藥物-Final TPP

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 andAdministration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 concernsDesired/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　 |