GMP Cytokines FAQ

1. Can I use PeproGMP® Cytokines for GMP manufacturing of investigational products, and for manufacturing commercial therapeutic products?

   Yes, PeproGMP® Cytokines are intended for use in GMP manufacturing of investigational or marketed clinical products, such as cell therapy, gene therapy, tissue-engineered products, combination products, or other Advanced Therapy Medicinal Products.

   PeproGMP® Cytokines are not, however, therapeutic products or excipients, and hence are not suitable for direct administration to humans. See USP Chapter <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products for more information, or contact PeproTech Technical Support.

2. What is the risk classification for PeproGMP® Cytokines?

   PeproGMP® Cytokines are classified as Tier 2 under USP Chapter <1043>:

   Tier 1: Low-risk, highly qualified materials (therapeutic drug or biologic, medical device)
   Tier 2: Low-risk, well-characterized materials, produced in compliance with GMPs, and intended to be used as ancillary matrials
   Tier 3: Moderate risk, not for use as ancillary materials
   Tier 4: High-risk materials

3. Is the facility where PeproGMP® Cytokines are manufactured GMP-certified by FDA? Has FDA inspected PeproTech? How would my QA department qualify PeproTech and PeproGMP® Cytokines?

   The US FDA does not perform inspections or GMP certification of manufacturing facilities for ancillary reagents. In some countries, the national regulatory authority does inspect and certify GMP manufacturing facilities for all types of products, but FDA GMP inspections are limited to manufacturing facilities for therapeutic products and medical devices.

   PeproGMP® Cytokines are manufactured in accordance with relevant US FDA GMPs, under a rigorous ISO 9001-compliant quality system. All aspects of manufacturing, testing, labeling, and packaging are stringently controlled, validated, and monitored by PeproTech QA. PeproTech provides detailed Certificates of Analysis and Certificates of Origin for all PeproGMP® product lines. SDS documents are also available.

4. Are PeproGMP® Cytokines animal-origin free and human-origin free?

   Yes. Cytokines in the PeproGMP® line are manufactured using defined media, enzymes, and chemicals, none of which are derived from animal or human tissues.

5. Do PeproGMP® Cytokines have the same biological properties as the PeproTech research-grade cytokines I have been using for R&D studies?

   Yes. PeproGMP® Cytokines are functionally equivalent to their research-grade counterparts.

6. How are PeproGMP® Cytokines shipped?

   The products are lyophilized, making them stable at a wide range of temperatures. Shipping is at ambient temperature. Upon request and at an additional cost, these products can be shipped on ice packs or dry ice.