ALMAC

Partnering to Advance Human Health

Q&A

Rapid Launch Services

Addressing Your Commercial Product Launch Needs

What is Rapid Launch?

Rapid Launch, as the name suggests, is an expedited commercial product launch service provided by Almac, where product is typically packed, released and shipped to wholesalers within 24 to 48 hours, following FDA approval. Within this service the critical path activities are planned, managed and completed to ensure the shortest possible commercial launch window is achieved.

The experience of the Almac team means that we are able to work with our clients to develop a tailored launch solution for their commercial product. Through this process we are able to customize each launch in order to meet the needs of our clients, their product and most importantly, their patients. A cross functional project team is assembled and tasked with executing the specific items that feed into a Rapid Launch.

When would a product need to use Rapid Launch?

All commercial pharmaceutical products can benefit from a Rapid Launch, but the majority of the products that have been launched via the Almac Rapid Launch service are high value orphan drug products which, when launched, can potentially make a huge difference to the lives of a patient population.

What are the benefits of using Rapid Launch?

The main benefits are:

a) The product, which is most often life-changing, can be made available to patients in an expedited timeframe. The reduction in time may only be a matter of weeks, however this can make a huge difference to lives of the patients.
b) The timeframe taken to recognize revenue from your first commercial sales is significantly reduced, with a return on investment delivered quicker.
c) Market needs are met quicker coupling your documented FDA commercial approval to an almost immediate availability of commercial product.

With the finalization of content and layout of printed materials typically happening prior to FDA approval, what steps do you take to ensure artwork is finalised and printed within such a short timeframe?

Our dedicated in-house Packaging Design team will be on standby to make any changes or updates required to product component artwork. This can be completed instantly, so the files are reviewed and approved by our clients as soon as possible. Once final artwork has been client approved, the components can be sent to our printing partners. We have identified and partnered with a number of strategically located key vendors who can complement our Rapid Launch capabilities. These vendors print and despatch the components required to launch each product, within the required time-frame, ensuring the quality of components are not affected.

In addition to the full Rapid Launch services, Almac can also offer a "print at risk" solution. In this scenario, the printed components are approved by the client and ordered "at risk" i.e. prior to FDA approval. These components are then stored until FDA approval has been received, when the packaging operation will then be completed. Proceeding in this manner removes the procurement of the printed components from the critical path of the Rapid Launch, however, if changes to the text are required by the FDA at approval, any stock will have to be destroyed and superseded with the approved text.

How do you ensure the product is packaged and shipped within the 24-48 hour timeframe?

The experience of the Almac team means that we are able to work with our clients to develop a tailored launch solution for their commercial product. This enables Almac to identify the key activities that will define the critical path for launch. Throughout this process we are able to customize each launch, in order to meet the needs of our clients, their product and most importantly their patients. A cross-functional project team is assembled and tasked with executing the specific items that feed into a Rapid Launch.

How do you overcome the logistical challenges if bulk drug product is manufactured by a third party vendor?

In addition to our US packaging service, Almac also offers a commercial drug product manufacturing service from our UK facility and therefore has a great deal of experience with the movement of bulk drug product. Our logistics team works closely with our clients and their nominated manufacturing sites to ensure that all of the required paperwork is in place, ahead of the first shipment. Every drug product handled by Almac has bespoke distribution and receiving instructions, into which our clients have input, and which capture all requirements in relation to the shipment of the batch, such as paperwork, monitoring requirements and preferred carriers, along with communication channels. Ahead of the first shipment, of both incoming bulk and outgoing finished packs, Almac also works with our clients to complete a supply chain risk assessment and can assist with the design and qualification of the chosen shipment method/format. These activities are completed as far in advance of the launch as possible, to remove them from the critical path. This ensures that both the bulk drug product and finished goods can be despatched as soon as they are available.

How do you keep communication channels open between the client and all involved with such a short launch time-frame?

One of the first stages of any Almac-led project is the completion of a responsibilities and communication matrix. The matrix defines key roles and responsibilities, as well as contact details for each team member. A framework for regular interaction and client governance is implemented as a project is scoped. A comprehensive project plan, specifying key deliverables and timelines, is also agreed up-front. In doing so, this allows our clients to align their own internal resources, to deliver and approve each of the expedited activities. The project plan drives weekly calls, which become daily, and then even hourly, as the launch approaches. We also recommend that our clients are onsite during the final stages of the launch to expedite and approve any changes needed.

What processes do you use prior to FDA approval to ensure the rapid launch of the drug product?

Our Rapid Launch service is made possible by Almac's robust standardized procedures, which have been developed and put into practice by an experienced multi-disciplinary team of subject matter experts, from Project Management, QA, QC, Packaging Design, through to Production and Logistics. These procedures, along with strong project management, enable Almac to complete the launch activities within a 24-48 hour timeframe, from FDA approval. At Almac we are renowned for our proactive approach and customized solutions to meet the rapid launch needs of our clients, which is imperative, as each client, and their product is unique, presenting each of their own challenges.

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