

Kitting Services for ATMP Manufacturers



 The world leader in serving science



Background

Thermo Fisher Scientific is proud to be a member of the Innovate UK funded Midlands-Wales and Northern Alliance Advanced Therapies Treatment Centres. The network of Advanced Therapies Treatment Centres (ATTCs) has been set up to enable collaboration across industrial and NHS partners to develop ways of working within and across centres that smooths the path to Advanced Therapy Medicinal Products (ATMPs) adoption into routine medical practice and support the dramatic increase in clinical trial activity across the country. They also present an opportunity to place the UK at the forefront of this technology and for the country to be the place to bring these treatments to patients as they move from clinical trial to marketed products.

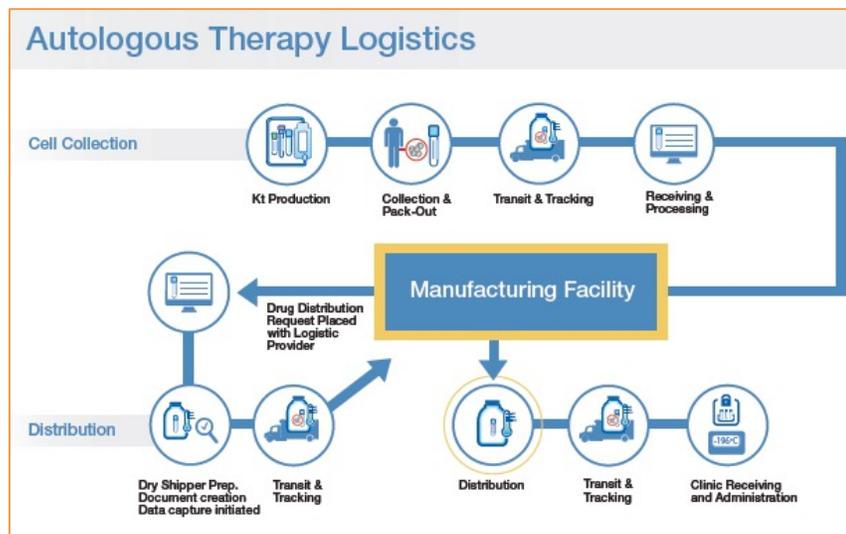
The ATMP industry is rapidly expanding and is predicted to be worth £10bn to the UK economy, supporting 18,000 high value jobs by 2035 (*CGTC Annual Review 2019/20*). Global investment in ATMP development in 2020 totalled \$19.9bn (Alliance for Regenerative Medicine Annual Report 2020) with manufacture of approximately 100m ATMP doses forecast by 2025 (*Phacilitate Advanced Therapies Investment Report 2017*).

Critical to delivering this increase is the supply chain which without the introduction of game changing innovations, will not be able to handle the predicted volumes throttling the opportunities presented by ATMPs. The supply chain though has the opportunity to learn from other sectors such as fast-moving consumer goods and the automotive industry to understand the characteristics and benefits of a highly developed and mature supply chain, whilst adapting them to the specific needs of the ATMP sector.



Introduction

Much of the discussion in the cell therapy 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. However, the supply chain is currently complex, labour intensive, organisationally fragmented and geographically spread. Reducing complexity and increasing efficiency of the supply chain will help the scale up of the industry by streamlining processes, improving productivity and reducing costs.



Introduction

Thermo Fisher Scientific is a provider of bio-specimen storage and bio-banking services as well as being a world leader in advanced therapy management services including the provision of final manufacturing (import, packaging, labelling, storage, quality release and distribution) of product. These capabilities have enabled us to identify opportunities to help manufacturers to overcome a range of challenges associated with the move from clinical trial to commercial scale up.

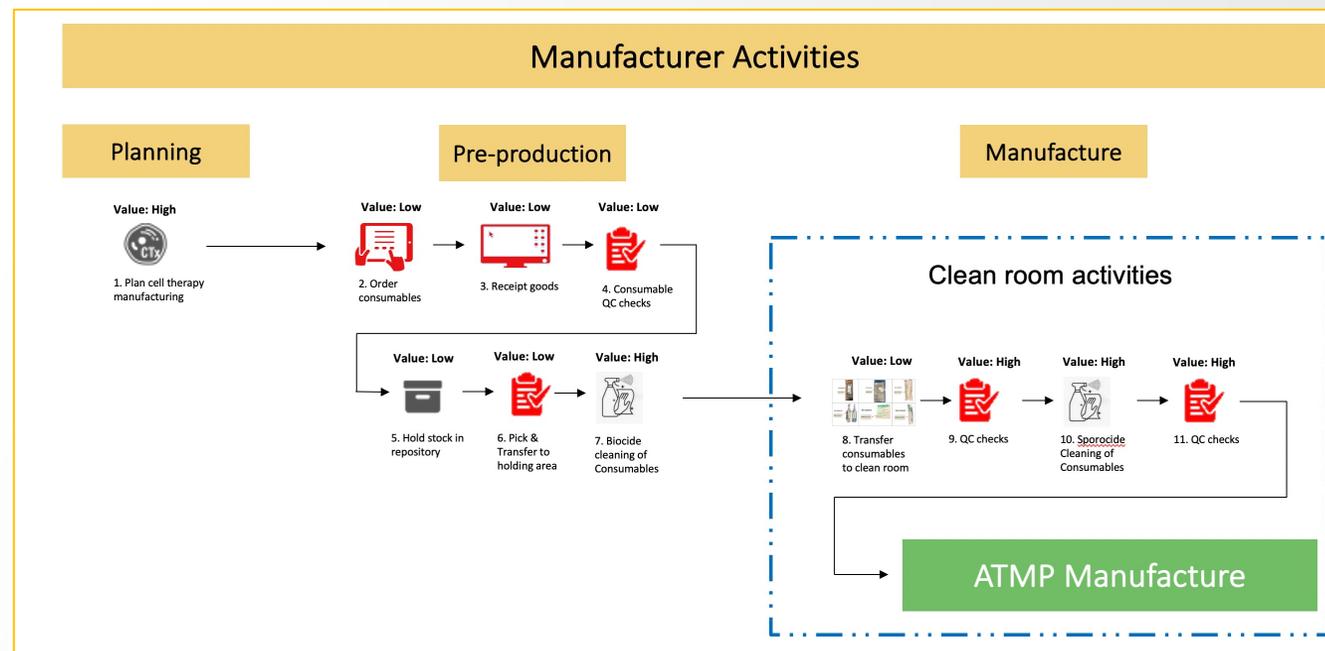
This document sets out one aspect of the development work that Thermo Fisher Scientific has undertaken as part of the ATTC programme to support manufacturers' future scale-up activities, improve their efficiency and enable them to concentrate on their high value core competencies of product manufacturing - 3PL kitting.

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 warehouse for all their inventory. The system is suited to early stage ATMP manufacturers during clinical trials and early commercialisation where production volumes are small. In the 3PL model an organisation outsources some or all of its logistics and warehousing activities to a third party enabling the organisation to concentrate on its core activities. The primary benefits of using a 3PL service to handle warehousing, fulfilment, packaging and distribution, are cost savings and flexibility allowing organisations to scale more easily, released from the need to house increasing levels of stock on their own site.

The Challenge of managing production consumables

Through discussion with manufacturers across the ATTC network, we recognised that the issue of pre-production consumable management and storage would become a growing issue as they commercialise and increase their output.

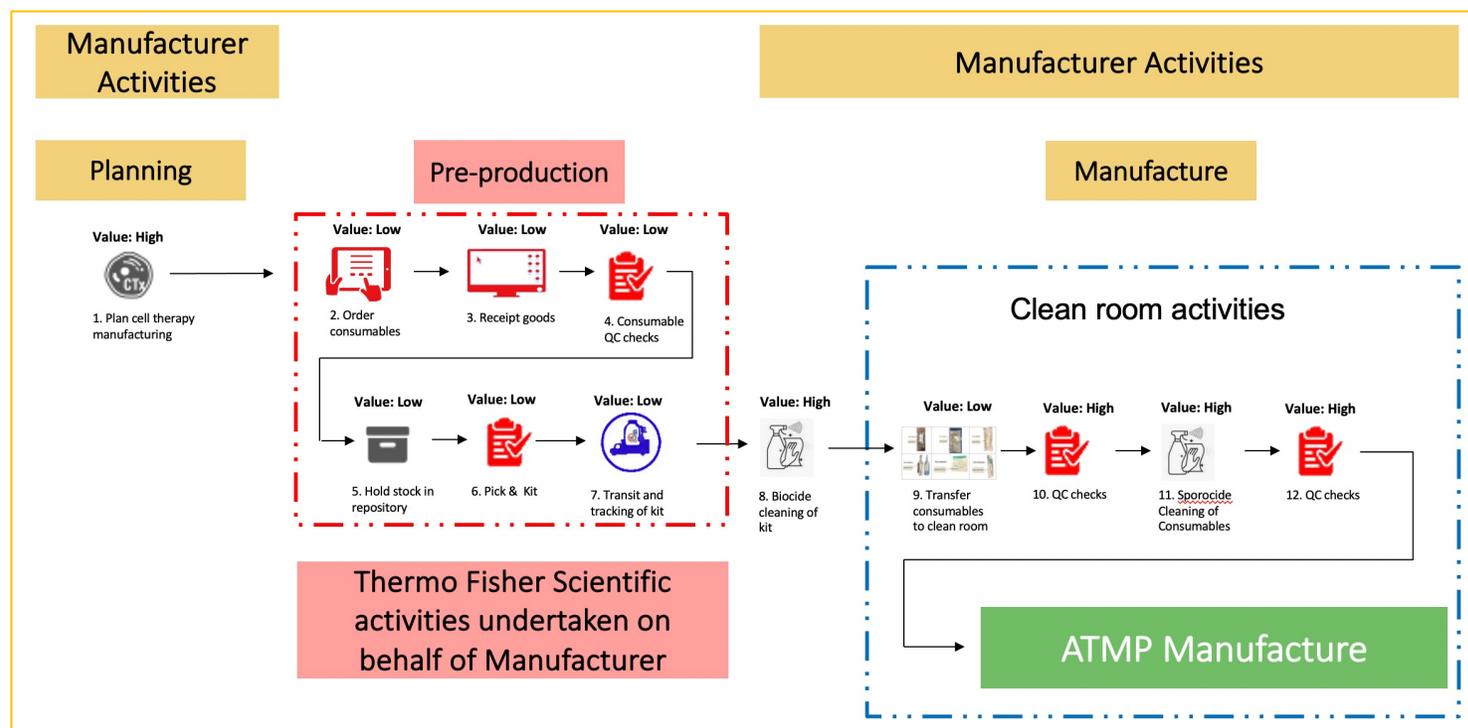
Manufacturers use significant labour resource during the pre-production phase to undertake a wide range of tasks including; procuring, receipting, storing, maintaining, collecting, cleaning, labelling and QC checking of consumables used in the manufacturing process. Each ATMP run may consist of up to 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.



3PL Kitting Service

As a secondary manufacturer Thermo Fisher Scientific has significant experience in the procurement, management of consumables and post-manufacture kit production. We recognised that we could use this expertise to develop a specialist service for manufacturers where we manage low value consumable related activities enabling them to concentrate on their core capabilities.

We have used our capabilities 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 as required. All kits are uniquely identified and traceable, removing the need for additional checks of raw material receipt at the manufacturing location.

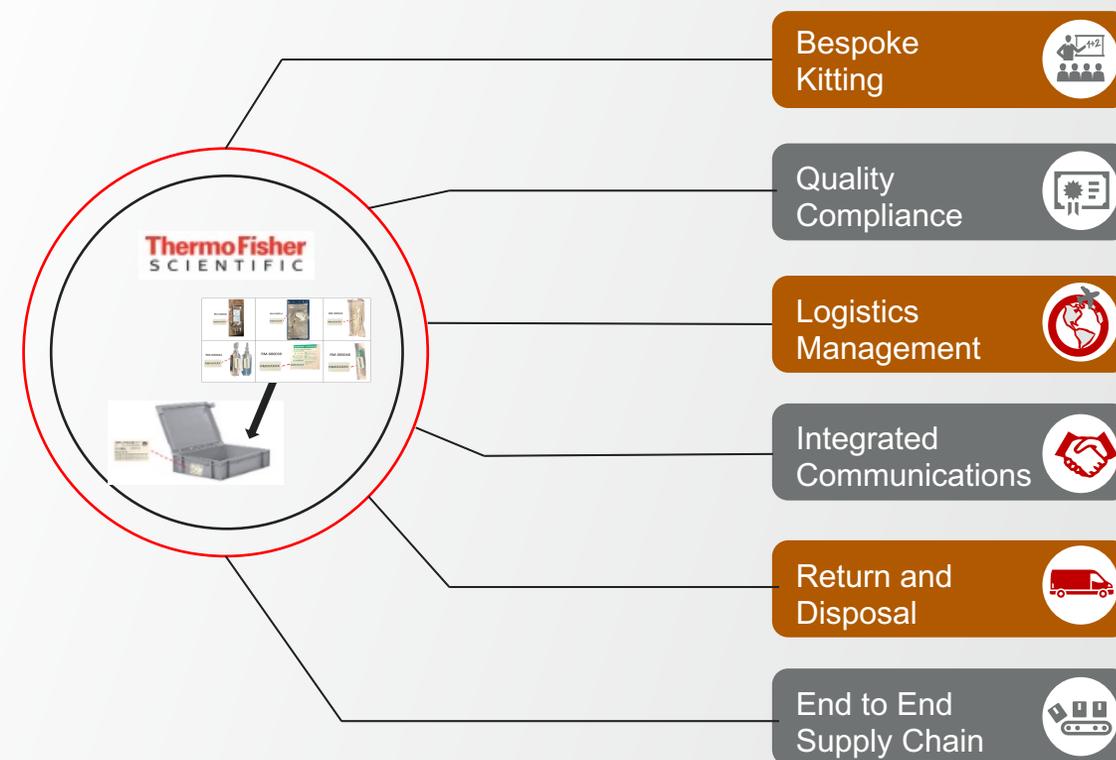


3PL Kitting Service

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

We tailor the service to individual manufacturer's needs through an initial planning and set up phase which brings the manufacturer together with our development, operations, QA, QC, dispatch, goods-in and project management teams to:

- Ideation
- Process map
- Value map
- Leading to
- Process development
- Inventory management system update
- Develop change control
- Creation of bill of materials master data
- Inventory space planning
- Training guides



Benefits

The 3PL kitting service 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 of laboratory technician time back to manufacturing.

Small manufacturers often have to buy a greater quantity of a particular consumable than is required because of minimum order sizes. Our 3PL kitting services 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, able 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.

FAQs

Q: How does it work?

A: An agreement between client and Thermo Fisher is obtained to manage and store ancillary/consumable items and package into kits that can be used throughout various stages in the manufacturing process

Q: What kind of ancillary/consumables items can be kitted together?

A: Anything that is related to carrying out a specific step within the manufacturing process i.e. broth bottle, alcohol pads, needles, manifold tubing, transfer bag, interconnecting lines and sterile sample lines.

Q: Can Thermo Fisher put together sterile 3PL kits?

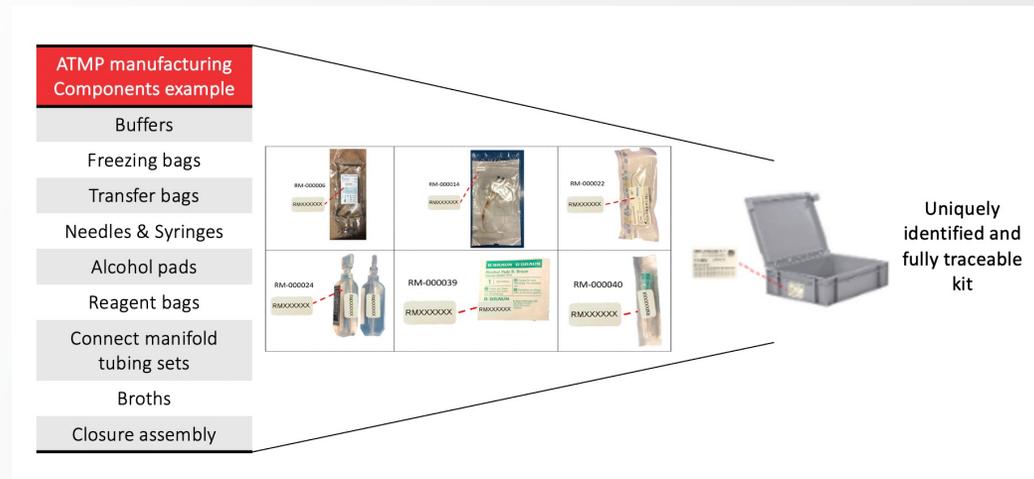
A: We are currently working on expanding our offering to include sterile kitting

Q: What is the lead time for 3PL kitting?

A: 3PL lead times can be agreed based on client forecasted requirements. This can be in the form of a fixed/variable number of kits required per week/month and called off accordingly

Q: Can temperature controlled material be included in kits?

A: Yes, we can include starting material that requires temperature control in the range from 2-8C through to cryopreserved.



About Thermo Fisher Scientific

With unwavering commitment to service, science and process engineering, Thermo Fisher Scientific is powered by people with an exceptional commitment to quality, deeply instilled ethics of personal responsibility and unrivalled expertise.

Thermo Fisher Scientific is the world leader in serving science, with revenues of more than \$24 billion and approximately 70,000 employees globally. Our mission is to enable our customers to make the world healthier, cleaner and safer. We help our customers accelerate life sciences research, solve complex analytical challenges, improve patient diagnostics, deliver medicines to market and increase laboratory productivity. Through our premier brands—Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific and Unity Lab Services—we offer an unmatched combination of innovative technologies, purchasing convenience and comprehensive services.

As the leading service provider to the cell and gene therapy community, Thermo Fisher Scientific, is uniquely positioned with the experience, resources, and global expertise to support our customers on their path towards commercialization. Our global infrastructure enables customers to seamlessly conduct clinical trials across multiple geographies while providing patients around the world with access to life changing therapies. Our cryogenic storage and logistics, combined with proven components and validated procedures, allow us to configure and replicate each site to meet the specific requirements of individual clinical trials with minimal variation, regardless of volume or geographic location. This is supported by a global comprehensive and integrated Quality System based on regulatory requirements, industry best practices and highly trained personnel.

About Advanced Therapy Treatment Centres

The ATTC network is a world-first, national system of Advanced Therapy Treatment Centres operating within the NHS framework and coordinated by the Cell and Gene Therapy Catapult to address the unique and complex challenges of bringing pioneering ATMPs to patients.

The centres include:

- Innovate Manchester Advanced Therapy Centre Hub (iMATCH)
- Midlands-Wales Advanced Therapy Treatment Centre (MW-ATTC, comprising Birmingham, Bristol, Cardiff, Leicester, Nottingham, Swansea, Oxford and Cambridge)
- Northern Alliance Advanced Therapies Treatment Centre (NA-ATTC, comprising Edinburgh Glasgow, Leeds and Newcastle)

The CGT Catapult is playing a central coordination role for the network and provide support to manufacturing, supply chain logistics, regulatory affairs, clinical trial capability, R&D support and upskilling via specialist training and development.

The network is supported by the UK Research and Innovation's Industrial Strategy Challenge Fund.

Funded by



Coordinated by





ThermoFisher
S C I E N T I F I C

The world leader in serving science