MANUFACTURERS FACE MANY CHALLENGES AT DIFFERENT STAGES:

- Process Development:
  - A complex process
  - Limited initial analysis
  - Lack of validated test plans
  - BIosqs can lead to the final clinical compound stabilization

- Safety Testing & Vector Characterization:
  - A complex analysis of the manufacturing process
  - Effects on the target tissue can lead to final clinical compound stabilization

- Regulatory:
  - A complex process that leads to the final clinical compound stabilization
  - Lack of compliance with all regulatory requirements
  - Risk of non-compliance with all regulatory requirements
  - Risk of non-compliance with all regulatory requirements

GET GENE THERAPY MANUFACTURING RIGHT BY FOLLOWING THESE KEY STEPS:

1. Source raw materials from peer-reviewed and validated suppliers
2. Design a risk-assessment approach using a strategy
3. Monitor product quality, safety, purity, and regulatory requirements
4. Develop a quality assurance system

WHAT TO EXPECT IN THE FUTURE:

- Advances in gene therapy manufacturing
- Improved regulatory guidelines
- Replacement of in vivo vectors with viral vector substrates

LEARN MORE

- Work to keep up with us!
- Visit the Merck website
- Visit the Pfizer website

MANUFACTURING
- Gene Therapy
- Process Development
- Safety Testing & Vector Characterization
- Regulatory

SOURCES
- Biotherapeutics
- Cytokine Therapy
- Gene Therapy
- Immune-Modulating Drugs
- Solid Tumor Therapy
- Liver and Skeletal Muscle Therapy

Gene Therapy:
- Overcoming the biggest hurdles in manufacturing

The gene therapy sector is booming, but our manufacturing timelines are greatly compressed.

Gene Therapy 360

300+
- Activities that may affect gene therapy

Gene Therapy

- Development of better manufacturing methods
- Improvement of universal regulatory guidelines
- Replacement of in vivo vectors with viral vector substrates

500+
- Benefits of new gene therapy developments

>10,000
- New gene therapy products in clinical trials