# The reality of automation in CGT

## Why closed systems matter

It is widely thought that automation is the future of cell and gene therapy (CGT) manufacturing, to maximize efficiency and reduce contamination risk. However, fully closed, automated processes are impossible until incoming raw/ancillary materials are provided in packaging that is amenable to automation and can be retrieved through closed-system processing e.g., welding. This infographic will explore advantages and bottlenecks in CGT automation, and introduce a closed-vial system that allows fully closed filling and retrieval.

### The importance of a fully closed system

Manual retrieval of raw materials creates risks.

Many current raw

in bottles and vials

open processing.

which **require** 

materials are provided

Challenges in CGT **Manufacturing** 

**Solution: CellSeal**® **Connect** 

The only vial enabling fully closed filling and retrieval via welding.

Provides **seamless** integration into automated processes and eliminates the need for biosafety cabinets/ isolators in retrieval.

Compliance with GMP standards can be **complex**.

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5 mL and 2 mL vial

4.9 mL and 1.9 mL,

respectively)

**USP Class VI** 

compliant

materials

sizes (maximum fill of

02

Designed to meet **GMP** packaging requirements.

#### The alternative

Why CellSeal® Connect wins over traditional vials

Closed Fill/Retrieval



**GMP Compliant Packaging** 



Compatible with Automation



Reduces Need for BSC/Isolator

No



Yes Varies

Compatible with storage down to -80°C

Closed-system concept allows for multiple welds with extra long tubing coiled on reserve

#### The future

To truly enable automation, manufacturers must first close out manual process steps.



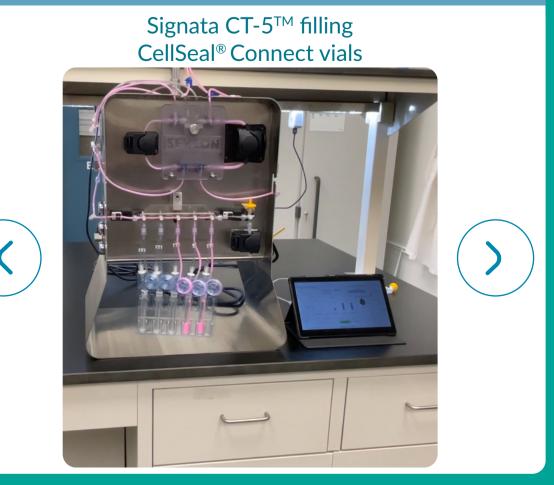
CellSeal® Connect provides a scalable solution to enable true automation-readiness.



Moving from open to fully closed systems is the key to efficiency, compliance, and scalability.



#### **Product images**



#### Learn more about CellSeal® Connect

CellSeal® Connect - Closed-vial filling and retrieval for CGT manufacturing

#### **Further reading**

How to prepare early for regulatory submissions from IND to BLA

Navigating current standards and compliance for cell and gene therapy (CGT) storage containers



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