Co-Weldability Sealability	Evaluates the ability for tubing to be thermally welded and aseptically sealed.	Manufacturer Defined Method	Final Article					Manufacturer Defined Method		*

* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section 1-6 for subassembly recommendations

C. Biological

- Updates
- Risk Assessment
  - ISO 10993-1
  - USP<1031>

C. BIOLOGICAL TESTS					
TEST TYPE	*GENERAL DESCRIPTION*	*TEST REFERENCES*	*TEST ARTICLE*	1 Chromatography	2 Connecto Valves Retainer
Bacterial Endotoxin	Quantify bacterial endotoxins in/on a test article	USP <85>	Final Article	USP <85>	USP <85>
		EP 2.6.14			
		USP <161>		USP <161>	USP <161>
		AAMI ST72		AAMI ST72	AAMI ST72
Bioburden	Effluent bioburden quantification of colony forming units per effluent volume (CFU/ml); identification and quantification based on standard methodology.	Manufacturer Defined Method based on USP methodology	Raw (adsorbent) material/Final Article	Manufacturer Defined Method based on USP methodology	Manufacturer Defi Method based on methodology
Biocompatibility Risk Assessment	Evaluates the interaction of SUT with blood or the biological reactivity of animals to polymeric material.	ISO 10993-1	Raw Material/ Final Article	ISO 10993-1	ISO 10993-1
		USP <1031>		USP <1031>	USP <1031>
Biological Reactivity In Vitro	Evaluates the response of mammalian cell cultures to extracts of polymeric materials.	ISO 10993-5	Raw Material/ Final Article	ISO 10993-5	ISO 10993-5
		USP <87>		USP <87>	USP <87>
Biological Reactivity In Vivo	Evaluates the interaction of medical devices with blood or the biological reactivity of animals to polymeric material:	Subsections	Raw Material/ Final Article		
	Intracutaneous	USP <88>		USP <88>	USP <88>
		ISO 10993-10		ISO 10993-10	ISO 10993-10
	Acute Systemic Toxicity	USP <88>		USP <88>	USP <88>
		ISO 10993-11		ISO 10993-11	ISO 10993-11
	Muscle Implantation	USP <88>		USP <88>	USP <88>
		ISO 10993-6		ISO 10993-6	ISO 10993-6
Hemolysis	Test that measures the breakdown of red blood cells by chemical or physical means.	ISO 10993-4	Final Article/Film		
		ASTM F756			
* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see sectio					

C. Biological

C. BIOLOGICAL TESTS				COMPONENT CATEGORY APPLICABLE TO THIS TEST						
TEST TYPE	*GENERAL DESCRIPTION*	*TEST REFERENCES*	*TEST ARTICLE*	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors	5 Tubing	6 Filters	7 Single-Use Assemblies
Bacterial Endotoxin	Quantify bacterial endotoxins in/on a test article	USP <85>	Final Article	USP <85>	USP <85>	USP <85>	USP <85>	USP <85>	USP <85>	USP <85>
		EP 2.6.14								EP 2.6.14
		USP <161>		USP <161>	USP <161>	USP <161>	USP <161>	USP <161>	USP <161>	USP <161>
		AAMI ST72		AAMI ST72	AAMI ST72	AAMI ST72	AAMI ST72	AAMI ST72	AAMI ST72	AAMI ST72
Bioburden	Effluent bioburden quantification of colony forming units per effluent volume (CFU/ml); identification and quantification based on standard methodology.	Manufacturer Defined Method based on USP methodology	Raw (adsorbent) material/Final Article	Manufacturer Defined Method based on USP methodology	Manufacturer Defined Method based on USP methodology					Manufacturer Defined Method based on USP methodology
Biocompatibility Risk Assessment	Evaluates the interaction of SUT with blood or the biological reactivity of animals to polymeric material.	ISO 10993-1	Raw Material/ Final Article	ISO 10993-1	ISO 10993-1	ISO 10993-1	ISO 10993-1	ISO 10993-1	ISO 10993-1	*
		USP <1031>		USP <1031>	USP <1031>	USP <1031>	USP <1031>	USP <1031>	USP <1031>	
Biological Reactivity In Vitro	Evaluates the response of mammalian cell cultures to extracts of polymeric materials.	ISO 10993-5	Raw Material/ Final Article	ISO 10993-5	ISO 10993-5	ISO 10993-5	ISO 10993-5	ISO 10993-5	ISO 10993-5	*
		USP <87>		USP <87>	USP <87>	USP <87>	USP <87>	USP <87>	USP <87>	
Biological Reactivity In Vivo	Evaluates the interaction of medical devices with blood or the biological reactivity of animals to polymeric material:	Subsections	Raw Material/ Final Article							*
	Intracutaneous	USP <88>		USP <88>	USP <88>	USP <88>	USP <88>	USP <88>	USP <88>	
		ISO 10993-10		ISO 10993-10	ISO 10993-10	ISO 10993-10	ISO 10993-10	ISO 10993-10	ISO 10993-10	
	Acute Systemic Toxicity	USP <88>		USP <88>	USP <88>	USP <88>	USP <88>	USP <88>	USP <88>	
		ISO 10993-11		ISO 10993-11	ISO 10993-11	ISO 10993-11	ISO 10993-11	ISO 10993-11	ISO 10993-11	
	Muscle Implantation	USP <88>		USP <88>	USP <88>	USP <88>	USP <88>	USP <88>	USP <88>	
		ISO 10993-6		ISO 10993-6	ISO 10993-6	ISO 10993-6	ISO 10993-6	ISO 10993-6	ISO 10993-6	
Hemolysis	Test that measures the breakdown of red blood cells by chemical or physical means.	ISO 10993-4	Final Article/Film			ISO 10993-4	ISO 10993-4	ISO 10993-4		*
		ASTM F756				ASTM F756				

* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section 1-6 for subassembly recommendations

D. Chemical Tests

- Updates
- Risk Assessment
- Chemical Process Compatibility

D. CHEMICAL TESTS					
TEST TYPE	**GENERAL DESCRIPTION**	**TEST REFERENCES**	**TEST ARTICLE**	**1 Chromatography**	**2 Connecto Valves Retaine**
Chemical Process Compatibility	Qualification of wetted parts to show compatibility (resistance) with chemical reagents used as process liquids.	Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.	Raw Material and/or Final Article		Manufacturer de method typically a with ASTM D543 and/or risk assess
Chemical Risk Assessment Process Compatibility	Materials should be robust and compatible with product and process fluids and should not be excessively prone to damage, which compromise structural integrity either by the shedding of any materials as solid particles which impact product quality and/or process performance. Process Compatibility (a) The physiochemical properties, mechanical strength, optical properties, and anticipated operating temperature of the Materials of construction shall be capable of withstanding the processing conditions such as temperature, pressure, and chemical corrosiveness, thus ensuring the purity and integrity of the product. (b) Materials shall be compatible with the stated bio processing conditions, cleaning/sterilizing solutions, and SIP conditions, etc.	Manufacturer Defined Method	Raw Material and/or Final Article	Manufacturer Defined Method	Manufacturer De Method
		ASTM D543-14		ASTM D543-14	ASTM D543-1
		ASME BPE SD 2.4.1.2			ASME BPE SD 2.4
Conductivity Test	Qualification of flush effluent for hydrophilic filters.	USP <645>	Final Article		
Elastomeric Closures for Injections	A battery of tests designed to determine pertinent physicochemical extraction characteristics of elastomeric closures. (Does not apply for silicones)	USP <381>	Final Article		USP <381>
EP/Physicochemical	A battery of tests specific to Silicone	EP 3.1.9	Raw Material or Final Article - Post Sterilization		EP 3.1.9
	A battery of tests specific to Thermoplastic Elastomers	EP 3.2.9			EP 3.2.9
Extractables	Quantitative and qualitative characterizations of extractables in model solvents. Semivolatiles, nonvolatile impurities, and identification of unknowns. Included should be regulatory compounds of interest (e.g., Bisphenol A (BPA, Per- and Polyfluoroalkyl substances (PFAS), nitrosamines (or N-Nitrosamines)	USP <665>	Final Article	USP <665>	USP <665>
		BPOG Extractables Protocol		BPOG Extractables Protocol	BPOG Extractab Protocol
Oxidizable Substances	Qualification of flush effluent for hydrophobic filters.	USP <1231>	Final Article		
pH Shift Test	Qualification of flush effluent for hydrophilic filters.	USP <791>	Final Article		
Total Organic Carbon (TOC)	Qualification of flush effluent for hydrophilic filters.	USP <643>	Final Article		

D. Chemical Tests

D. CHEMICAL TESTS				COMPONENT CATEGORY APPLICABLE TO THIS TEST						
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors	5 Tubing	6 Filters	7 Single-Use Assemblies
Chemical Process Compatibility	Qualification of wetted parts to show compatibility (resistance) with chemical reagents used as process liquids.	Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.	Raw Material and/or Final Article		Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.	Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.	Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.	Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.	Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.	*
Chemical Risk Assessment Process Compatibility	Materials should be robust and compatible with product and process fluids and should not be excessively prone to damage, which compromise structural integrity either by the shedding of any materials as solid particles which impact product quality and/or process performance. Process Compatibility (a) The physiochemical properties, mechanical strength, optical properties, and anticipated operating temperature of the Materials of construction shall be capable of withstanding the processing conditions such as temperature, pressure, and chemical corrosiveness, thus ensuring the purity and integrity of the product. (b) Materials shall be compatible with the stated bio processing conditions, cleaning/sterilizing solutions, and SIP conditions, etc.	Manufacturer Defined Method	Raw Material and/or Final Article	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	
		ASTM D543-14		ASTM D543-14	ASTM D543-14	ASTM D543-14	ASTM D543-14	ASTM D543-14	ASTM D543-14	
		ASME BPE SD 2.4.1.2			ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	
Conductivity Test	Qualification of flush effluent for hydrophilic filters.	USP <645>	Final Article						USP <645>	*
Elastomeric Closures for Injections	A battery of tests designed to determine pertinent physicochemical extraction characteristics of elastomeric closures. (Does not apply for silicones)	USP <381>	Final Article		USP <381>			USP <381>		*
EP/Physicochemical	A battery of tests specific to Silicone	EP 3.1.9	Raw Material or Final Article - Post Sterilization		EP 3.1.9			EP 3.1.9		*
	A battery of tests specific to Thermoplastic Elastomers	EP 3.2.9			EP 3.2.9			EP 3.2.9		
Extractables	Quantitative and qualitative characterizations of extractables in model solvents. Semivolatiles, nonvolatile impurities, and identification of unknowns. Included should be regulatory compounds of interest (e.g., Bisphenol A (BPA, Per- and Polyfluoroalkyl substances (PFAS), nitrosamines (or N-Nitrosamines)	USP <665>	Final Article	USP <665>	USP <665>	USP <665>	USP <665>	USP <665>	USP <665>	*
		BPOG Extractables Protocol		BPOG Extractables Protocol	BPOG Extractables Protocol	BPOG Extractables Protocol	BPOG Extractables Protocol	BPOG Extractables Protocol	BPOG Extractables Protocol	
Oxidizable Substances	Qualification of flush effluent for hydrophobic filters.	USP <1231>	Final Article						USP <1231>	*
pH Shift Test	Qualification of flush effluent for hydrophilic filters.	USP <791>	Final Article						USP <791>	*
Total Organic Carbon (TOC)	Qualification of flush effluent for hydrophilic filters.	USP <643>	Final Article						USP <643>	*

* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section 1-6 for subassembly recommendations

E. Regulatory

- Updates
- Additions
  - EMC
  - PFAS
- Food Contact Deletion

E. REGULATORY				
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography
Electromagnetic Compatibly (EMC)	EMC requirements for immunity and emissions for sensors with active electronics	EN/IEC 61326-1	Final Article	
PFAS and BPA Combined Chemical Statement	Combined Chemical statements inclusion of components which use of restricted chemicals. EG bisphenol A and PFAS.	Manufacturer Define Risk Assessment	Final Article	Manufacturer Define Risk Assessment
REACh Statement	European Community Regulation on chemicals and their safe use.	EC/1907/2006	Raw Material	EC/1907/2006
RoHS 3 Statement	Restriction of Hazardous Substances in Electric and Electronic Equipment.	2002/95/EC	Raw Material	2002/95/EC
TSE BSE/Animal Origin Free Statements	Statement of inclusion of components and processes which contain animal-derived materials, minimizing the risk of transmitting spongiform encephalopathy agents via medicinal products.	EMA 410/01	Raw Material / Final Article	EMA 410/01
		EC 1774		EC 1774
* Individual components within the Single-Use Assembly are subject to test recommendations within specific catego				

E. Regulatory

E. REGULATORY				COMPONENT CATEGORY APPLICABLE TO THIS TEST						
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors	5 Tubing	6 Filters	7 Single-Use Assemblies
Electromagnetic Compatibly (EMC)	EMC requirements for immunity and emissions for sensors with active electronics	EN/IEC 61326-1	Final Article				EN/IEC 61326-1			*
PFAS and BPA Combined Chemical Statement	Combined Chemical statements inclusion of components which use of restricted chemicals. EG bisphenol A and PFAS.	Manufacturer Define Risk Assessment	Final Article	Manufacturer Define Risk Assessment	Manufacturer Define Risk Assessment	Manufacturer Define Risk Assessment	Manufacturer Define Risk Assessment	Manufacturer Define Risk Assessment	Manufacturer Define Risk Assessment	*
REACh Statement	European Community Regulation on chemicals and their safe use.	EC/1907/2006	Raw Material	EC/1907/2006	EC/1907/2006	EC/1907/2006	EC/1907/2006	EC/1907/2006	EC/1907/2006	EC/1907/2006
RoHS 3 Statement	Restriction of Hazardous Substances in Electric and Electronic Equipment.	2002/95/EC	Raw Material	2002/95/EC	2002/95/EC	2002/95/EC	2002/95/EC	2002/95/EC	2002/95/EC	2002/95/EC
TSE BSE/Animal Origin Free Statements	Statement of inclusion of components and processes which contain animal-derived materials, minimizing the risk of transmitting spongiform encephalopathy agents via medicinal products.	EMA 410/01	Raw Material / Final Article	EMA 410/01	EMA 410/01	EMA 410/01	EMA 410/01	EMA410/01	EMA410/01	EMA410/01
		EC 1774		EC 1774	EC 1774	EC 1774	EC 1774	EC 1774	EC 1774	EC 1774

* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section 1-6 for subassembly recommendations

F. Sterilization/Sanitization

- Updates

F. STERILIZATION / SANITATION				COMPONENT CATEGORY APPLICA			
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors
Irradiation Validation	Qualify the sterilization of healthcare products by ionizing irradiation: Gamma irradiation, X-ray or E-Beam.	ANSI AAMI ISO 11137	Final Article		ANSI/AAMI/ISO 11137	ANSI/AAMI/ISO 11137	ANSI AAMI ISO 111
		AAMI TIR 35			AAMI TIR 35	AAMI TIR 35	AAMI TIR 35
		ISO TS 13004			ISO/TS 13004	ISO/TS 13004	ISO TS 13004
		AAMI Technical Information Report 33				AAMI Technical Information Report 33	
Moist Heat Sterilization	Sterilization of healthcare products.	ANSI AAMI ISO 17665	Final Article		ANSI/AAMI/ISO 17665	ANSI/AAMI/ISO 17665	ANSI/AAMI/ISO 176
Sanitization Test (Bacterial Challenge Test)	Evaluation of anti-microbial effectiveness and endotoxin removal with recommended cleaning protocols; i.e. clean in place (CIP).	Manufacturer Defined Method based on USP methodology	Final Article	Manufacturer Defined Method based on USP methodology			
Sterilization Process Compatibility	Confirmation of manufacturer's specified performance claims after sterilization process. Perform or repeat Functional and Physical Testing after worst case sterilization process.	BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment	Final Article		BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment	BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment	BPSA X-Ray Sterilizat of Single-Use Bioproc Equipment
		Manufacturer Defined Method			Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defi Method
	Guidance on sterilization process material compatibility	AAMI TIR 17			AAMI TIR 17	AAMI TIR 17	AAMI TIR 17
* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section 1-6 for subassembly recommendatio							

F. Sterilization/Sanitization

F. STERILIZATION / SANITATION				COMPONENT CATEGORY APPLICABLE TO THIS TEST						
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors	5 Tubing	6 Filters	7 Single-Use Assemblies
Irradiation Validation	Qualify the sterilization of healthcare products by ionizing irradiation: Gamma irradiation, X-ray or E-Beam.	ANSI AAMI ISO 11137	Final Article		ANSI/AAMI/ISO 11137	ANSI/AAMI/ISO 11137	ANSI AAMI ISO 11137	ANSI/AAMI/ISO 11137	ANSI/AAMI/ISO 11137	ANSI/AAMI/ISO 11137
		AAMI TIR 35			AAMI TIR 35	AAMI TIR 35	AAMI TIR 35	AAMI TIR 35	AAMI TIR 35	AAMI TIR 35
		ISO TS 13004			ISO/TS 13004	ISO/TS 13004	ISO TS 13004	ISO/TS 13004	ISO/TS 13004	ISO/TS 13004
		AAMI Technical Information Report 33				AAMI Technical Information Report 33				*
Moist Heat Sterilization	Sterilization of healthcare products.	ANSI AAMI ISO 17665	Final Article		ANSI/AAMI/ISO 17665	ANSI/AAMI/ISO 17665	ANSI/AAMI/ISO 17665	ANSI/AAMI/ISO 17665	ANSI/AAMI/ISO 17665	ANSI/AAMI/ISO 17665
Sanitization Test (Bacterial Challenge Test)	Evaluation of anti-microbial effectiveness and endotoxin removal with recommended cleaning protocols; i.e. clean in place (CIP).	Manufacturer Defined Method based on USP methodology	Final Article	Manufacturer Defined Method based on USP methodology					Manufacturer Defined Method based on USP methodology	*
Sterilization Process Compatibility	Confirmation of manufacturer's specified performance claims after sterilization process. Perform or repeat Functional and Physical Testing after worst case sterilization process.	BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment	Final Article		BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment	BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment	BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment	BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment	BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment	*
		Manufacturer Defined Method			Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	
	Guidance on sterilization process material compatibility	AAMI TIR 17			AAMI TIR 17	AAMI TIR 17	AAMI TIR 17	AAMI TIR 17	AAMI TIR 17	

* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section 1-6 for subassembly recommendations

Component Categories

1. Chromatography
2. Connectors, Valves and Retainers
3. Containers and Film
4. Sensors
5. Tubing
6. Filters
7. **Single-Use Assemblies**

7. Single-Use Assemblies

- Representative of the full assembly as the test article.
- for the components within which are spelled out in the tables 1-6.
- Suitable for a Single-Use Assembly as the “test article”,
- It does not preclude the need for component-specific qualification testing and verification on the full assemblies; therefore, the reader should consult tabs 1 to 6 (i.e., filters, containers, sensors, as applicable) as well to follow the test expectations listed for those qualify components within the assemblies.
- The level of lot release testing required is to be determined by the end user based on the product and process requirements where the single use assembly is utilized.

7. Single-Use Assemblies

Table 7: SINGLE USE ASSEMBLIES

The tests listed in Table 7 are representative of the full assembly as the test article. It does not preclude the recommendation or "requirement" to apply tests listed for the components within which are spelled out in the tables 1-6. The tests listed in this tab under columns F to I are suitable for a Single-Use Assembly as the "test article", unless further specified. It does not preclude the need for component-specific qualification testing and verification on the full assemblies; therefore, the reader should consult tabs 1 to 6 (i.e., filters, containers, sensors, as applicable) as well to follow the test expectations listed for those qualify components within the assemblies. The level of lot release testing required is to be determined by the end user based on the product and process requirements where the single use assembly is utilized.

				TEST APPLICATION				
TEST TYPE	*GENERAL DESCRIPTION*	*TEST REFERENCES*	*TEST ARTICLE*	Material Qualification	Product (Article) Qualification	Batch/Lot	Material Change	Article Change
A. PHYSICAL								
Chamber Integrity/ Seal Integrity-Peel (Bags only)	Used to measure manufactured product and seal barrier performance of a variety of package types and forms, as well as seal and/or closure types.	Manufacturer Defined Method	Packaging		●	O	●	O
Integrity (Leak) Test	Standard Test Method for Physical Integrity Testing of Single-Use Systems. Confirmation of integrity for components and assemblies at a given temperature. This includes pressure testing under operating conditions and at elevated pressures.	ASTM E3244-20 ASTM E 3251-20 ASTM E3336-22	Final Article		●	O	O	O
	Junction Testing (barbed fittings) Single-use assembly junction connections should be qualified by the supplier to ensure they meet performance criteria as stated in their specification. The supplier shall have an established testing program to substantiate performance of the mechanical connection. The testing should reference at least one of the following: (a) Pressure Testing (b) Leak Testing (c) Tracer Gas Testing	Manufacturer Defined Method			●			
Tensile Strength	Determines resistance of loading on a jointed union/connection/fitting.	Manufacturer Defined Method			●	O	O	O
B. FUNCTIONAL								
Accelerated or Real Time Aging (Shelf Life)	Accelerated and/or real time studies to determine the effects, if any, due to the passage of time and environmental effects on the properties of product, and on the sterile integrity of packages and the physical properties of their component packaging materials.	Manufacturer Defined Method ASTM F1980-21	Final Article		●		O	O
General Functionality Fit for Intended Use	The Manufacturer/user shall establish that the Single-Use components, SUS assemblies, and SUS systems are designed for integrity and functionality, appropriately. These considerations should be maintained during installation and ensured throughout the use of the item based on scientific product and process understanding for both SUS manufacturing and end user requirement. Qualification of design, manufacturing, testing and distribution should be	Manufacturer Defined Method ASTM 3051 ASME BPE SD 2.4.1.2	Final Article		●	●	●	●
Package Testing/ Transportation Shipping Integrity	Qualify that product packaging will protect the product during shipping. Standard practice for performance testing of shipping containers and systems to provide a uniform basis of evaluating, in a laboratory, the ability of shipping units to withstand the distribution environment.	ASTM D4169-14 ASTM D4728-06 DIN ISO 2872 ISTA 2A ISTA 3A ISTA 3B ISTA 3E	Final Article		●		O	
		BPSA Recommendations for						

2023 Completion

- 7/10-7/12 BPSA Summit-7/11 presentation
- 7/14-SAB review complete
- 7/14-QTM meeting if needed at summit.
- 7/14 SAB comments to QTM if any.
- 7/20-QTM meeting to address SAB comments if needed.
- 7/21-Final to BPSA Board
- 7/28-BPSA Board approval

Future QTM Updates

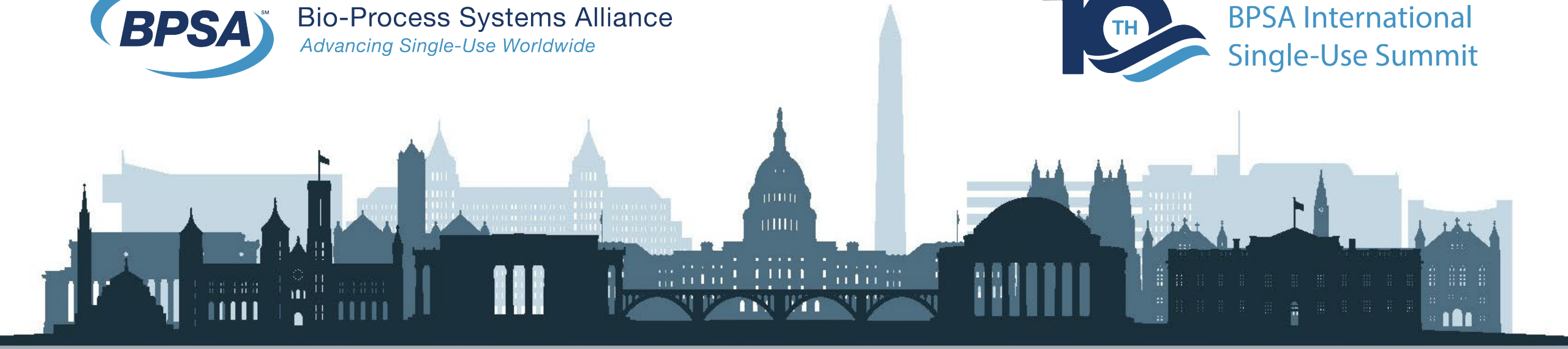
- Items did not make the cut
- Standard Updates
- Industry guidance

Topics

- Endotoxin/Pyrogen Free
- Accelerated Aging-Humidity
- Animal Testing
- Physical Joining
- Others?

Bio-Process Systems Alliance
Advancing Single-Use Worldwide

BPSA International
Single-Use Summit



COLLABORATION, TECHNOLOGY & INNOVATION: SHAPING THE FUTURE OF SINGLE-USE

JULY 10-JULY 12, FOUR SEASON HOTEL, WASHINGTON, DC