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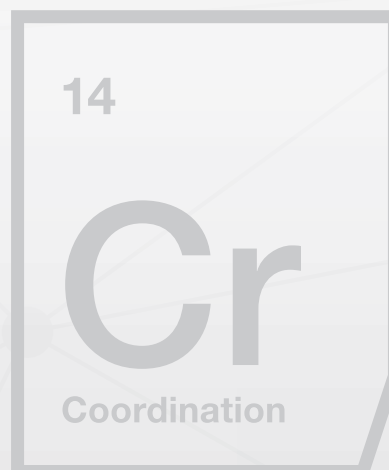
Clinical trials

Global reach, biotech speed: Clinical packaging & labeling that deliver

Ensuring speed, flexibility, and security for biotech innovation

Contents

Global reach, biotech speed: Clinical packaging & labeling that deliver	3
Finding the right balance: Infrastructure with biotech flexibility	4
Core capabilities: Designed for efficiency and compliance	4-5
Solving key challenges in biotech clinical packaging and labeling	6
A partner in clinical packaging and labeling solutions	7



Global reach, biotech speed: Clinical packaging & labeling that deliver

Ensuring speed, flexibility, and security for biotech innovation

Emerging biotech companies are driving transformative therapies, but the path from discovery to commercialization presents significant challenges. Many operate under compressed timelines and resource constraints, making it critical to have a clinical packaging and labeling partner that can adapt to shifting requirements while maintaining regulatory integrity and supply chain security.

To support the evolving needs of biotech companies, a clinical packaging and labeling partner must provide solutions that address both immediate operational needs and long-term scalability. **Non-negotiables include:**



Agility across all trial phases.

Early-phase trials require rapid execution and flexible supply strategies, while later-stage studies demand increased scale and consistency. A partner with scalable capabilities ensures seamless transitions from Phase I through commercial launch, minimizing disruptions and optimizing efficiency.



A risk-mitigated supply chain.

Many emerging biotechs lack the infrastructure of larger organizations, making supply chain reliability critical. A well-structured system, backed by highly automated quality controls, safeguards trial continuity by integrating compliance, quality, and speed at every step. Oversight across packaging, labeling, storage, and distribution reduces delays, mitigates compliance risks, and prevents disruptions.



Expert regulatory guidance.

Given the complexity of clinical trial requirements—especially for companies entering global markets—biotech sponsors need a strategic partner with deep industry knowledge to anticipate challenges, proactively mitigate risks, and provide tailored solutions to keep trials on track. For example, Thermo Fisher's experienced project managers help biotech sponsors navigate evolving regulations, coordinate complex supply logistics, and adjust packaging and labeling strategies to maintain trial momentum.

By integrating these capabilities, biotech companies can eliminate supply bottlenecks, improve operational efficiency, and accelerate trial execution—bringing life-changing therapies to market faster.

Finding the right balance: Infrastructure with biotech flexibility

For biotech sponsors, the ideal clinical packaging and labeling partner must provide not just global infrastructure, but the speed and flexibility required for fast-moving programs. A provider that is big enough to scale but agile enough to adapt helps ensure trials progress without unnecessary bottlenecks.

Achieving this balance requires:

✓ A seamless transition from Phase I to commercialization with scalable services tailored to evolving trial needs, minimizing the disruptions and delays that often come with switching providers mid-trial

✓ Adaptive solutions that keep studies moving despite protocol changes and shifting regulatory demands

✓ Global regulatory expertise that streamlines approvals and simplifies market entry

With deep industry expertise, an extensive global network, and tailored solutions, the right partner helps biotech sponsors maintain momentum, mitigate risks, and keep trials on track.

Core capabilities: Designed for efficiency and compliance

A strong clinical packaging and labeling strategy is essential for meeting regulatory requirements, optimizing timelines, and ensuring product integrity. Biotech companies need a partner that combines deep expertise, global infrastructure, and advanced technologies to streamline processes and reduce risk.

Thermo Fisher Scientific supports biotech sponsors with an integrated, risk-mitigated approach that enhances speed, flexibility, and compliance at every stage. With fully owned cGMP facilities, digital tracking systems, and patient-centric innovations, Thermo Fisher delivers scalable solutions tailored to the demands of early-phase through late-stage development.

The following key capabilities help biotech companies navigate complex clinical supply challenges with confidence:

In-house label manufacturing

Reliable and efficient label production is essential to clinical trial readiness, ensuring that investigational medicinal products (IMPs) remain compliant and on schedule. In-house label manufacturing provides greater control over production timelines, reduces reliance on third-party suppliers, and enhances regulatory compliance. This approach supports:

- Faster turnaround times by eliminating outsourcing dependencies
- Full regulatory compliance with single-panel, multi-panel, and booklet labels
- Consistency and quality assurance through single-batch control

Regulatory labeling translation services

Global clinical trials require accurate, multi-language labels that meet diverse regulatory standards. Traditional translation and approval processes can introduce bottlenecks, delaying trial initiation. Thermo Fisher's ATLAS (Alternative Translation and Label Approval System) streamlines these processes by integrating automation, regulatory tracking, and a certified phrase library. This system includes:

- Automated translation workflows that significantly shorten approval cycles
- A pre-approved phrase library that reduces regulatory review times
- Integrated compliance tracking for real-time label approval status

Tamper-evident packaging

Protecting the integrity of clinical trial supplies is crucial, particularly for temperature-sensitive and high-value therapies. Traditional adhesive labels can fail under extreme conditions, increasing the risk of compromised security. Thermo Fisher's Tamper Evident Carton safeguards product security throughout the supply chain by providing:

- Built-in tamper evidence that eliminates reliance on adhesive labels, reducing the risk of label failure
- Secure containment for a range of vial sizes from 2R to 20R, ensuring product integrity under various storage conditions
- A sustainable design that eliminates foam and glue, offering an eco-friendly alternative without compromising protection

Cold chain packaging and labeling for sensitive biologics

Strict temperature controls are necessary to preserve the stability and efficacy of biologic and advanced therapies. Improper handling can result in temperature excursions, compromising product integrity and leading to regulatory setbacks. Thermo Fisher's cold chain packaging and labeling solutions help maintain compliance and product quality by supporting a full range of temperature requirements, from 2-8°C refrigeration to ultra-low storage at -80°C and below, and offering:

- Protection against temperature excursions through secondary packaging and labeling at ultra-low temperatures
- Reliable and sustainable shipping with validated, reusable packaging solutions that ensure compliance and reduce environmental impact
- Continuous oversight with end-to-end temperature monitoring, enabling real-time tracking to mitigate risks and maintain regulatory adherence

Prefilled syringes and auto-injectors

Accurate labeling and secure assembly of prefilled syringes and auto-injectors are essential to ensuring patient safety and regulatory compliance. These devices require precise handling to maintain dosing accuracy, product integrity, and sterility throughout the supply chain. Thermo Fisher offers specialized solutions to meet these requirements, including:

- 100% label inspection with high-precision syringe labeling ($\pm 0.5\text{mm}$ accuracy)
- Precision-controlled assembly in temperature-controlled environments to maintain sterility
- A custom syringe tray design that prevents plunger movement during transit, reducing the risk of leakage or contamination

Optimized cycle times

Fast, reliable turnaround times are essential for keeping clinical trials on schedule. By offering scalable capacity and rapid cycle times, Thermo Fisher helps sponsors stay on track—even when unexpected regulatory or drug manufacturing delays occur. Efficient workflows and automation contribute to industry-leading cycle times, helping biotech companies accelerate trial execution while maintaining compliance.

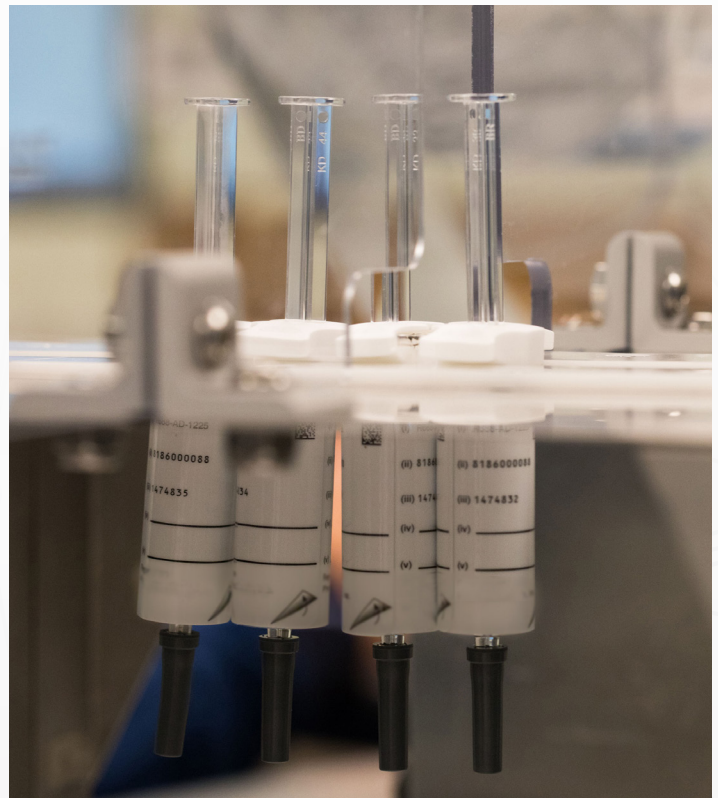
Standard cycle times include:

- Single-panel label production: 5 days
- Bulk booklet manufacturing: 10 days
- Variable print capabilities: 5 days

Smart packaging

Patient adherence is a critical factor in clinical trial success, yet traditional tracking methods can be unreliable. Smart packaging technology integrates real-time monitoring to improve data accuracy and trial outcomes. Features of Thermo Fisher's smart packaging include:

- Passive microcircuit technology to track dosing patterns
- Connectivity with cloud-based platforms for secure data sharing
- Early identification of adherence issues, allowing study teams to intervene proactively



Solving key challenges in biotech clinical packaging and labeling

Biotech companies face a range of challenges in clinical trial packaging and labeling, from regulatory complexities to supply chain constraints. These obstacles can lead to delays, increased costs, and compliance risks if not properly addressed. The following are common industry challenges and ways Thermo Fisher's clinical packaging and labeling solutions can help overcome them.

Challenge 1: Accelerating label approval timelines for global trials

- ❗ **The problem:** A biotech company preparing for a multi-country Phase I trial must comply with multiple regulatory agencies for label translations. Manual review processes delay approvals, pushing back first-patient-in and overall study timelines.
- ✅ **The solution:** Standardized translation approval systems with a certified phrase library can reduce regulatory review cycles by more than 50%, ensuring that clinical trials stay on schedule.

Challenge 2: Mitigating cold chain excursions for temperature-sensitive therapies

- ❗ **The problem:** An advanced therapy sponsor requiring -80°C storage faces risks of label detachment and temperature excursions during packaging and shipping, leading to potential compliance failures.
- ✅ **The solution:** Conducting secondary packaging and labeling at ultra-low temperatures eliminates time-out-of-environment (TOE) risks, ensuring full compliance and product integrity.

Challenge 3: Strengthening product security with tamper-evident packaging

- ❗ **The problem:** A biotech company concerned about label lifting at ultra-low temperatures seeks a more reliable tamper-evident solution to prevent regulatory issues and potential product compromise.
- ✅ **The solution:** Integrating tamper evidence directly into carton packaging eliminates adhesive failure risks, enhancing product security and simplifying regulatory compliance.

Challenge 4: Ensuring just-in-time labeling for fast-moving trials

- ❗ **The problem:** An emerging biotech needs just-in-time labeling for a trial with last-minute protocol changes, but traditional supply models introduce risk.
- ✅ **The solution:** On-demand label printing and regulatory integration ensure agile response to protocol amendments without compromising compliance.

Challenge 5: maintaining supply chain efficiency for global trials

- ❗ **The problem:** A Phase III trial spans multiple continents, requiring consistent packaging, labeling, and distribution across regions with differing regulations.
- ✅ **The solution:** A unified packaging and labeling system with region-specific regulatory oversight ensures compliance and streamlined global distribution.

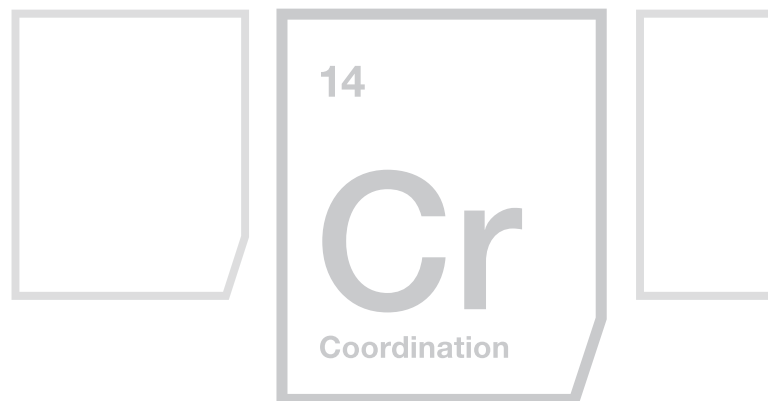


A partner in clinical packaging and labeling solutions

Choosing the right packaging and labeling partner is essential for maintaining trial momentum and ensuring regulatory compliance. For biotech companies, that means a partner with the expertise, flexibility, and global infrastructure to adapt to the industry's evolving needs.

With scalable support across all phases, deep regulatory expertise, and advanced packaging innovations, Thermo Fisher Scientific provides tailored solutions that accelerate trial execution, ensure compliance, and mitigate supply chain risks—helping biotech sponsors bring life-changing therapies to patients faster.

To explore how our clinical packaging and labeling solutions can support your trial, [contact us today](#).



Find your missing element
with Thermo Fisher Scientific.

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