藥物-Final TPP

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| **No** | **TPP Attributes** | **TPP (產品現狀)** | **可接受範圍(競品分析)** | **最佳範圍(產品目標)** |
| 1 | Product Description  產品敘述 | Text description • Include type of agent (small molecule, peptide, Ab) • Include proposed target |  |  |
| 2 | Indications and Usage  產品指示用途 | Clinical indication(s) -if more than one, specify lead indication • Intended patient population • Outline clinical development plan |  |  |
| 3 | Clinical Pharmacology  產品臨床藥理特性 | Desired and realistically achievable characteristics • Absorption, distribution, metabolism, excretion • Half-life in plasma or serum • Protein binding • Pharmacological duration of effect • etc. |  |  |
| 4 | Dosage and Administration  產品劑量與使用方法 | Dosing amount, route, frequency, etc. |  |  |
| 5 | Safety & Toxicity  產品安全性及毒性 | Known on-target or off-target predicted safety concerns Desired/achievable therapeutic window |  |  |
| 6 | How Supplied/Storage  保存方式 | Formulation • Estimated shelf life, required storage conditions, etc. |  |  |
| 7 | Financial considerations  財務規劃 | Basic economics: ROI, NPV • Affordability to end user • Cost of goods • Projected pricing • Cost to develop • Partners • Reimbursement |  |  |
| 8 | Intellectual property  智慧財產佈局 | Path forward • Freedom to operate • Patentability |  |  |
| 9 | Regulatory considerations  法規途徑規劃 | Presumed path forward • Eligibility for Orphan drug status, Fast Track, Subpart H • Are there clear precedents |  |  |
| 10 | Competitive Environment  市場現況分析 | Analysis of competition and marketing | | |