



# 2020 Speaker Series

**Friday, July 17, 2020  
10:30-11:15 AM EDT**

**Single-Use Bioprocessing  
Growth and Adaptations:  
Lessons from Space**



**Featured Speaker**  
Scott Patterson,  
ILC Dover

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Bio-Process Systems Alliance  
Advancing Single-Use Worldwide



**Flexible Vinyl Alliance**



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# *Single Use BioProcessing Growth and Adaptations Lessons from Space*

July 2020



**100% focus on  
the Patient**

**Lessons from  
Space**



# ..”Not because they are easy”

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**Sep 1962**

We choose to **go to the moon** in this decade and do the other things, not because they are easy, but because they are hard, because that goal will serve to organize and measure the best of our energies and skills, because that challenge is one that we are willing to accept, one we are unwilling to postpone, and one which ...



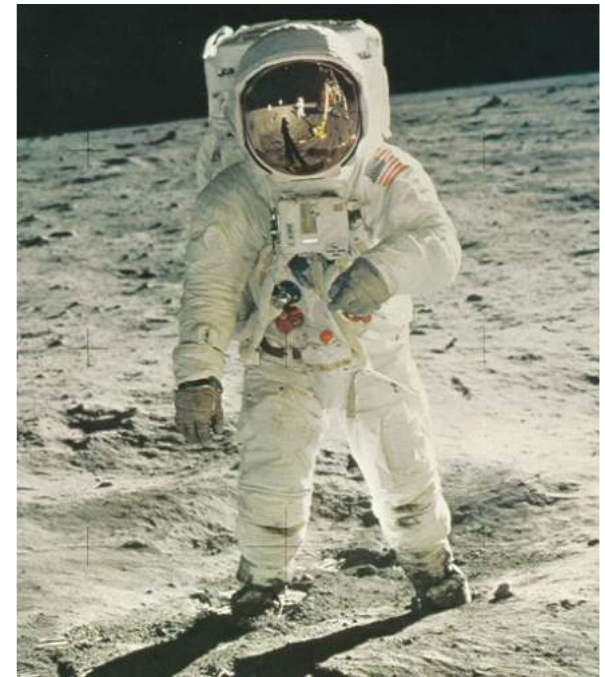
# Planning a Program

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**JFK declares the  
commitment  
Sep 1962**

**7 Year Mission?**

**The first moon walk  
July 1969**





# Planning a Program

ILC Dover saw the  
need for a lunar suit

It was really a 15 Year Mission!

Circa 1954

Sep 1962

July 1969



**ILC DOVER**  
*creating what's next*





# Planning a Program

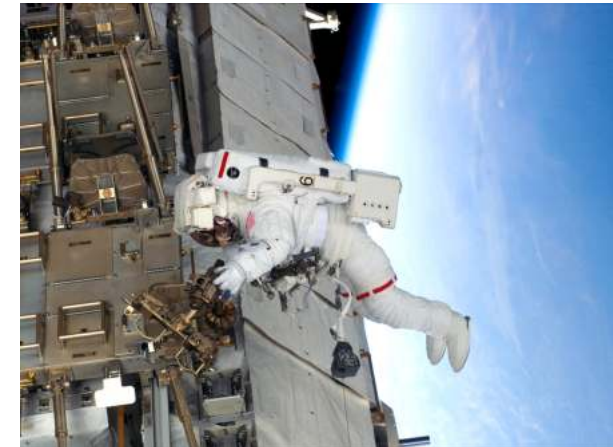
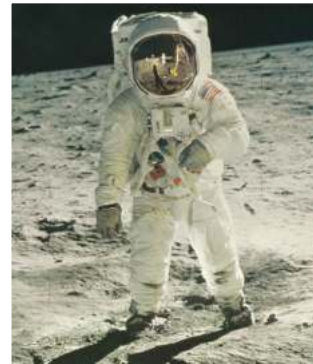
Apollo program ended and the need for a suit to walk on a planet ended. A suit for space walks on the space station differ in many ways

Circa 1954

Sep 1962

July 1969

2020



# Planning a Program

Mission to Mars and the return of the  
space suit design for planet exploration

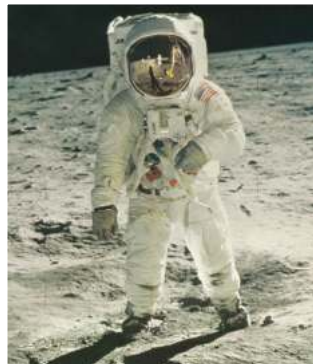
Circa 1954

Sep 1962

July 1969

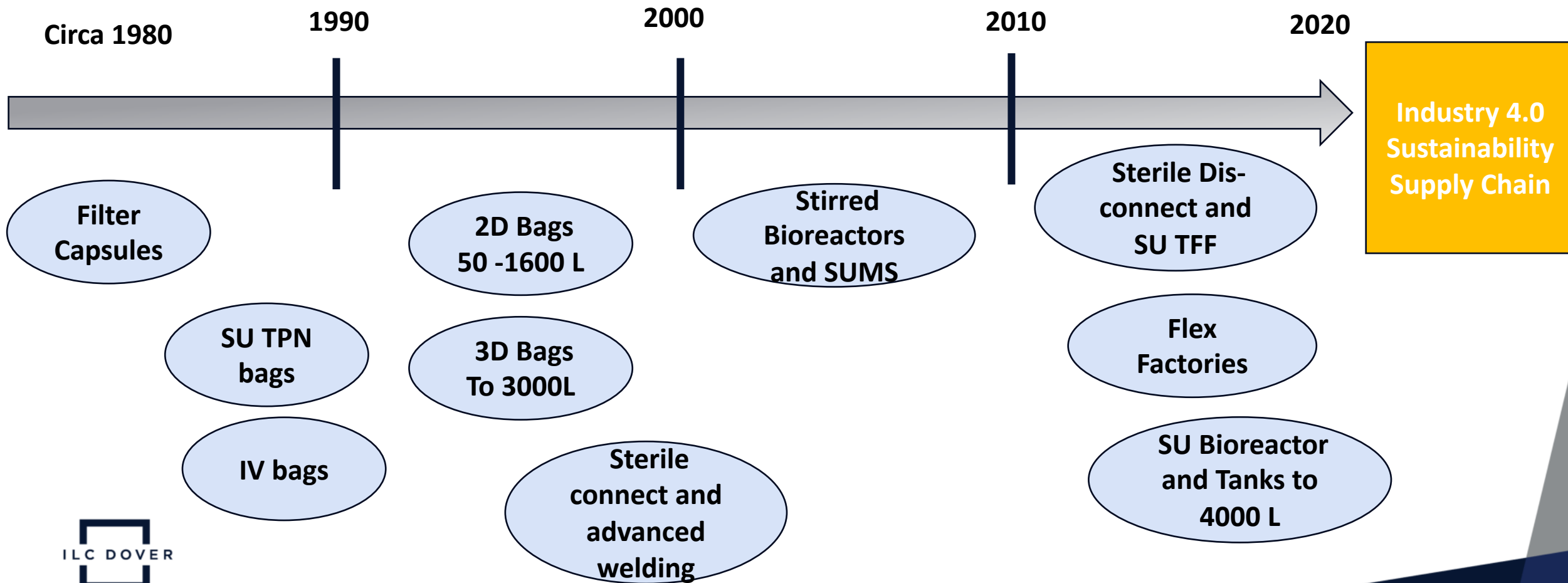
2020

Circa 2030



# BioPharm Single use timeline

*Like in space travel, the requirements are a continuum of constant change / improvement*





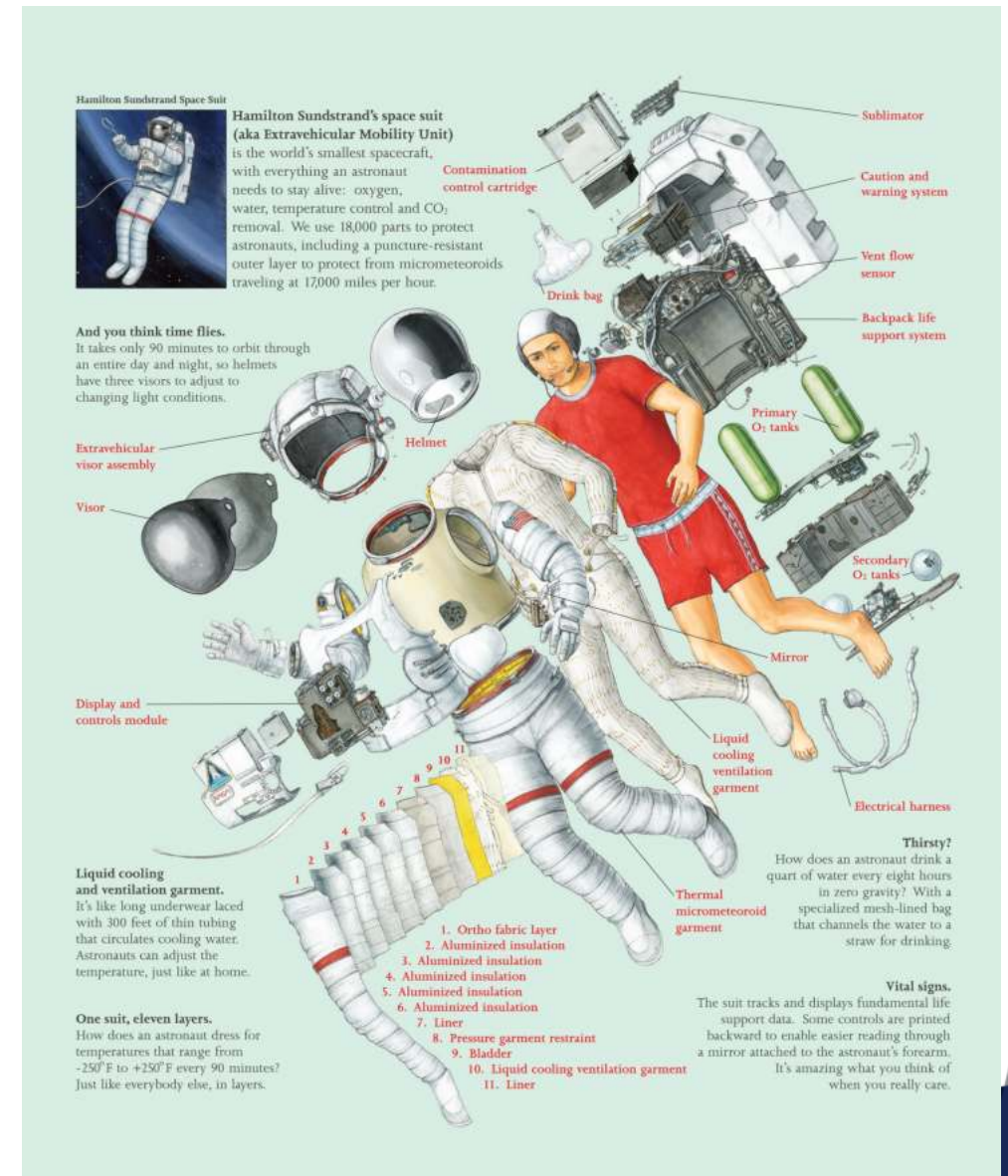
# Space Travel Integrity testing

The Space Suit is very much like a complex single use system made up of multiple components that need to come together and perform as a whole

“The Show Is On” <sup>2</sup>

The astronaut suits up for an Extra Vehicular Activity or Space Walk.

- ✓ All activities performed have been choreographed on earth
- ✓ Standing by at NASA are dozens of experts
- ✓ Before stepping out the door the suit is tested
- ✓ If there is a problem and must be worked and solved real time
- ✓ Suit integrity has never been the reason for a cancelled EVA



# Single Use System Integrity

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## **What is Integrity for biopharma SU processing?**

ASTM F17-08 “the physical capability of a given package to protect it’s contents with the desired level of protection over a defined period of service”

USP<1207> the MALL (Minimum Allowable Leakage Limits) is the greatest leakage rate (or leak size) tolerable for a given product/package that will pose no risk to product safety or inconsequential impact on product quality <sup>1</sup>

# Single Use System Integrity

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## **What causes the failure of single use systems?**

- Choice of the single use material
- Flaws in individual components within an assembly
- Manufacturing practices
- Packaging methods

## **The Challenges continue even after the product is manufactured**

- Shipping and handling
- Installation procedures
- Operating conditions (pressure, temp, flow rate)



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“Okay, Houston, We’ve had a problem.”

Command Module Pilot John L. “Jack” Swigert, Apollo 13



# Single Use System Integrity

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## **What occurs when Integrity fails in biopharm SUS?**

- Leaks / Droplets that contaminate the local environment
- Aerosolization that extends the area of contamination and risks exposure to personnel
- Product contamination from non-sterile exposure
- Lost production batches and delayed delivery schedules
- Lots more

# Single Use System Integrity

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## Development of standards for integrity testing

- There has been a lack of a regulatory guideline specific to biopharma production components
- Initial products were tested to the manufacturer standard allowing for variability in the methodologies
- SUS can be made from multiple components from different suppliers making the final assembly a “collaborative” QA project

## Evolution of standard guidelines





# Single Use System Integrity

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## Integrity testing methodology

- Visual Inspections (not recommended)
- Pressure based tests
- Tracer-gas based tests

## Testing throughout the product Life Cycle

- Before testing there must be a QbD system to build in the Quality
- Product testing before shipping
- Product testing before use
- Product testing post use – Can be beneficial

# Single Use System Integrity – Here's a real problem

Development of standards for integrity testing

**How do you test for that????**

Glove bladder, restraint, heaters and more required special test instruments and procedures for testing properly

Challenge - How do you test the migration of lunar dust and improve?

Step 1 – Get lunar dust....

Step 2 – Create the lunar environment

Step 3 .....



# Space Travel Integrity

## Challenges

- “the development of larger and complex, multi component systems has made integrity assurance a critical attribute of the system”
- “the challenges include practical aspects, test methodology with appropriate sensitivity, and result interpretation.”
- “economics of testing is a further challenge”



“Building a gateway to deep space”





# ~~Space Travel Integrity~~— SU Integrity Test

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## **Challenges**

- “the development of larger and complex, multi component systems has made integrity assurance a critical attribute of the system”
- “the challenges include practical aspects, test methodology with appropriate sensitivity, and result interpretation.”
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***ASTM E3244-20, Standard Practice for Integrity Assurance and Testing of Single Use Systems, ASTM International 2020***

# Space Travel Integrity Testing

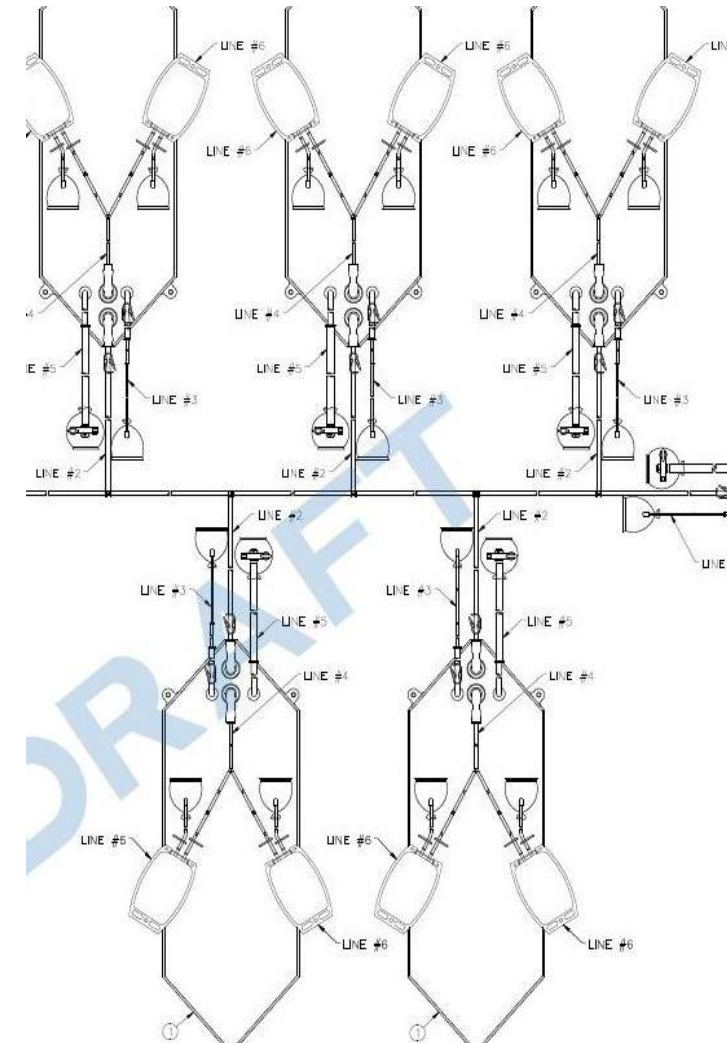
## Cooling / Heating Garment

Mission critical system maintains integrity to cool and warm the astronaut over a typical 6.0 hour space walk

- 300' of Tubing that is integrated into 4 discrete sections
- Connectors for the fluid transfer in / out of the Garment
- Integrity testing starts with visual inspection followed by multiple tests including a flow test with colored dye



**Typical SUS with 127' of tubing and multiple connectors**



# Materials selection and Improvements

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## BioPharma Single Use Systems

- Improve the ability for manufacturing of all components needed in the process chain
- Reduce the potential for extractable and leachable that can adulterate the drug product
- Reduced particulate levels to protect the “patient”
- Better strength for packaging configurations and shipping conditions
- Sustainability

## What's important in space travel?

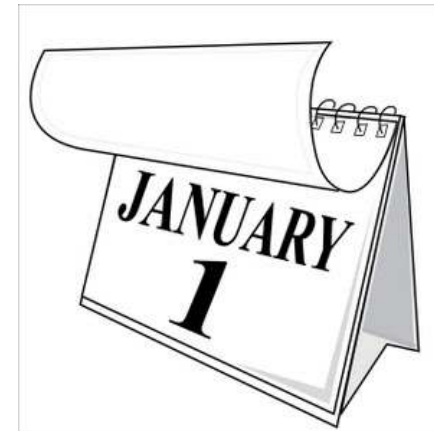
- Reduce the weight of all components to increase the payload that can be carried on board the mission
- Smaller package sizes to reduce the space required to increase the payload that can be carried on board the mission
- Protect the “patient” for all conditions lunar dust, mini meteorites, temperature, environment....
- Have a product that will sustain a 30-year shelf life

# Material selection and then implementation

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## Now that we have found the next best thing, how do we use it?

- Regulatory standards ranging from USP, FDA, EMA, EP, JUSP, SFDA, ANVISA ....
- Extractable / Leachable standards and testing
- Particulate and sterility testing for the product and manufacturing process
- Customer standards and Quality Assurance review
- Change Control to actually implement the improvement



# Economics and Supply Chain- Space

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- The first Space Suits were valued at \$1.0 M Each and had nearly 5000 labor hours
- The Apollo program was small with a defined number of astronauts and a defined number of missions so only 300 suits were made – They were single use!
- This was not a sustainable cost model for future missions and standardization was required
- Whenever possible, common materials are used to reduce the materials costs and to assure they remain available for as long as possible but some materials can be obsoleted
- The Suits were redesigned to be modular and the components are put together to fit a range of body sizes
- The components themselves adjust for fit to the astronaut
- In board the space station they have two sizes which are built up by the component parts – Total standardization



# Economics and Supply Chain

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- Studies have proven the economics of single use systems vs stainless steel components
- BPOG standards of materials testing for E & L intends to reduce the reliance on specialty materials and create cost savings thru competition
- The shear volume of SUS is increasing at a faster CAGR than biopharma manufacturing creating economy of scale for further cost controls and savings
- The reliance on SUS in the manufacturing processes requires a secure supply chain – The products have to be available and perform when “the show is on”
- Suppliers are currently extending lead times causing strain on the supply chain and risk. More standardization and capacity is needed to keep up with the growth

# Contributors and References

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Thank you to our contributors:

- Bill Ayrey, Author, *Lunar Outfitters, Making the Apollo Suit (available September 15)*
- Patricia Stoll, ILC Dover VP and Division Manager, Houston Business Operations
- Chris Rombach, VP of Sales & Marketing, Asahi Kasei Bioprocess America

## References:

1 USP<1207> *Package Integrity Evaluation: Sterile Products*. United States Pharmacopeial Convention, Inc. Rockville, MD, 1 May 2018

2 ASTM E3244-20, Standard Practice for Integrity Assurance and Testing of Single Use Systems, West Conshohocken, PA, April 2020

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