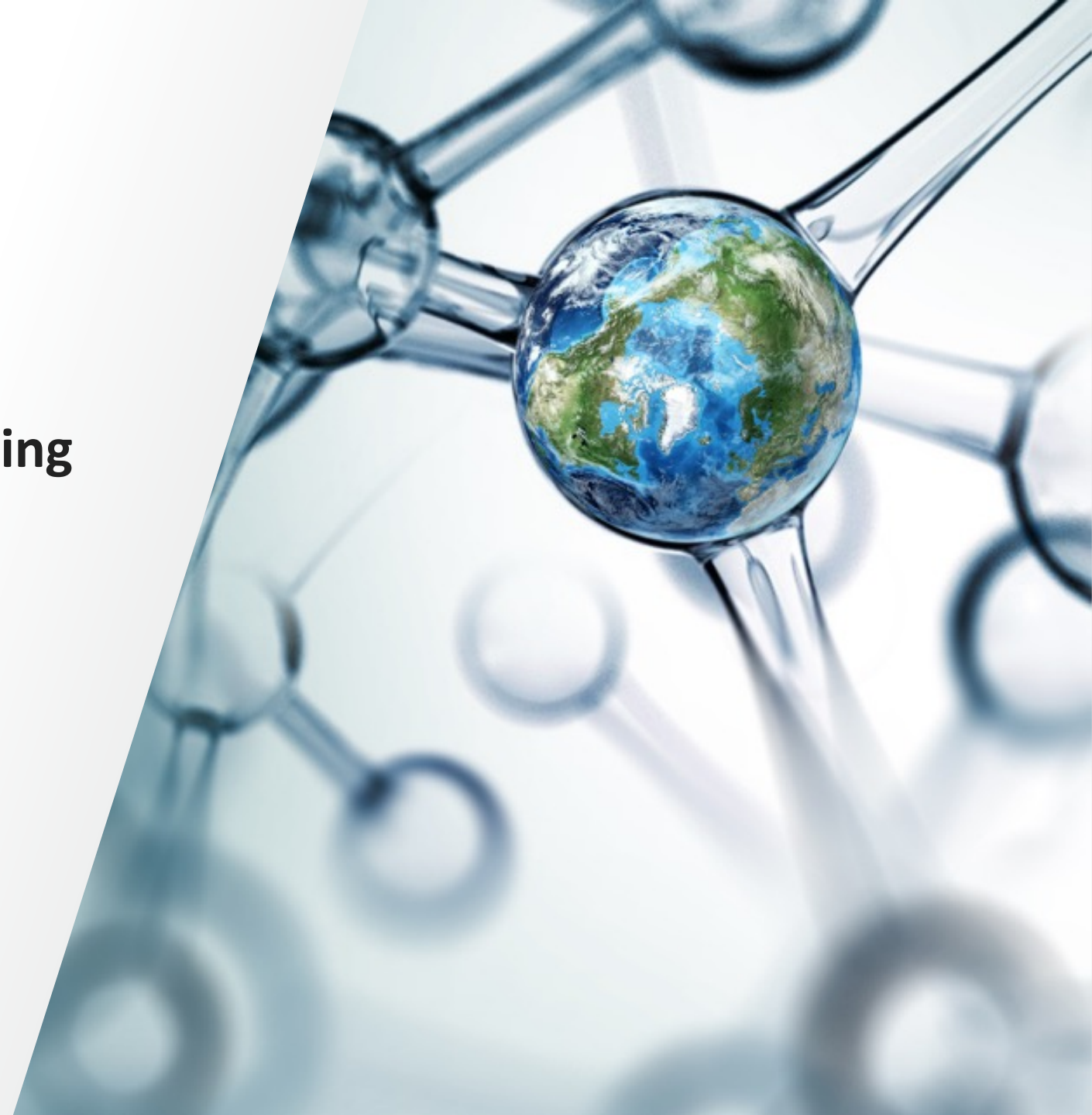


Just in Time delivery of ATMPs - Late-stage customisation of packaging and labelling



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Background

Thermo Fisher Scientific is proud to be a member of the Innovate UK funded Northern Alliance Advanced Therapies Treatment Centre. 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 testing 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 expansion is the continual development of the supply chain to ensure that the significant increase in volumes can be delivered in an efficient and responsive manner

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.

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 responsiveness in meeting the growing market needs.



The Challenge of Packaging and Labelling for Multiple Markets

Regulation places strict requirements on the 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 to launch a product into, 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.

This can present significant challenges to an expanding ATMP manufacturer:

The need to produce the correct 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 stock holding and management.

The risk of wastage due to stock going out of date before use increases.

Although stock can be repackaged to meet the need in a different market this adds additional operations and complexity, leading to higher costs.



Late-Stage Customisation

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 ATMP manufacturers to address the highlighted challenges of packaging and labelling, whilst also meeting the growing need for market flexibility and responsiveness.

Through consultation with a range of manufacturers within the ATTC network we have developed a late-stage customisation process to address the challenges. The process allows manufacturers to customise product labelling for markets and patients quickly post order receipt without having to stock individual packaging components for each possible variant. In consultation 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 split the modules into those that can be prepared ahead of order receipt and those that require completion post order, i.e., at a late stage in the process.

As an example of this module hierarchy:

Pre order receipt - Regionalised preparation: Multiple market languages, creating a specific region, can be applied to packaging to meet those collective market requirements and can be done ahead of order receipt.

Post order receipt - Market specific: Once the order is received the late-stage customisation of the market specific requirements such as Blue Box information and reimbursement labels and can be applied.

Working with the Manufacturer

Using our global knowledge of market requirements, we work with the manufacturer to tailor the service to their needs. The process includes bringing the manufacturer together with our development, QP, operations, QA, QC, dispatch, goods-in and project management teams to:

- Ideation
- Packaging and labelling hierarchy mapping
- Value map

Leading on to:

- Process development
- Develop change control
- Inventory management system update
- Label content and design
- Creation of templates for rapid personalisation
- Creation of training guides

Late-Stage Customisation Benefits

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

- **Increased flexibility** on stock usage and presents the ability to respond more rapidly to variable patient and market 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.
- **Reduced wastage** due to stock going out of date.
- **Reduced rework and repackaging** in case of errors or changes in regulations.

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

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 (FMCG), to reduce costs and improve value. Further work within the ATTC network, led by Thermo Fisher Scientific, will identify and develop additional tools and services to accelerate the adoption of just-in-time across the industry to deliver further increases in flexibility and responsiveness.

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.

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