

**ISPE-CaSA**

# *Education Webinar*

*This event is Sponsored by:*

**wood.**



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Carolina-South  
Atlantic Chapter

## **Trends in CDMOs:**

*A Panel Discussion on the Recent Industry Growth*



**Daniel R. DeVido, PhD**  
*Sr. Director, Strategic Business  
Development*



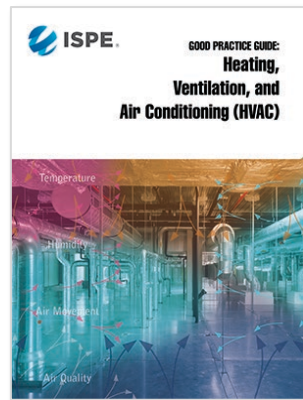
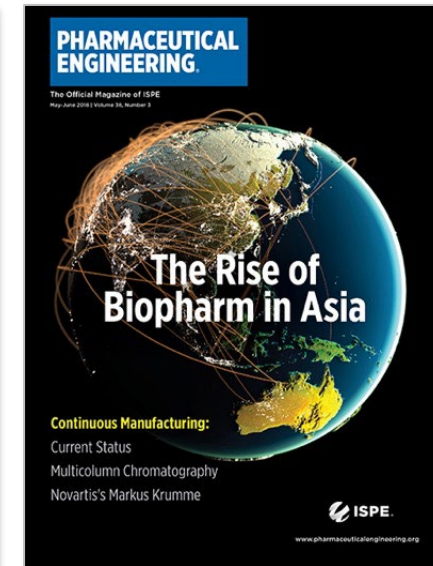
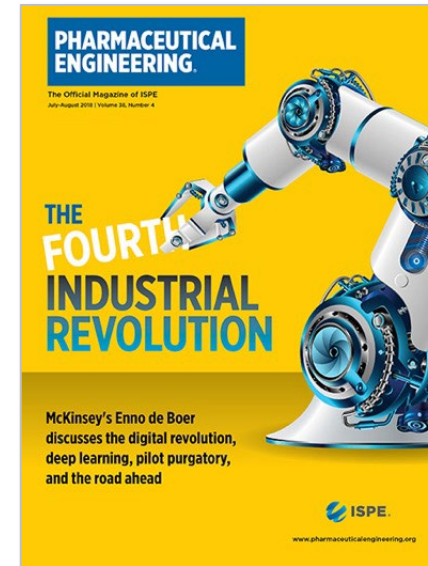
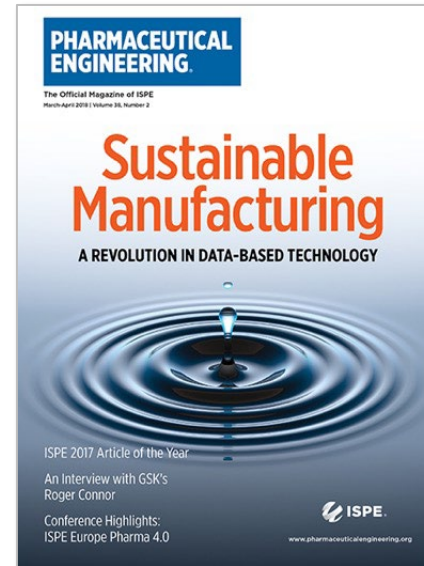
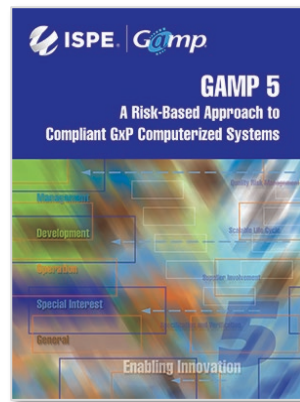
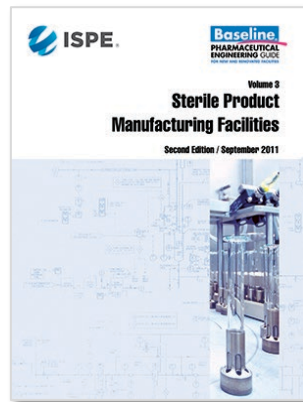
**Gary Schoenhouse, PE**  
*Chief Technical Officer (CTO)*



**Kevin Kelly**  
*Director, Business Development*

*Discussion Moderated by John Garner, Education Committee Co-Chair*

# ISPE Guidance Documents = Best Practices



## Pharmaceutical Engineering® Your News Source

Use this QR to become  
an ISPE member.



# Networking Committee: Upcoming Events

Space is limited, register early!

**ISPE** | WOMEN **@ DRIVE SHACK**  
IN PHARMA

**Thursday, June 1 • 5-7pm**



**KÖRBER** **Quality Confidential** **CRB** **INFO PATHWAYS**

Drive Shack  
Registration



**ISPE** | Carolina-South Atlantic Chapter

**LUNCH AND LEARN**  
**REGISTRATION**  
**NOW OPEN**

**KENDED A LIVING BUILDING TOUR**  
**JUNE 8, 2023 | 11:30 AM**  
**GEORGIA TECH, ATLANTA**

Thank you to our event sponsor:

**35° NORTH**



GA Tech L&L  
Registration



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# Networking Committee: Upcoming Events

## **Therapeutic Thursdays – Mark your calendar!**

*Dates:* June 29<sup>th</sup>, July 27<sup>th</sup>, August 31<sup>st</sup>, and October 26<sup>th</sup>

*Locations:* TBD

## **Annual Sporting Clays Event**

*Date:* September 14<sup>th</sup>

*Location:* Hunters' Pointe Sporting Clays, Washington, NC



## **Oktoberfest (Education & Networking Dual Event)**

*Date:* September 14<sup>th</sup> (*Location:* TBD)

### **Education Session (2 – 5 PM) - ISPE CASA GAMP Think Tank**

*GAMP Panel & Round table discussions focused*

*On CSA, AI/ML, and the Blockchain*

### **Oktoberfest Event (5:30 – 8 PM)**

*Drinks, Food, Music, and more...*

*More information soon!*



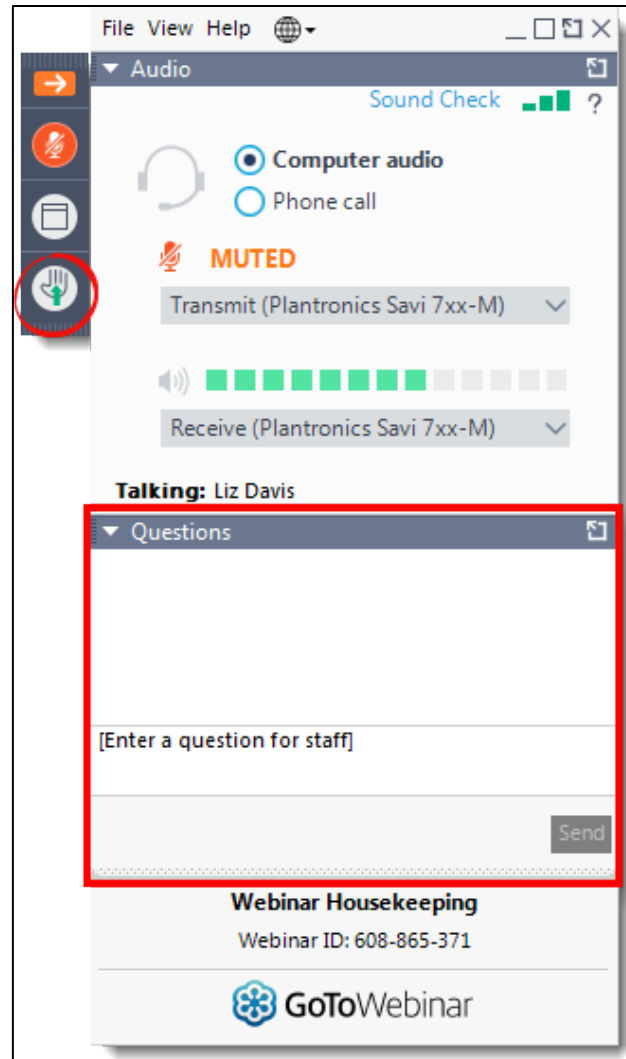
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# GoToWebinar “How To’s”



## Your Participation

- Please submit your text questions and comments using the Questions panel
- There is a Q&A Session at the end of the presentation

**Note:** Today's presentation is being recorded and will be provided within 48 hours.



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**ISPE-CaSA**  
Webinar Series

# **Trends in CDMOs**

## ***Discussion on the Recent Industry Growth***

**May 18, 2023**

Sponsored by:

**wood.**



**Nathan Seitz**  
*Director, Engineering & Architecture*

# Wood is a world leading consulting and engineering company across energy and **materials** markets.

**160+**

year history

**c35,000**

people

**60+**

countries

**c\$5.5bn**

revenue

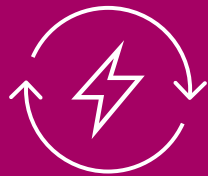
Connected by our shared values of  
**care, commitment** and **courage**

**AA leader** rating from MSCI for environmental,  
social and corporate governance

## Areas of expertise:



Energy Security



Energy Transition



Decarbonisation



Digital Delivery



Circular Economy



# Energy.

Oil & Gas | Hydrogen | Carbon Capture

## Energy security:

delivering safe, reliable and affordable energy

## Energy transition:

enabling a low carbon energy future

# Materials.

Minerals | Chemicals | Life Sciences

## Raw materials demand:

sustainably deliver key minerals and chemicals

## Life sciences growth:

advanced, scalable manufacturing post-pandemic

## Decarbonisation

Enabling clients to reach net zero through sustainable design and operations

## Digitalisation

Leading independent partner for operational technology and digital transformation

# Wood Life Sciences

**50+**

Years of history  
in Life Sciences

**1500+**

Advanced  
manufacturing  
specialists

**ENR**

Top 5 International  
Design Firm



## People

Architecture  
Engineering  
Procurement  
Construction  
Management  
CQV



## Full EPCMV Services

Master Planning  
Feasibility Studies  
Conceptual Design  
Basis of Design  
Detailed Design  
Pre-Construction

Project Controls  
Procurement  
Construction Management  
Turn Over Packages & Start Up  
Commissioning & Qualification  
Validation Master Planning



# ISPE-CaSA

Webinar Series

## Trends in CDMOs

*Discussion on the Recent Industry Growth*

### *Poll Question #1*



# Panelist Introduction



Daniel R. DeVido, PhD  
Sr. Director, Strategic Business Development



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# Global Vision and Core Purpose

To be the leading and most trusted global Contract Development and Manufacturing Organization partner in the biopharmaceutical industry.

Partners for *Life*

Advancing tomorrow's medicines



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## Our Core Values

trust



delighting our  
customers



gemba  
go see



genki  
being  
enthusiastic





# Global Locations

FUJIFILM

Diosynth  
biotechnologies



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# End-To-End CDMO Service Offering

## Pre-Clinical



### Pre-Clinical Development

- Expression Studies
- Strain Development
- Cell Line Development
- Process Invention
- Pre-Clinical Drug Substance
- Pre-Clinical Drug Product

## Phase I, II



### Early Phase Clinical

- Process Development
- Process Optimization
- Analytical Development
- Formulation Development
- cGMP Drug Substance
- cGMP Drug Product
- DS/DP Stability

## Phase III



### Late Phase Clinical

- Process Characterization
- Process Validation
- Analytical Method Validation
- Formulation Optimization
- cGMP Drug Substance
- cGMP Drug Product
- DS/DP Stability

## Regulatory Approval / Launch



### Commercial Production

- cGMP Drug Substance
- cGMP Drug Product
- Finished Goods (ALP)
- Post-Approval Activities
- Product Life Cycle Management



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# Panelist Introduction



Gary Schoenhouse, PE  
Chief Technical Officer (CTO)





# We envision a world where cures thrive. GeneSuites can make this a reality.

**GeneSuites provides a flexible, alternative solution to internal build capital projects (Build) or buying access to contract manufacturing (Buy).**

GeneSuites offers purpose-built cGMP manufacturing **suite solution** and **High-Performance Shell solution** with supporting infrastructure so that customers can occupy the space, install their process equipment, start their facility prior to clinical manufacturing with the option to launch their commercial product all under one roof. As a result, life science companies can **secure advantages that lower barriers to entry**:

Significantly lower upfront customer capital outlay	Standardized facility design maximizes flexibility to establish a variety of CGT modalities	Quicker time to market than Build; Potentially faster start than Buy
Allows focus & investment on science and clinical execution in earlier phase of development	Maximize protection of IP and manufacturing process	Accelerated tech transfer and time into production

DEVELOPED IN COLLABORATION  
WITH INDUSTRY LEADERS

Including but not limited to:



North Carolina  
Biotechnology Center.



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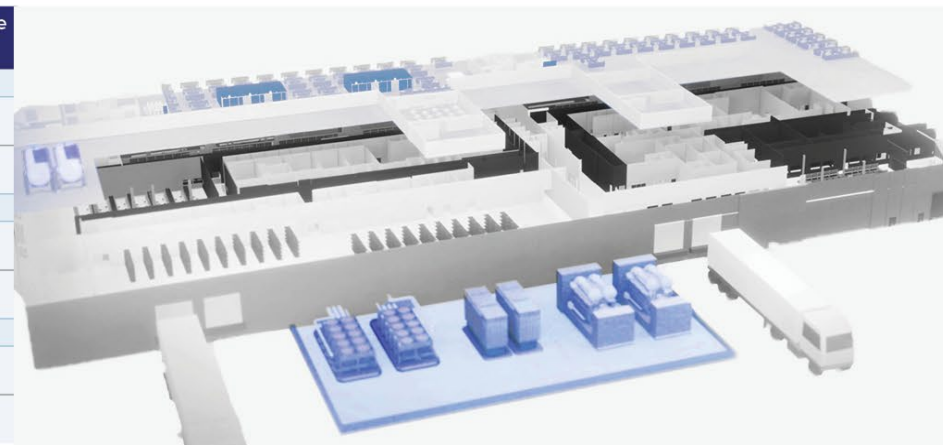
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ACCELERATING SPEED TO MARKET

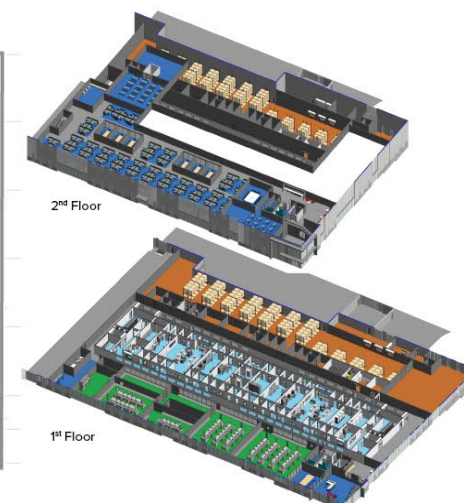
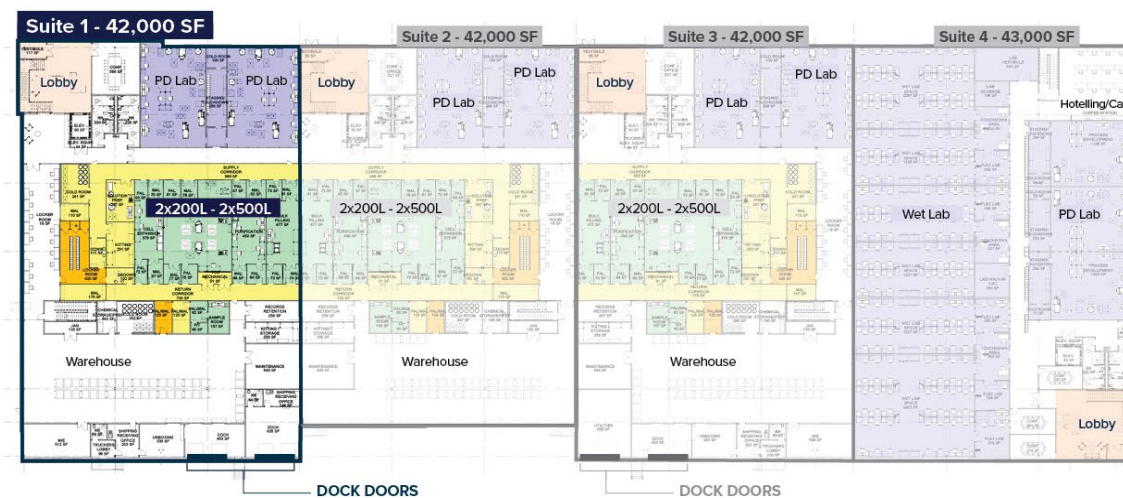
# High-Performance Shell & Suite Solution

## HIGH-PERFORMANCE SHELL

	Typical Industry Cold Shell	High-Performance Shell
MECHANICAL		
Chiller Plants		✓
Boiler Plants		✓
ELECTRICAL		
Backup Generators		✓
Switchgear		✓
ADDITIONAL INFRASTRUCTURE		
Mezzanine		✓
cGMP-Specific Components		✓



## SUITE SOLUTION



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# Catalyst BioCampus - Holly Springs, NC



	Typical Cold Shell	Catalyst Shell	Catalyst HPS
MECHANICAL			
Chiller Plants			✓
Boiler Plants			✓
ELECTRICAL			
Backup Generators			✓
Switchgear		✓	✓
ADDITIONAL INFRASTRUCTURE			
Mezzanine		✓	✓
cGMP-Specific Components			✓

## PROJECT HIGHLIGHTS

26-Acres, 3-Building Campus up to 460K SF

In partnership with affiliates of Apollo Global Management

- Two cGMP buildings, each totaling 163,000 SF (103,000 SF Ground Floor + 60,000 SF Mezzanine)
- The only cGMP facility with secured power to the site (6MW with the ability to increase to 15MW)
- Catalyst offers a unique advantage that can accelerate speed to market by 9-15 months through the installation of primary infrastructure
- Building Shell Complete: Dec 2022
- Mezzanine Complete: April 2023



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# Panelist Introduction



**Kevin Kelly**  
**Director, Business Development**



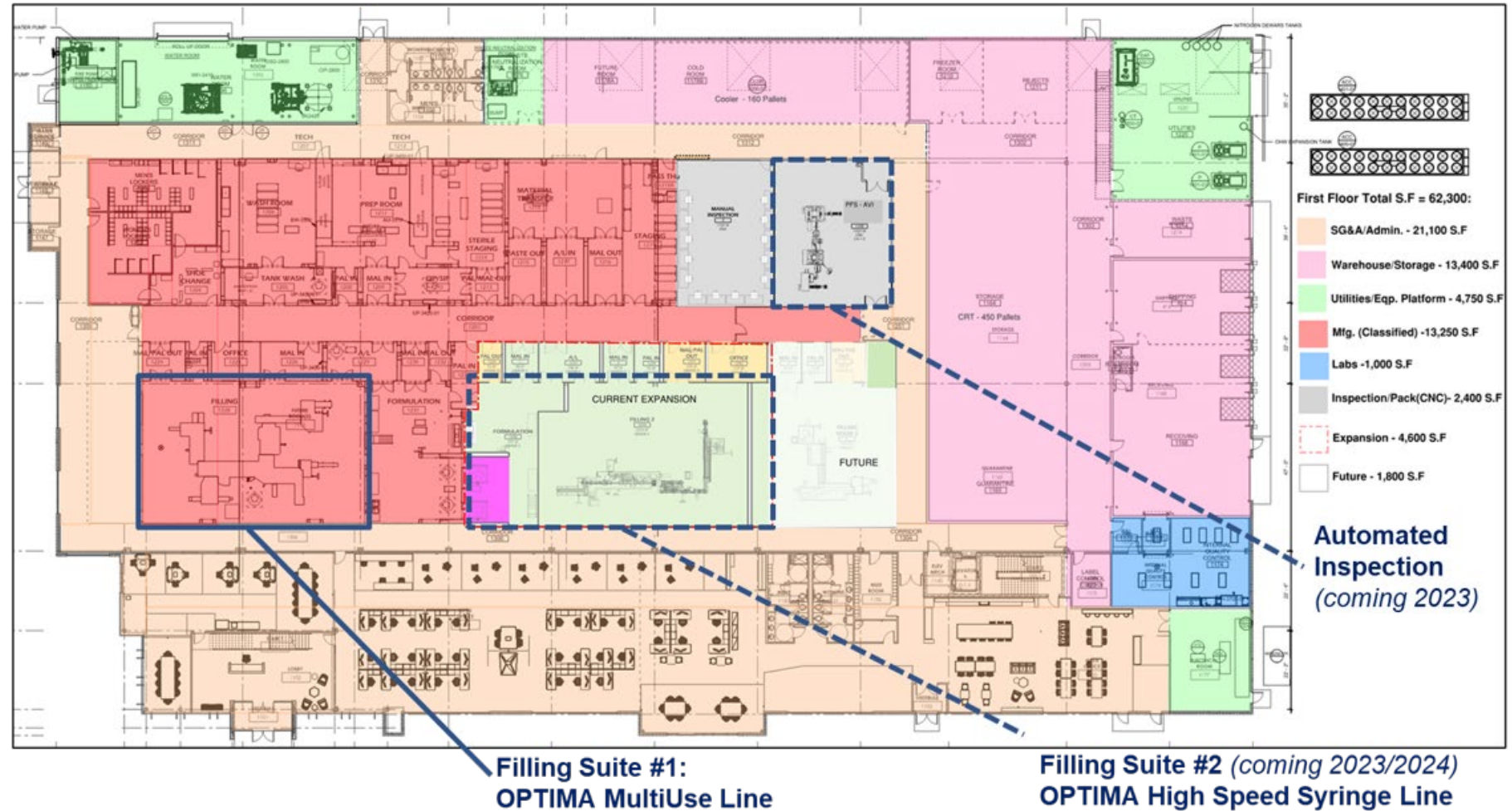


# INCOG BioPharma Services, located in Fishers, Indiana





# First Floor Layout of INCOG BioPharma



# Features of our OPTIMA MultiUse line

## Syringe | Cartridge Filling Specifications

- 7,200 units/hr. (up to 600L batch size)
- Time pressure or peristaltic pump mechanism
- 100% IPC; Redosing-On-Request
- N<sub>2</sub> gassing
- Vacuum or vent tube stoppering
- Syringes: 0.5mL, 1mL Long, 1-3mL, 5mL, 10mL
- Cartridges: 1.5mL, 2mL, 3mL

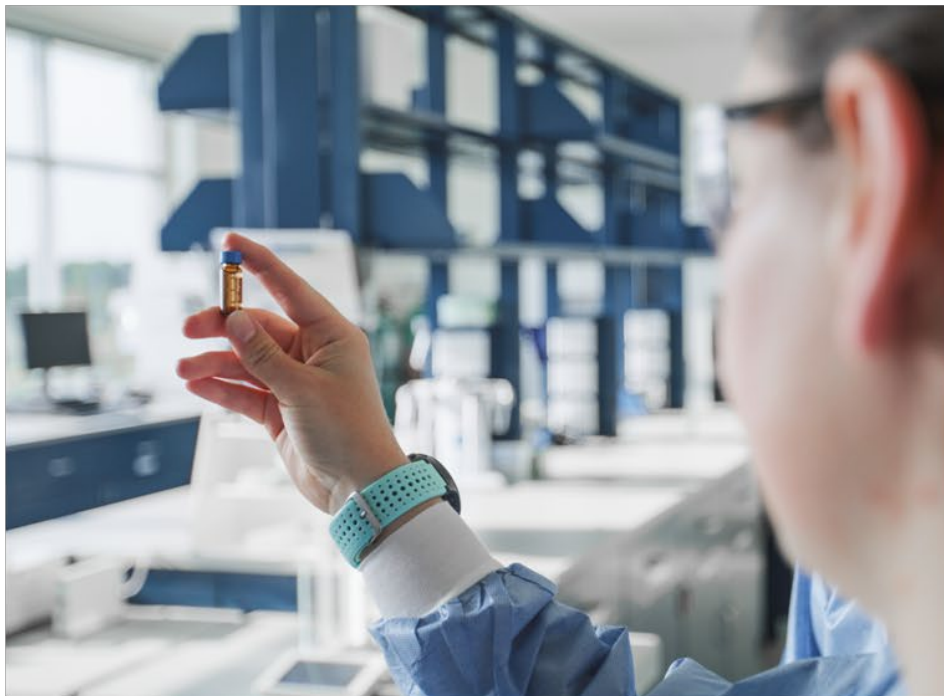


## Vial Filling Specifications

- 9,000 units/hr. (up to 600L batch size)
- Time pressure or peristaltic pump mechanism
- 100% IPC; Redosing-On-Request, Re-stoppering
- N<sub>2</sub> gassing
- RTU (Tub/Nest & Tray) and Bulk Configurations
- 2R-30R vial size bracket
- Lyophilization (Future)



# What makes us different?



## Better solutions

We are proud to manufacture for the future of medicine.

With world-class facilities, state-of-the-art equipment, and some of the industry's most talented people, **you can feel confident that your drug product is in safe hands.**



## Better outcomes

Every decision we make about your product will be made with you, **full transparency**, for the success of your project.

Better outcomes, delivered on time and on budget, every time.



## Better experiences

We are creating a new standard of CDMO that considers the customer's experience from initial discussion, **to being welcomed on-site for every step of the way.** Providing an all-around better experience is our mission.

We will always act in the best interest of you, your company, and your product.



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## Trends in CDMOs

*Discussion on the Recent Industry Growth*

### *Poll Question #2*



# Panel Discussion



**Daniel R. DeVido, PhD**  
**Fujifilm Diosynth Biotechnologies**



**Gary Schoenhouse, PE**  
**GeneSuites**



**Kevin Kelly**  
**INCOG BioPharma**



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# Questions & Answers

## Panel Q&A:

### *Trends in CDMOs: A Discussion on the Recent Industry Growth*

Join our **growing** Chapter!

*Use the QR Code below for a shortcut to the ISPE CaSA Member Registration page.*



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