





## "Demystifying the Gene Therapy Process"

Friday, June25th 2021 • 10am PST



Speaker Series #62521
Keith Sutton, PhD, Charles River Laboratories
Introduction & Summary Slide for:
"Demystifying the Gene Therapy Process"

## An Overview of what to expect in this talk:

- Understanding the roadmap for getting a Gene Therapy to the clinic
- Approaches to address the potential liabilities of Gene Therapies
- Outline of the Regulatory phase
- The challenges of CMC for Gene Therapies





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**Keith Sutton, PhD- Charles River Laboratories** FINAL HIGHLIGHTS:

"Demystifying the Gene Therapy Process"

## **Key Take-aways**

- There are strategies to manage the challenges of developing a Gene Therapy
- The importance of having clearly defined decisionmaking points
- The regulatory expectations for Gene Therapies although still evolving, are established
- ➤ The complexities of manufacturing Gene Therapies require an early engagement with the CMC challenges

