

BPSA Annual Membership Meeting

October 6, 2020 9-10:45 AM EDT



Bio-Process Systems Alliance

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EXECUTIVE DIRECTOR REPORT

Kevin Ott,

BPSA Executive Director



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Where We've Been...



18

newsletters
sent



1315

tech guide
downloads



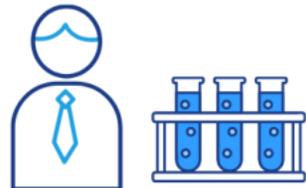
8

webinars executed



752

attendees



> 33%

webinar attendees & downloads
are non-member end-users

544

members

204

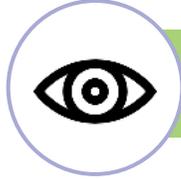
non-members



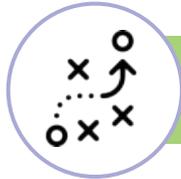
Where We're Going



Mission



Vision



Strategies - ACES

A Adoption

Safety, cost, performance, barriers/hurdles, supply chain, tech guides

E Engagement

Summits, webinars, regional meetings

C Communication

Weekly newsletter, member outreach, membership marketing

S Sustainability

Sustaining BPSA, Single-Use sustainability

BPSA Sustaining Sponsors



AdvantaPURE
NEWARK INDUSTRIES



Broadley James[®]



bürkert
FLUID CONTROL SYSTEMS



CPC[™]



cytiva



Entegris



MILLIPORE
SIGMA



Nordson
MEDICAL



PALL[®] Biotech



PENDOTECH
Adding Value To Your Process



RENOLIT
Reli on it.



SAINT-GOBAIN



SaniSure[™]
Be sure.



SARTORIUS



SavilleX



ThermoFisher
SCIENTIFIC



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BPSA Members



What is a Sustaining Sponsor?

Sustaining sponsors are critical to continuing BPSA's mission to educate and inform constituent groups on the efficacy and benefits of Single-Use.



Reason 1

To Support Industry Events

BPSA's webinar speaker series, national, and international events focus on member education & peer-to-peer networking.

Reason 2

To Fund Technical Workstreams

BPSA technical workstreams address the challenges inherent to further the adoption of Single-Use Technologies.

Reason 3

To Launch New Initiatives

BPSA identifies and acts upon member-initiated business topics and projects, such as Market Data.

Reason 4

To Position Your Company as an Industry Leader

BPSA sponsorship showcases your company's dedication to the industry to your customers, colleagues & competitors.



Become a Sponsor Today

Learn more at bpsalliance.org



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Reasons to be a BPSA Sponsor



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TREASURER'S REPORT

Eric Isberg, Savillex

BPSA Treasurer

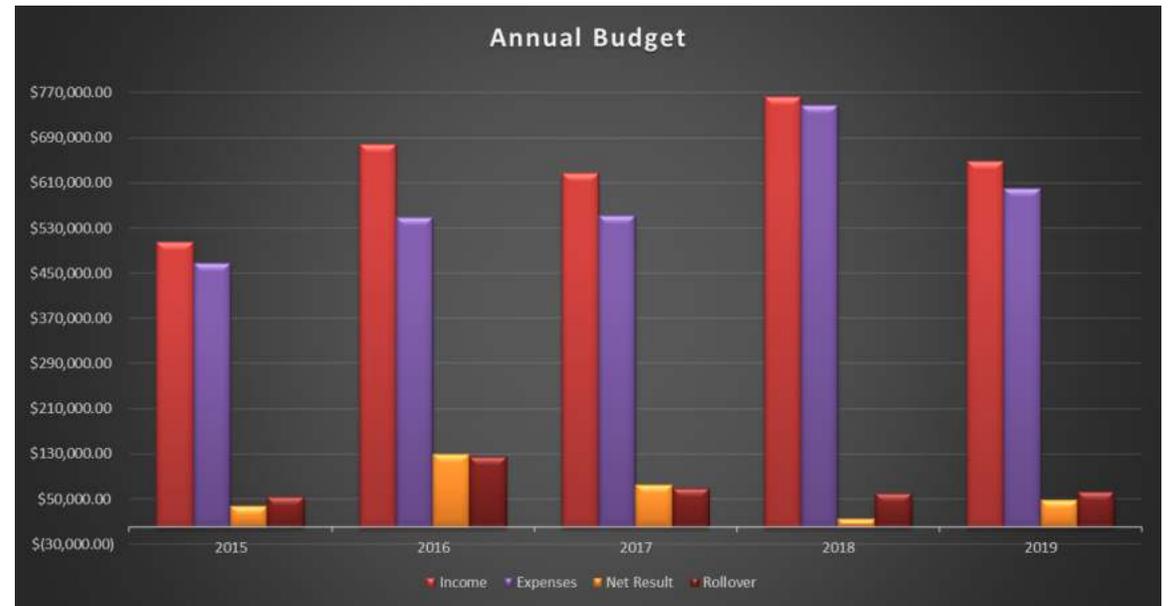


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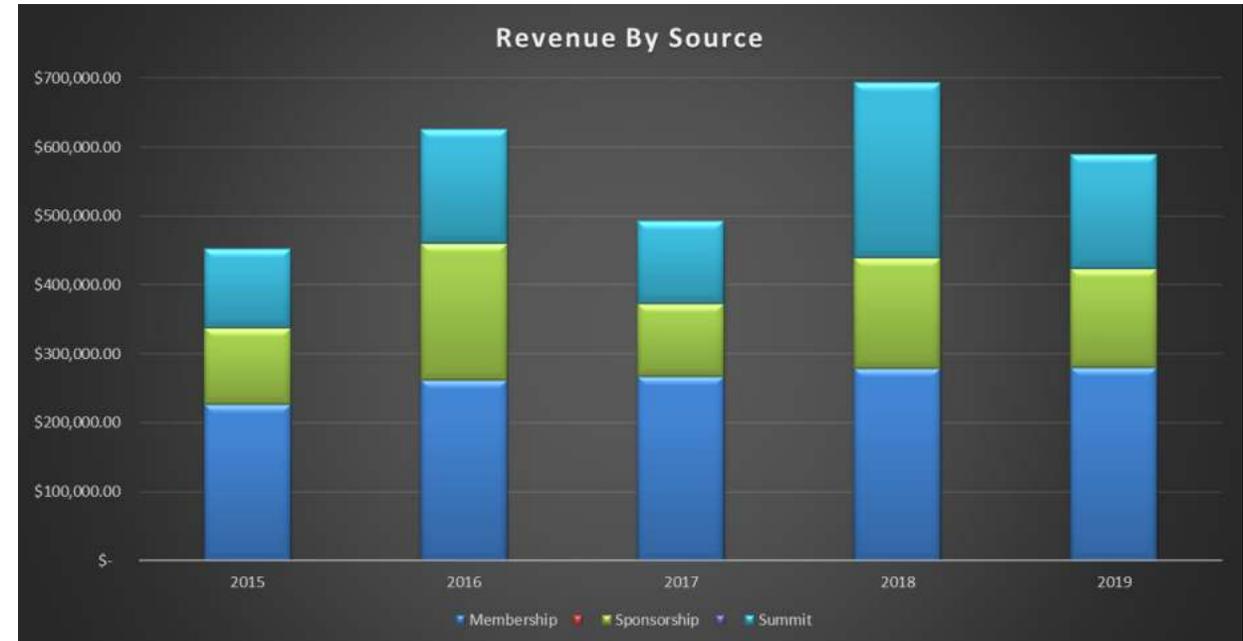
2019 Summary

- Finished the year within budget
- Funded 7 committees
- Published multiple papers
- Record Summit revenue
- \$48,000 rollover into 2020



2019 Sources of Revenue

- Memberships – “Keeps the Light On”
- Summit – “Very Profitable”
- Sponsorships
 - Fund Committees
 - Fund Technical Papers
 - Fund Collaborations with Industry Groups
 - Fund Scholarships
 - Allow 10% Reserve
- Sponsorships are essential for us to continue to produce meaningful content



BPSA Secretary Report – 2020 By-Law Revisions

- Instituting term limits for Directors at-large
 - Each Board member will be allowed to run for three consecutive two-year terms (six years total). After this time, the person must take a two-year break before they are allowed to run for another term.
- Increasing the size of the Board of Directors
 - 4 open Board-at-large positions (moving from 15 to 19).
- Managing an open board seat
 - Occupied by the person, not by the person's company.
 - Vacated person may nominate a replacement.
 - Approved by Board vote, special election or deferred to next scheduled election.
- Instituting a Scientific Advisory Board (SAB)
 - A dedicated technical group will be best suited to manage the technical portfolio.



TECHNICAL REPORT

Presented by: Kirsten Strahlendorf, Sanofi Pasteur

Technical Committee Chair



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Agenda

- A New Scientific Advisory Board
 - Mission
 - Structure
 - Call for Candidates
 - 2021
- Technical Committee Review
 - What BSPA achieved during a pandemic
 - 2020 Project Updates





Scientific Advisory Board

A New Scientific Advisory Board



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Mission

The BPSA Scientific Advisory Board (SAB) provides the technical direction of the Alliance to promote and maintain the adoption of single-use. We strive to build integrity in this direction that is backed by sound scientific and technical outputs in our voice to support both the BPSA membership and bioprocessing field.



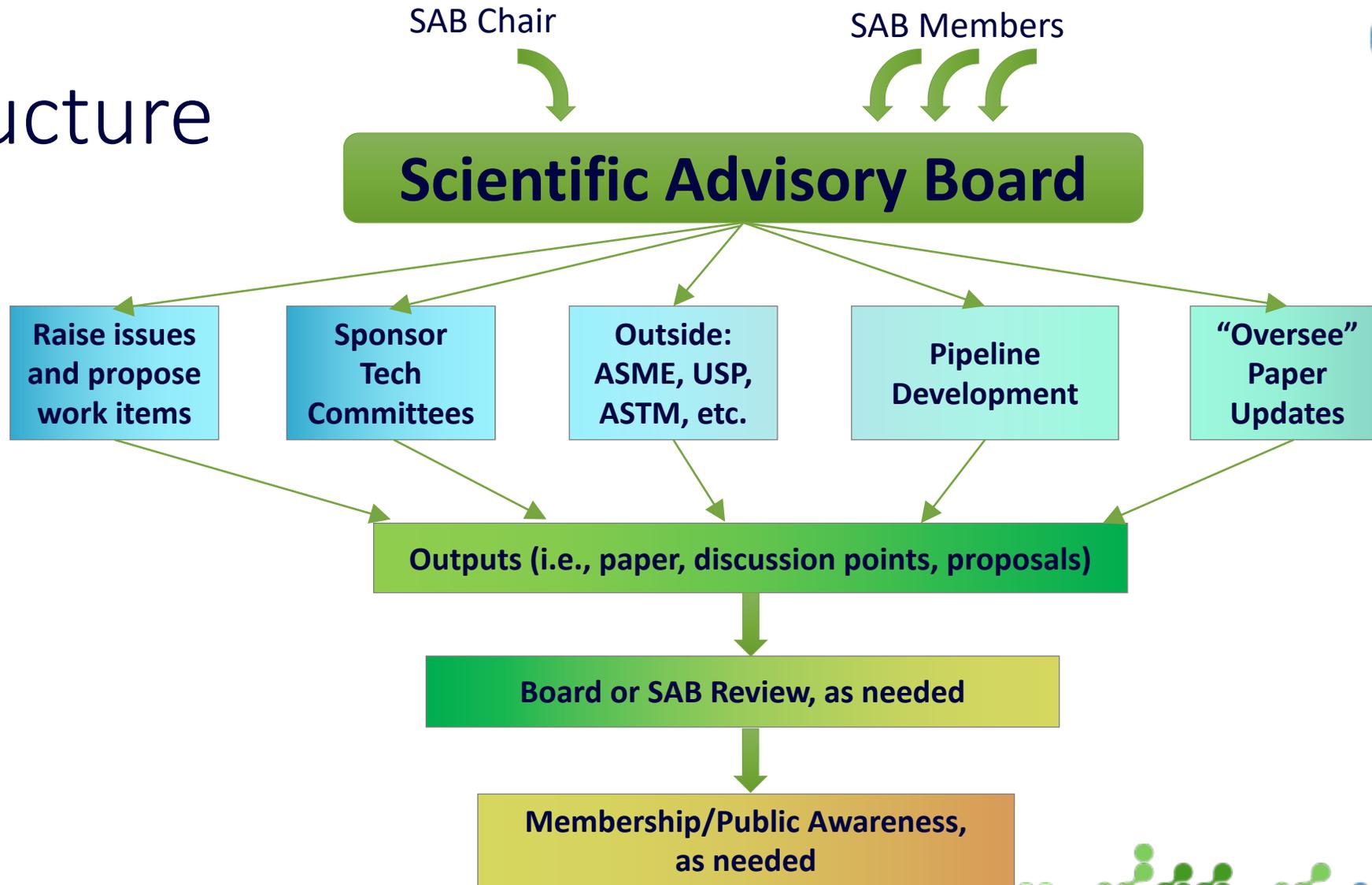
Scientific Advisory Board



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Structure



BSPA will be Seeking Candidates for the SAB



Scientific Advisory Board

- Looking for 4-6 candidates to start
- 2-year term
- Open, transparent members
- Diverse backgrounds with solid over-arching experience in SU industry (suppliers and users)
- Does not necessarily mean candidates are technical committee members or chairs or board members
- Time commitment: min 30 minutes/month



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What's in Store for 2021?



Team Formation & Kick-off meeting



Team to draft Project Charter



Evaluation of Technical Portfolio



Objectives setting for 2021+

Technical Committee Review



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What was Achieved during a Pandemic?



Courtesy of Shutterstock, 2020

March 2020 hit us - Did we need to scale down our Technical Committee commitments?

- What activities were almost done?
- What activities were planned for 2020?
- What could continue with current funding?
- Were people going to disappear?

COVID-19 Status/Proposals

| Technical Stream | Lead/Board Sponsor | Activities Near Completion | Additional 2020 Activities | Activities that can continue w/o funding | Proposal to continue/pause... |
|---------------------|----------------------------------------------------------|-------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| Particulates Update | Klaus Wormuth/ Jim Vogel | <ul style="list-style-type: none"> Paper ready for publication after 2 wk legal review | <ul style="list-style-type: none"> Summit update Marketing | <ul style="list-style-type: none"> Publication Updated, see right-most column | Keep going to complete paper...  |
| Transit Testing | Richard Salzstein/ James Raw/ Kirsten Strahlendorf | <ul style="list-style-type: none"> Paper for tech writer in 9 weeks | <ul style="list-style-type: none"> Need tech writer Final version June Summit Update | <ul style="list-style-type: none"> Emails to continue paper contributions Updated, see right-most column | Keep going...  |
| Integrity Paper | Helene Pora | <ul style="list-style-type: none"> Final review of case studies paper by 10/15 | <ul style="list-style-type: none"> Final paper to submit to Board + PI final team review w/ Webinars | <ul style="list-style-type: none"> Everything except meetings Updated, see right-most column | Continue...  |
| Sustain-ability | Brian Horowski/ Mark Petrich | <ul style="list-style-type: none"> Board-approved paper to be sent to Editor | <ul style="list-style-type: none"> Writing team meetings Monthly meetings Determine if Paper #1 is published with BPI Paper #2 writing | <ul style="list-style-type: none"> Paper #2 writing (started) Emails Updated, see right-most column | Continue...  |
| CGT | Brendan Lucey (Board Sponsor) | <ul style="list-style-type: none"> Done paper July or soon | <ul style="list-style-type: none"> BL update in meetings Virtual meetings and paper draft ongoing | <ul style="list-style-type: none"> Health writer for BL WebEx paid 2021 Mass Bio event (sponsored, revenue generator) | Continue...  |
| X-Ray (New) | J. Hathcock/ H. Pora | <ul style="list-style-type: none"> Kick-off meeting occurred | <ul style="list-style-type: none"> Collecting outline ideas from team | <ul style="list-style-type: none"> Discussions (meetings) Updated, see right-most column | Continue:  |

-Every committee

continued.

-Every deliverable

progressed.

-Not a single meeting was cancelled



Cell and Gene Therapy Committee

Brendan Lucey, Gemini BioProducts
Board Sponsor

Todd Kapp, Entegris, Inc.
Committee Chair

Committee Members

Scott Anderson, Millipore Sigma
Manjula Aysola, Millipore Sigma
Max Blomberg, Meissner
Jerry Branscomb, Thermo Fisher
Jeff Carter, Cytiva
Ruchit Chanekar, Corning
Paul Cummings, Smithers
Ralph Daumke, FILTROX
Ken Davis, Nordson
Clive Glover, Pall Biotech
Jayanthi Grebin, CPC

Armin Hauk, Sartorius Stedim Biotech
Scott Herskowitz, Qosina
Brian Horowski, Wood PLC
Todd Kapp, Entegris
Tim Korwan, Avantor
Kara Levine, Millipore Sigma
Brendan Lucey, Gemini BioProducts
Jessica Martin, Corning
Ruth McDermott, Sartorius Stedim Biotech
Elizabeth Misleh, Corning

Rachelle Morrow, Qosina
Hernan Parma, Renolit
Derek Pendlebury, CPC
Joe Petrosky, PBS Biotech
Paul Priebe, Qosina
Hasan Saleheen, Cytiva
Bob Sassa, W.L. Gore & Associates
Joseph St. Laurent, Chemic
Kirsten Strahlendorf, Sanofi Pasteur
Travis Ward, Repligen



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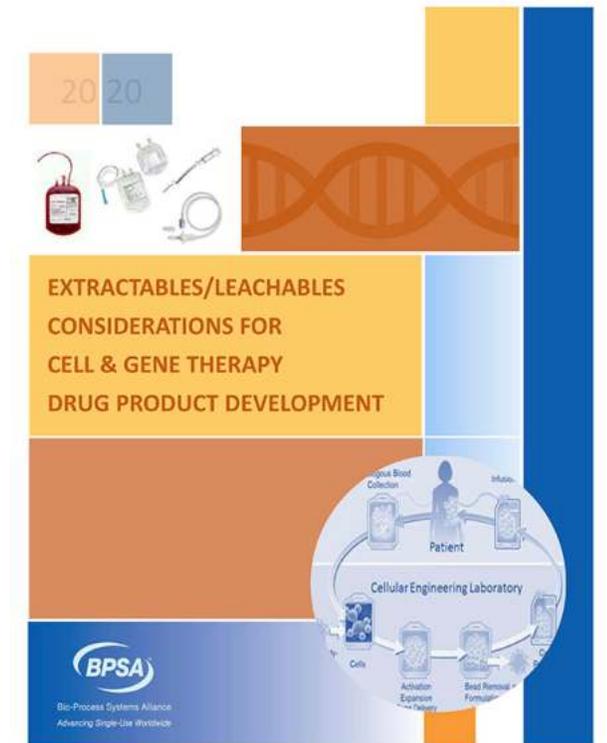
BPSA CGT Committee Update

Accomplishments since last Annual Meeting

- **CAR-T Process Map Paper** has 354 downloads since posted Feb '19
Available online: <https://bpsalliance.org/technical-guides/>
- **CGT Extractables Paper** Published and Available – Webinar 9/23
 - White paper: <https://bpsalliance.org/technical-guides/>
 - Webinar resources: <https://bpsalliance.org/bpsa-webinar-speaker-series/>
- **Viral Vector Overview Paper** – Drafting in Committee, expect ready for technical writer by November and release after first of the year

Upcoming Deliverables

- Will have a state of CGT webinar after the first of the year
- Will promote papers and get additional feedback for educating end users
- Committee meets monthly and subcommittees meet at least monthly as well
- Feel free to reach out to Todd or Jeanette if you would like to participate in the committee



X-Ray Committee

Hélène Pora, Pall Biotech
Board Sponsor

Samuel Dorey, Sartorius Stedim Biotech
James Hathcock, Pall Biotech
Committee Co-Chairs

Committee Members

Janmeet Anant, MilliporeSigma
Dennis Annarelli, PendoTECH
Ken Baker, AdvantaPure/NewAge
Industries
John Benson, PendoTECH
Amit Bhatt, Merck Millipore
Monica Cardona, MilliporeSigma
Jeff Carter, Cytiva
Samuel Dorey, Sartorius Stedim
Biotech

Etienne Durant, GSK
CD Feng, Broadley James
James Hathcock, Pall Biotech
Stephen Hodder, Pall Biotech
Noel Long, Cytiva
S Lynch, AdvantaPure/NewAge Industries
Mary Marcus, AdvantaPure/NewAge Industries
Dominic Moore, Sanofi Pasteur
John Murphy, Merck Millipore

Larry N, SaniSure
Timo Neumann, Merck Millipore
Jeffrey Noyes, Steris
Mark Petrich, Merck & Co., Inc.
Rafael Rodriguez, Cytiva
Kirsten Strahlendorf, Sanofi Pasteur
Nick Troise, PendoTECH
Clive Wingar, Thermo Fisher



Qualification of X-ray Sterilization of SUT

- ✓ Webinar. **‘X-ray Sterilization of SUT. It’s coming sooner than you think!’** (Sept 2, on demand)
- ✓ **Qualification Requirements for X-ray Sterilization of SUS White paper** (White Paper, Q4, 2020)
 - ✓ Business continuity and supply/demand need for alternative to gamma
 - ✓ Requirements for implementing x-ray
 - ✓ Consensus industry risk assessment and test protocol
- ✓ **Cross-Industry Data Supporting Qualification and Implementation of X-ray Sterilization for SUS** (white paper, Q4, 2021)

X-ray Sterilization Requirements for Single-Use Equipment



Introduction to the Physics of Radiation Sterilization: Can X-ray replace Gamma?

Thomas Kroc
Fermilab



X-Ray Radiation:
A pathway to transfer from gamma

John Logar
Johnson & Johnson

Panel Discussion



James Hathcock
BPSA X-ray task group
Pall Biotech



Samuel Dorey
BPSA X-ray task group
Sartorius Stedim Biotech

| TEST TYPE | TEST REFERENCES | Component Type | | | | |
|----------------------------|------------------------------------------------------------------------------|-----------------------------------|----------------------|---------|--------|---------|
| | | Connectors Valves Retainers | Containers & Film | Sensors | Tubing | Filters |
| A. PHYSICAL TESTS | | | | | | |
| Pressure Burst Test | Manufacturer-defined method, ISO 7241-2, ASTM D1599-99, EN 12266-1, ISO 1402 | ● | - | ● | ● | ● |
| Integrity (Leak) Test | Manufacturer-defined method, USP 87_{p}, ISO 10993-5 | ● | ● | ● | ● | ● |
| B. FUNCTIONAL TESTS | | | | | | |
| Tensile (Pull-Off) Test | Manufacturer-defined method | ○ | ○ | ○ | ○ | ○ |
| Puncture | Water Flow Rate and Pressure Drop | ○ | - | ○ | ○ | ● |
| Tear Resistance | ISO 7241-2, ISO 3968, Manufacturer-defined method | ○ | - | ○ | ○ | ● |
| O2 and CO2 Permeability | Accelerated Aging (Shelf Life) | ○ | ○ | ○ | ○ | ○ |
| WVTR | Accelerated Aging (Shelf Life) | ○ | ○ | ○ | ○ | ○ |
| Compression Set Test | Particulate Matter | ○ | ○ | ○ | ○ | ○ |
| Durometer (Hardness) | Kink Resistance/Ben- tharulus | ○ | ○ | ○ | ○ | ○ |
| C. BIOLOGICAL TESTS | | | | | | |
| | Biological Reactivity - In Vitro | ○ | ○ | ○ | ○ | ○ |
| | USP 87_{p}, ISO 10993-5 | ○ | ○ | ○ | ○ | ○ |



Integrity Assurance Committee

Hélène Pora, Pall Biotech
Committee Chair

Committee Members

Emily Alkandry, Saint-Gobain

Jeff Carter, Cytiva

Genine Dale, Saint-Gobain

Patrick Evrard, Pall Biotech

Marc Hogreve, Sartorius Stedim Biotech

Carole Langlois, Sartorius Stedim Biotech

Charlotte Masy, GSK Vaccines

Scott Patterson, ILC Dover

Mark Pennington, Saint Gobain

Mark Petrich, Merck & Co., Inc.

Helene Pora, Pall Biotech

Erik Storm, Cytiva

Kirsten Strahlendorf, Sanofi Pasteur



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Integrity Assurance Workstream

- Public webinar in October 2020
- 2nd paper case studies to be published in Q4 2020
- Next step of activities:
 - Revision of the white paper published in 2017
 - Training development

Key Success : our white paper has been used as a basis for 2 best practises ASTM guidances issued in 2020



Transit Testing Committee

Kirsten Strahlendorf, Sanofi Pasteur
Board Sponsor

Rich Salzstein, Smithers
James Raw, Smithers
Committee Co-Chairs

Committee Members

Frederick Bazin, Sartorius Stedim
Biotech

Donnie Beers, Entegris

Dianne Heiler, Repligen

Courtenay Moulton, Sanofi Pasteur

Andrew Quick, CPC

James Raw, Smithers

Rich Salzstein, Smithers

Peter Stedehouder, Pall Biotech

Kirsten Strahlendorf, Sanofi Pasteur

Elisabeth Vachette, Sartorius Stedim Biotech

Travis Ward, Repligen

Kimberly Weir, MSU



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BPSA Transit Testing Committee Status Update

White Paper draft process: Nearing completion

- Oct 5: Team meeting for final comments, for team leads to incorporate
- Mid Oct: Smithers editors to refine formatting
- Oct 26: Team meeting to approve final draft for BPSA leadership review
- Nov / Dec: BPSA leadership review / comments; determine any next steps

Team review comments / next steps, if any

BPSA publishing to follow



Sustainability Committee

Mark Petrich, Merck & Co., Inc.
Board Sponsor

Magali Barbaroux, Sartorius Stedim Biotech
Committee Co-Chair

Committee Members

Farhan Ahmad, Honeywell
Megan Baillie, High Purity New England
Magali Barbaroux, Sartorius Stedim Biotech
Nate Belke, Avantor
John Boehm, CPC
Philippe Busson, Cytiva
Jeff Carter, Cytiva
Joy Chen, Entegris
Jordan Cobia, Thermo Fisher
Russell Darley, Sealed Air
Ken Davis, Nordson
Denise DeTomasso, ILC Dover
Dianne Heiler, Repligen
Jacqueline Hollands, Millipore Sigma

Brian Horowski, Wood PLC
Jacqueline Ignacio, Millipore Sigma
Travis Imhoff, Sartorius Stedim Biotech
Jeteca Larson, Thermo Fisher
Greg Love, Burkert
Mark Meyer, Saint-Gobain
Merete Miles, Thermo Fisher
Sade Mokuolu, Watson Marlow
Matthew Olsen, Sartorius Stedim Biotech
Matt Olsen, Sartorius Stedim Biotech
Kaycee Palumbo, Cytiva
Scott Patterson, ILC Dover
Mark Pennington, Saint-Gobain

Mark Petrich, Merck & Co., Inc.
Catherine Piton, Pall Biotech
David Pollard, Sartorius Stedim Biotech
Mihir Shah, Repligen
Melanee Short, Sanofi Pasteur
Jeffery Smith, Sanofi Pasteur
Mitch Snyder, Saint-Gobain
Cristina Van Loy, Thermo Fisher
Travis Ward, Repligen
Michael Waslin, Merck
Maria Watson, Pall Biotech
Don Young, Thermo Fisher



Sustainability Committee

- Welcome our new chair – Magali Barbaroux
 - Transition from Cristina Amorim, Thermo
 - Thank you to Thermo for supporting this committee!

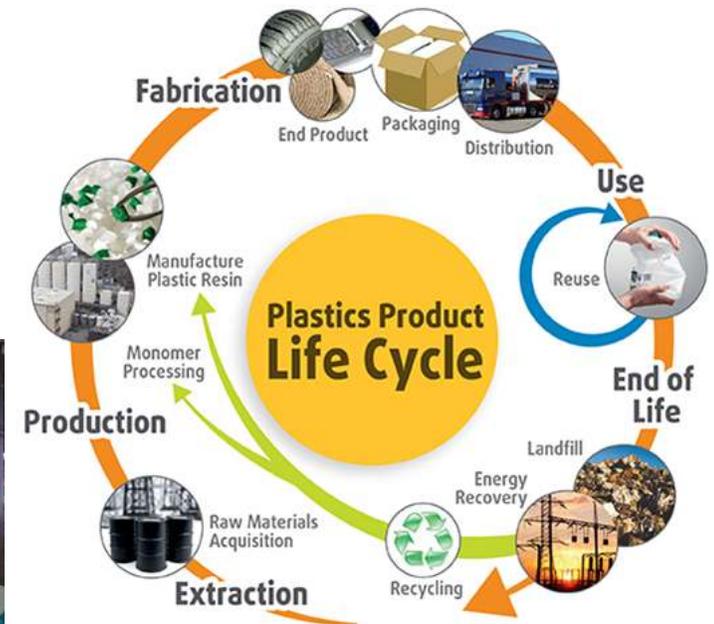
- 2020 Publications in progress (3 parts)
 - Part One – at bpsalliance.org/technical-guides/

The Green Imperative

Part One: Life-Cycle Assessment and Sustainability for Single-Use Technologies in the Biopharmaceutical Industry

Magali Barbaroux, Brian Horowski, Sade Mokuolu, Mark Petrich, and William Whitford; with the BPSA Sustainability Subcommittee and Bill Flanagan

- Part Two: Reduce waste, design for recyclability
 - Part Three: Waste management options, present and future
 - Thank you to Brian Horowski (Wood PLC) for leading the authoring team!
- Re-starting meeting series in November; planning for 2021



Particulates Committee

Kirsten Strahlendorf, Sanofi Pasteur
Board Sponsor

James Dean Vogel, The BioProcess Institute
Committee Co-Chair

Committee Members

Emily Alkandry, Saint-Gobain

Ken Davis, Nordson

Maureen Eustis, The BioProcess Institute

Patrick Evrard, Pall Biotech

Jayanthi Grebin, CPC

Jay Harp, Avantor

Eric Isberg, Savillex

Ernie Jenness, Millipore Sigma

Tim Korwan, Avantor

Mark Petrich, Merck & Co., Inc.

Chuck Raye, Millipore Sigma

Sebastien Selzer, Eppendorf

Heidi Sinkovich, Meissner Filtration

Kirsten Strahlendorf, Sanofi Pasteur

Jim Vogel, The BioProcess Institute

Klaus Wormuth, Sartorius Stedim Biotech

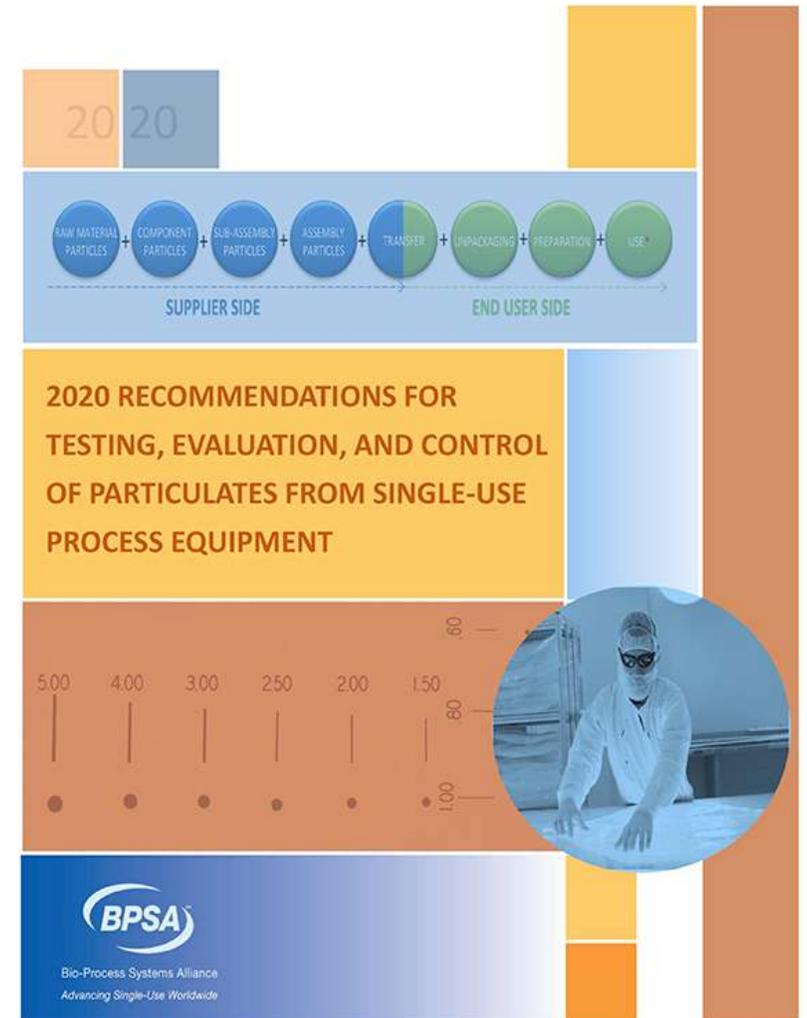


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Particulates Committee

- **Particulates White Paper** Published May 2020, available online: <https://bpsalliance.org/technical-guides/>
- **Webinar, BPSA's New 2020 Particulates Publication: Guidance for Single-Use Equipment Providers and Users** held on May 27.
 - 79 attendees
 - Recording and slides available on <https://bpsalliance.org/bpsa-webinar-speaker-series/>



Technical Core Achievements in 2020

- **3** Papers Published
- **6** Papers in Draft/Approval (*Sustainability Articles #2, #3; Viral Vector; Transit Testing; Integrity Assurance; X-Ray*)
- **1** New Committee
- **3** Free Technical BPSA Webinars (*X-Ray, Extractables & Leachables, Particulates*)
- **137** Technical Committee Members
- **38** Participating Companies and Institutions



Market Data Report

Steve Teslik, K545 Analytics LLC



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2020 Benchmarking Report

Background

- An annual BPSA report tracking customer complaints for 5 product types across 9 complaint categories
- Report data are for calendar years 2016 thru 2019 with benchmarking figure stated in terms of “Complaints per 1000 units”
- 1st Public report issued in 2019 showing data and 3-year trend lines *(2016-2018)*

Status

- 2020 Preliminary Benchmarking report under review by participants
- Expect public report to be issued in the near future
- Initial data shows Overall complaint benchmark for CY 2019 as ~1.0 per 1000 – roughly in-line with prior year’s figures



Operation Warp Speed

mass produce in parallel multiple promising Vaccines and accelerate production of Therapeutics



Operation Warp Speed set-up to **support promising candidates accelerate the development, manufacturing, and distribution** of their COVID-19 vaccines & therapeutics



Considering current situation, **U.S. government decided** to go into mass production **ahead of any conclusive clinical data** from candidates, with very tight production timelines



To ensure on-time delivery of promised treatment supply, need to ensure **all key equipment, materials & consumable will be available** to our candidates when needed



OWS leadership started to **engage with key suppliers to ensure materials supply**, and will continue this engagement as candidates refine their manufacturing plans

Operation Warp Speed

mass produce in parallel multiple promising Vaccines and accelerate production of Therapeutics



OWS leadership started to **engage with key suppliers to ensure materials supply**, and will continue this engagement as candidates refine their manufacturing plans.



Colonel Michael P. Post, USA
Operation Warp Speed
Plans, Ops & Analytics (POA)
HHS (Hubert Humphrey Bldg), Rm 741F



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SIPR: Michael.p.post.mil@mail.smil.mil



Operation Warp Speed

*mass produce in parallel
multiple promising
Vaccines and accelerate
production of
Therapeutics*



Defense Production Act of 1950

The Defense Production Act of 1950 is a United States federal law enacted on September 8, 1950 in response to the start of the Korean War. It was part of a broad civil defense and war mobilization effort in the context of the Cold War. Its implementing regulations, the Defense Priorities and Allocation System. Since 1950, the Act has been reauthorized over 50 times. It has been periodically amended and remains in force.



On March 23, Trump issued an executive order classifying "health and medical resources necessary to respond to the spread of COVID-19" as subject to the authority granted by DPA to prohibit hoarding and price gouging.



Trump also named Peter Navarro national policy coordinator for the DPA.

OWS Supply Chains under pressure: high demand for scarce resources

Equipment & consumables in high demand

- Single Use Bioreactors
- Single Use Mixers
- TFF Skids
- Resins
- Filters
- Bags
- Freezers
- Etc.

Critical input materials

- Custom media
- Critical reagents
- Specialized enzymes
- Etc.

Example suppliers with
whom OWS has discussed



How BPSA members can support the mission

- **Prioritize delivery** of equipment, materials, and consumables requested by OWS candidates
- **Engage in a timely manner** when contacted by OWS leadership
- **Communicate** supply chain challenges or roadblocks to OWS to plan for anticipated high demand

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Broadley James[®]



bürkert
FLUID CONTROL SYSTEMS



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Entegris



MILLIPORE
SIGMA



Nordson
MEDICAL



PALL[®] Biotech



PENDOTECH
Adding Value To Your Process



RENOLIT
Reli on it.



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