

# The development and evolution of final containers for cell and gene therapies

## Considerations for final containers



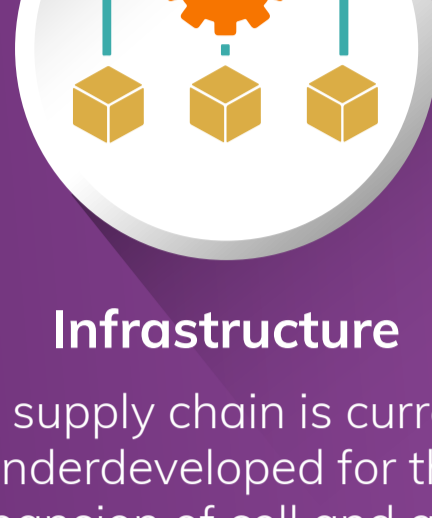
### Preserving integrity

Effective containment requires maintaining sterility and reducing particulates, leachables and air bubbles.



### Highly sensitive

Cell therapy products are metabolically sensitive to environmental conditions such as temperature.



### Infrastructure

The supply chain is currently underdeveloped for the expansion of cell and gene therapies.



### Costly products

Cell and gene therapies are highly costly products which amplifies the risk of supply chain errors.

These considerations shape the design of the final container for cell and gene therapies

## How have final containers evolved to address these considerations?

### Pros

### Cons

Inexpensive

### Cryogenic straws

Unviable for cell and gene therapies

Low barrier to entry

### Screw-cap vials

Unsuitable for industrial upscaling

Not hermetically sealed

Questionable GMP-compliance

Closed system

Safe for cryogenic temperatures

Low barrier to entry

### Closed vials

Volume constraints greater than 50 mL

Require dedicated filling equipment

Allow for larger volumes

Legacy product from the blood industry

Well understood

### Cryo Bags

Susceptible to fracture

Potentially high particulate generation

Challenges with high throughput and automation

Specifically designed for cell and gene therapies

Appropriate for low throughput through to full-scale automation

Closed-system solution

### CellSeal™ Cryovials

Limited to small volumes

Rigid container resistant to fracture

Volume range that meets current criteria for approved therapies

Appropriate for low throughput through to large-scale manufacturing

### CellSeal™ CryoCase

New to the industry

## Specificity

As the field of cell and gene therapies expands, different design principles for final containers are being developed.

These are departing from common designs in favor of increasingly cell and gene therapy-specific final containers.

### CellSeal™ CryoCase

### CellSeal™ Cryovials

### Cryo Bags

### Closed vials

### Screw-cap vials

### Cryogenic straws