

Early Phase Cell Therapy Product Development: Potency Assays Examples of Application

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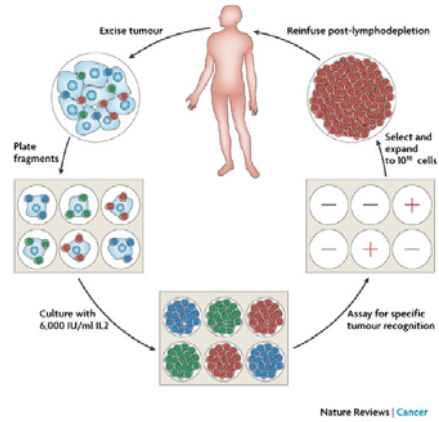
Potency assays in early phase cell therapy product development

Investigational New Drug (IND) Application

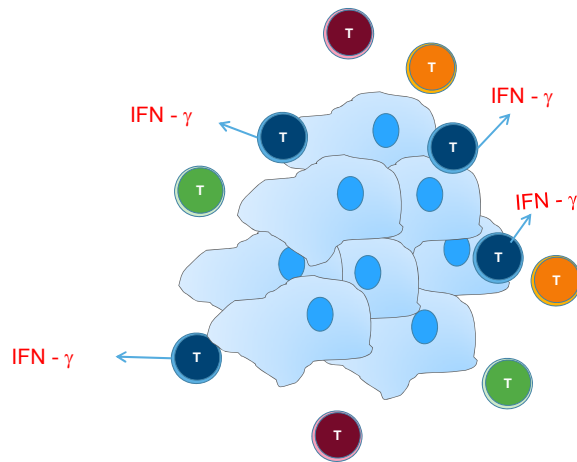
“Submit data to assure the identity, quality, purity, strength, stability of products used during all phases of clinical study.”

- In early phase clinical investigations, it may not be possible to meet all of the requirements for licensed biological products
- The amount of information required will vary with the phase, duration and dosage of the investigation
- Products in pre-clinical, Phase 1 and early Phase 2 studies with limited quantitative information on relevant biological attributes may be sufficient
- Potency assays for early clinical studies are likely to have wider acceptance ranges than assays used in later phase investigations
- Develop and implement potency measurement(s) that quantitatively assess relevant biological product attribute(s) where and when possible
- Implore an incremental approach to the implementation of potency tests

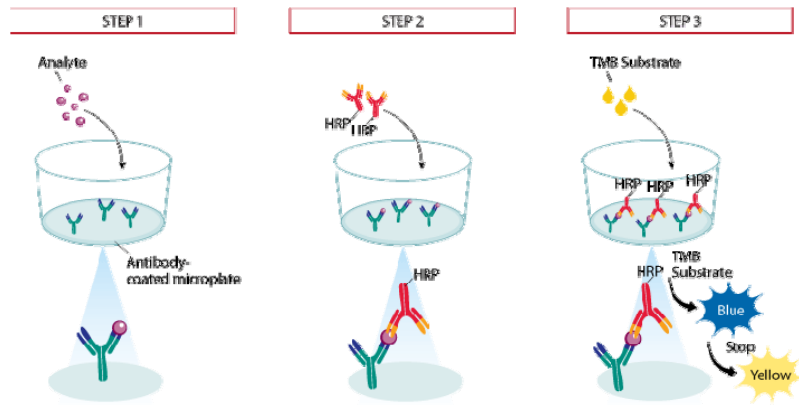
Manufacturing Protocol for Tumor Infiltrating Lymphocytes (TIL)



Mechanism of Action

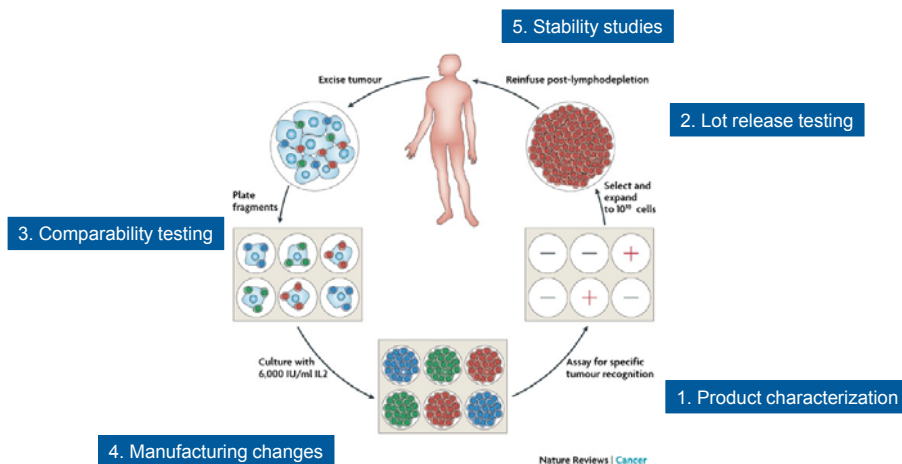


Enzyme-linked Immunosorbent Assay

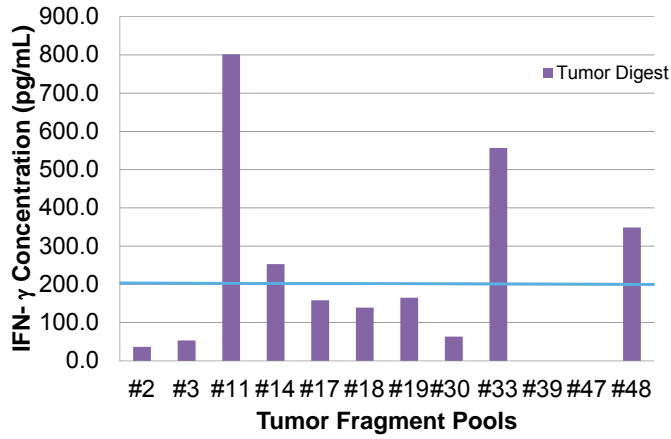


<https://www.rndsystems.com/products/quantikine-colorimetric-sandwich-elisa-assay-principle>

Examples of potency assay application

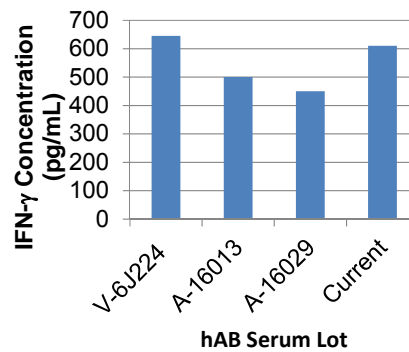
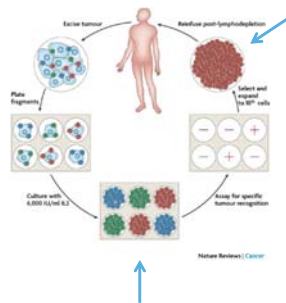


Product Characterization

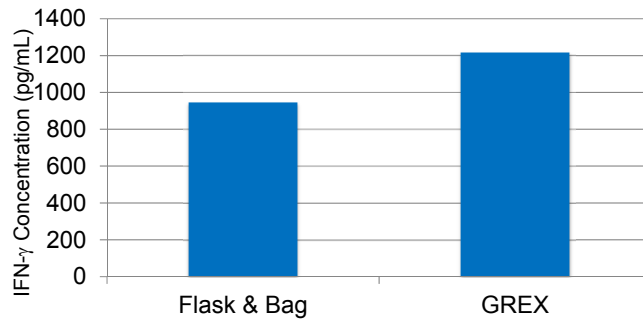
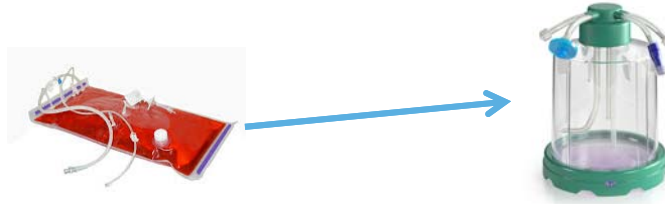


Comparability Testing

Lot-to-lot testing of hAB serum

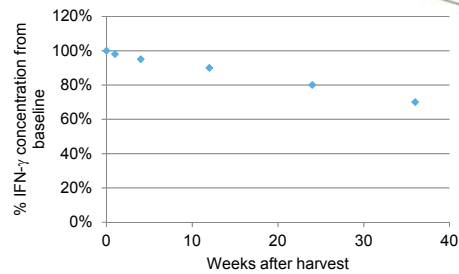


Manufacturing changes



1996 FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products

Stability Studies



Summary

