

# BPSA Annual Membership Meeting

October 5, 2021 9-10:45 AM EDT



# EXECUTIVE DIRECTOR REPORT

Kevin Ott

BPSA Executive Director





# BPSA Annual Meeting Agenda



2021 Annual Meeting

9:00 AM: Welcome and Opening Remarks: **Jeff Carter, Cytiva, BPSA Chair**

9:05 AM: Antitrust & Executive Director's Business Report: **Kevin Ott, BPSA (Ott Consulting Group, LLC)**

- Business Intelligence Census Results: **K. Ott**
- Election Committee/Chair 2021 – **Todd Andrews, CPC**

9:15 AM: Treasurer's Report: **Eric Isberg, Saville**

9:20 AM: Secretary's Report: **Janmeet Anant, Millipore Sigma**

9:25 AM: BPSA Technical Committee & SAB Chair Report Overview – **Kirsten Strahlendorf, Sanofi Pasteur**

- 2021 Project Updates
  - Automation Committee
  - Cell & Gene Therapy Committee
  - Continuous BioProcessing Committee
  - Integrity Assurance Committee
  - Sustainability Committee
  - Transit Testing Committee
  - X-Ray Committee
  - Scientific Advisory Board
- Market Data/Industry Reliability Data Report, Part 2: **Steve Teslik, K545**

9:50 AM: Discussion of New Business/Future Projects/Member Concerns: **Group**

- Other Business: **Group**

10:00 AM: Update on Covid Vaccine Production: **Gary Disbrow, Biomedical Advanced Research and Development Authority (BARDA)**

10:45 AM: Adjourn

# Where BPSA's Been...

October 2020-October 2021



2021 Annual Meeting



**16**

newsletters  
sent



**2143**

tech guide  
downloads



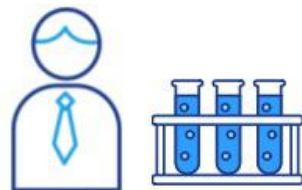
**11**

webinars executed



**1057**

attendees



**> 20%**

webinar attendees & downloads  
are non-member end-users

**954**

members

**103**

non-members

# Where We're Going



2021 Annual Meeting



**Mission**



**Vision**



**Strategies - ACES**

**Adoption**

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

**Engagement**

**E** Summits, webinars, regional  
meetings

**Communication**

**C** Weekly newsletter, member  
outreach, membership marketing

**Sustainability**

**S** Sustaining BPSA, Single-Use  
sustainability

# BPSA Members

As of Jan. 1, 2021



2021 Annual Meeting



# BPSA Members

As of Jan. 1, 2021



2021 Annual Meeting



# Sustaining Sponsors



2021 Annual Meeting



## 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.



2021 Annual Meeting

### 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.

# Reasons to be a BPSA Sponsor



**Become a Sponsor Today**

Learn more at [bpsalliance.org](https://bpsalliance.org)

# Sustaining Sponsors



2021 Annual Meeting



# BPSA ELECTION COMMITTEE REPORT

# BPSA Election Committee Update



2021 Annual Meeting

- Todd Andrews, CPC, announced as Election Committee Chair
- Notice to all Voting Members, active committee members and member webinar guests sent on September 13 asking for candidates.
- Ballot to voting members went out Monday, Oct. 4
- **Votes due on Monday, October 25<sup>th</sup>**
- Certified results to be announced by **November 10<sup>th</sup>**

# BPSA TREASURER'S REPORT

Presented by: Eric Isberg, Savillex

BPSA Treasurer

# BPSA Treasurer's Report



2021 Annual Meeting

- 2020 BPSA Budget Results
- 2021 End of Year Forecast
- 2022 Dues

# 2021 BPSA Financial Position Forecast



2021 Annual Meeting

- Will end year with \$266,680 of cash reserve
- This rainy-day fund puts us in excellent shape and greatly reduces our financial risk
- Will help us continue to weather the COVID storm
- I recommend we keep this amount in reserve going into the 2022 budget process

# 2022 BPSA Dues Increase



2021 Annual Meeting

- The BOD approved a 6% dues increase for 2022
- Will allow us to budget additional SOCMA staff to support technical workstreams, F2F Summit, dues and sponsorship collections
- Fund website upgrade
- Fund technical workshops
- Fund CRM database implementation
  - Targeted mailings
  - Recruitment
  - Meeting notices
  - Summit promotion
  - Committee management

# BPSA SECRETARY'S REPORT

Janmeet Anant, MilliporeSigma

BPSA Secretary

# BPSA Secretary Report – Last year's By-Law Revisions – Implementation?



2021 Annual Meeting

- 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.

Completed  
19 BoD  
Clarified  
Instituted

# BPSA Secretary Report – Changes to USP Bioreactivity General Chapters



2021 Annual Meeting

USP Position (USP <87>, <88>, and <1031>) – 3R's	BPSA Executive Board – Discussion Points for Membership Vote
Reduce the amount of redundant testing of existing plastic and elastomeric materials and unnecessary animal testing for new materials;	Further emphasize that plastic components and systems used in the manufacturing of pharmaceutical drug products & biopharmaceutical drug substances/products are NOT in the scope of these biological reactivity chapters, which will be covered in the upcoming USP <665> general chapter.
Refine the type of testing performed to align with the potential risk;	Updates are not necessary for USP <87>, since the <i>in vitro</i> cytotoxicity testing approach is sufficient as is. No further genotoxicity, mutagenicity or other toxicity testing is needed.
Replace in vivo testing with in vitro testing or utilize other information using a risk-based approach focused on the knowledge of the material and pharmaceutical application.	

Deadline for your BPSA vote to approve BPSA comments is **COB, Tuesday, October 5, 2021.**

Non-votes will count as approval! You can vote here: <https://www.surveymonkey.com/r/99QRXMR>

# BPSA TECHNICAL REPORT

Presented by: Kirsten Strahlendorf, Sanofi Pasteur

BPSA Scientific Advisory Board/Technical Committee Chair

## Agenda

- Scientific Advisory Board
  - Mission
  - Structure
  - Accomplishments for 2021
  - Outlook for 2022
- Technical Committee Review
  - Project Updates



Scientific Advisory Board

# Scientific Advisory Board

# BPSA Scientific Advisory Board



2021 Annual Meeting



**Ross Acucena, Entegris**



**Adam Goldstein, Thermo Fisher**



**Duncan Low, Independent**



**Helene Pora, Pall**



**Thomas Warf  
BARDA**



**Jim Vogel,  
The BioProcess Institute**



**Kevin Ott,  
BPSA Executive Director**



**Kirsten Strahlendorf,  
Sanofi Pasteur (Chair)**

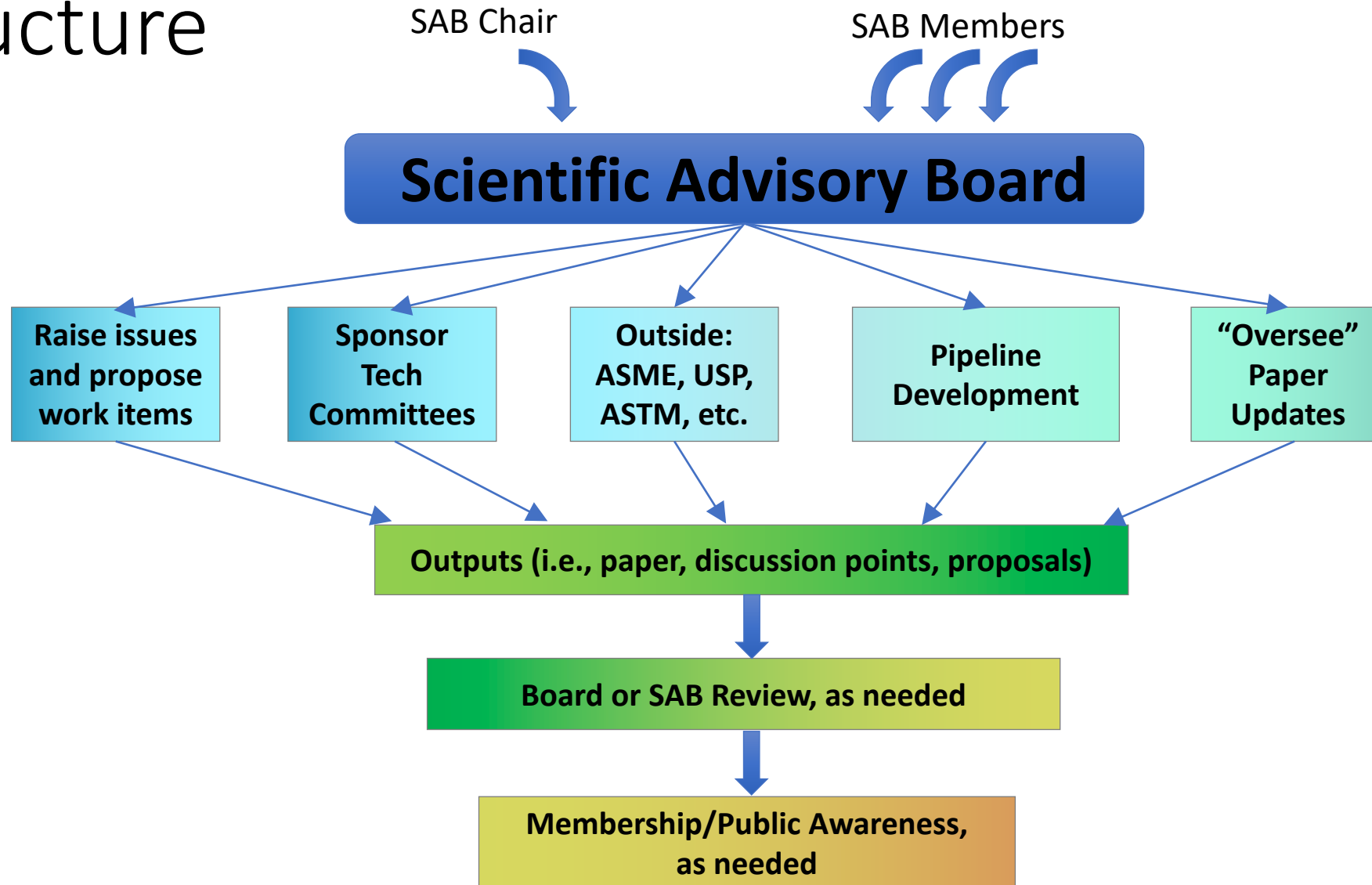
# Mission

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

# Structure



# Main Activities for 2021



Team Appointments



Team Formation & Kick-off meeting



Initial Discussion pertaining to Technical Points of Emphasis



Hot Topic – X-Ray for next meeting



Scientific Advisory Board

# What's in Store for 2022?



Team to draft Project Charter



Evaluation of Technical Portfolio



Ranking and Prioritization of Activities



Objectives setting for 2022+



Scientific Advisory Board

# BPSA Technical Committee Review

# BPSA Technical Committee Status/Proposals

Technical Stream	Lead/Board Sponsor	Activities Near Completion	2021 Accomplishments
Automation	Floris Hooijenga/Kirsten Strahlendorf	<ul style="list-style-type: none"> <li>Survey and webinar planning ongoing</li> </ul>	<ul style="list-style-type: none"> <li>Team formation</li> </ul>
CGT	Brendan Lucey/Bob Sassa	<ul style="list-style-type: none"> <li>Paper ongoing: An overview of the cell and gene therapy market manufacturing</li> </ul>	<ul style="list-style-type: none"> <li>Viral Vector Paper (pending publish Q4)</li> </ul>
Continuous BioProcessing	Davinder Chawla David Chau Kirsten Strahlendorf/Janmeet Anant	<ul style="list-style-type: none"> <li>Drafting ongoing</li> </ul>	<ul style="list-style-type: none"> <li>Team formation</li> </ul>
Integrity	Patrick Evrard	<ul style="list-style-type: none"> <li>Content agreed, drafting ongoing for Integrity White Paper, Part 2</li> </ul>	<ul style="list-style-type: none"> <li>Committee renewal (60% of members changed)</li> <li>Paper published in BPI magazine - Sept 30, 2021</li> </ul>
Sustainability	Magali Barbaroux/ Mark Petrich	<ul style="list-style-type: none"> <li>Green Imperative Paper #3 anticipated Q4 publication</li> </ul>	<ul style="list-style-type: none"> <li>Green Imperative Paper #2 published</li> </ul>
Transit Testing	Richard Salzstein/James Raw/Kirsten Strahlendorf	<ul style="list-style-type: none"> <li>Committee closed</li> </ul>	<ul style="list-style-type: none"> <li>Published paper on SU and shipping design and testing in Q1 of 2021.</li> </ul>
X-Ray	J. Hathcock Samuel Dorey / H. Pora	<ul style="list-style-type: none"> <li>Paper #2 ongoing</li> </ul>	<ul style="list-style-type: none"> <li>Paper #1 Published</li> <li>Webinar Conducted (May 2021)</li> </ul>

# BPSA Automation Committee



2021 Annual Meeting

**Kirsten Strahlendorf**, Sanofi Pasteur  
*Board Sponsor*

**Floris Hooijenga**, Thermo Fisher Scientific  
*Committee Chair*

## Committee Members

Sebastien de Bournonville, My Cell Hub  
Carsten Lau, Thermo Fisher Scientific  
Chrisford Ling, Sanofi Pasteur  
Greg Love, Burkert  
Kyle Kolb, Thermo Fisher/ Patheon

Hernan Parma, American Renolit  
Kirsten Strahlendorf, Sanofi Pasteur  
Stuart Tindal, Sartorius Stedim Biotech  
Charlie Zhang, Sanofi Pasteur

# BPSA Automation Committee Update



2021 Annual Meeting

- Goal: hear the biopharmaceutical industry's experience with single-use automation:
  - Good practices and lessons learned
  - Future needs (current gaps) that should take users to the next level.
- Have 3 end-users present their journey on this matter (past, current, future) in webinar. So far we have end-users onboard from Sanofi, Thermo Fisher (Patheon), looking for 3<sup>rd</sup> end-user to join.
  - Prior to the webinar, a survey will be held to get a broader view on this matter.
- The survey results and information presented by the end-users will be used for a round-table discussion with vendors/suppliers.
- First meeting held with committee on September 1<sup>st</sup> (introduction of team, and discussing the setup. In this meeting the idea was generated to add survey, besides the 3 end users presenting, to get a broader industry view)
- Next meeting is on October 6<sup>th</sup>.

# BPSA Cell and Gene Therapy (CGT) Committee



2021 Annual Meeting

**Robert L. Sassa, W.L. Gore,**  
*Board Sponsor*

**Brendan Lucey, Entegris, Inc.**  
*Committee Chair*

## Committee Members

Scott Anderson, Millipore Sigma  
Manjula Aysola, Millipore Sigma  
Max Blomberg, Meissner  
Nicole Brackett, Chemic Laboratories  
Emmanuelle Cameau, Pall Corporation  
Jeff Carter, Cytiva  
Paul Cummings, Smithers  
Ralph Daumke, FILTROX  
Maureen Eustis, The BioProcess Institute  
Natalie Fekete, Saint-Gobain  
Jayanthy Grebin, CPC  
Armin Hauk, Sartorius Stedim Biotech  
Scott Herskowitz, Qosina  
Brian Horowski, Wood PLC

Tony Hsiao, Thermo Fisher Scientific  
Nicole Hunter, Watson Marlow  
Todd Kapp, Entegris  
Stacy Kilgore, Avient  
Tim Korwan, Avantor  
Kara Levine, Millipore Sigma  
Brendan Lucey, Entegris  
Jared Marshall, Rubius Therapeutics  
Ruth McDermott, Sartorius Stedim Biotech  
Elizabeth Misleh, Corning  
Rachelle Morrow, Qosina  
Alex Mura, Solvias  
Vidya Murthy, Cytiva  
Ravi Naryanan, Nordson Medical

Sheila O'Callaghan, Johnson & Johnson  
Hernan Parma, Renolit  
Derek Pendlebury, CPC  
Joe Petrosky, PBS Biotech  
Paul Priebe, Qosina  
Forrest Roush, Corning  
Hasan Saleheen, Cytiva  
Bob Sassa, W.L. Gore & Associates  
Joseph St. Laurent, Chemic  
Kirsten Strahlendorf, Sanofi Pasteur  
Geri Trautman, Qosina  
Ping Wang, Johnson & Johnson  
Travis Ward, Repligen

# BPSA CGT Committee Update

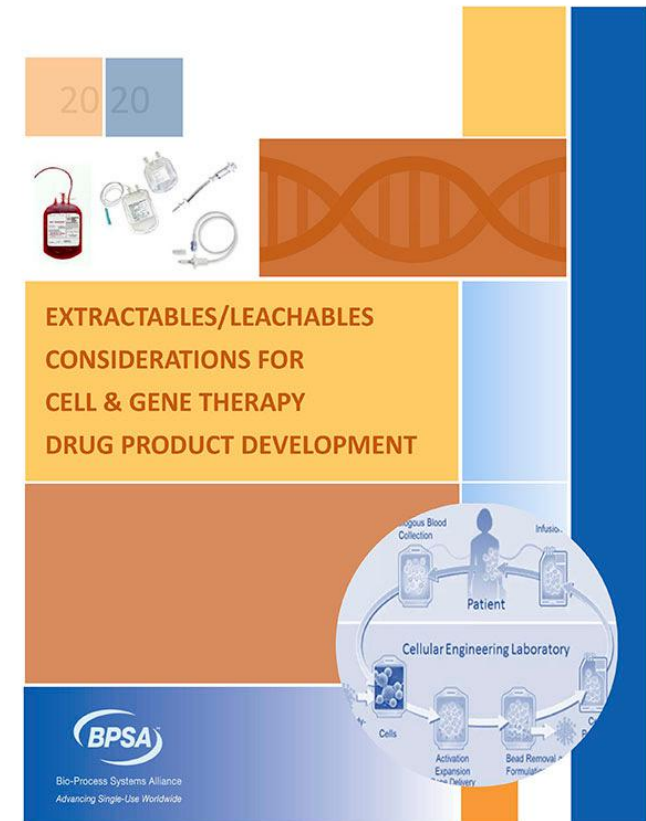


2021 Annual Meeting

- CAR-T Process Map Paper - 113 downloads (Oct 2020-Oct 2021)
- CGT Extractables Paper (243 downloads); 9/23/20 webinar (94 attendees)
  - 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
- Feel free to reach out to Todd or Jeanette if you would like to participate in the committee



# BPSA Continuous BioProcessing Committee



2021 Annual Meeting

**Kirsten Strahlendorf**, Sanofi Pasteur  
**Janmeet Anant**, Millipore Sigma  
*Board Sponsors*

**Davinder Chawla**, Sanofi Pasteur  
**David Chau**, 3M  
*Committee Co-Chairs*

## Committee Members

Gareth Alford, GSK Vaccines  
Janmeet Anant, Millipore Sigma  
Jessica Cannon, Thermo Fisher Scientific  
David Chau, 3M  
Davinder Chawla, Sanofi Pasteur  
Jim Furey, Pendotech  
Brian Horowski, Wood PLC  
Benjamin Madsen, Thermo Fisher Scientific  
Charlotte Masy, GSK Vaccines

David Matsushita-Fournier, Sanofi Pasteur  
Jim Sanford, Watson-Marlow  
Robert Sassa, W.L. Gore & Associates  
Sebastian Selzer, Eppendorf  
Mihir Shah, Repligen  
Oleg Shinkazh, Chromatan  
Kirsten Strahlendorf, Sanofi Pasteur  
Eric Van Voorhees, W.L. Gore & Associates  
Charlie Zhang, Sanofi Pasteur

# BPSA Continuous BioProcessing Committee Update



2021 Annual Meeting

- Team Established - several meetings held
- Table Of Contents Defined
  - Objective and Importance
  - Part 1: Advantages of Continuous Bioprocessing; Facilitating Continuous Bioprocessing; The Gamuts of SU Technos; Roadblocks and Challenges
  - Part 2: Qualification Challenges of Continuous Bioprocessing
  - Part 3: Recognized and Regulatory Opinions
- Focused on Part 1: with subteams formed and subteam leads identified, outline of each subsection being defined by the subteam
- Meet on Monthly basis to review the progress

# BPSA Integrity Assurance Committee



2021 Annual Meeting

**Patrick Evrard**, Pall Corporation  
*Board Sponsor and Committee Chair*

## Committee Members

Emily Alkandry, Saint-Gobain  
Michael Avraam, ChargePoint Technology  
Sebastien Barry, Sanofi Pasteur  
Richard Bhella, Pall Corporation  
Patrick Evrard, Pall Corporation  
Marc Hogreve, Sartorius Stedim Biotech  
Nicole Hunter, Watson Marlow

Charlotte Masy, GSK Vaccines  
Scott Patterson, ILC Dover  
Mark Petrich, Merck & Co., Inc.  
Ryan Randall, Thermo Fisher Scientific  
Rafy Rodriguez, Cytiva  
Alain Vanhecke, Pall Corporation  
Charlie Zhang, Sanofi Pasteur

# BPSA SUS Integrity Committee Update



2021 Annual Meeting

- Public webinar on October 21, 2020 (89 attendees)
- 2<sup>nd</sup> paper case studies was published September 30, 2021, *BPSA Integrity of Single-Use Systems: Practical Applications and Deployment*.
- Part 2 of the white paper will focus on practical illustrations of principles described in Part 1, as well as last technology updates - draft expected end of the year

**Key Success: our white paper has been used as a basis for  
2 ASTM standards issued in 2020**

# BPSA Sustainability Committee



2021 Annual Meeting

**Mark Petrich**, Krystal Biotech  
*Board Sponsor*

**Magali Barbaroux**, Sartorius  
*Committee Co-Chair*

## Committee Members

Megan Baillie, Entegris  
Nate Belke, Avantor  
Anna Maria Bertasa, Solvay  
John Boehm, CPC  
Anne-Laure Brison, Sartorius Stedim  
Biotech  
Phillippe Busson, Cytiva  
Marisa Caliri, Cytiva  
Jeff Carter, Cytiva  
Bryce Cormier, Rubius Therapeutics  
Joy Chen, Entegric  
Jordan Cobia, Thermo Fisher Scientific  
Russell Darley, Sealed Air Corporation  
Alain Goasguen, Sanofi Pasteur

Dianne Heiler, Repligen  
Jaqueline Hollands, MilliporeSigma  
Brian Horowski, Wood PLC  
Travis Imhof, Sartorius Stedim Biotech  
Clair Jarmey-Swan, Pall Corporation  
Justin Lin, Merck & Co, Inc.  
Greg Love, Burkert  
Mark Meyer, Saint-Gobain  
Merete Miles, Thermo Fisher  
Scientific  
Sade Mokuolu, Watson-Marlow  
Ravi Narayanan, Nordson Medical  
Matthew Olsen, Sartorius  
Kaycee Palumbo, Cytiva

Scott Patterson, ILC Dover  
Mark Pennington, Saint-Gobain  
Ahalya Selvaraj, Saint-Gobain  
Mihir Shah, Repligen  
Melanee Short, Sanofi Pasteur  
Jeffery Smith, Sanofi Pasteur  
Mitchell Snyder, Saint-Gobain  
Chor Sing Tan, Cytiva  
Konstantinos Vrontis, Merck & Co.,  
Inc.  
Michael Waslin, Merck & Co, Inc.  
Bill Whitford, DPS Group  
Don Young, Thermo Fisher Scientific

# BPSA Sustainability Committee Update



2021 Annual Meeting

## 2021 objectives and achievements

Create and clearly state an industry message inside and outside linked to SDGs goals	Formalize key messages, define support and communication strategy	Will continue in 2022. Will require quantified "plastic" data for credibility.
Publication of "green imperative" Paper 2 and Paper 3	Paper 2 – published February 2021 Paper 3 - publication Q2 → Q4	Will be expanded in 2022 with an online glossary of terms.
1-2 webinars	1- Sealed Air experience in the liquid food/beverage packaging (Russel) - Done 2- BPSA Green Initiative papers (Sade/Bill and "paper" team) - Done	We will keep the target of 1 or 2 webinars linked to sustainability.

In 2021, all meetings (monthly) have been remote.  
Hopefully, in 2022 we could have in-person activities.

### Mission

The BPSA Sustainability Committee is a community of interest which provides members stakeholders information on how Single-Use Technologies support biomanufacturing call for sustainability and takes actions to prove that BPSA seriously tackle sustainability concerns.

- It allows members to be informed on environmental sustainability tools and trends in the biomanufacturing industry and in the polymer industry, to share ideas and good practices. The committee is the natural liaison between BPSA and other industry bodies and consortium with regard to sustainability of SUT.
- The team's programs include an active social media presence, an up-to-date listing of information, educational activities and other projects as agreed to by BPSA membership

# BPSA Transit Testing Committee



2021 Annual Meeting

**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  
Andrew Quick, CPC  
James Raw, Smithers  
Rich Salzstein, Smithers

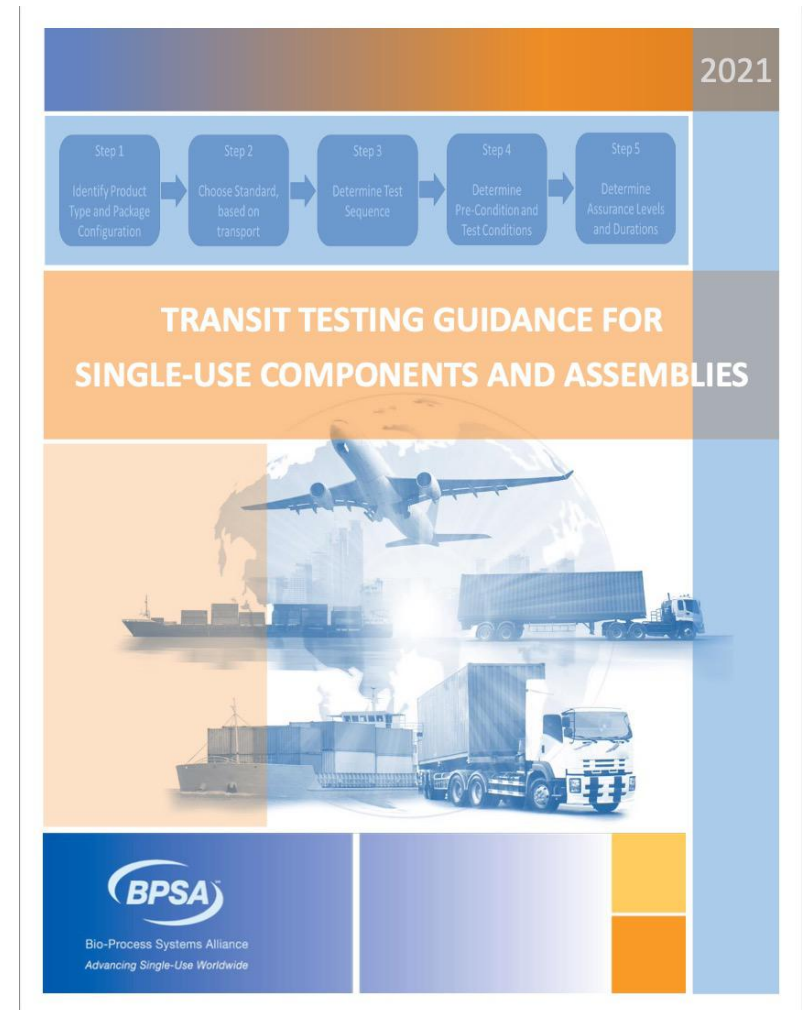
Peter Stedehouder, Pall Biotech  
Kirsten Strahlendorf, Sanofi Pasteur  
Elisabeth Vachette, Sartorius Stedim Biotech  
Travis Ward, Repligen  
Cimberly Weir, MSU

# BPSA Transit Testing Committee Update



2021 Annual Meeting

- White Paper published, Q1, 2021, *Transit Testing Guidance for Single-use Components and Assemblies* (212 downloads to date)
- Presented webinar on white paper on April 14, 2021 (122 attendees)
- Committee achieved its goals and has closed.



# BPSA X-Ray Committee



2021 Annual Meeting

**Kirsten Strahlendorf**, Sanofi Pasteur  
*Board Sponsor*

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

## Committee Members

Janmeet Anant, MilliporeSigma  
Ken Baker, AdvantaPure/NewAge  
Nick Troise, PendoTECH  
Dennis Annarelli, PendoTECH  
Amit Bhatt, Merck & Co., Inc.  
John Murphy, Merck & Co., Inc.  
Mark Petrich, Merck & Co., Inc.  
Andrew Trolio, AdvantaPure/NewAge  
Monica Cardona, MilliporeSigma  
Timo Neumann, Merck Millipore  
Samuel Dorey, Sartorius Stedim Biotech  
Chad Kratochwill, Entegris

Etienne Durant, GSK Vaccines  
Charlotte Massy, GSK Vaccines  
CD Feng, Broadley James  
James Hathcock, Pall Corporation  
Stephen Hodder, Pall Corporation  
Noel Long, Cytiva  
Rafael Rodriguez, Cytiva  
Jeff Carter, Cytiva  
Dominic Moore, Sanofi Pasteur  
Kirsten Strahlendorf, Sanofi Pasteur  
Ravi Narayanan, Nordson  
Maria Bollensen, CPC

Gary Harris, CPC  
Larry Nichols\*, Steritek  
Paul Calverly\*, Sterigenics  
Jeffrey Noyes, Steris  
Deepak Patil, Steris  
Cody Wilson, IBA  
Ariana Gleisberg, Thermo Fisher Scientific  
Nicole Hunter, Watson Marlow  
Mike Allard, VenAir  
Gabrielle McIninch, Saint-Gobain  
Max Blomberg, Meissner  
Roger Hendrick, Dupont

# BPSA X-Ray Committee Update



2021 Annual Meeting

- ✓ **Paper.** X-Ray Sterilization of Single-Use Bioprocess Equipment. Part I  
– Industry Need, Requirements and Risk Evaluation (May 2021)

- ✓ **384 downloads**

- ✓ **Webinar.** *Discussion on X-ray for Single-Use (May 2021)*

- ✓ **183 attendees**

- ✓ **Ongoing engagement**

- ✓ Example report templates
- ✓ Sharing status of component families being qualified
- ✓ Planned workshop on how to qualify and FAQs

- ✓ **Part Deux - Cross-Industry Data Supporting Qualification and Implementation of X-ray Sterilization for SUS** (*white paper, Q4, 2021*)



# Resources Available on BPSA Website



2021 Annual Meeting

## Webinars



## Technical Guides



<https://www.bpsalliance.org/bpsa-webinar-speaker-series/>

<https://bpsalliance.org/technical-guides/>

If you wish to join a technical committee, please contact  
Leslie Pizarro at [lpizarro@socma.org](mailto:lpizarro@socma.org)

# BPSA Technical Core Achievements Since Last Annual Meeting (Oct. 2020)

- **4** Papers Published
- **2** Papers Pending Publication
- **2** New Committees
- **3** Free Technical BPSA Webinars
- **2143** Technical Paper downloads
- **230** Technical Committee Members
- **43** Participating Companies and Institutions

# BPSA RELIABILITY DATA REPORT

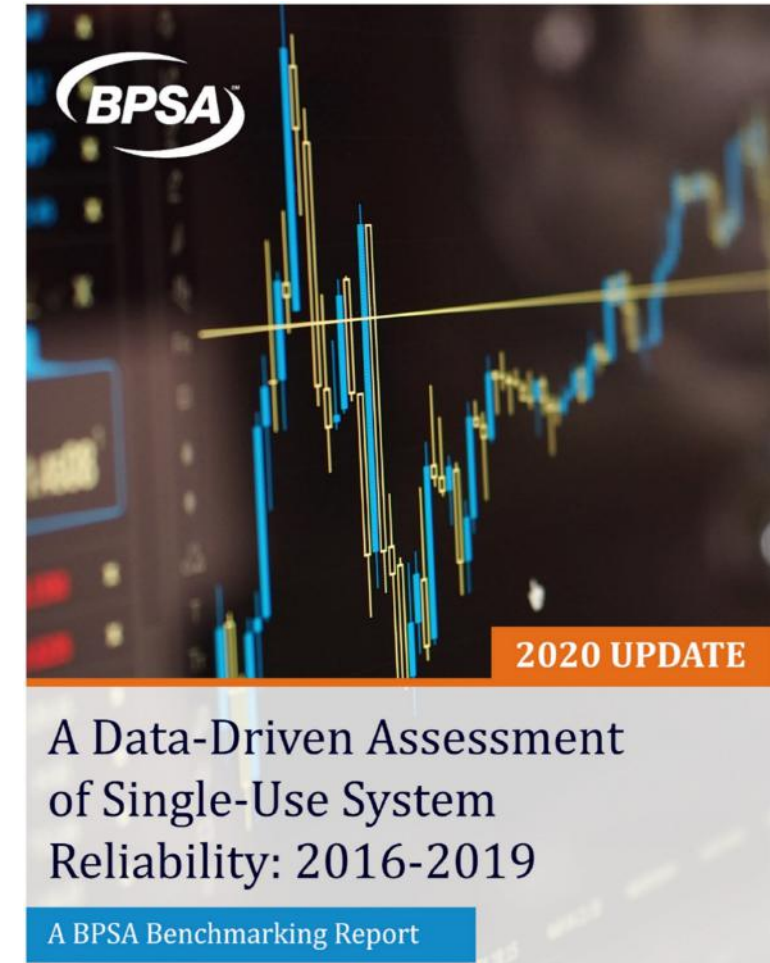
Steve Teslik, K545 Analytics LLC

# 2020 Industry Single-Use System Reliability Report



2021 Annual Meeting

- Current 2020 Report Reflects 2016 – 2019 Data
- Five product categories assessed against nine 'complaint' categories
- Report can be obtained by members through BPSA/Kevin Ott
- 2021 report reflecting 2020 data pending committee direction
- Requests to expand the report to include yr/yr market growth
- Potential to refine/expand complaint categories given member data legacy improvements
- K545 Analytics as third-party data collection and compilation



# 2020 Industry Single-Use System Reliability Report



2021 Annual Meeting

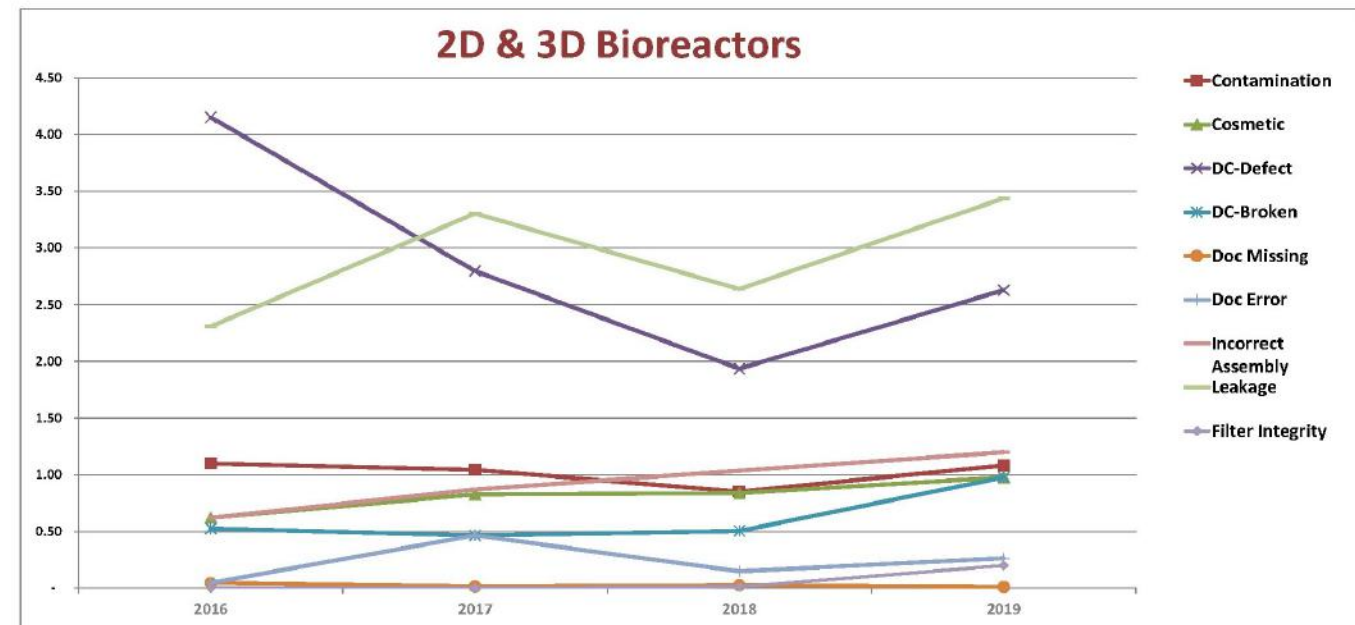
- Sample data page: 2D & 3D BioReactors
- Current 2020 Report Reflects 2016 – 2019 Data

## 2020 BENCHMARKING REPORT

	2016	2017	2018	2019
Contamination	1.10	1.04	0.85	1.08
Cosmetic	0.62	0.83	0.84	0.98
Defective Component-Defect	4.15	2.80	1.94	2.63
Defective Component-Broken	0.53	0.46	0.51	0.98
Doc Missing	0.05	0.01	0.02	0.01
Doc Error	0.05	0.46	0.15	0.26
Incorrect Assembly	0.62	0.87	1.04	1.20
Leakage	2.31	3.30	2.64	3.44
Filter Integrity	-	-	0.01	0.20
Overall	9.42	9.78	7.99	10.77

(\*0" interpreted as statistically insignificant)

## 2D & 3D BIOREACTORS





**ASPR**

# **BARDA's Vaccine Capacity Expansion Efforts**

**Gary Disbrow, PhD**

Director, Biomedical Advanced Research and Development Authority  
Deputy Assistant Secretary for Preparedness and Response  
Department of Health and Human Services

Unclassified/For Public Distribution

# The BARDA Model

BARDA develops and makes available medical countermeasures (MCMs) by forming unique public-private partnerships to drive innovation off the bench to the patient to save lives.



Flexible, nimble authorities

Multi-year funding

Cutting edge expertise

Facilitate partnerships

Promote innovation



# COVID-19 Response

**152**

COVID-19 Partnerships

**4536**

Market Research Submissions

**676**

CoronaWatch Meetings

**1**

FDA Licensure

**26**

Diagnostic Test EUAs

**144M**

Diagnostic Test Kits Shipped

Emergency Use Authorizations Supported by the USG

**3**

Vaccines

**4**

Therapeutics

**91**

Products Supported

**\$47.3 billion**

Awarded

**\$33B \$14B \$0.3B**

vaccines therapeutics diagnostics

COVID-19 Vaccine Doses

**478M**

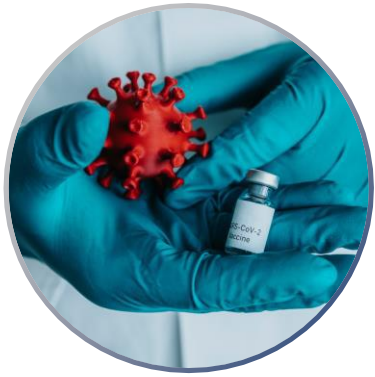
Delivered

**396M**

Administered

As of 10/04/2021

# BARDA's Pivotal Role in Development of Safe and Effective COVID-19 Vaccines



## Accelerated process

**EUA granted within 9 months** to three vaccine candidates



## Complex operations

**\$33B+ in funding** currently supporting 6 vaccine candidates



## Unprecedented results

**396M+ vaccine doses** administered & 56%+ Americans fully vaccinated



## Ongoing impact

**1.1B dose** commitment to support international needs

# Key Lessons Learned in COVID-19 Response

## Key lessons learned:

- Future pandemic vaccine platform requirements unknown
- Medium-to-long lead times to build new capacity
- Capacity re-allocation for pandemic need disrupts production of other critical medicines
- Concentration of capacity in a single site location increases susceptibility to power outages, labor shortages, etc.
- Lack of domestic surge capacity necessitates reliance on HRPAS to secure manufacturing requirements
- Securing foreign capacity at risk during a global pandemic

## Implications for domestic industrial base expansion (IBX):

Support production across different vaccine platforms

Accommodate different manufacturing methods

Provide redundancy

Ensure commercial sustainment

# Funding Allocated for IBx Efforts under the American Rescue Plan: Defense Production Act

## TITLE III—COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS Subtitle A—Defense Production Act Of 1950

### SEC. 3101. COVID-19 EMERGENCY MEDICAL SUPPLIES ENHANCEMENT.

(a) SUPPORTING ENHANCED USE OF THE DEFENSE PRODUCTION ACT OF 1950.—In addition to funds otherwise available, there is appropriated, for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, \$10,000,000,000, to remain available until September 30, 2025, to carry out titles I, III, and VII of such Act in accordance with subsection (b).

#### (b) MEDICAL SUPPLIES AND EQUIPMENT.—

(1) TESTING, PPE, VACCINES, AND OTHER MATERIALS.—Except as provided in paragraph (2), amounts appropriated in subsection (a) shall be used for the purchase, production (including the construction, repair, and retrofitting of government-owned or private facilities as necessary), or distribution of medical supplies and equipment (including durable medical equipment) related to combating the COVID-19 pandemic, including—

(A) in vitro diagnostic products for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19, and the reagents and other materials necessary for producing, conducting, or administering such products, and the machinery, equipment, laboratory capacity, or other technology necessary to produce such products;

(B) face masks and personal protective equipment, including face shields, nitrile gloves, N-95 filtering facepiece respirators, and any other masks or equipment (including durable medical equipment) needed to respond to the COVID-19 pandemic, and the materials, machinery, additional manufacturing lines or facilities, or other technology necessary to produce such equipment; and

(C) drugs, devices, and biological products that are approved, cleared, licensed, or authorized for use in treating or preventing COVID-19 and symptoms related to COVID-19, and any materials, manufacturing machinery, additional manufacturing or fill-finish lines or facilities, technology, or equipment (including durable medical equipment) necessary to produce or use such drugs, biological products, or devices (including syringes, vials, or other supplies or equipment related to delivery, distribution, or administration).

(2) RESPONDING TO PUBLIC HEALTH EMERGENCIES.—After September 30, 2022, amounts appropriated in subsection (a) may be used for any activity authorized by paragraph (1), or any other activity necessary to meet critical public health needs of the United States, with respect to any pathogen that the President has determined has the potential for creating a public health emergency.

# IBx Investments Across the Domestic Supply Chain in support of Pandemic Preparedness

**IBx mission:** domestic capacity to inoculate the US population within 6 - 9 months of identifying a pandemic pathogen, and with minimal disruption to the baseline public health supply chain

*Observed supply / capacity constraints for COVID-19 pandemic response:*

Non-exhaustive

Consumables & Raw Materials	Fill – finish capacity	Vials	Needles & Syringes
<ul style="list-style-type: none"><li>• Nucleotides</li><li>• Lipid nanoparticles &amp; Synthetic cholesterol</li><li>• Chromatography resins</li><li>• Cell culture media</li><li>• Single-use assemblies (e.g., flow kits, manifolds, tubing)</li><li>• Single-use bags</li><li>• Filtration equipment</li><li>• Sterilization capacity</li></ul>	<ul style="list-style-type: none"><li>• Biosafety level 1 lines</li><li>• Biosafety level 2 lines</li><li>• DS / DP storage (e.g., ultra cold storage)</li><li>• Labeling, inspection and packaging capacity</li></ul>	<ul style="list-style-type: none"><li>• Type 1 vials (glass borosilicated)</li><li>• Valor glass (aluminosilicate)</li><li>• Hybrid vials</li></ul>	<ul style="list-style-type: none"><li>• Needles &amp; syringes (low-dead space N/S in particular)</li></ul>

# Key Considerations for selection of BARDA IBX Investment Partners



**Commercial experience and track record supporting COVID-19 response**



**Jurisdictions of operation: domestic production required**



**Commercial business and growth plan**



**Innovative technology, equipment and digital systems**



**Environmentally sustainable operating practices**

# BARDA, JPEO-CBRND & ACC Partnership

## Leverages Industry Subject Matter Expertise and Acquisition Excellence

### BARDA PCI subject-matter expertise

- Requirement definition
- Market research
- Pandemic preparedness
- Post-award support
- Industry engagement and relationships
- Supply chain intelligence



### JPEO-CBRND acquisition expertise

- Acquisition support
- Project management

### ACC contracting expertise

- Legal support
- Contract / agreement award



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