

# How can we ensure downstream success in cell and gene therapy?

Using high quality reagents that will perform well is critical to clinical success and product approval. Incorporating these early in development clears the path of major downstream hurdles.

There are a few aspects to consider, but the most important considerations are the following:

1

## Regulatory requirements

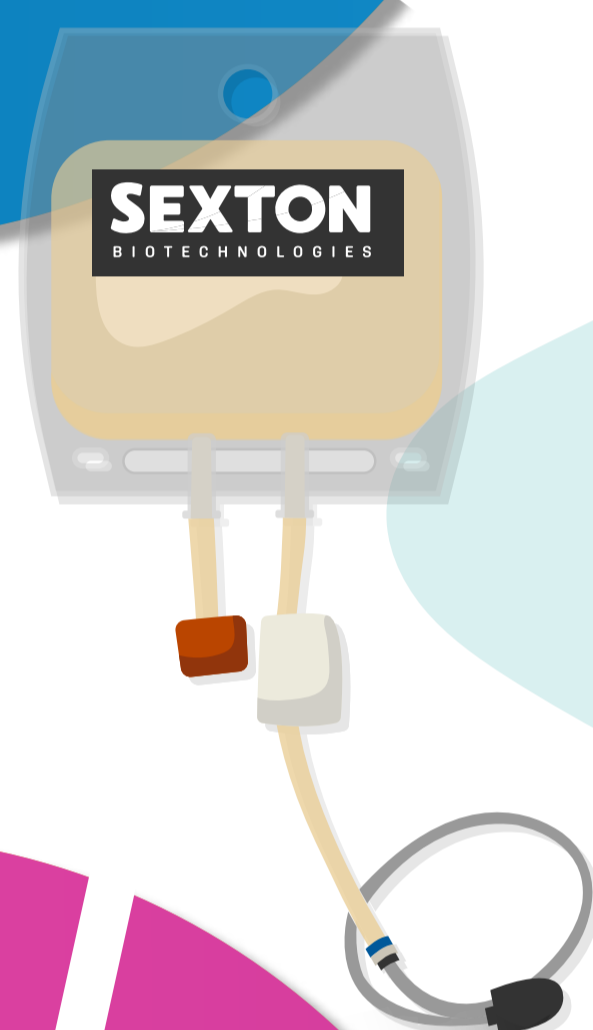
- USP/EP/JP/etc.
- Traceability
- Safety testing



2

## Quality

- Critical attributes
- Incoming quality control
- Supplier control



3

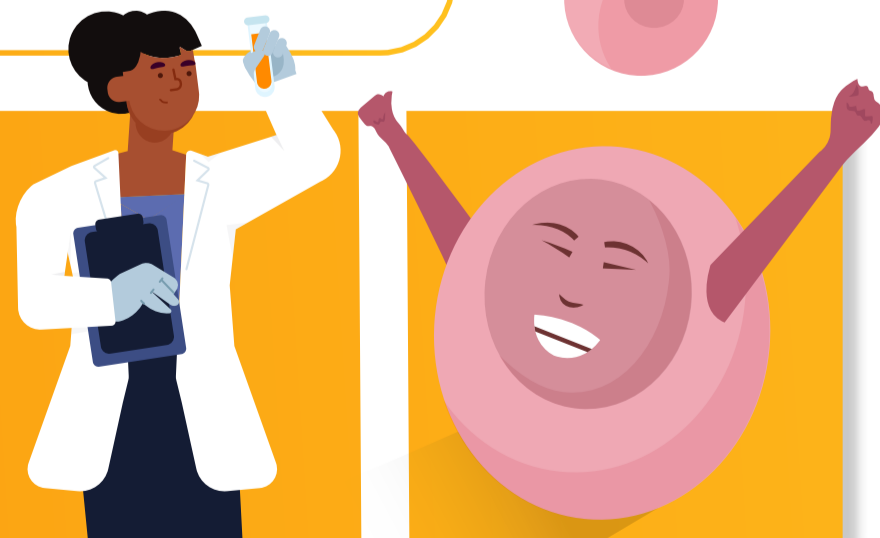
## Performance

- Optimizing for purpose
- Reliability and reproducibility
- Backed by data

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## Supplier

- Supports audits and regulatory reviews
- Understands customer needs
- Solid product support



While high quality ancillary materials are often neglected during early stages of development due to perceived cost, the expensive cost of conversion at late-stages can be prohibitive and detrimental to program success.

How and where to source reagents is a key to consistency and safety of final product.