Piramal
Pharma Solutions

FAST TRACK ADC DEVELOPMENT

A client requested the manufacture of an ADC for Toxicology studies to support IND filing within 14 weeks of technology transfer start. The conjugation process had been developed by an external CRO.

PROBLEM

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APPLICATION

Upon receipt of the technical information from the customer the data was immediately reviewed and a list of knowledge gaps and targeted improvements wrt scalability was written. After a technical assessment a number of key development areas were targeted for this particular project:

- Process solution shelf-lives
- Reaction time windows
- Filtration requirements and throughputs
- Increase in process productivity (linked to cost benefits upon scale-up)
- TFF clearance data and loading
- Control strategy wrt an excipient present in ADC formulation with introduction of a new in-process test

In parallel to the above development activities, equipment, raw materials and consumables were specified and ordered early to enable delivery in time for manufacture.

All the areas of development highlighted led to modification of the original process transferred, which were incorporated and tested in a pre-TOX intermediate scale batch, confirming the improvements, ahead of the actual toxicology batch manufacture.

Manufacture of the Toxicology batch was carried out in Piramal Process Development batch, incorporating all the knowledge gained and using the same in-process controls as would be used in our GMP environment. All product quality were met and the revised process is suitable for future scale-ups.

OUTCOME

Within 12 weeks Piramal successfully manufactured to specifications 40 grams of ADC to enable the in-vivo studies to take place as per customer schedule. Within the same period some key aspects of the process have been modified and the learning has been incorporated into the Toxicology batch manufacture. The improved process is suitable for GMP manufacture.

Piramal Pharma Solutions is a contract development and manufacturing organization (CDMO), offering end-to-end development and manufacturing solutions across the drug life cycle. We serve our clients through a globally integrated network of facilities in North America, Europe and Asia. This enables us to offer a comprehensive range of services including Drug Discovery Solutions, Process & Pharmaceutical Development services, Clinical Trial Supplies and Commercial supply of APIs and Finished dosage forms. We also offer specialized services like development and manufacture of Highly Potent APIs, Antibody Drug Conjugation and are well versed in technologies such as Bio-catalysis, Route Scouting etc. Our capability as an integrated service provider & experience with various technologies enables us to serve Innovator and Generic companies worldwide.

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