

Outsourcing from the viewpoint of a contract manufacturing organisation

A case study

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Pages
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The mission

- Define the best suited Manufacturing strategy for a start up company engaged in the immune therapy field

The Client's needs

- R&D capabilities in cell culture & processes
- Optimisation & scale up of manufacturing process
- Attached services (formulation, analytical, quality, fill and finish, regulatory affairs...)

- Experienced team
- Location with relevant scientific network
- Trust in the management team

The proposed options

- 1/ Investing in a brand new R&D site
- 2/ Buying an empty shell
- 3/ Buying a small biotech (with relevant setting & experience)
- 4/ Investing in a CMO

Financials

Options	Investment (first 2 years)	First revenues	EV/ CE	Shareholder's value	Shareholder's value creation
1/ Brand new site	2.5	Year 3	1.2	2.3	0.5
2/ Empty shell	2.5	Year 2	1.4	2.7	0.7
3/Biotech Cy	3	Year 1	1.4	4.3	1.3
4/ CMO	1	Year 1	3.1	2.7	1.9

All figures are proportional to the option 4 and based on a 5 year project

Pros & cons of the 4 options

Options	Pros	Cons
1/ Brand new site	Custom made Know-how kept	High investment Possible delays Lowest ROI
2/ Empty shell	Building time Flexibility of design Know-how kept	Remodeling Substantial Capex
3/ Biotech Cy	Potential IP Ready to go Know-how kept	Most expensive Redundancies
4/ CMO	Better financials Reduced operational risks Avoid delays to market Delays (site construction) Lack of effective experience Poor capacity planning	Getting to knowing each others Loss of control

Recommendation: CMO option

- **Corresponding team & experience**
 - Pre-clinical & clinical development & manufacturing for cell culture & therapy
- **Location:**
 - Lyon and its well known pharma & biotech network

First class pharmaceutical site (previously Schering Plough)

Tax benefits (« jeune entreprise innovante »)

- ➔ This led to the creation of  Bio Elpida
Innovative Bio-Pharmaceutical Approaches
- ➔ Lyon (with Benoît Pinteur) in March 2009



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