

Future Challenges

“Those who cannot remember the past are condemned to repeat it.” –
George Santayana

David Radspinner
President, PharmBio
ILC Dover



Role of BPSA – our mission, our purpose

- “...encouraging and accelerating adoption of single-use manufacturing technologies used in the production of biopharmaceuticals and vaccines.”
- Smart, safe, environmentally sound
- Educate everyone we can
- Support and challenge each other
- Be open and honest
- Fact-based, science based
- Considers the entire value chain (supply, materials, quality, regulatory, technical)



The COVID effect



- Material availability across the supply chain – footprint, equipment, people
- Converters – capacity, materials, labor, location
- Panic buyers – cancelled orders, excess inventory, shelf-life extension
- US Rated orders – disruption in supply chain – lack of trust on future supply
- Global footprint – capacity wasn't where it was needed to response

What have we learned? How will we (BPSA leaders and communities) respond



Single-use hierarchy of needs – the effect of COVID



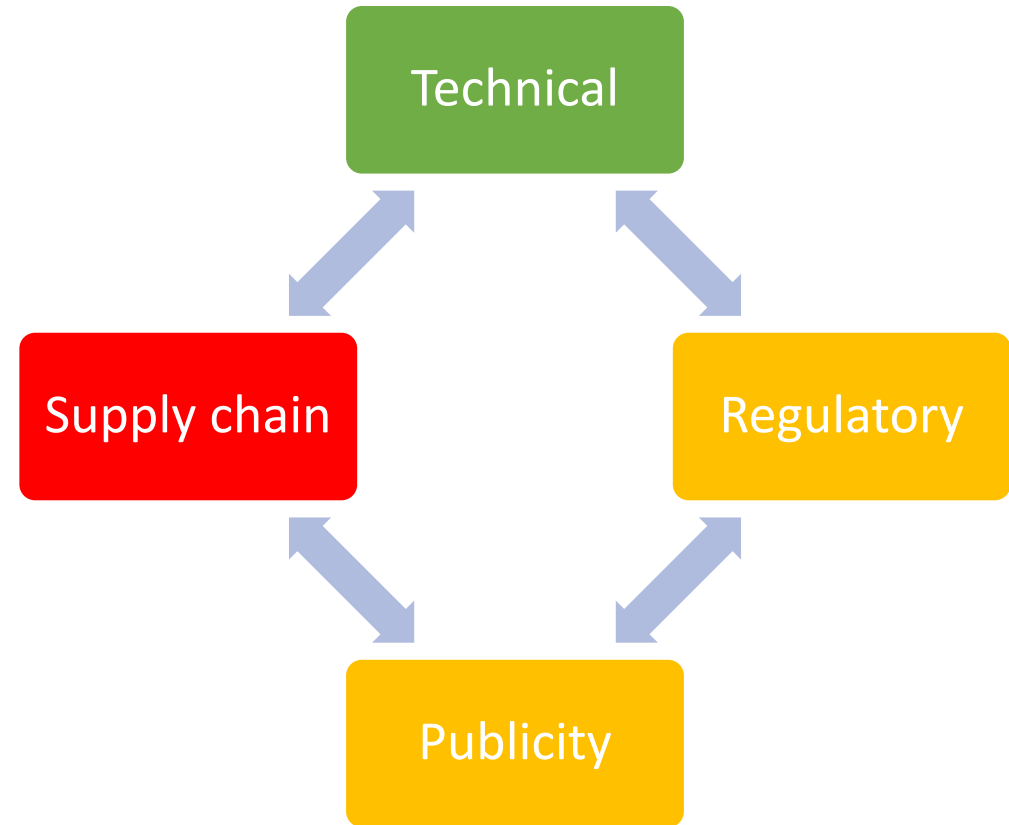
- Sustainability
- Extractables / leachables
- Particulates
- Traceability data
- Irradiation
- Secondary sources
- Shelf-life

What have we learned? How will we (BPSA leaders and communities) respond

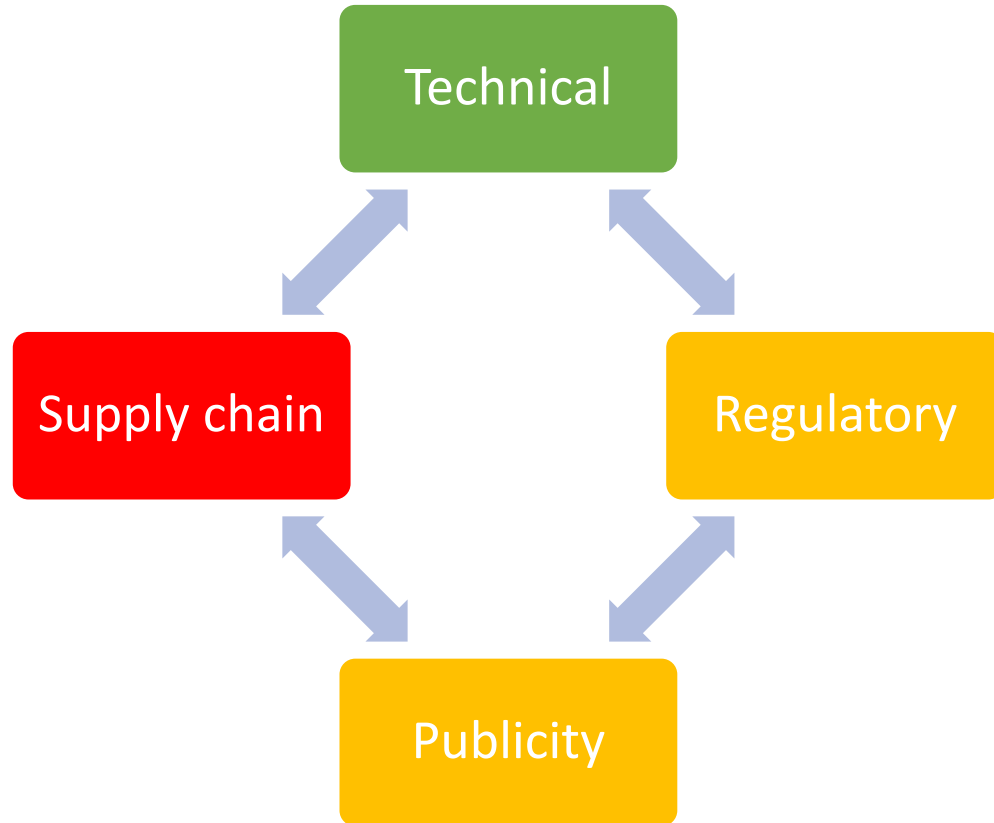


Framework for our **Influence** and **Impact**

- The Bio-Process Systems Alliance (BPSA) was formed in 2005 as an industry-led international industry association dedicated to encouraging and accelerating the adoption of single-use manufacturing technologies used in the production of biopharmaceuticals and vaccines.



Framework for our **Influence** and **Impact**



- **Technical** – guidance on how to develop, test, release, and use SUT
- **Regulatory** – engagement with standards, monographs, and inspection guides development and deployment
- **Supply Chain** – market dynamics that affect the demand/supply balance
- **Publicity** – general visibility and engagement with global government bodies

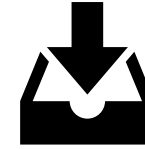
BPSA role in industry dynamics

What we've done



- We have helped drive the adoption of single-use in bioprocess
- We have the SAB with strong technical committees
- We have a strong and growing community

What can we do?



- Science/Technology
 - Keep going – expand beyond API - liquid
- Supply chain
 - Inventory and demand
 - End user and consolidated supplier view
- Regulatory
 - Standards, monographs, inspection guides
- Publicity and Government Relations
 - Beyond BARDA

