

Outsourcing Workshop: Hypothetical Case Study

1. You are the External Supply Head for a large US biopharmaceutical company, Wyzer BioPharma, and have just been assigned a monoclonal antibody (mAb) project to outsource, due to lack of internal capacity.
2. The objective is to deliver clinical supplies for Phase 1 clinical trials of a mAb (*Curemumab*), and submit an Investigational New Drug (IND) application in a 15-month time frame.
3. You have a budget of M\$8 and 2 Full-Time Equivalent (FTEs), including Process, Analytical, Quality, Regulatory colleagues and yourself, to get this project off the ground. You only need to outsource the production of the Drug Substance since your company has excess Drug Product capacity. Please refer to the Request for Proposal for more details on deliverables.
4. Assume that both upstream and downstream processes are appropriately developed and are “platform”, and that all the analytical test methods are appropriately developed, and are “platform” except for Identity and Potency. With these assumptions, there is no need to consider process development and analytical methods development activities at the CMO, except for Identity and Potency.
5. Using the tools that have been provided to you in this workshop, you will encounter hypothetical problems during the progression of the contract, and solving /eliminating these problems will help ensure a successful project. Anticipation of the problems and pre-empting them by the appropriate use of risk assessment tools are the much sought after goals.
6. CMO Selection Process: You will be provided 6 CMOs to choose from, with varying profiles, strengths and weaknesses. Select your CMO and justify your choice. The goal is to enable the correct usage of selection process parameters which will be provided to you, so as to expeditiously complete the Terms of Contractual Agreement with a CMO, and mitigate problems before they occur. N.B. You have 60 minutes to complete this exercise.