

SINGLE USE TECHNOLOGIES

UNANSWERED QUESTIONS

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- 1. Introduction
- 2. Supply Chain Robustness
- 3. Open Source Single-Use Components
- 4. Sustainability and Solid Waste



1. INTRODUCTION

Alejandro Kaiser, PE



Goal:

 To share concerns and potential solutions on the industry with SU technology. Open discussion and new ideas are welcome.

Disclaimers:

- I have no partnership or invested interest in any company mentioned during this presentation.
- Presentation is not intended to recommend any company's technology. Companies and technologies mentioned during the presentation are considered as illustrative examples.





Established 1984





\$680M 2019 revenues















Pharmaceutical

Knowledge

2. SUPPLY CHAIN ROBUSTNESS

Supply Chain Robustness SS vs. SU

In the past two decades:

- From 100% SS
- To 85%SU

Why did the change come?

- Avoid CIP and SIP
 - Time
 - CAPEX
 - OPEX
 - Validation
 - Integrity Failures



Supply Chain Robustness SS vs. SU BRX





Pharmaceutical

Supply Chain Robustness SS vs. SU BRX





Supply Chain Robustness SS vs. SU Transfer Line





Pharmaceutical

Knowledge

Supply Chain Robustness SU Bright Side

Tremendous upside:

- Shorter time to market
- Higher turnaround
- Lower production cost
- Flexibility
- Reduced cross-contamination
- Environmentally friendlier (energy and water)



Supply Chain Robustness SU Concerns

Are we now in Shangri la?

- Leachables
- Extractables
- Extrusion/ Particulates
- Gas permeability
- Biocompatibility
- Disposable failures





Supply Chain Robustness

The 2020 nightmare

Global Political Tensions

- Covid and OWS Lead time
- Thermoplastic elastomer shortage
- Bag Holders 28 Weeks
- Mixing bags 38 Weeks
- RTU Vials 72 Weeks

Sartorius – Coronavirus Bonus

- SU was the solution to SS equipment long lead times:
- Hardware Solution
- Disposables Problem



Supply Chain Robustness

Supplier



- Proprietary single use tubing takes 2-3 times more time to be delivered than its hardware
- Warehouse and business projections
 - Death by success three-year projection (limited wiggle room)
 - Shelf Life and Black Friday philosophy
- SS Skids Uncertainty is the enemy of business
 - Chrom and TFF skids
 - Tube sets cost
- Big players All expanding capacity



Supply Chain Robustness End User



Sufficient disposables inventory

- Warehouse Space
- Shelf-life dependency
- Production area storage



Supply Chain Robustness

Open Issues

Suppliers M&A

- Will I still get my disposables?
- Lead to monopoly
- Disposable cost pressure
- Dependency from a single source

Design Standardization

• Automated vs. manual assembly at vendor's shop

Testing Standardization

- Certain SU material compounds can negatively impact cell growth (e.g., bDtBPP)
- Leachables and Extractables



3. OPEN SOURCE SINGLE USE COMPONENTS

Open Source Single Use Components Suppliers



Current Conundrum:

 SU technology brought flexibility to the industry but what happens when it actually makes it captive?

Hardware – One time CAPEX

Disposables

- No shopping around
- Fairy tale ending: happily ever after?
- Technical quality and supply agreements

Communication architecture

 Open Architecture for easy integration with different vendors?



Suppliers

SUMs

- Patented designs (geometry, top/bottom entry, impellers, baffles)
- How do you couple the motor?
- No flexibility
- You want flexibility?...That'll cost you...

Filters and tube sets

Agreements with several suppliers

Bag Holders

- Smaller bags on the same holder
- Customed Systems Double edge sword
- A wall works both ways
- Row A, B, C fiasco Do we want to repeat it?





Filters and tube sets

Issue – Time spent designing customized tubeset

- Well over 50% of vendors business are customized disposables
- Constant redesign

Map out the entire process

- Detail it as it was an isometric And make end user its owner!
- Lego or Ikea Concept
 - Smaller warehouse
 - Easier on operator
- Plan for the worst Redundancy
- Standardize sets among different company sites
- Some subcomponents are not available irradiated

Line up at least three suppliers

Open to competitor's filter, sensor, connector





Road Map





Road Map





Tube Sets





Open Issues – Potential Solutions

Where do I get my SUMs, SUBs and tubesets? The computer says no...

- Allow other manufacturers to produce your design in exchange of a fat royalty.
- Patents aren't eternal.

Bag holders – The special case

- What makes them special?
 - Different designs
 - Footprints
 - Sizes
 - Connectors
- Can we all align on the design?





Open issues – Potential Solutions

On a boat – Either we all succeed, or we all fail.

Proprietary Disposables MOC

• Properties, leachables, extractables

Interconnectivity between different vendors

- Standardization
- Code 7 cartridges example

CDMOs – To the mercy of Tech Transfer

- Different hardware may be required
- Do I buy it ahead of time or when the need comes?
- Warehouse space





Open issues – Potential Solutions



Different initiatives:

- BPOG End-user forum
- ASME BPE Reorganizing guidelines
- Bioprocessing Collaboration Center (BCC)





4. SUSTAINABILITY & SOLID WASTE

Processing Waste

- Liquid vs. Solid waste
- Liquid Process waste Dictated by the process and regulations
- Liquid Support waste (WFI, CIP, Condensate) Space for improvement
- Solid waste (Disposables) New WIN-WIN battleground





Solid Waste

Boom in the industry

- Cell and Gene Therapy
- COVID-19
- Biotech is the new real Estate investment

Single Use Share of the industry drastically increasing

- Flexibility More important than ever
- MABs Last barrier was broken SU Centrifuges
- C&G All SU On its infancy: Personalized medicine Very tailored.
- More Plants + More throughput + More Disposables = What the heck do I do with so much solid waste??



Solid Waste

What have been my options? Landfill

- Low cost
- Traps water
- Earth not too happy

Incineration

- Water goes back its cycle
- Releasing noxious fumes to the atmosphere
- Off-site (typically)
- Coupled with cogeneration Waste to Energy (WtE)

Recycling

- Solid waste is repurposed for something else
- Overall carbon footprint is reduced





Recycling

Solid Waste: tubing sets, equipment bags, filters capsules/cartridges, cover-up bags, PPE

Is initial content important? Hazardous material? What is the BSL level of the facility?

- BSL3 requires decon autoclave. NIH recommended for BSL2
 Challenge Different types of plastics in SU disposables are difficult to separate.
- Recycling magnets used in impellers Separation by weight





Recycling

How much space do I need? How much waste do I produce?

- Mapping tubesets cornerstone of this analysis
- Schedule programs (i.e., SchedulePro) Can be tailored to couple with this information.

Off-site shredding and treating

- Shreds and sterilizes
- Steam condensate used to preheat boilers





Shredder + Sterilizer

- Reduces waste volume between 50-80%
- Can handle every type of waste (liquid, solid)
- Steam sterilizes waste
- Occupies less space than an autoclave
 - No need to reinforce floors
- Material can now be repurposed



Shredder + Sterilizer









Pharmaceutical

Shredder + Sterilizer



Steps:

- Load
- Shred
- Sterilize
- Drain
- Unload
- Lather Rinse Repeat...



Shredder + Sterilizer





Shredder + Sterilizer







Waste Reincarnation

If shredded material is 90% polyolefins (LDPE, PP, HDPE), you can make money!





Other Recycling Ways





Syngas for energy production in electrical power plants Shredded off-site and

transformed into Naphtha

Waste Reincarnate











More ways of recycling

Use expired tube sets/bag for:



- OQ/Engineering runs
- R&D facilities



Initiatives





Bio-Process Systems Alliance Advancing Single-Use Worldwide

- Triumvirate Recycling Program
- Bio-Process System Alliance (BPSA's)



Business Proposition

Why would you do it?

Higher Initial Capital Costs

- Recouped in few years and turn into profit
- Future addition does not need to be installed immediately
- Corporate Social Responsibility New Normal
 - Shift from 20th Century Employee engagement
 - Shareholders demand it Profit is not the only KPI
 - Green Index Funds

Corporate Image

- LEED Certification
- Social media trends Can raise or destroy corporate image
- Company rankings

New Sustainability Regulations Increasing Global Competition



Questions?

For further information, please contact:

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