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Biomanufacturing Programmes for Early Phase mAb Development

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Editorial Note: The pipeline of monoclonal antibody and related therapeutics remains strong. Many smaller companies outsource the process development and manufacture of early phase clinical batches to CDMOs. Determining the ideal programme for progressing from drug discovery to GMP production can be a challenge as many firms develop their strategy that incorporate aggressive timelines. Very often they are attempting this before the final stages of drug development are complete. Planning work packages that allow organizations to achieve their IND filing under this level of uncertainty can lead to missed milestones, unexpected costs and a failure to incorporate the medium and long-term objectives for drug development that will maximize the net present value of the biologic.

Fortunately, within the world of monoclonal antibodies it is possible to leverage experiences from successfully developed products to mitigate these risks. Robust programmes can be built around standard work flows for cell line and formulation development, process establishments, transfers, analytical method qualification and GMP manufacture that will work perfectly for a wide range of mAb molecules and have been designed to enable process fit within a mAb-dedicated, single-use facility. Individual project needs, such as the supply of material during development, can then be anticipated by managers with experience of running multiple early phase mAb programmes.

Conclusion: Biopharmaceutical companies attempting to plan their early phase mAb development programme face can be challenged by considerable technological, financial and commercial uncertainties. The solution is to leverage prior experience of similar mAb-programmes using workflows from CLD to GMP then IND submission that have been designed from the ground up to navigate uncertainties and risks to ensure critical milestones are successfully achieved.

Keywords: monoclonal antibodies, bispecifics, FC-fusion proteins, early phase development, CDMO

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