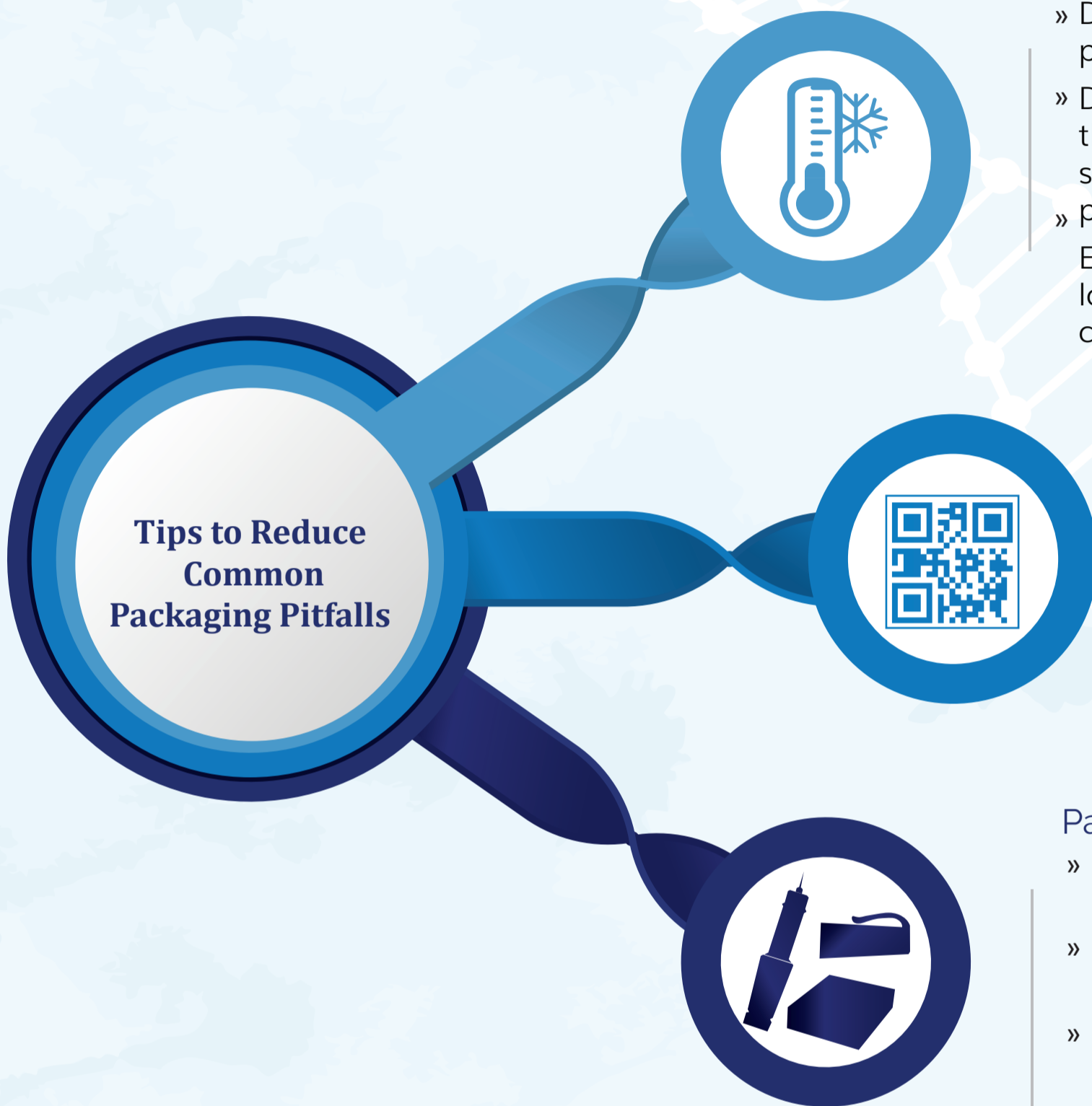


# Tips to Address Common Packaging Pitfalls of Gene Therapy Clinical Programs

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In the fast-paced industry of Gene Therapy, departments need to align to successfully move a program through the clinical phases. As a program progresses to phase 2 and 3, there are 3 common packaging oversights that could jeopardize the timeline of clinical trials. It is critical for these oversights to be addressed with proper expertise and experience.



## Cold Chain & Shipping Qualification

- » Develop and qualify a cold chain shipping system for up to  $-80^{\circ}\text{C}$
  - » Develop a cold chain shipping platform that supports multiple needs at multiple temperature ranges
- Establish a sustainable source of very low volume, high performing cold chain components

## Traceability

- » Ensure serialization/UDI compliance with DSCSA
- » Develop traceability to an individual patient
- » Use a proven methodology to guarantee accuracy

## Packaging Development

- » Develop and qualify primary and secondary packaging
- Ensure packaging meets regulatory requirements: FDA, Hazmat, DSCSA
- Meet drug requirements: environmental protection, ease of use, thawing functionality
- Account for packaging manufacturing operations: speed and scalability

## Adept Packaging Can Help:

Adept Packaging is the trusted expert for packaging engineering and serialization, providing teams with focused capability through staffing, engineering services, business processes and technology. With wholly-owned operations in the US and Europe, Adept Packaging has experience and expertise from a successful track record of delivering hundreds of projects for over 100 clients.

Within pharmaceuticals and gene therapy Adept has:

- » Developed packaging for hundreds of molecules
  - » Experience from hundreds of traditional pharmaceutical programs
  - » Expertise and foresight from working on phase 3 gene therapy programs
- The most developed program for phase three gene therapy packaging

Contact us today to learn how to avoid these common oversights in your packaging strategy.



Contact us for assistance with your packaging department needs

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