ALMAC

Partnering to Advance Human Health

Case Study

Bespoke fully automated packaging solution helps secure success of Global Phase III Mega Trial

Once drug manufacturers have established key findings from Phase I and Phase II studies, such as safe dosage, side effects and patient response to new therapeutic interventions, it's time to move on to a Phase III trial. Seeking to compare the new drugs to standard treatments already available on the market, Phase III studies can involve thousands of patients, across multiple clinical sites and across multiple global locations.

This brings with it several supply and demand-based challenges. One of these challenges relates to packaging and, more specifically, the design, materials, operating forecasts and equipment needed to effectively and compliantly process and package clinical supplies. Mega trials, involving more than 10,000 patients, take these challenges to the next level.

For one of the world's biggest, global pharmaceutical companies, rising to these challenges was essential to ensure the success of its Phase III clinical trial. This meant packaging a forecasted 3,000,000 injector pens over a five-year period, whilst managing peaks in patient recruitment by packing over 100,000 injector pens per month.

But with such a large-scale project, and unique set of requirements, it soon became clear that a bespoke solution was needed. Enlisting the support of Almac Clinical Services, processes were soon in place to meet the demands of this crucial Phase III study.

The business challenge:

Weighing up the risks of complexity and scale

Given the scale and complexity of this Phase III clinical trial, the client was faced with a number of packaging challenges that required close scrutiny by Almac before the most appropriate approach could be defined.

The study's protocol dictated the need for a large volume of labels. These labels would need to be accurately printed and applied to packaging and would require inspection by both Label Control operatives and Quality Control personnel each month. Despite being a necessary process, this level of manual intervention would bring with it cost and time implications.

Due to the global nature of the study, multi-country labels were required to ensure compliance with an array of country-specific regulations, whilst being readable to patients in their native languages. Additionally, multiple teams would be needed to physically label and assemble patient kits. Given the five-year period, personnel costs presented a significant investment factor.

Further challenges for the sponsor relating to packaging design included the need for a dosing window inspection, which was a requirement on each injector pen. Medication numbered supplies were also required, as was tamper evidence for the cartons that would house the pens.

The Almac solution:

Embracing packaging automation to promote precision, agility and cost-efficiency

After reviewing the client's requirements, Almac's packaging experts recommended that the optimum solution would involve the manufacture of a bespoke, fully automated and validated processing line. The line would be capable of achieving an output of 100,000 pens per month and would offer a number of cost and efficiency benefits to the client.

Bringing together experts from Almac's in-house Engineering Services, Information Services (IS), Production, Validation, Business Projects and Business Development teams, Almac quickly developed a production strategy to quickly deliver on the client's requirements.

Given the need to commence packaging activity quickly to meet the initial phase of kits required, Almac recommended that an interim semi-automated solution be utilised, while the design, build and validation of the fully automated line was underway.

In the interim, a semi-automated packaging line was developed by Almac and involved the use of modified label applicators to apply labels to injector pens and cartons. A number of features were introduced to optimise the kit design and to ensure blinding was safeguarded during the transfer between the semi and fully automated processes. Initial features included integrated tamper evidence within the carton design and carton dividers for ease of assembly.

While packaging was underway using the semi-automated method, Almac worked with the client to develop the optimal solution: a fully automated label print and packaging line that would support the client through the duration of its Phase III study. Modifications were made by Almac's in-house engineering teams to support the fully automated packaging line. The engineering team incorporated a specially made rotatory device to accommodate the irregular shape of the injector pens. Vision systems were also introduced to the machines. This provided verification of the dosing information and verbal information printed on the pen and carton labels.

Launched early in the study, the fully automated solution replaced the interim semi-automated process, with design features that included:

- A robotic loading arm for individual placement of pens into the carousel.
- An orientation mechanism to ensure correct placement of each pen.
- A vision system to provide verification of dosing information.
- An automatic rejection mechanism, in the event of failure.
- Variable information printed at point of label application.
- A label applicator employed with capability to apply a long wrap around label to accommodate multiple languages.
- A label applicator employed with capability to apply a carton label uniformly to maintain blinding throughout the process.
- Automatic verification of variable information on the pen and carton labels – reducing the need for visual checks, as the line is fully validated.
- Configuration of a line able to process one medication number at a time - eliminating the risk of miscompilation.

The client results:

Facilitating a seamless supply to patients

Several benefits were realised, following Almac's development of a fully automated packaging process. The new line could produce kits three times as quickly as the semi-automated method, ensuring a rapid response to changes in monthly demand.

The team size was also reduced from four operatives to two, which had a significant effect on the associated costs of production, without compromising quality standards.

Further cost and time savings were derived from the integration of label printing into the line. The need for Label Control to manually print and inspect, and Quality Control to verify labels ahead of production operations, were eliminated – streamlining the process for maximum efficiency.

Manual label application can heighten the risk of unblinding issues occurring. In this trial, blinding was successfully safeguarded throughout the transfer from the semi to fully automated packaging process, with the use of automation providing precise and consistent label placement during each phase. The vision system was also programmed to detect variations outside of the set tolerances, resulting in a one-hundred percent success rate for meeting the study's blinding criteria.

Ultimately, through Almac's intervention and by combining a short-term strategy to meet immediate need with an innovative, automated approach to best serve the long-term objectives of the study, an optimised packaging operation was achieved. As such, the client's packaging strategy was delivered, demanding monthly forecasts were met and a seamless supply of drugs provided to patients.

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