CoP Session: Disposables CoP Single-Use Supply Chain Resilience and Sustainability

20th September 2023
Dharti Pancholi

1

Speaker
Dharti Pancholi, MS
https://www.linkedin.com/in/dhartipancholi

Founder and CEO, Omni Consulting Services LLC
Past Chair, ISPE Disposable (Single Use) Community of Practice

- 20+ years of experience primarily in Biotech-Pharma industry as consult and end-user
- Strategic leader with technical knowledge and business prospective
- Skilled in growing clients, teams, accounts (company business) and technologies
- Process Engineering, Design, CQV and project management
- Bacterial (aerobic, anaerobic) and mammalian (MDCK, CHO, Vero) cell culture development.
- Recombinant proteins, seasonal and pandemic vaccines, Biofuel, API, drugs
- Single-use technologies and conventional stainless-steel equipment
- Active member of ISPE
  - Past Chair of the Disposables Community of Practice
- Education
  - M.S. Chemical Engineering with emphasis in Biotechnology
  - Undergraduate in Plastics Engineering

2

Disposables/Single Use Technologies CoP Focus

The ISPE Disposables CoP provides ISPE members a venue for support among biopharmaceutical professionals working in the area of single-use disposables technologies.

The aim of Disposables CoP is to support the growing adoption of single-use technology by providing recommendations for selection, validation and implementation of single-use technology.

Our members include end-users, vendors, consultants, and regulators that are involved in the design, manufacturing, quality, validation, implementation and use of single-use technology in pharmaceutical processes.

3

Areas of work

SUT SUPPLY CHAIN RESILIENCE

- SUT supply is complex with multiple interactions between different stakeholders
- SUT supply shortages increase risk of medicines shortages.
- Collaboration within the industry is key

DISPOSABLES SUSTAINABILITY

- “Single-Use” brings sustainability concerns.
- What is the actual size of the problem?
- How is the industry dealing with the problem?

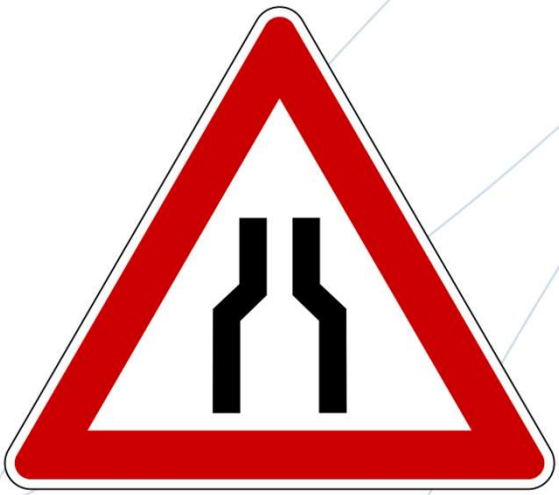
4

Supply Chain Resilience

5

Supply Chains Resilience

- COVID-19 pandemic brought to the forth many challenges:
  - Dramatic increase on lead times
    - Bags' lead time more than 40 weeks
  - Shortages of key components and materials,
    - Aseptic Connectors
    - Tubing material
    - Raw Materials, plastics
  - Bottlenecks on sterilization capacity



6

Supply Chain RoundTable Event

- Bringing together industry leaders from different backgrounds:
  - Designers
  - Suppliers
  - Quality
  - MSAT
  - End users
- Multiple virtual tables covering a range of topics:
  - Bottlenecks
  - Change Management
  - Standardization of Designs
  - Standardization of Materials
  - Like for like
  - Multisourcing
  - Supplier+End-User Relationship

Objectives at each table

- Talk about/Share successful solutions to the topic
- Identify problems and barriers experienced
- Consider potential root cause(s)
- Brainstorm potential solutions

Path Forward Action Items

- Interested stakeholders, and industrial organizations (ISPE, BPOG, ASME etc.) teaming up to prioritize “SMART” goals
- Demand Planning at each stage of supply-chain
- ‘Transparent’ communication between supplier and end-users
- Optimize regional supply network
- Define equivalency status
- Streamline of change management and multi-sourcing

Single-Use and Sustainability

Why we need to take sustainability seriously!

Memo from leading CEOs from industry:

- Climate crisis is real
- Healthcare sector contributes ~5% of global greenhouse gas emissions
- Joint action by vendors as partners is needed
- We must work across the value chains
- Collaboration across sectors / boarders

ISPE is partnering with BPOG, BPSA and NIIMBL to drive standardization for sustainability

Sustainable Markets Initiative

OPEN LETTER ON SUPPLIER TARGETS FROM MEMBERS OF THE SUSTAINABLE MARKETS INITIATIVE HEALTH SYSTEMS TASK FORCE

Dear Supplier,

The climate crisis is one of the most urgent risks to global health. The science is clear: there is a rise in non-communicable and infectious diseases due to climate change, with seven million people dying prematurely each year from air pollution alone. At the same time, the healthcare sector contributes approximately 5% of global greenhouse gas emissions, with around half of this footprint coming from healthcare supply chains.

Joint action at scale is needed to move the needle. Driven by this urgency, we, as the global leaders of seven global biopharmaceutical companies, have united with the World Health Organization (WHO) and key public sector partners through the Sustainable Markets Initiative, to accelerate the transition to net zero, patient-centric health systems. As a partner to the WHO-led Alliance for Transformative Action on Climate and Health (ATACH), we also aim to share our knowledge, experience and positive contribution with ATACH partners and over 70 countries worldwide.

Healthcare supply chains must become greener, more efficient and circular. We must work across the value chain to decarbonise operations and do all we can to move away from fossil-fuelled heat and power. Having launched a set of core commitments at COP27, we are scaling our impact above and beyond the actions we are taking within our own organisations. As part of this, we have set joint, minimum climate and sustainability targets for suppliers which aim to address emissions across the value chain and reduce the complexity of multiple asks.

These joint, minimum supplier targets are as follows[1]:

- Assess and disclose Scope 1, 2, and 3 emissions[2] by 2025
- By 2025, commit to set near-term targets aligned with the 1.5 degree pathway (SBTi)
- By 2025, set targets to reduce waste (including solvents) and energy and reuse materials in manufacturing
- Commit to switch to at least 80% renewable power[3] by 2030 and make commitment public
- By 2030, explore options to source green heat
- Transport suppliers to make SBTi-aligned commitments by 2025 and include green transportation solutions in their core offering by 2030
- Commit to set standards for own suppliers
- Set targets to increase water efficiency and commit to adopt water stewardship standards

As a valued partner, we urge you to sign up to these targets as a minimum and share them onwards across your network. Shifting to net zero, climate resilient health systems cannot be achieved in siloes. We must collaborate, across the sector and across borders, to secure a healthier tomorrow.

Sincerely,

Lars Fruergaard Jørgensen, CEO, Novo Nordisk
Belén Garijo, CEO, Merck
Paul Hudson, CEO, Sanofi
John Rim, CEO, Samsung Biologics
Severin Schwan, Chairman, Roche
Pascal Soriot, CEO, AstraZeneca
Emma Walmsley, CEO, GSK

Sustainability Sub-team

- Focus on environmental sustainability topics for disposables/single use technologies
- Conducted a survey on end of life for single-use assemblies
  - 41 survey respondents with global participation
- Released two blogs:

PHARMACEUTICAL ENGINEERING / ISPEAK / END-OF-LIFE MANAGEMENT FOR SINGLE-USE PRODUCTS IN BIOPRODUCTION

iSpeak Blog | 14 March 2023

End-Of-Life Management for Single-Use Products in Bioproduction

Users Perspective on End of Life Management for Single-Use Products used in Bioproduction

PART 1

PHARMACEUTICAL ENGINEERING / ISPEAK / END-OF-LIFE MANAGEMENT FOR SINGLE-USE PRODUCTS IN BIOPRODUCTION PART 2

iSpeak Blog | 24 March 2023

End-Of-Life Management for Single-Use Products in Bioproduction Part 2

In the iSpeak Blog posting on 14 March 2023, the first part of this blog series introduced the results of a survey that was conducted of users of single-use assemblies. The focus of the survey was on current sustainability goals that end user organizations have committed to and the practices of disposal for those single-use assemblies. In Part 2 of this series, we further summarize the survey findings with a focus on identifying opportunities to improve end of life management of single-use assemblies' disposal. This includes both the actions users are willing to own at the site level as well as how suppliers could be a part of more robust solutions.

Key findings – Blog 1

- Current status for handling single-use assemblies at end of life:
  - Half of respondents' companies have a sustainability waste goal and/or initiatives focused on improving waste end of life
  - For disposal – ~90% of respondents use incineration or landfilling
  - Functions responsible - ~65% by EHS and Manufacturing, 20% by Facilities, 42% of respondents indicated multiple functions
  - 63% of respondents dispose without disassembly
    - If they did disassemble, most common parts removed were metals, PVC, tubing and filters.
  - 23% of respondents indicated their waste is non-hazardous
    - 38% have a mix of non-hazardous and hazardous, with an estimated 50% being non-hazardous.

Key findings – Blog 2

- Identifying opportunities to improve end of life management of single-use assemblies' disposal:
  - 92% of respondents are willing to take further action in handling for better end of life options (sorting, removing components, and decontamination)
  - 64% of respondents indicated they would pay a premium price for better end-of-life management by the supplier of the products they purchase (5-10% more was most selected)
  - If product designs were improved, 59% of respondents would consider replacing in existing processes
  - 81% of respondents would dedicate additional resource time to support improved end of life options

What's next?

15

Path forward – Growth through Collaboration

- Drive for standardization across the industry through collaboration, started conversations with ASTM and ASME BPE:
- One and only sustainability targets across the industry, potential collaboration with other industries associations (BPSA, Biophorum, etc)

16

Work in progress and upcoming events

- X-Rays vs. Gamma-irradiation Sterilization Webinar, 7th September
- Working towards a podcast on standardization opportunities
- Upcoming PE magazine article on Single-Use Technology Sustainability
- Providing input to ISPE Sustainability CoP
- Definition of next project on Disposables Sustainability

ISPE Disposables COP Committee

- Javier Lozano, Chair
- Addison Raine, Vice-Chair
- Chris Smalley, Secretary
- Dharti Pancholi, Former Chair
- Adam Goldstein
- Cristina Van Loy
- Pietro Perrone
- David Wolton
- Jeff Lewis
- Michele Morelli
- Charlie Zhang
- Katell Mignot
- Esmail Esketafai
- Additional members of Sustainability Sub-Team: Andrew Sinclair, Eric Langer, Treasa Rohrer