ALMAC

Partnering to Advance Human Health

Case study

Ensuring excellence in over-encapsulation manufacture amid supply chain challenges

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Maintaining the integrity and efficacy of manufacture of over-encapsulated (OE) comparators across multiple studies is paramount. This case study showcases Almac's commitment to excellence, particularly in the face of unforeseen supply chain disruptions.

Background and initial scope

Our client was a US-based small biotech company who were in late phase clinical trials with a small molecule antibiotic drug. Almac had performed an OE manufacture to supply of the drug product for the client for the first stage of the trial. However, an additional manufacturing run was required to support further work, and an issue arose with sourcing the drug. For the initial manufacture, a branded comparator was used, which had become unavailable in the intervening period. A delay in the clinical trial would have had a significant impact on all stakeholders, with an estimated cost of $100,000 a week. Almac's drug sourcing team performed an extensive market review to try and source the original brand, but it was not possible to obtain the required volumes. An alternative supplier was identified, but work was needed to demonstrate that this alternative formulation would be suitable for use in trials.

The initial OE manufacture encompassed all standard items, including comparative dissolution, method validation, and stability studies. The analytical team had a comprehensive understanding of the analytical methods and the testing profile of the OE material.

The technical team conducted a review, and whilst the excipient list appeared comparable, the change in manufacturer necessitated additional analytical scrutiny to ensure the continued suitability of the OE manufacture for its intended purpose.

Expanded scope and methodology

This new scope of work involved a comprehensive assessment of the existing OE dissolution method with the new formulation to ensure that the excipient composition had not adversely affected the OE formulation. A repeat of the comparative dissolution was conducted to verify that the F2 similarity factor remained unaffected by the formulation change. The data was compared to that of the commercial material and the original OE manufacture, and it was deemed that the material was suitable for use in clinical trials.

Technical discussions were held regarding the necessity of generating additional stability data. It was subsequently deemed unnecessary, provided that sufficient justification could be derived from the F2 data generated.

Following the thorough dissolution assessment, the OE manufacture was analysed under the previous release specification to confirm that there were no issues with any other key quality

attributes, such as chemical and microbial purity. As these tests returned results within the required specification limits, no investigational work in these areas was required.

Collaboration and communication

The success of the project was contingent upon exceptional communication between the customer and Almac's analytical team, particularly given the time-sensitive nature of the formulation change. Almac's drug sourcing and analytical teams worked closely with the client to respond promptly to new information, assessing multiple vendors for the supply of the drug for the additional campaign.

Proactive measures and results

The potential impact on the client was significant, with delays costing approximately $100,000 per week. Therefore, manufacture needed to commence at the earliest available opportunity. The teams communicated effectively to identify a drug source that was similar in composition, readily available in sufficient quantities and with adequate shelf life to support the clinical trial.

Conclusion

The importance of a cohesive and proactive team in situations like these cannot be overstated. Representatives from sourcing, manufacture, analytical, QA, and QP collaborated at every stage to align stringent GMP requirements with the clients' ambitious timelines. This case study highlights the critical role of effective communication and meticulous planning in overcoming supply chain challenges whilst ensuring the continued excellence of OE manufacture.

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