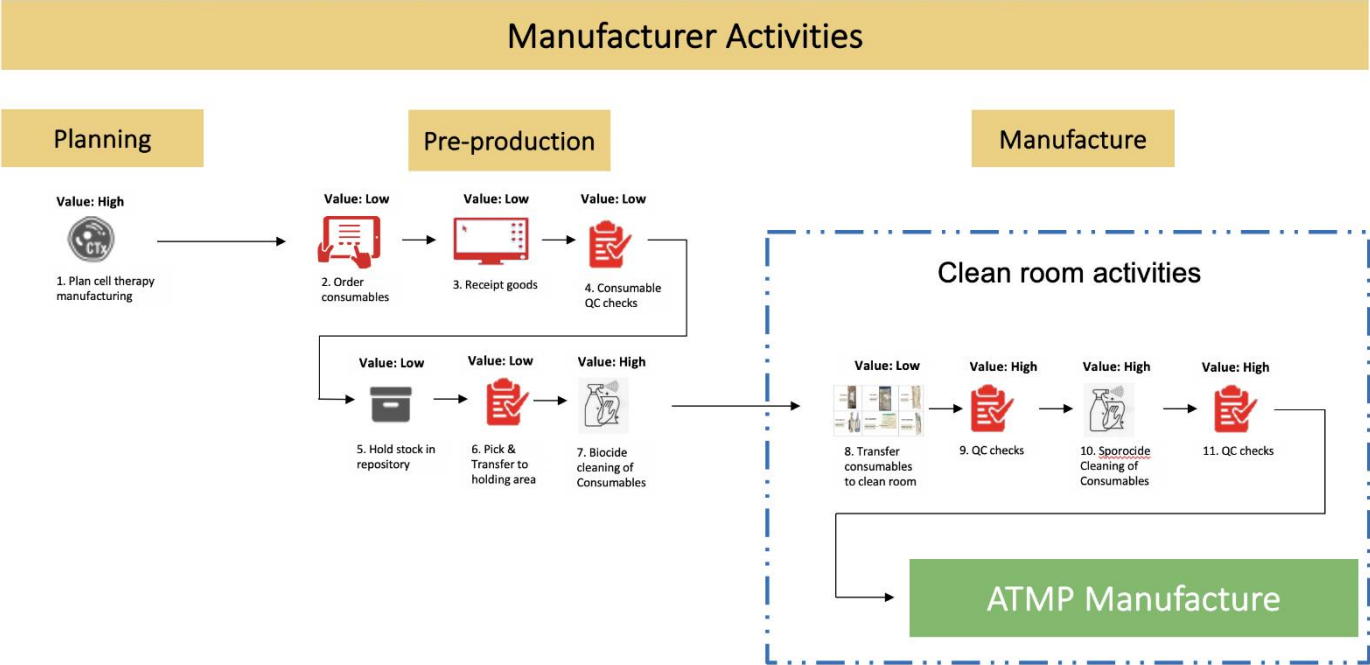


Kitting Services for ATMP Manufacturers

The challenge

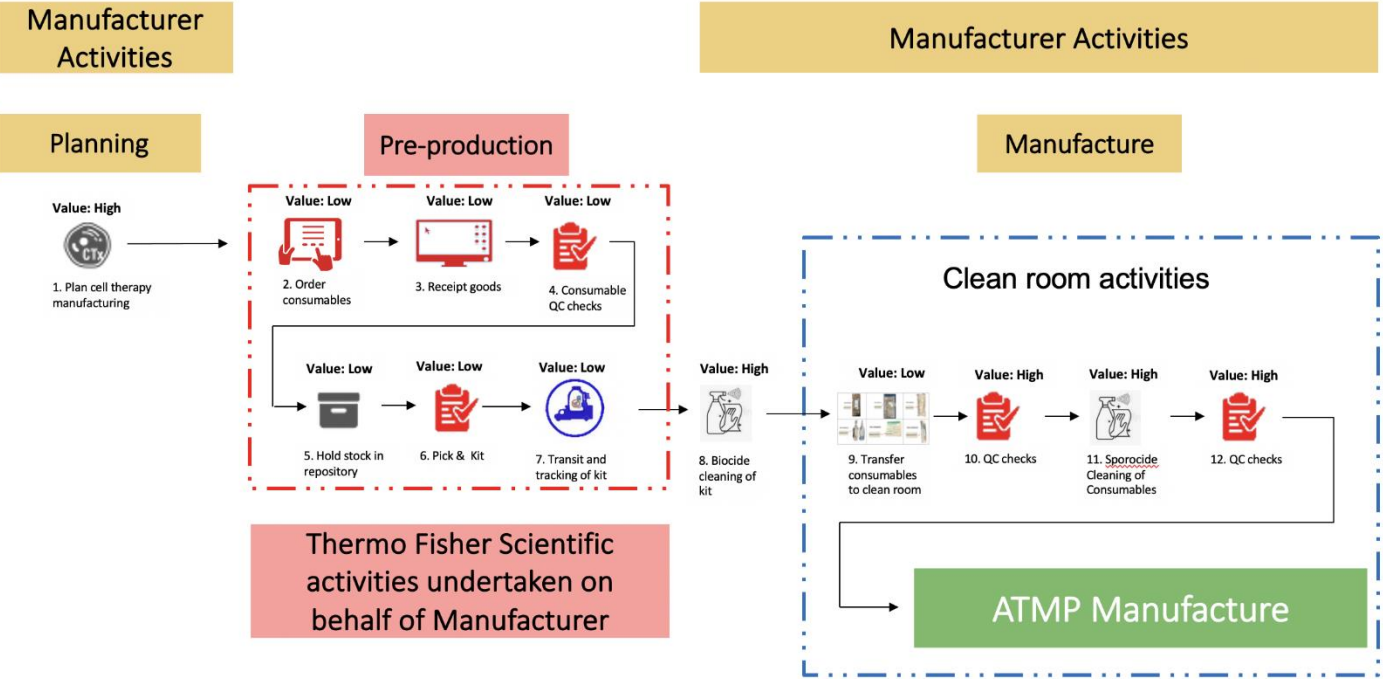
Through discussion with ATMP manufacturing partners in the MW-ATTC, including Orbsen, Rexgenero and University of Birmingham, Thermo Fisher Scientific recognised that the issue of pre-production consumable management and storing would become a growing issue for manufacturers as they increase their output, moving from clinical trials to commercial scale up.

Manufacturers use significant labour resource during the pre-production phase to undertake a wide range of tasks including; procuring, receipting, storing, maintaining, collecting, cleaning, labelling and QC checking of consumables used in the manufacturing process. Each ATMP run may consist of up to 100 individual items, each having to be cross referenced to a specific 'pick list'. Although these activities are critical, they are of relatively low value compared to the core manufacturing activities. This combined with the storage space required for consumables, which can account for over 90% of inventory, has a significant impact on the efficiency and cost of the operation.



The solution

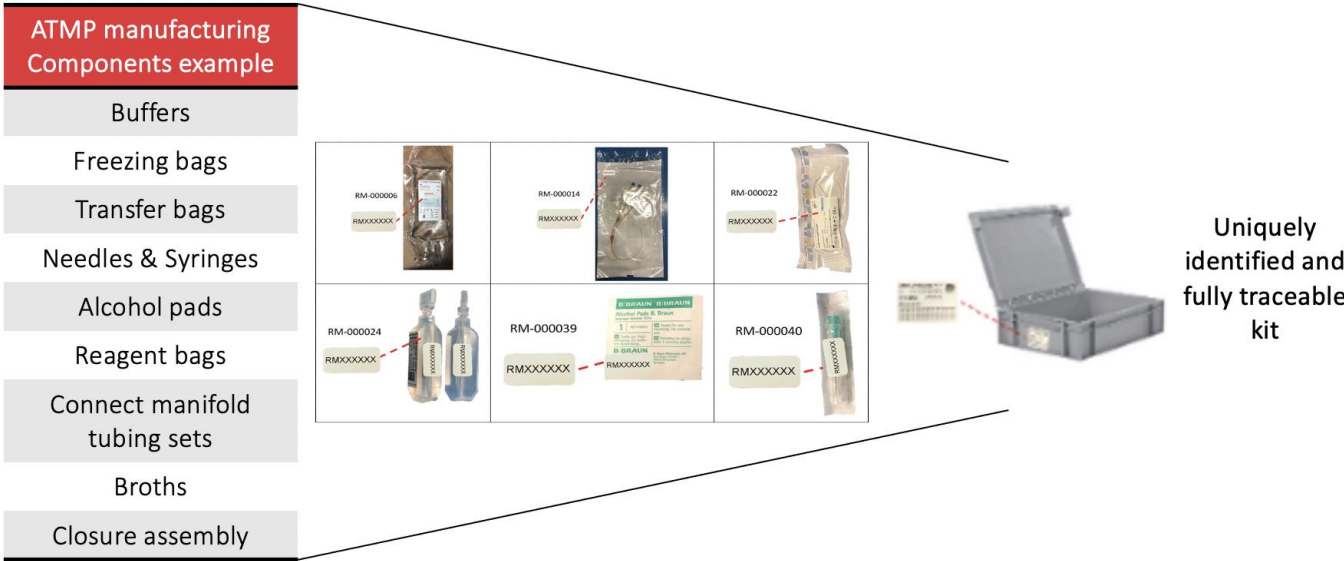
Thermo Fisher Scientific is a world leader in advanced therapy management services including the provision of final manufacturing (import, packaging, labelling, storage, quality release and distribution) of product. It was recognised that this expertise and skill could be used to develop a specialist pre-production service for manufacturers, enabling them to concentrate on their core high-value capabilities.



Third Party Logistics (3PL) is widely used in industries such as food & drink, apparel, and construction, but as yet has little uptake within the ATMP sector. The majority of ATMP manufacturers currently run what is termed “first party logistics” (1PL). This is where an organisation handles all aspects of the entire fulfilment process from order receipt through to dispatch and all activities in between, with the organisation stocking and maintaining their own stockroom or warehouse for all their inventory. The MW-ATTC programme, with its extensive and diverse network of organisations provided a unique opportunity to develop and evaluate the benefits that 3PL can bring to the sector.

As part of the MW-ATTC, Thermo Fisher Scientific worked with other partners to develop a 3PL kitting service that addresses manufacturers’ pre-production needs with QC/QA released kits of consumables and raw material labelled and dispatched to manufacturers ahead of ATMP production.

The 3PL kitting service provides inventory management, storage, kitting, and logistics of consumables supply on behalf of ATMP manufacturers. It delivers a fully customisable approach to managing, organising and assembling individually separate but related consumable/ancillary items for manufacturer providing regulatory compliance, logistics management, integrated communications, bespoke kitting and return & disposal.



The individual kits, which can be temperature controlled if required, are tailored to manufacturers' needs and contain all consumables required to carry out a specific step within the manufacturing process i.e. broth bottle, alcohol pads, needles, manifold tubing, transfer bag, interconnecting lines and sterile sample line. All kits are uniquely identified and traceable, removing the need for additional checks of raw material receipt at the manufacturing location.

The results

The 3PL kitting service provides many benefits to ATMP manufacturers:

- It allows manufacturers to concentrate on their core high value activities, maximising utilisation of resources and facilities. From initial modelling we estimate the 3PL kitting service can release around 1,000 hours per annum laboratory technician time back to manufacturing.
- Small manufacturers often have to buy a greater quantity of a particular consumable that required because of minimum order sizes. The Thermo Fisher Scientific 3PL kitting service removes this issue and due to our purchasing volumes often results in lower piece costs. The challenge of managing stock use-by dates along with wastage is also removed.

- Kits are delivered on an as-needs basis, improving the ability to respond to change in manufacturing runs, either timing or output volumes, providing significant flexibility.
- The flexibility of the service also supports long-term scale up with manufacturers not needing to consider the implications of production increases on inventory storage requirements.
- **The 3PL kitting service enables manufacturers to concentrate on their core competencies, improving resource efficiency and lowering costs, whilst also enabling them to become more agile.**

Making further impact

This MW-ATTC project has highlighted how the adoption of 3PL services within the sector can improve efficiency. As a result of this Thermo Fisher Scientific are investing in a clean room at their facility in Bishops Stortford to enable them to deliver sterile kits to manufacturers. This will enable manufacturers to take the kits directly in to their production room without the need for additional sterilisation prior to use, further streamlining the process and reducing costs.

The 3PL approach is now being further developed by the partners of MW-ATTC and the NA-ATTC to evaluate the opportunities and benefits of “just-in-time” delivery of ATMPs to clinics, which are likely to include increased throughput, reduced wastage, lower cost of goods and improved patient value.

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