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Example Target Product Profile (TPP) for a Biological Product

As explained in Creating a Target Product Profile for New Drug Products a TPP is a planning tool introduced by the FDA to streamline the drug development process. NIH SEED has developed the following sample TPP for a biological product. It is intended to be illustrative and demonstrate potential content based on various stages of product development and a summary of the quality characteristics a drug product should possess. An actual TPP would require more detail and be based on thorough scientific, regulatory, and market research.

Sample Target Product Profile for a Biological Product

Product Type: Biologic (mAB)	Indication: Rheumatoid Arthritis	
Attributes	**Minimal Acceptance Criteria**	**Preferred Acceptance Criteria**
Efficacy	50% reduction in disease activity score (DAS28)	70% reduction in disease activity score (DAS28)
Safety & Tolerability	Comparable to existing biologics	Improved profile with fewer adverse events
Route of Administration	Subcutaneous injection	Subcutaneous injection with autoinjector
Dosage Form	Pre-filled syringe	Autoinjector
Dosage Frequency	Bi-weekly	Monthly
Stability & Shelf Life	Requires refrigeration	Stable at room temperature for up to 6 months

Preclinical Studies	
Pharmacodynamics (PD)	Demonstrate target antigen binding and modulation in relevant in vitro and in vivo models.
Pharmacokinetics (PK)	Show efficacy in animal models of arthritis, reducing inflammation and joint damage.
Toxicology	Assess potential immunogenicity within silico and in vitro assays.

Quality	
Critical Quality Attributes (CQAs)	Identifiable physical, chemical, biological, and microbiological attributes within appropriate limits.
Sterility	For products that must be sterile, such as injectables.

Quality	
Manufacturability	Considerations regarding manufacture, scalability, and yield of the production process.
Purity & Impurities Profile	Within appropriate limits for the host cell and manufacturing process.
Formulation	Acceptability of the composition of the drug product.
Immunogenicity	Potential for inducing an immune response within appropriate limits.
Potency	Biological activity within appropriate limits.
Cost of Goods (COGs)	Crucial for commercial viability and includes costs associated with raw materials, manufacturing, quality control, and packaging.

Clinical Trials	
Phase I	Safety, pharmacokinetics, and preliminary efficacy in a small group of patients.
Phase II	Dose-finding studies assessing efficacy markers, such as DAS28, and monitoring for adverse events.
Phase III	Large-scale, multicenter trials comparing the biologic to the standard of care, with long-term efficacy and safety endpoints.

Market Analysis	
Competitive Landscape	Identify areas where current treatments are insufficient (e.g., refractory patients).
Target Population	Stratify the market based on disease severity, previous treatment history, and biomarkers.
Pricing Strategy	Align pricing with clinical value demonstrated and engage with payers early for reimbursement strategies.

Regulatory Guidelines	
FDA/EMA	Compliance with guidelines for developing biologics for rheumatoid arthritis, including demonstrating significant improvement in clinical outcomes.
ICH	Adherence to ICH guidelines for biologics, including Q6B for the characterization of biotechnological products.

Additional examples:

TPP for a Small Molecule Drug
TPP for a Vaccine Product
TPP for a Cell and Gene Therapy Product