



2020 Speaker Series

Thursday, November 19, 2020

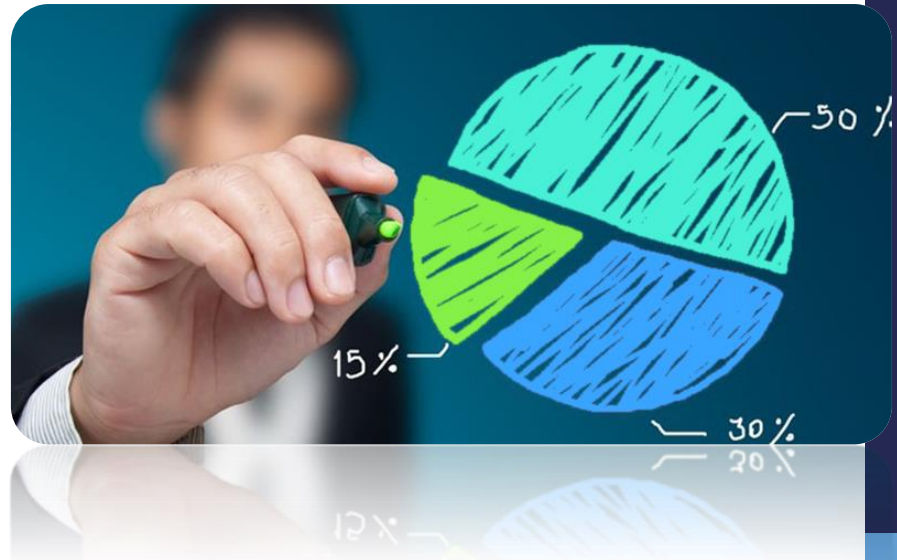
10:00-11:00 AM EST

Guide to Single-Use Training Series: Part 3

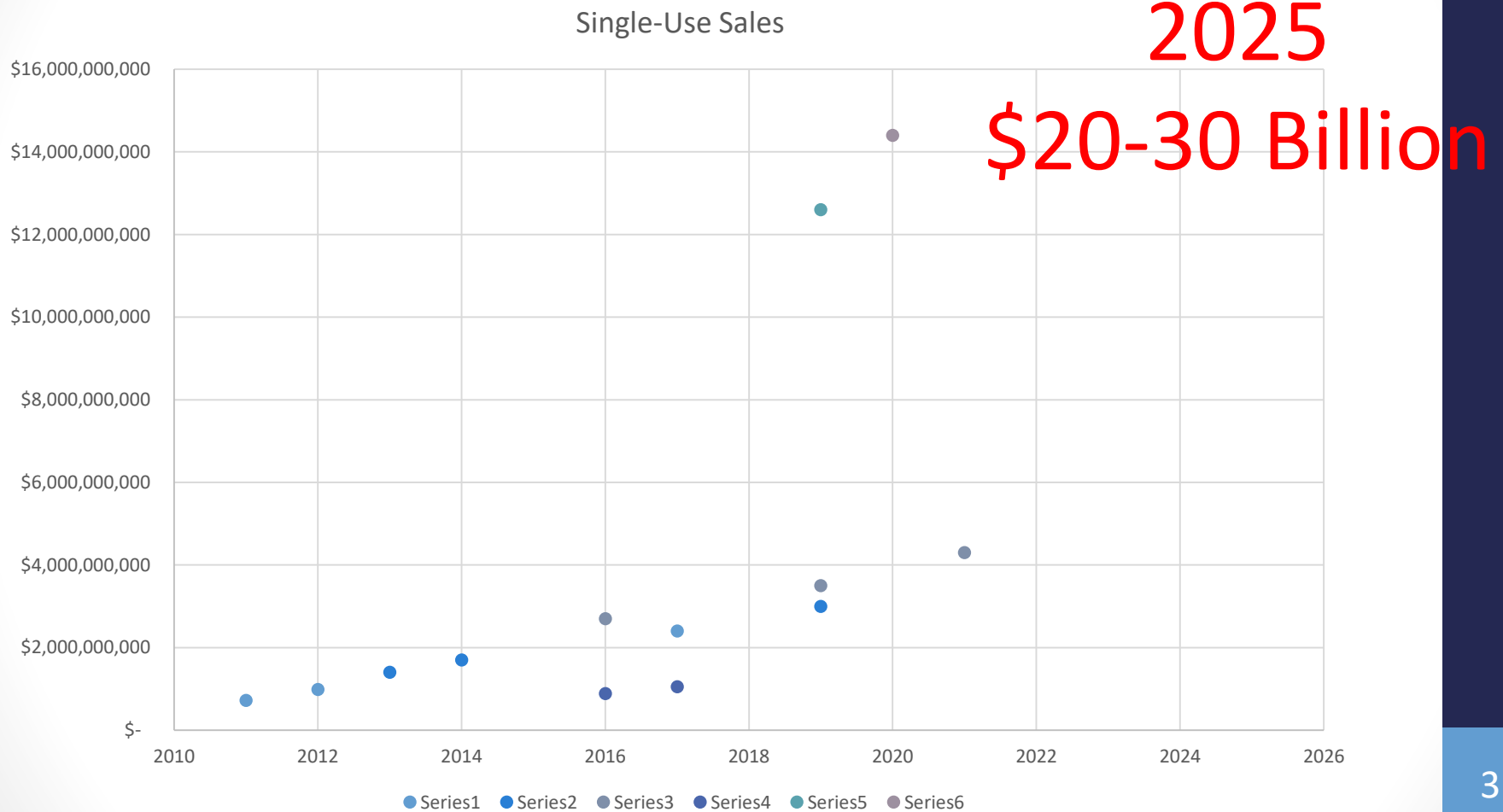
**Current Trends and the Top Ten Things to
Consider to Manufacture and use SUT**

Market Share

- Billions
- 10-20% growth
- Flexibility
- Almost all research
- CMOs
- CROs
- Bioreactors
- Filtration



Single-Use Sales



Clear Advantages of SUT

1. Reduction of cross contamination;
2. Enabling faster clinical trials;
3. Enabling faster speed to market;
4. Speed of manufacturing capacity expansion;
5. Flexibility with respect to multiproduct production.



Single-Use Success!

but there is a cost



Single-Use Complaints

Complaint Category	Description
Contamination	Suspected presence of unintended foreign matter
Cosmetic	Blemishes, scratches, or other visual defect not including foreign matter
Defective Component	Nonfunctional component due to manufacturing defect
Broken Component	Nonfunctional component due to post manufacturing damage
Missing Documentation	Self-explanatory
Documentation Error	Self-explanatory
Incorrect Assembly	Assembly not conforming to specifications / design due to assembly error
Leakage	Self-explanatory
Filter Integrity	Filters incorporated into SUS that fail pre- or post-use integrity test

Root Causes

- Poor design
- Defective material
- Damaged material
- Poor Manufacturing Controls
- Supplier Human Error
- User Human Error

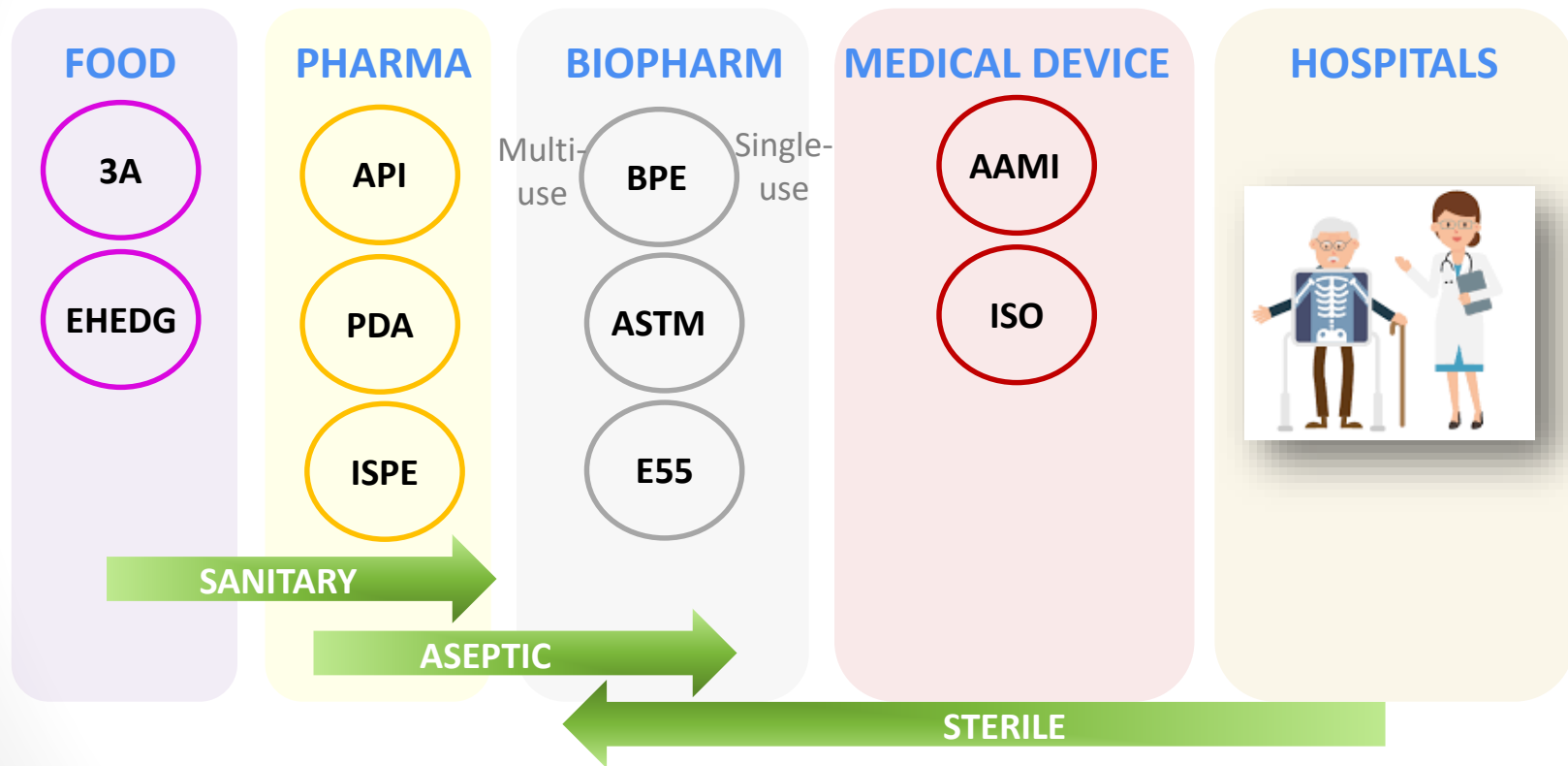
Result of Failure

- Reduced Yield
- Loss of Product
- Loss of Time
- Financial Loss
- Environmental
- No Measurable Effect

Bioprocess SUT Standardization



Food and Medical Device Lead into What BioPharm is Doing



SUT Requirements for Standardization



There are overlaps and gaps in the requirements applicable to SUT

Regulatory
Compendial:

FDA, USP

Standards:

AAMI/ISO
Standards

Guidelines

FDA, USP

ASME BPE Standard,
ASTM E-55 Tests

BPSA Guidelines

FDA, USP

ASME BPE Standard,
ASTM E-55 Tests

ISPE Guidelines

The Road to Standardization

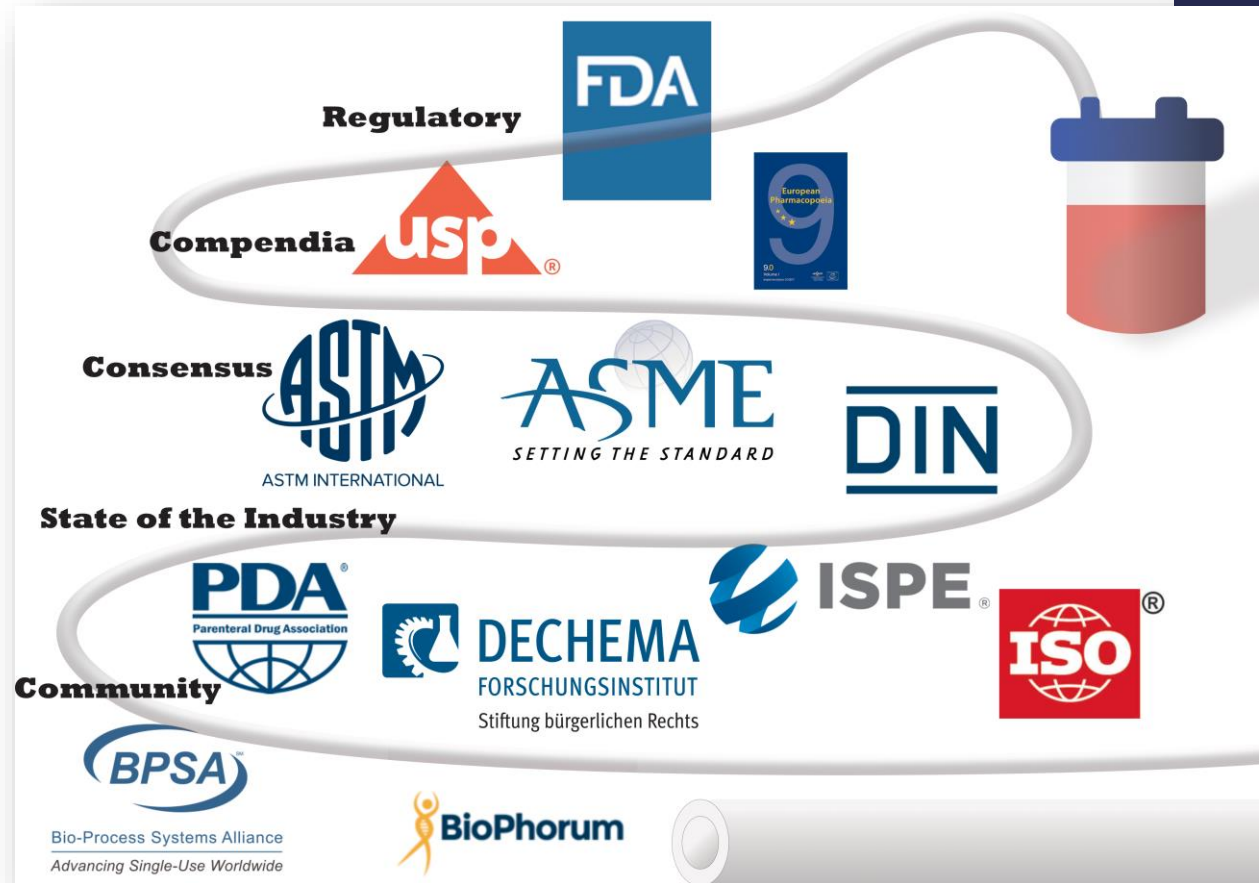


Needs driven by
Community – Develop
guidelines

Develop guidelines –
builds consensus

Creates consensus –
requirements developed
based on guidelines

Regulations vs. Compendia vs. Standards vs. Guidelines



Top 10 Lists for Single-Use Technologies



What are your Top Tens?...Threes?...One?

Let Us Know?

A blue speech bubble graphic with a white outline and a drop shadow, containing the text "TELL US WHAT YOU THINK!".

TELL US
WHAT YOU
THINK!

www.bioprocessinstitute.com
info@bioprocessinstitute.com

Updates will be posted



Reference Documents for Single-Use Technologies

- 1 [ASME BPE \(BioProcessing Equipment\)](#)
- 2 [BPSA Quality Test Matrices and Technical Guides](#)
- 3 [ISO 11137 Sterilization of Health Care Products: Radiation](#)
- 4 [United States Pharmacopeia \(USP\)](#)
- 5 [Biophorum Operations Group \(BPOG\) Extractables and Leachables Portal](#)
- 6 [ASTM E3051 Standard Guide for Specification, Design, Verification, and Application of Single-Use Systems in Pharmaceutical and Biopharmaceutical Manufacturing](#)
- 7 [ASTM F1980: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices](#)
- 8 [PDA TR66 Application of Single-Use Systems in Pharmaceutical Manufacturing](#)
- 9 [ISPE Good Practice Guide: Single-use Technologies](#)
- 10 [Regulations: Good Manufacturing Practices/Quality Systems \(CFRs 210,211, 820, 600, 610, ICH Q7\)](#)

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TOP

Considerations for Single-Use Components

- 1 Biocompatibility
- 2 Bioburden control
- 3 Animal Derived Ingredient-Free
- 4 Integrity
- 5 Application/Chemical Compatibility
- 6 Particulates
- 7 Extractables & Leachables
- 8 Endotoxins
- 9 Packaging/Chain of Custody/Shelf Life
- 10 Qualification/Validation



Best Practices for Single-Use Suppliers

- 1 Quality Management Systems
- 2 Change Management
- 3 Manufacturing Control and Metrics
- 4 Robust supply chain & support
- 5 Product/component knowledge
- 6 Bioprocess application knowledge
- 7 Regulated industry exposure
- 8 Technical support
- 9 Documentation support
- 10 Sustainability



Best Practices for Single-Use Implementation

- 1 Handling procedures, protocols and training
- 2 Verification of the fluid path, maintaining process integrity when connecting
- 3 Integrity testing (package and assembly)
- 4 Verification of component assembly
- 5 Pre-use testing
- 6 Visual inspection (before, during and after)
- 7 Review of documentation
- 8 Bag deployment
- 9 MMI (Man Machine Interface)
- 10 Sustainability

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TOP

Single-Use Trends

- 1 Automation and BIG DATA!
- 2 Continuous Processing
- 3 Cell & Gene Therapy and Miniaturization
- 4 Manufacturing Efficiencies
- 5 Integrity Testing of Each Assembly
- 6 Particulate & Endotoxin Claims
- 7 Robust Storage
- 8 ISO 13485 for Medical Devices
- 9 Single-Use Centrifugation
- 10 Standardization (ASTM, ASME BPE technical guides, etc.)

Single-Use 2030? Direction to Where?



What is Needed?

- Alignment is needed, even with regulators
- Current and future drugs need it
- Patients need it
- Volunteers needed!

Call for Volunteers

- This effort is valuable to get the most out of Single-Use Technology to deliver high quality and safe therapeutics
- This effort is valuable in many ways, including to your “day job” and your career

Conclusion

- It is imperative that we, **as an industry**, set a course for Single-Use Standardization!
- Then set out to do it
- We **have** to do it **together** as a **community**!



Single-Use Summary

- Single-Use present many benefits
 - Increased flexibility
 - Cost savings in many applications
- Single-Use also present additional challenges
 - Handling
 - Storage
 - Disposal
- There is an important place in most processes for Single-Use

Single-Use 2030!

Where we want to go!



Single-Use 2030!

Where we want to go!



Questions Please contact us



After today you may send questions to info@bioprocessinstitute.com

end users
Our goal is to help our clients make better drugs
suppliers

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