

Target Product Profile (TPP) Template

This table provides an example framework for a Target Product Profile (TPP) for mRNA-based therapeutics or vaccines. Complete each section with detailed information to guide development, regulatory planning, and commercialisation.

Section Number	Section Title	Guidance / Placeholders
1	Product Description	Provide a concise overview of the mRNA product, including its intended indication, mechanism of action, and therapeutic rationale.
2	Intended Indication and Clinical Use	Specify the disease or condition targeted, patient population, and anticipated clinical setting.
3	Key Product Attributes	Outline desired characteristics, including: • Efficacy targets (minimum vs. preferred) • Safety and tolerability profile • Dosing regimen and route of administration • Stability and shelf-life requirements • Storage conditions (e.g., cold chain needs)
4	Regulatory Pathway	Describe anticipated regulatory strategy, including target agencies (FDA, EMA, TGA), accelerated pathways, and key submission milestones.
5	Manufacturing and Scalability	Detail production approach, scalability considerations, and ability to meet global demand. Include platform technology and GMP compliance.
6	Intellectual Property Strategy	Summarize current IP position, patents filed or planned, and freedom-to-operate analysis.
7	Commercialisation Strategy	Provide plans for market entry, partnerships, licensing, pricing, and reimbursement.
8	Project Timeline and Milestones	Include major development phases (preclinical, clinical trials, regulatory submissions) and anticipated launch date.
9	Internal Resources and Partner Roles	Identify team members, expertise, infrastructure, and external collaborators with defined roles.



10	Risks and Mitigation Strategies	List potential technical, regulatory, and commercial risks, along with mitigation plans.
11	Detailed Project Budget	Provide a comprehensive budget covering R&D, clinical trials, regulatory, manufacturing, and commercialisation costs. Include funding sources and contingencies.