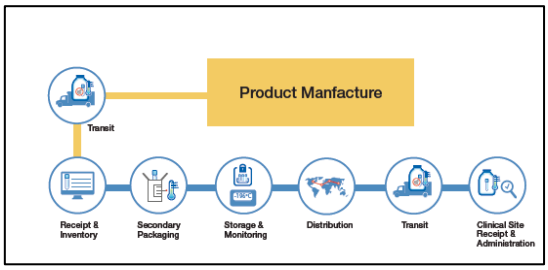
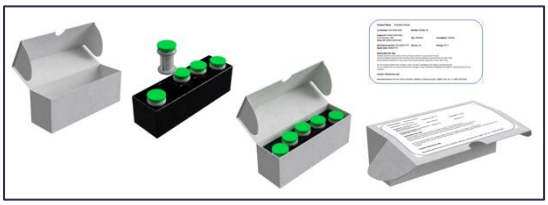
Just in Time delivery of ATMPs - Late-stage customisation of packaging and labelling

The Challenge

Much of the discussion in the ATMP industry today focuses on the complexity of manufacturing and the often-unique characteristics of each dose. The ultimate success of ATMPs though also relies on the ability to deliver a viable, potent product to the patient. Ensuring this living drug is delivered to the right patient at the right time, location, and temperature is essential to patient safety and product efficacy. Having an effective, robust and responsive supply chain is critical to achieving this goal.



Regulation places strict requirements on packaging and labelling of ATMPs, the complexity of which multiplies as manufacturers enter new geographic markets. For example, the European market is one of the most challenging, with each member state requiring labelling and packaging of a product to be in their official language, necessitating the generation of specific pack design and management of packaging components. Through discussion with manufacturers within the ATTC network we identified the following challenges that this presents to an expanding ATMP manufacturer:



- Meeting the required packaging and labelling for each market can result in significant downtime in production cycles whilst relevant specification changes are made.
- Holding stock for specific markets leads to increased inventory holding and management.
- Although stock can be repackaged and redirected to meet urgent demand in a different market, this adds additional operations and complexity.
- The increased risk of wastage due to expiry of stock.

These aspects raise costs for manufacturers and ultimately lower value to patients.

The Solution

Thermo Fisher Scientific has significant experience in packaging and labelling of product for global distribution. Using this specialist knowledge, we have developed a packaging and labelling strategy that addresses the highlighted challenges and utilises late-stage customisation to significantly improve a manufacturer's flexibility and responsiveness.

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Through discussion with the manufacturer, we identify a hierarchy of packaging and labelling modules that cascade from common requirements across all markets through to individual market/patient requirements. The late-stage customisation service uses this hierarchy to assign the modules into those that can be prepared ahead of order receipt and those that require completion post order, but prior to dispatch.

The results

The benefits of late-stage customisation for the manufacturer are:

- **Increased agility and responsiveness** to meeting market and patient requirements with a smaller number of therapy configurations held in stock.
- **Reduced cost of goods**: The use of pre-made packs before customisation removes the need to run smaller batches for each individual market therefore, allowing for larger batch runs, which in turn reduces the unit cost.
- **Minimising storage space** requirements as well as reducing the value of material held in stock.
- **Increased flexibility** on stock usage
- **Reduced wastage** due to minimising risk of stock going out of date.
- **Reduced rework and repackaging** in case of errors or changes in regulations.

Late-stage customisation allows manufacturers to focus more on their core competencies, improving resource efficiency and further lowering costs whilst also enabling them to become more agile.

Making further impact

Late-stage customisation is a significant step towards the creation of a Just-in-time supply chain for the ATMP industry. Just-in-time supply is used to great effect within a broad range of industries, such as Automotive and Fast-Moving Consumer Goods, to reduce costs and improve value.

This work has paved the way for the follow-on activity within the ATTC network to identify and develop additional tools and services to accelerate the adoption of just-in-time delivery across the industry to further increase flexibility and responsiveness, ultimately delivering greater value for the patient.

With thanks to contributing NA-ATTC partners, this work was led Thermo Fisher Scientific.

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