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Clinical Trial Supply 2026

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Building on our world-renowned Clinical Trial Supply conference series, Arena International is proud to present the 2026 edition of the Clinical Trial Supply Handbook. This year's edition delivers timely, practical insight into how organisations can continue to strengthen, future-proof and optimise their clinical trial supply chains in an increasingly complex global environment.

As the industry continues to evolve, new challenges and opportunities are shaping clinical trial supply strategies. Ongoing geopolitical uncertainty, evolving regulatory expectations, and sustained pressure on timelines and costs remain key considerations. At the same time, decentralised and hybrid trial models are becoming more embedded, sustainability is moving from ambition to action, and innovation across digital, data and automation technologies is redefining how supply chains are designed and managed. The rapid growth of advanced therapies, including cell and gene therapies, also continues to demand greater flexibility, resilience and collaboration across the supply ecosystem.

The 2026 handbook explores these developments through in-depth chapters covering key industry themes, including outsourcing and partnership models, technology and innovation, supply and logistics, sustainability, and the future of clinical trial supply operations. Featuring expert insights written by industry leaders alongside specialist analysis, this edition also includes a comprehensive supplier directory, offering readers a trusted, one-stop resource for identifying partners to support their evolving supply chain needs.

With contributions from our valued sponsors and partners, we hope this latest edition provides you with both strategic perspective and practical guidance as you navigate the next phase of clinical trial supply.

Jaz Sidhu, Editor,
Arena International

Clinical Trial Supply Advisory Board

Chris Wallace, Head of Distribution EMEA, Argenx

Chris has over 35 years' varied supply chain experience, having worked for several blue chip companies in a number of industries including 3rd party logistics services, automotive, medical device, nuclear fuels and biotech/pharmaceuticals.

Originally from the UK but now based in Switzerland, he has been involved in life science - biotech/pharmaceuticals & medical device - for over 20 years of his career and has latterly been SVP Global Supply Chain at Clover Biopharmaceutical before last year moving to Argenx as Head of Distribution EMEA.
He has developed, implemented and managed global healthcare supply chain strategies and operations on 6 continents. This has included different set-ups in multiple countries, including many in the Emerging Markets as well as the developed world.

Chris has a degree in economics from Manchester University, an MBA from Aston University and a postgraduate diploma from London University. In his spare time, he plays golf badly and loves to sample great Italian food and red wines!

Luiz Barberini, Head of External Manufacturing Latin America, Bayer

- Over 25 years' experience in Logistics, Supply Chain, Procurement and Demand Planning areas.
- Solid knowledge and experience in the whole S&OP process and its KPI´s inter-relationships with stakeholders
- Demand Planning process management - pre-S&OP, with Sales, Marketing, Trade Marketing, Industrial Planning and Finance and customized tool design for such process
- Management skills: experience with multidisciplinary and international teams (Brazil / Latin America / US).
- Experience in S&OP, 3PL and Supply Chain Organization projects' implementation
- Strong experience with Pharmaceutical and Consumer companies and Brazilian distribution model / 3PL contracts
- Solid team management skills, as well as Customer Service relationship and management
- Teacher for major Post Graduation Schools - Demand Planning and Procurement/Negotiation areas

CSCP & CPIM APICS. Logistics & Supply Chain driven strategy. Distribution & Logistics, Demand Planning, S&OP, Procurement and Export experiences, focusing on Business necessities through effective leadership. Working as External Manufacturing Operations Manager Latin America at Bayer, in charge for external partners for CHC Division. Previously

as Relationship Associated Director at Merck , Logistics Manager at Takeda/Nycomed Pharma, focusing on demand management, planning and distribution activities. Also has worked as Pfizer´s Logistic Manager and EFD´s Supply Chain Manager. Souza Cruz´s Procurement Manager and Rhodia's Logistic Supervisor. Specialties: Logistics, Supply Chain, Materials, Procurement , Services, Negotiation, 3PL contracts, S&OP, Demand Planning.

Amanda Briceno, Clinical Supply Management & Patient Centricity Unit Manager, Chiesi Farmaceutici

Amanda Briceno is an experienced clinical supply professional with over 10 years in clinical research and supply chain operations. Originally from Venezuela, now based in Italy. She currently serves as Clinical Supply Manager and Head of the Patient Centricity Unit at Chiesi Farmaceutici, where she leads initiatives to design and deliver patient-focused clinical supply solutions that improve trial compliance and enhance the experience of both patients and site staff.

Her career began as a Clinical Research Associate at IQVIA, where she gained extensive experience in global trial monitoring and operations. Since joining Chiesi, Amanda has held positions of increasing responsibility within the Clinical Supply department, before assuming her current leadership role.

Amanda holds a Master's degree in Drug Biotechnology from the Università degli Studi di Milano and a Bachelor's degree in Medical Biotechnology. Amanda brings a strong blend of technical knowledge and operational leadership. Passionate about innovation in clinical supplies, she is dedicated to advancing more accessible, patient-centric clinical trials.

Paul Hingst, Supply Chain Consultant, Crinetics Pharmaceuticals

Paul is an experienced Clinical Supply Chain Professional with a 25-year career in the BioPharmaceutical industry.

His extensive career includes roles at major companies like Amgen and Thermo Fisher Scientific, where he honed his skills and made a significant impact. He has served in varied roles from basic research and contract manufacturing to client services and account management. He is a Principal Consultant and Co-Founder of Beacon BioPharm Associates, a clinical supply chain consulting firm, providing variable staffing solutions to small and mid-sized BioPharm clients. Paul is an industry veteran and respected leader known for his expertise in clinical supply chain.

Amaury Jeandrain, VP Market Strategy, N-SIDE

Amaury Jeandrain has a Master's Degree in Business Engineering with a specialization in supply chain optimization. He joined Clinigen in 2015, then N-SIDE in 2016 where he last held the position of VP of Strategy for clinical supply solutions.

Over the past decade, his objective has been to make clinical trial supply chains more efficient by redefining CTS strategies and driving measurable performance improvements. His expertise also includes forecasting, planning, waste reduction, and shortage risk mitigation. Since 2024, while accompanying his wife on humanitarian missions abroad (Niger, then Colombia), Amaury has continued his work as a CTS advisor and trainer, partnering with pharmaceutical companies worldwide to enhance clinical supply performance.

Francesco Santo, Director Clinical Supply Chain, Orano Med

A highly experienced and passionate Director Clinical Supply Chain, Francesco has dedicated the past 17 years to ensuring the seamless execution of clinical trials by optimizing supply chain operations. His deep commitment to this field is driven by a relentless pursuit of excellence in delivering life-saving treatments to patients worldwide. Throughout his career, he has honed a diverse skill set, encompassing:

- Strategic Supply Chain Management
- Regulatory Compliance
- Cross-Functional Collaboration
- Risk Management
- Innovative Problem-Solving

Francesco's dedication to the clinical supplies industry is rooted in a profound understanding of the critical role it plays in advancing medical research and improving patient outcomes. He is committed to continuing his journey in this field, always striving to contribute to the betterment of global health.

Arnaud Dourlens, Global Head Clinical Supply Chain Operations, Sanofi

Arnaud Dourlens is an Arts et Métiers engineer, he began his industrial career in the FMCG sector where he held growing responsibilities. Then he joined the LVMH group where he reorganized new product launches and industrial investments in the Make-up segment in order to adapt to the need for innovation and time to market, thus providing a competitive advantage. He then managed the entire portfolio of industrial launches and investments in Perfumes, Skincare and Make-up for Parfums Christian Dior Group.

During his career Arnaud held a wide variety of industrial roles. He joined Sanofi in 2017 as Production Director of a major solid oral form production site (>2.5 billion € turnover). He has been a key player in the development of the continuous improvement mindset and in the transformation of the site through IT projects, investments and activity growth following the acquisition of Boehringer Ingelheim consumer healthcare portfolio. Since the beginning of 2020, he's been the Global Head of Sanofi Clinical Supply Chain Operations, managing worldwide clinical supply teams involved in more than 300 clinical studies.

Paul Larochelle, Senior Director Global Clinical Supply Chain, Takeda

Paul Larochelle has over 17 years of experience in a variety of positions within Clinical Supplies, including roles in clinical planning, production scheduling and planning, secondary packaging operations management, and business expert for a clinical inventory management system. Paul currently leads a team of Clinical Planning Leads at Takeda and is a member of the Global Clinical Supply Chain (GCSC) Leadership Team. He also oversees Takeda's GCSC Post-PharmD Fellowship Program in partnership with the Massachusetts College of Pharmacy and Health Sciences (MCPHS). Paul's prior organizations include Genzyme/Sanofi and Biogen, supporting therapies across all indications and stages of development.

In addition to his primary responsibilities, Paul served as a coordinator of Pharmacy Industry Fellowships for the Genzyme/Sanofi MCPHS Fellowship Program (2009-2014) and precepted over 50 pharmacy students interested in a career in industry for several schools. He is currently the Chair of the Dean's Advisory Board for MCPHS Boston School of Pharmacy and a member of the Pharmacy Advisory Board for Western New England University. He is also a member of the Clinical Trial Supply Conference Series Advisory Board.

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Outsourcing & Supply Operations

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A Little Story About the Strange Behavior of Dry Ice

Denis Look CEO & Founder of TSafe

Denis Look is the CEO & Founder of TSafe, the temperature critical courier with extensive experience in the field of global shipments of API, IMP and biological and pharmaceutical samples.

For any questions or professional exchange, Denis is happy to be contacted at **denis.look@tsafelogistics.com**

Anyone who has worked with dry ice knows its ghostly chill: it hisses, smokes, and seems to stubbornly stay at –78.5 °C. Yet sometimes a thermometer shows lower values – perhaps –83 °C or even –90 °C.

How can that be, if dry ice "only" sublimates at –78.5 °C? And why do large, old chunks stay cold much longer than fresh pellets?

The answers take us deep into the fascinating world of **thermodynamics** – into the delicate interplay between pressure, energy, and states of matter.

Dry Ice – a Different Kind of Ice

Dry ice is simply the solid form of carbon dioxide (CO_2). Unlike water ice, it does not melt into a liquid when heated. Instead, it goes directly from a solid to a gas. This process is called sublimation.

As long as the surrounding pressure remains constant, sublimation always happens at a very specific temperature.

At normal atmospheric pressure (1 bar), that temperature is –78.5 °C. When dry ice warms up, it turns into gas at exactly that temperature – without ever melting in between.

The key point: the heat energy supplied does not make the ice warmer. It is entirely used to free CO_2 molecules from their solid lattice structure.

That's why the temperature stays constant during sublimation – just as water ice remains at 0 °C while melting.

The Misconception About "–78 Degrees"

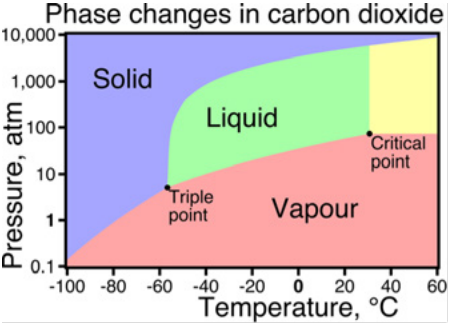
Many people believe dry ice is so cold because it sublimates. In reality, it is the other way around: it sublimates because it's that cold. The temperature is not the result of the sublimation itself – it is determined by the pressure under which it happens.
That distinction may sound subtle, but it is essential: the surrounding pressure defines the temperature at which solid and gaseous CO_2 coexist in balance.
This balance is what gives dry ice its "self-stabilizing" temperature.

How Pressure and Temperature Are Connected

The behavior of carbon dioxide can be shown in a phase diagram – a map of how matter changes with temperature and pressure. It reveals:

- At 5.1 bar and –56.6 °C, we find the triple point, where solid, liquid, and gaseous CO_2 can all exist at once.
- At 1 bar, the sublimation point drops to –78.5 °C.
- At 0.5 bar, it's already around –83 °C.
- And at even lower pressures, the temperature continues to fall.

In short: **the lower the pressure, the lower the temperature at which dry ice remains stable.**



What Happens When the Pressure Changes

If the pressure decreases – for example, inside an airplane's cargo hold, where it is typically only 0.5 to 0.7 bar – the CO_2 sublimates more readily.

That rapid sublimation absorbs heat from the surroundings, cooling the remaining dry ice further until a new equilibrium is reached – this time at a lower temperature.
That is why dry ice can sometimes be colder than –78.5 °C: it has simply adjusted to the lower ambient pressure. It is not a measurement error – it is physics at work.

A Little Thought Experiment

Imagine taking a piece of dry ice at –100 °C out of a deep freezer and placing it on the table:

- At 1 bar (normal pressure), it slowly warms up until it reaches –78.5 °C and stays there until it's gone.
- At 0.5 bar (as in an airplane), it would only warm to about –83 °C – and then remain steady.

This shows that it is not time or location that determines the temperature, but the pressure under which the phase transition occurs.

Influencing Factors: Heat, Surface Area, Mass, Motion, and Moisture Or: Why Clumped Dry Ice Stays Cold Longer

In practice, a large, solid block of dry ice "lives" much longer than a handful of pellets. The reason lies in the surface area.

Sublimation always happens at the surface.

The larger the surface area relative to the mass, the faster the CO_2 gas escapes – and the faster the dry ice disappears.

A compressed, clumped, or "aged" block has less active surface area, so it sublimates more slowly and retains its cold longer.
The temperature itself (depending on pressure) remains the same, but the cooling capacity lasts longer because there's less surface for heat to enter.

Several factors affect how well dry ice holds its cold:

- **Heat input:** Accelerates sublimation.
- **Surface area:** Smaller grains → faster sublimation.
- **Mass:** Larger blocks warm more slowly.
- **Movement:** Strong vibration or transport shaking causes forced sublimation, pulling extra heat from the surroundings – temporarily making the dry ice even colder.
- **Moisture and aging:** Air humidity forms frost, which binds pellets together. This "old," clumped ice has less exposed surface, sublimates more slowly, and, due to its dense mass, maintains deep temperatures longer – especially after pressure changes or agitation that cause additional cooling.

That is why dry ice is so well-suited for transporting vaccines, APIs, and biological or pharmaceutical samples – it is reliable and predictable.

When Movement Changes Everything

Motion itself can alter the temperature.
When dry ice is shaken or vibrated – for example, during transport – friction and air mixing cause extra CO_2 to sublimate at once. This sudden gas formation absorbs additional heat, making the remaining ice briefly colder until equilibrium is restored.

In other words, movement can temporarily make dry ice colder than its theoretical sublimation point at that pressure – before it warms back to equilibrium.

Dry Ice Above the Clouds

This phenomenon is particularly relevant in air transport. In airplane cargo holds, the pressure is reduced to about 0.5–0.7 bar.

That means dry ice doesn't sublimate at –78.5 °C but at around –82 °C.

A compact block reaches this temperature slowly, but once there, it stays remarkably stable – ideal for long-distance cooling.

How to Use Dry Ice Safely

To use dry ice effectively and safely, keep a few simple rules in mind:

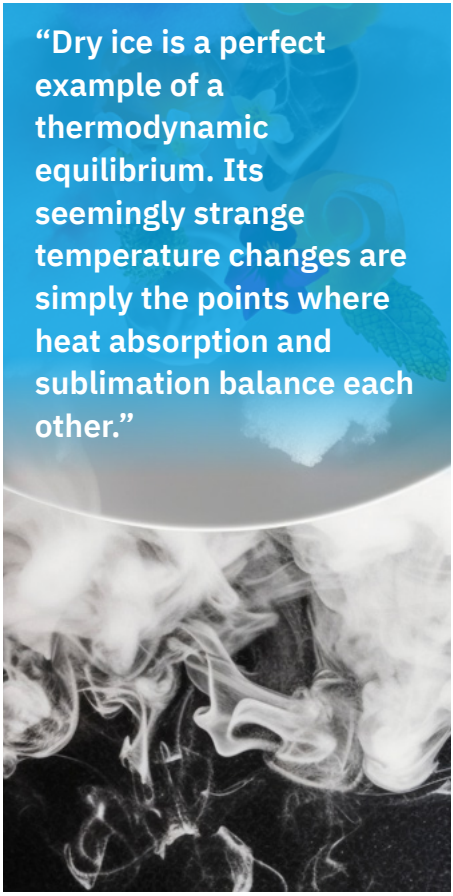
1. **Ensure ventilation:** CO_2 gas is heavier than air and can displace oxygen – risk of suffocation!
2. **Never seal tightly:** Sublimation creates gas pressure – closed containers can explode.
3. **Protect your skin:** Direct contact causes severe frostbite. Always use gloves.
4. **Plan your cold chain:** Temperature depends on pressure. Shipments traveling by air will experience slightly lower dry-ice temperatures, which should be accounted for in storage planning.

The Physical Takeaway

Dry ice is a perfect example of a **thermodynamic equilibrium**. Its seemingly strange temperature changes are simply the points where heat absorption and sublimation balance each other.
When pressure drops, that balance point shifts downward – and the ice becomes colder.
When it moves or sublimates rapidly, it draws even more heat from its surroundings – cooling further until equilibrium returns.
At the same time, a smaller surface area – as in compact or moisture-clumped ice – slows that balancing process.
That is why old, solid dry ice stays cold longer than fine, fresh granules.

What Is Cold, Really?

Dry ice reminds us that cold is not a thing in itself – it is the absence of heat.
Its temperature isn't random but governed by energy, pressure, and molecular motion.



Anyone who understands why dry ice can become colder than –78.5 °C – and why compact pieces retain their chill longer – is, in a sense, peering into the basic mechanisms of nature: Everything strives for balance – even a block of frozen CO_2.

In short:

- The temperature of dry ice is determined by pressure, not by sublimation itself.
- Lower pressure → sublimation below –78.5 °C.
- Motion or rapid gas formation can make it temporarily colder.
- Compact or clumped pieces hold that deeper cold longer because they sublimate more slowly.

BRAZIL: Improving Your External Relationship Management for More Effective Temperature-Controlled Logistics.

Luiz Alberto Barberini CQE, CPIM, MBA
External Relationship Operations Manager LatAm – Bayer SA Brazil

There is growing recognition that companies no longer compete as individual entities, but rather as part of a broader network (Chen-ha et al, 2014; Christopher, 2016). The strength of these networks is largely determined by the quality of relationships that connect companies and the business processes that sustain them.

While the resource-based view of the firm attributes competitive advantage to the ownership, control of resources, and the unique capabilities of a single firm, the relational view extends this theory, considering interfirm relationships as an important unit of analysis for understanding differential performance in business and according to this relational view, rents are created when companies combine, exchange or invest in unique assets, sharing complementary knowledge, routines, resources and capabilities, as well as effective governance mechanisms. Implementing cross-functional and cross-company business processes provides managers with responsibilities that facilitate the exchange of knowledge and skills across internal and external organizational boundaries and this is very special in logistics, where the core business is radically different from the one a tradicional company uses to handle.

We've all heard that Brazil is a giant. And, like the giants we know from fairy tales, it has its own unpredictable nature that can make things difficult. This analogy can be used in our logistics and supply world. When in such a situation, what exactly happens and how do we manage the giant's bad mood?

First of all, we should take a closer look at this giant. Brazil is 8.514.000 km2 in area and is home to 204 million people. (2010 data). In 2014, Brazil's estimated nGDP was as high as US$ 3,072t. Just to compare, Canada has 9.984.000 km2 and is home to 34 million people, with an estimated GDP of US$ 1,793t. Brazil is a giant that offers a Human Development Index (HDI) of 0.755 and his bad mood becomes apparent when we notice Canada has a an HDI rating of 0,913. To keep things working, Brazil logistics issues result in costs that that represents GDP's 11.7%, a tad higher than USA's 8% 2013-based costs.

On such a complex scenario, our daily challenge is to avoid damages to perishables loads, mitigating situations that could ruin goods – thus impacting service level - and to continuously search for solutions to risky situations. In the same sense, some big companies must be humble enough to admit that logistics is not their core business and must rely on partners that do know what the best alternatives or suggested actions on each distribution problem are that appears. To find the correct, trusted and reliable partner is the "More-than-a-Million" worth situation. The company in which we deposit our goods, and our brand must surely deal with topics like proper training of their personnel and a correct use of devices such as thermal blankets/ containers, in the same way they guarantee adequate contingency plans even for well-known routes.

Looking at the broader view, over the last twenty-or-so years many companies have increased the usage of 3PL companies along

Enormous contrast in Brazilian highways – from modern and safe ones to others impacted by rainy season on the North region

their supply chain process as most have identified the correct core-business and migrated to this solution. As pharmaceutical companies we are not different, but with one added roadblock for proper service providing, which is the need for robust Good Distribution Practices & Good Manufacturing Practices systems that guarantee that all offered services are in compliance with the strict requirements we face – even some pharma-based companies working with OTCs and Cosmetics must follow good manufacturing requirements. Despite having quality systems in place that have proven themselves as state-of-the-art service providers and verified through frequent audits, there is a natural tendency to control these activities from a vendee perspective and hence increase these controls over activities from time to time. When we have systems and processes with proven reliability and confidence, it's time to move one step further towards other activities that once were kept in our hands. This kind of virtuous dynamic cycle system, although being a recognized value-added one, needs some intelligence to be supported as we frequently get ourselves in crossroads like:

Partnership X Relationship

How to take that step forward that moves us from a partnership to some kind of stable reliable relationship where both parts wants to achieve success?

Reliability X Commitment

Is our counterpart reliable or committed? What's the difference between these two concepts and how do we enhance one over the other?

Productivity X Costs

Do we need to lower costs through lower prices? Or are we mismatching words, when what we do strive for is productivity and excellence?

These are a few of the main questions we have when dealing with external partnerships, rated as important as costs increase, contract negotiations, penalties, price adjustments and so on. But there's always a light at the end of this tunnel. After defining that we do want and need in a long-lasting relationship, only its adequate management will turn this model into reality. An effective Relationship Management goes beyond a governance model overcoming the sense of "the processes of interaction and decision-making among the actors involved in a collective problem that led to the creation, reinforcement, or reproduction of social norms and institutions."[1]

[1] https://en.wikipedia.org/wiki/Governance

This relationship management naturally includes metrics and actions that are monitored as any in governance model but also aggregates values and behaviors that although being somewhat intangible are the fundamental stone on the way we want to do business. When we rely on values that are common to both companies – or that are built up together - the basic idea is to increase CMO/3PL reliable productivity. This is something that both parties want, since it permits continuous growth and is what will add value to the company, either to the vendor or vendee. The Virtuous Cycle that results from this relationship has just one target: an everlasting consistent service level. We want our counterpart to be successful and the mental image I have is that of a paddle ball game, beach tennis like, where the objective is to play in such a way that our "opponent" hits and continues giving the ball back to me.

I've mentioned earlier the need and benefits of a correct relationship management, but what does it really stand for? From my perspective, it's basically the approach and the way we interact with others. A basic but more-than-vital relationship management happens at home with your wife and children – and as father of three boys, sometimes I face scenarios much more challenging and complex than some situations with my Director's Board. Imagine a hypothetical situation when your wife wants to visit her parents on a Sunday afternoon, in the same time you want to see that football match on your favorite couch. Not so uncommon, right? How do you manage this situation? Would you say "I won't go" or even "you go alone" (which is much worse) and create a tense situation or would you rather state "Ok, I want to go too but could it be just after the game?" The point is to understand the other perspective/constraints and negotiate

Different from tennis, where we want to beat the other player, collaborative relationship is like a paddle ball game, where the objective is a continuous playing mode.

it in a win-win agreement, most of the time with no direct monetary values involved. Someday you might have to watch the game with your not-so-dear father-in-law, and deal with it the same way you deal with complex situations at work. If it happens frequently, deeper discussions are needed but always with respect and focus on the main topic. I believe that economics, administration and negotiation background are needed for someone in an external relationship model, but Conflict Management training are the ones that do make the difference in this role.

Inn a 3PL or CMO – Contract Manufacturing Organization – you will always seek to optimize a committed business relationship over an engagement-type one. To differentiate both, I use the "Eggs and Bacon Postulate" comparison, simply explained as: For your brunch, when you want bacon and eggs, the chicken is engaged in the process, while the pork is committed. Not that your professional partners have to be sacrificed – lucky them! - but the level of involvement we have is remarkably different. We want a 3PL that suffers and succeeds with us.

In order to get a strong and respectable connection one simple point is needed: you must like the other part, and to like it you must know your counterpart. It's surprising, from a professional perspective, how you must go deeper into their process, be familiar with their hardware and equipment, and feel relaxed when walking through their warehouses to become increasingly like feeling at home. After knowing your partner's company and their potential better, you'll feel comfortable enough to start teaching them what you want.

I remember a situation when I was hired to work in a Danish pharmaceutical company. They had moved between different 3PLs in a short time. Service level was nothing but terrible and we were losing market share due to poor On Time in Full – OTIF - rates. Thus, the Director's Board was considering moving back to one previous partner. As the new Logistics Manager, I was then asked about what to do and my very first comments were "Did anyone tell this new partner what do we expect from them? Do they know our process in detail? Do we know their bottlenecks? If we move back to previous suppliers, we'll lose our negotiation advantage". As a matter of fact, no one was very sure which path we should take. It was then decided to keep the current supplier and get deeply involved in their operation. So I did, and OTIF numbers rose from 40% to 94% in just about three months.

This is just to reinforce that when you like and know your partner, you can easily teach the way

you want things done and can pick the low hanging fruits in a short period.

Each vendor, partner, CMO or 3PL has its unique and special features that must be known. Our role while on external managerial functions is to help them to develop into precious stones. Part of their commitment to us starts when they realize we do not want just positive audit results, but a joint-growing process. Continuous discussion and a true help in developing our partners, managing them with transparency and honesty while keeping our contractor's hat will be perceived with true respect for business continuity. And we must remember that in certain moments we will drift from B2B to people-to-people relationships, and for these times mutual respect is the driver for all further actions.

After building up a true relationship, with respect for the people and knowledge of other capabilities, we can move forward to guarantee that sensible topics, like cold-chain distribution processes, are properly managed by our counterpart.

As a matter of fact, to effectively manage your temperature-controlled logistics through an improved external relationship management, some steps might be considered. First, one must be sure to have a strong Customer Relationship Management - CRM - equivalent implemented for formal governance and in this sense a Vendor Managed Inventory – VMI - process would even improve this control. But please also take into account that a solid Sales & Operations Plan Process permits a feasible delivery route through the use of planned dispatches, with transit times within 48 hours for most customers. And one question here: have you ever wondered about bringing your 3PL to your company's S&OP? If not, why? Have you ever thought how committed they'd be upon joining you into this process? The open-hearted talk obtained through this relationship model guarantees full support to quality, and avoids unnecessary risks taken by the 3PL.

Some products are noticeable damaged under improper transport conditions, others don't . Only an open honest dialogue will guarantee that our customers receives adequate product

I do believe that the main steps to success in this journey can be easily achieved through use of simple steps such as:

- Maintain an inter-dependent team with shared goals and honest cooperation between both companies. A commitment and compromised group is born when common targets are set.
- Obsession for Performance. Both sides must be set for a never-ending chase for Quality, Service, Technology, Cost, No Waste...
- Bear in mind that you might be building up a robust long-term P2P relationship, rather than only contract-managed discussions. Today I have former contractors in my Facebook page! Companies may even fade away, but the relations you build will last much longer.
- Celebrate. Take some time to celebrate your achievements. Invite your 3PL partner for a lunch – and not the contrary, as we use to see.

Relationship management is an exercise of patience and tolerance - internal and external to your company, but when properly done I guarantee you will build up MASSIVELY STRONG bonds that can positively reflect in your daily challenges. Hope you do get such gigantic connections as strong as the giant we met earlier in this article.

Data and relationships can mitigate clinical supply chain risk and cost

This shift towards biologic trials also underscores the growing complexity of clinical trials and the resulting increase in clinical trial costs that has been witnessed over the past decade.

Risk is inherent in clinical supply chains. "The secret to risk mitigation is people," shared Francesco Santo, director of Clinical Supply Chain at Orano Med (Plano, TX), speaking at the Clinical Trial Supply (CTS) New England conference in Boston, Massachusetts. "Strong communication and relationship management creates visibility, and visibility gives you greater control over potential supply chain issues such as vendor delays, label changes, customs hold-ups, and under-forecasting or overcommitting clinical supply," said Santos in a session named "Protecting your clinical supply chain: minimising disruption through effective risk mitigation planning." Many speakers at the conference noted the importance of establishing meaningful connections with suppliers, vendors, and other stakeholders, as they are extensions of a sponsor's team in managing clinical trials and the supply chain.

Santo shared that common blind spots in clinical supply chains are underestimating label approval timelines, assuming regulatory timelines without confirming, not fully vetting import requirements, Interactive Response Technology (IRT) site training gaps, or overconfidence in vendor readiness. By building strong relationships with external stakeholders from the beginning of the trial or even before the trial begins, sponsors can leverage the relationships to mitigate these blind spots or other supply chain disruptions. While using these relationships to establish contingency protocols from the beginning of the trial may not prevent disruption, it can ensure that the disruptions do not stop the trial.

While implementing contingency protocols and other mitigation tactics can ensure a trial's successful completion, there are also other factors, such as cost, that need to be considered in developing flexible clinical trial supply manufacturing strategies. Speakers in a panel discussion at CTS New England titled "Exploring strategies for flexible clinical trial supply manufacturing" stressed that the scale and capacity of a trial drive the cost. They highlighted the importance of understanding the scope of the trial, geographic location, the demand for and the type of the drug, and the timeframe for trial start-up, as these are all factors that will influence cost. For example, a biologic is more costly to develop than drugs of other molecule types, as it requires longer development timelines and specialised requirements for trials and manufacturing due to its complexity. According to GlobalData, biologic trials have also been increasing in proportion over the past 12 years, indicating an overall shift in focus of the industry to biologics over small molecules for innovator drugs (Figure 1).

This shift towards biologic trials also underscores the growing complexity of clinical trials and the resulting increase in clinical trial costs that has been witnessed over the past decade.

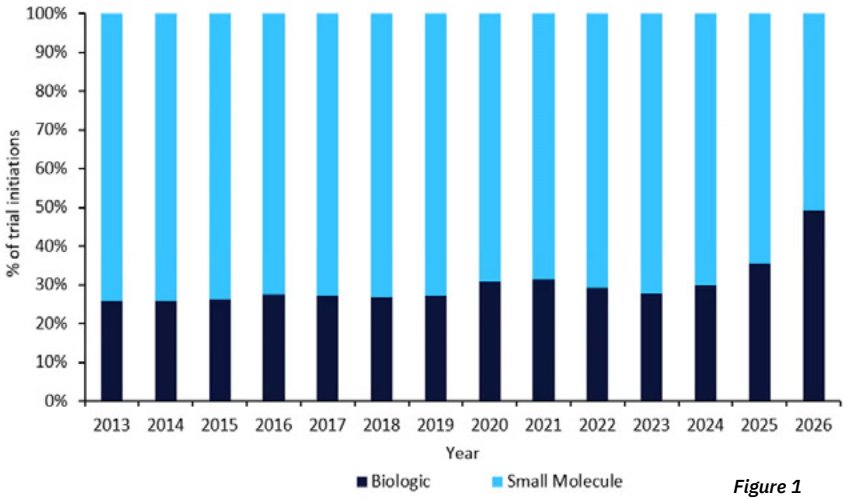


Figure 1

Other considerations shared at the conference include using target product profiles, epidemiology data, and market size information to help ground assumptions when comparing CDMO capabilities to the needs of the drug programme in choosing a clinical supply manufacturer. Speakers also suggested considering a CDMO's readiness for global expansion, such as facility location or the ability to obtain raw materials and in the required quantities. According to GlobalData, the highest number of clinical dosage form contract manufacturing sites can be found in the US, followed by India and then Germany (Figure 2). Due to the impending US Senate decision on the passing of the BIOSECURE Act, the US may see an increase in contract manufacturing sites, which could also help offset the costs associated with Trump's tariffs. However, the BIOSECURE Act could spur opportunities for emerging markets, with Indian CDMOs well-positioned to witness growth due to their cost-effectiveness and highly skilled workforce.

Estimating demand

Although employing larger batch sizes to cover trial demand variability is often a typical solution in the supply chain, costs are a concern with this strategy. Considering the previously mentioned data types and factors as a part of a supply chain strategy can help sponsors more accurately predict batch size and manufacturing size to help ensure a CDMO's capacity can support the needs of the clinical trial.

Credit: Shutterstock.com

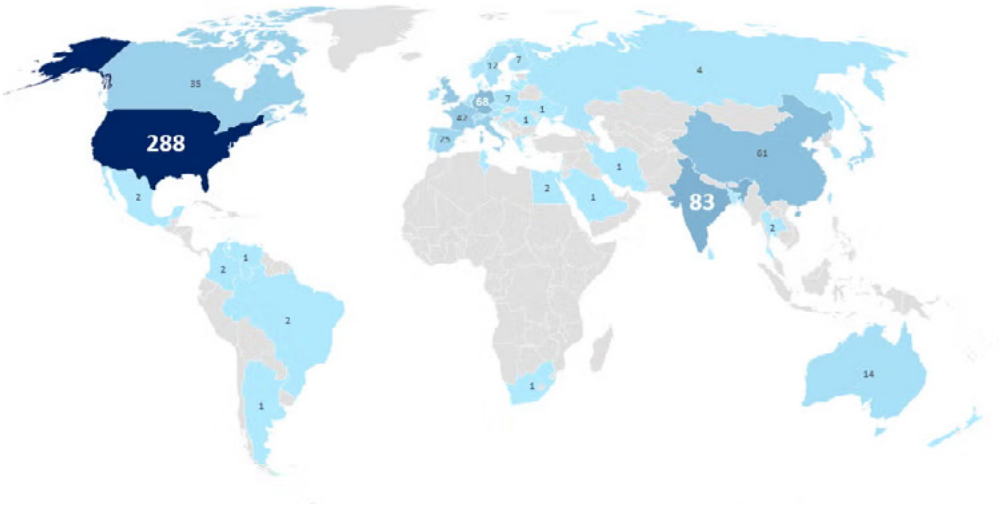


Figure 2: Worldwide clinical dosage form contract manufacturing facilities

For example, speakers at CTS New England suggested taking a phase-appropriate approach to batch size, since the manufacturing needs for a Phase I trial differs from a Phase III trial. Material for a Phase III trial should closely resemble a sponsor's commercial process once a drug has received marketing approval, which will also likely be a higher volume than Phase I. Some, but not all, manufacturing facilities can grow with a trial, moving from lower to higher capacity manufacturing. Smaller CDMOs can be more cost-effective, efficient, or in the best geographic location for a Phase I trial, which are important considerations for sponsors with drugs in earlier development stages. However, if the drug progresses to later trial phases, a sponsor may need to move to a larger or more commercially oriented manufacturer. Scoping and tracking a CDMO's future capacity is important, so that clients can pivot to the larger CDMO more easily and efficiently when the drug moves to later stages.

When choosing a manufacturer from a commercial perspective, the inherent assumption is that demand for the drug will continue to increase, especially for a large disease indication. However, not all drugs reach later stages, or demand forecasts may not materialise. Thus, speakers at CTS New England reiterated that leveraging any available data—such as staying informed on future capacity using drug product profiles, epidemiology data, market size, and facility-specific geographies and information—can build in flexibility from the start of the trial, whether that be by choosing the appropriate CDMO strategy or creating transparency in the decision-making process as sponsors build and maintain these relationships with external stakeholders and vendors.

Chapter 2
Technology and Innovation

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Beyond the Basics: Navigating the Complexity of Modern Clinical Trial Supply Chains

www.s-clinica.com

Sponsors today face ever increasing costs in running clinical trials, making every opportunity for efficiency and savings critical. A major contributor to overall trial cost is the production and management of the Investigational Medicinal Product (IMP)—from manufacturing and storage to temperature controlled logistics and site level distribution. These challenges are amplified by the inherent uncertainties of clinical research, often resulting in significant waste. McKinsey reports an alarming average of 50% medication waste across the industry.

Investment required to develop a single medicine requires approximately 2.6 billion US dollars, up to 15 years of research and success rates below 10% . A question naturally arises: can we leverage technology advancement to improve these odds and deliver medicines to patients faster and more efficiently? Should we embrace it in regulated environments, or be cautious about the risks?

As studies grow more complex and IMP costs rise, the need for smarter, more adaptive supply strategies becomes undeniable. Supply managers must not only stay informed but anticipate risks and mitigate them proactively. Dr. Irena Seredina and Jasvinder Osan, Executive Director and VP of Business Strategy at S Clinica, explain how the company's deep understanding of clinical operations—combined with advanced mathematical algorithms and predictive technologies—is helping clinical supply teams plan more accurately, reduce waste, and ultimately lower costs.

RTSM System: The Nerve Center of Clinical Supply

Randomisation and Trial Supply Management (RTSM), also known as IRT, sits at the heart of clinical trial operations. As trials become more expensive and operationally demanding, study teams increasingly expect RTSM systems not only to manage supply availability but also to forecast, plan, and optimize supply strategies throughout the study lifecycle.

While experienced supply planners often rely on complex spreadsheets, this approach has a major flaw: it oversimplifies reality. High level metrics alone cannot capture the nuances that drive accurate forecasting.

"The devil is in the details," says Seredina. "Successful supply chain management requires a granular understanding of every study parameter. That's why we developed an algorithm capable of integrating multiple variables—something spreadsheets simply cannot achieve."

A Unified Algorithm: Speaking the Same Language

Seredina, a medical doctor and health care economist, recalls the origins of S Clinica's forecasting platform:
"S-Clinica developed ClinVision with a biotech partner who needed a portfolio level forecasting tool and wanted to leverage our unique drug supply algorithm. The key is that both forecasting and supply management use the same algorithm—they speak the same language."

This unified approach eliminates inconsistencies and ensures that planning and execution remain aligned.

Is Real Time Sufficient? The Case for Preventive Control

ClinVision, S Clinica's RTSM platform, is founded on a central operational principle: real time detection occurs downstream of the actual problem event. By the time a deviation is

visible, it has already generated operational, financial, or logistical consequences. As Seredina notes, "**Real-time is too late** - real time indicates that the deviation has already manifested. Effective operational control requires preventing such deviations before they arise." This shift from reactive monitoring to preventive control is not only operationally advantageous—it is economically essential. Every unanticipated stock out, overage, or misaligned shipment carries measurable cost implications, from expedited manufacturing to site level delays.

ClinVision supports decision making from the earliest phases of study planning—even prior to protocol finalization—by enabling quantitative estimation of supply requirements and facilitating early production pre orders. This early stage modeling reduces financial exposure by minimizing unnecessary manufacturing commitments while ensuring adequate buffer capacity. As the trial progresses, the system integrates newly available data, allowing teams to reassess risk profiles, update forecasting assumptions, and plan subsequent operational steps with greater precision.

This continuous recalibration is not merely a forecasting exercise—it is an optimization engine. By dynamically balancing demand uncertainty, production lead times, depot capacity, and site level consumption patterns, ClinVision helps teams converge on the most cost efficient supply strategy at each stage of the study. The ability to simulate alternative scenarios, quantify their cost risk trade offs, and select the optimal path forward reduces both operational volatility and budgetary waste. Such dynamic adaptability is critical in clinical research environments characterized by protocol amendments, variable recruitment trajectories, and persistent uncertainty. In these conditions, preventive control is not a luxury—it is the only sustainable approach to minimizing risk, controlling cost, and optimizing supply performance across the study lifecycle.

AI or Not AI? Cutting Through the Noise

With AI dominating industry conversations, many vendors promise "AI powered accuracy." But what does that really mean for clinical supply?

Jasvinder Osan references a recent research paper noting that **AI is fundamentally mathematics, probability, and statistics**—disciplines that have long underpinned S Clinica's work.

Built on a foundation of biostatistics and advanced mathematics, S Clinica pioneered the **predictive probabilistic adjusted real time supply management algorithm**. "We've been refining our algorithm for over 20 years," Osan says. "It remains the secret sauce behind ClinVision."

The algorithm has been validated in 1,200+ clinical studies across all phases and therapeutic areas, proving its robustness in real world conditions.

Adaptability: The Key to Reducing Waste

"The key to reducing waste and saving costs is the ability to adapt supply strategies immediately during a trial," Seredina emphasizes. Achieving this requires breaking down silos—not only between departments but also between the systems they use.

When S Clinica's full platform is deployed, forecasting and RTSM operate seamlessly together. Supply managers can evaluate real time study data, adjust strategies, and implement changes instantly within the same system. Study teams can collaborate, explore scenarios, and identify optimal paths forward during complex situations.

A Practical Solution for Biotech and Smaller Sponsors

S Clinica's integrated approach is particularly attractive for midsize and smaller biotech companies—or sponsors tied to third party IRT providers but still relying on spreadsheets for forecasting.

"S Clinica offers an easy to use forecasting solution," Osan explains. "By integrating forecasting with IRT, we deliver a cost effective, tailored option for smaller and midsize organizations."

Accountability and Reconciliation in Clinical Trials: Requirements, Challenges, and Best Practices

By **Paul Hingst** Supply Chain Consultant, Crinetics Pharmaceuticals

Drug accountability, reconciliation, returns, and destruction often do not receive the attention they deserve at the start of a clinical trial. Sponsors tend to focus on protocol design, supply/demand forecasting, and investigational product (IP) supply strategies—leaving accountability details to be "sorted out later." This reactive approach can create significant challenges at study closeout, when regulators and auditors expect complete documentation and reconciliation down to the smallest accountable unit.

Building accountability and reconciliation practices into study planning before the first shipment is dispatched is critical. This article reviews the regulatory expectations across major geographies, clarifies the difference between accountability and reconciliation, highlights emerging inspection themes, and shares best practices for avoiding costly delays at the end of a study.

Accountability vs. Reconciliation

Although often used interchangeably, the terms have distinct meanings:

- **Accountability** = the ongoing recordkeeping of IP throughout its lifecycle: receipt at the site, storage, dispensing to subjects, return from subjects, and return or destruction at the end.
- **Reconciliation** = the periodic or final check to confirm that every unit of IP is accounted for (received = dispensed + in stock + destroyed/returned).

Accountability is the continuous ledger; reconciliation is the audit to zero.

While day-to-day recordkeeping is typically delegated to sites and CROs, the sponsor remains ultimately accountable. Delegation is operational, not regulatory: the responsibility for ensuring complete, accurate, and inspection-ready documentation rests with the sponsor.

Label Development, Packaging, and Startup Activities

Accountability begins well before dosing. At startup, sponsors must plan label development, packaging, and labeling activities with reconciliation in mind. Label text should comply with regulatory requirements while ensuring that key identifiers (kit number, batch, expiry) are consistently recorded in accountability logs (paper or electronic). Packaging strategies—whether bottles, vials, or kits—should anticipate how units will be tracked, dispensed, and returned. By designing packaging and labeling processes with accountability requirements in view, sponsors set themselves up for smoother reconciliation later.

"Building accountability and reconciliation practices into study planning before the first shipment is dispatched is critical."

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Regulatory Requirements at a Glance

While regional nuances exist, the fundamentals are consistent worldwide: investigational product must be fully traceable from sponsor to subject and back again, with complete documentation of receipt, dispensing, return, and destruction

Note on ICH Guidance:

- ICH E6(R2) GCP is guidance, not law, in the U.S. It reflects internationally harmonized best practices but does not itself carry statutory authority.
- ICH E6(R3) remains in draft form and is not yet finalized.

Table: Accountability, Reconciliation, and Returns Requirements by Region

Region	Key References	Core Requirements
USA (FDA)	21 CFR 312.57, 312.59, 312.62, 312.69	Investigator must maintain disposition records; sponsor must ensure return or authorize destruction; controlled substances require secure storage; inspections increasingly focus on unit-level reconciliation.
EU	EU CTR 536/2014 (Art. 51); EudraLex Vol. 4 Annex 13	IMP traceability in dossier; destruction requires sponsor authorization; returned IP quarantined and inventoried; GDP Ch.6 requires written recall/return procedures.
UK	Medicines for Human Use (Clinical Trials) Regs 2004; MHRA guidance referencing Annex 13	Aligned with EU expectations; MHRA promotes risk-based monitoring; local destruction permissible with sponsor authorization.
Canada	Food & Drug Regs Division 5 (C.05.012); ICH E6(R2) guidance	Accountability records required; retention for 15 years; destruction only with sponsor authorization.
Japan	MHLW GCP Ordinance (Art. 17, 26-12)	Records of supply, accountability, and disposal required; storage managers designated; retention ≥3 years or until marketing approval.
China	GCP for Drugs (2020)	Institutions must document receipt, dispensing, and recovery; returned IP either shipped to sponsor or destroyed on-site with sponsor authorization.
ICH Guidance	ICH E6(R2) (guidance only); Draft ICH E6(R3)	Investigator must maintain IP records; essential documents 8.4.1 and 8.4.2 require accountability logs and destruction documentation.

Emerging Inspection Themes

- Unit-Level Reconciliation Across Product Types: FDA inspectors have cited sponsors for reconciling only at the container level rather than the unit level. This principle applies not only to capsules and tablets but also to vials and devices. Regulators expect complete traceability of investigational products regardless of format.

- Depot Recounting of Returns: FDA has cited examples where depots did not recount returned IP to confirm site records. One emerging approach applies tamper-evident seals at the site before return shipment, which reduces the need for depot recounts while maintaining chain-of-custody integrity.

- Delayed Certificates of Destruction: Even after unused IP is returned, final Certificates of Destruction (CoD) can take months to be issued, delaying Trial Master File (TMF) finalization.

- Why Discrepancies Often Emerge at Closeout: During monitoring visits, accountability checks typically focus on completeness of documentation, not on comparing shipments with returns. As a result, omissions on return logs often remain invisible until final reconciliation, when shipped quantities are matched against site records of returned or destroyed IP. By that point, discrepancies are harder to resolve—underscoring the importance of strong processes at study startup.

Best Practices

1. **Define the Process and System of Record Up Front**
   The sponsor should clearly define the accountability process and the primary system of record (IRT, electronic DARF, or paper) in the Pharmacy Manual. This ensures sites and CROs understand expectations for documentation, reconciliation, and destruction. Minimize exceptions from the sponsor's standard process. Many sites prefer to use their own logs or forms; while this may be efficient locally, it creates major reconciliation challenges at study closeout. Standardization protects the sponsor from data mismatches.

2. **Don't Use Accountability Data as a Surrogate for Compliance**
   Accountability logs confirm product disposition, not patient adherence. Compliance should be measured through diaries, biomarkers, or adherence tools.

3. **Leverage IRT or Electronic Systems**
   Real-time, electronic capture reduces transcription errors, simplifies monitoring, and improves inspection readiness.

4. **If Paper is Used, Standardize the Format**
   If sites must use paper, provide a consistent, sponsor-approved template. This simplifies end-of-study reconciliation and TMF filing.

5. **Consider Tamper Seals on Returns**
   Tamper-evident packaging at the site can reduce the burden of depot recounting and provide additional assurance of integrity in transit.

6. **Plan for Destruction Early**
   Define destruction locations, authorization processes, and timelines in the Pharmacy Manual or protocol appendix. Anticipate that Certificates of Destruction may lag and plan TMF closure accordingly.

7. **Don't Shut Down the IRT Until Final Reconciliation Is Complete**
   Sponsors may be tempted to deactivate IRT quickly to save maintenance fees once enrollment ends. However, closing the system too soon can backfire: unresolved discrepancies or pending destruction records may require manual workarounds. Keeping the IRT live until reconciliation is complete ensures smoother close-out and often saves time and money in the long run.

“Accountability, returns, reconciliation, and destruction are too often afterthoughts in clinical trial planning.”

8. **Reconcile Frequently, Not Just at Study End**
   Interim reconciliations during monitoring visits allow issues to be identified and corrected before final close-out. For Phase 3 and longer-duration studies, the sponsor should also periodically check site-level reconciliation and accountability records—not just rely on CROs or monitors. These periodic sponsor checks help identify discrepancies early, when they are still correctable, and prevent large variances from emerging at study closeout.

Conclusion

Accountability, returns, reconciliation, and destruction are too often afterthoughts in clinical trial planning. Yet regulators expect complete traceability of investigational products—whether tablets, vials, or devices—from sponsor to subject and back again.
By designing packaging and labeling with accountability in mind, defining processes in the Pharmacy Manual, minimizing site-level exceptions, and anticipating how discrepancies will be uncovered, sponsors can avoid costly delays. When paired with tamper-evident returns, thoughtful IRT management, and early destruction planning, these steps make final reconciliation and TMF closure faster, easier, and more reliable.

Chapter 3
Supply and Logistics

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Biological Materials CHECKLIST

Use the questions below to assist with importing biological materials into the United States. Visit **cbp.gov/biologicals** for additional U.S. Customs and Border Protection (CBP) information.

1

Gather Documents

Do you have the required paperwork for the material, such as invoices or permits from regulating partner government agencies?

2

Package and Label

Have you confirmed if the material is packaged and labeled according to transportation regulations, especially if it is a hazardous item?

3

Declare or Manifest

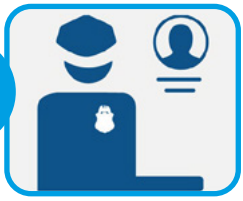
Did you satisfy CBP declaration or manifest requirements for the material, either orally or in writing?

4

File Entry

Have you confirmed if the material requires an entry filing, such as commercial goods exceeding $2,500 in value?

5

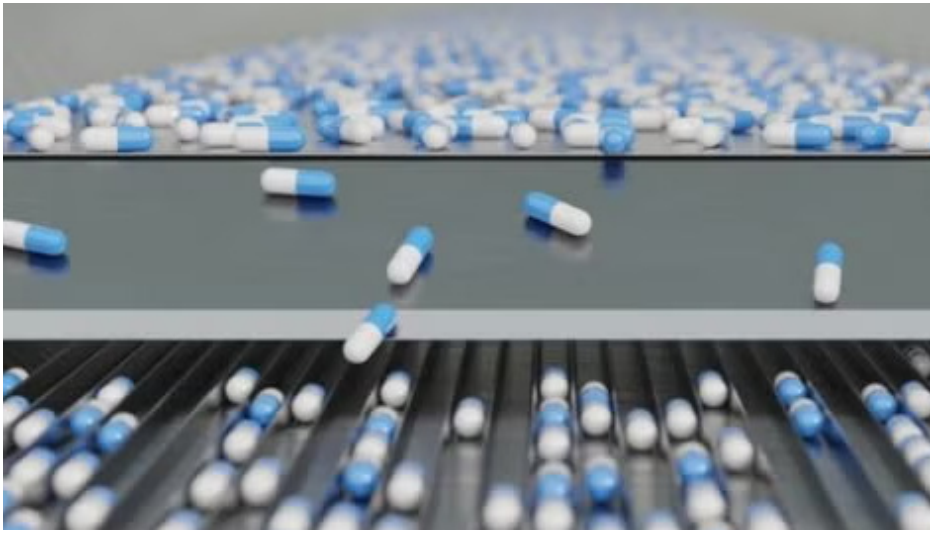


Schedule Inspection

Did you know all imported materials are subject to inspection? Use the CBP Link mobile application to make an appointment at participating airports.

Uncertainty looms over FDA scheme to boost US manufacturing

The FDA's new PreCheck programme is aimed at facilitating the introduction of new US drug manufacturing facilities.



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The US Food and Drug Administration (FDA) has launched a new scheme that will streamline the introduction of new pharmaceutical manufacturing facilities in the US, a strategy in line with US President Donald Trump's ambition to reduce overreliance on imports.

The PreCheck programme, unveiled by the FDA on 7 August 2025, comprises a two-phase approach to facilitate new US drug manufacturing facilities.

The first stage, called the Facility Readiness phase, will allow more frequent communication with the FDA to discuss facility design, construction, and pre-production. Companies will be encouraged to provide information on their proposed facilities, such as site operations layouts and quality control elements. The FDA says this should be done via Type V Drug Master File (DMF), a document that can be incorporated into drug applications to support approval.

The Application Submission phase, the second portion of the scheme, focuses on Chemistry, Manufacturing, and Controls.

The FDA stated the programme will "increase regulatory predictability and facilitating the construction of manufacturing sites in the US."

The agency did not immediately respond to Pharmaceutical Technology when asked for more details.

America first strategy

Diderik Stadig, sector economist for TMT and Healthcare at ING, told Pharmaceutical Technology the new PreCheck programme looks "promising" on paper, offering a way to streamline US manufacturing and drug approvals.

"However, with the FDA facing budget cuts, its long-term impact remains to be seen," said Stadig. "The press release also highlights a goal of reducing dependence on foreign drugs and APIs but achieving that will require a far more concerted effort, particularly in the area of generics."

Apart from knock-on effects from tariffs, the PreCheck programme is the first FDA policy directed at bolstering US pharma manufacturing. Decreasing reliance on drugs manufactured overseas has been a key ambition of the Trump administration. In May, Trump also signed an executive order that will streamline the path for pharma companies to build new US drug manufacturing production sites and improve inspection times for US facilities.

Big pharma has been responding to Trump's pressurised calls by outlaying significant funds to boost US manufacturing sites. Johnson & Johnson is set to invest $55bn over the next four years, including a $2bn biologics production site in North Carolina that promises to create 500 jobs. Roche outlaid a similar amount, planning $50bn worth of investment in the US, which will generate more than 1,000 jobs in new and expanded facilities.

A spokesperson for trade body Pharmaceutical Research and Manufacturers of America (PhRMA) told Pharmaceutical Technology: "In recent years, the number of manufacturing facilities in the U.S. has grown by more than 50%. Biopharmaceutical companies continue to build, expand and upgrade facilities across the country to supply the next generation of cutting-edge therapies to American patients.

PhRMA said the investments signal an "ongoing commitment to the US".

More than half of pharmaceuticals distributed in the US are manufactured overseas. The country is particularly exposed in the active pharmaceutical ingredients (APIs) supply chain. Of the manufacturers that produce APIs used in FDA-approved products, only 11% are based in the US.

"Our gradual overreliance on foreign drug manufacturing has created national security risks"

FDA commissioner Marty Makary in a 7 August statement

"Our gradual overreliance on foreign drug manufacturing has created national security risks," shared FDA commissioner Marty Makary in a 7 August statement.

"The FDA PreCheck initiative is one of many steps FDA is taking that can help reverse America's reliance on foreign drug manufacturing and ensure that Americans have a resilient, strong, and domestic drug supply."

GlobalData Life Sciences research analyst Cyrus Fan commented: "The FDA PreCheck program is intended to encourage companies to onshore their manufacturing presence and increase US drug production. US president Donald Trump has warned of pharma specific tariffs arriving in the "next week or so" and has pushed for drug manufacturing to be onshored."

Fan, however, added a caveat: "Though Trump intends to give a grace period, to allow set up of US drug manufacturing, before implementation of tariffs, setting up pharma manufacturing facilities can take years."

Chapter 4
Future Supply Models

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Patient Centricity in Clinical Trial Supplies (CTS): A Strategic Imperative for CTS Professionals

A.Briceno, C. Carmi, E. Cipollari

In today's clinical research environment, patient centricity is no longer a buzzword, it's a strategic priority. For professionals working in CTS, this shift presents both a challenge and an opportunity: how to evolve supply strategies from purely logistical operations into patient-focused enablers of trial success.

As trials become more decentralized, diverse, and digitally enabled, supply managers are uniquely positioned to influence the patient experience.

Why is it important to make a meaningful change to the way we engage with patients in clinical development?

The first reason is a very pragmatic one: it's no longer optional. Bodies like ICH, FDA and MHRA now expect patient engagement in clinical development, making it a compliance and quality need. However, patient engagement shouldn't only be done because regulations require it but because it strengthen trust and ensures our work truly reflects their needs.

What Does Patient Centricity Mean for CTS?

At its core, patient centricity means designing clinical trials around the needs, preferences, and lived realities of patients. This might seem something only for clinicians to consider, but this is not the case. For CTS teams, this translates into rethinking how supplies are packaged, delivered, explained, and supported. Historically, supply management focused on ensuring the right product reached the right site at the right time. Today, this is not enough: as CTS professionals we must now consider how our supplies impact patient engagement, compliance, and retention.

Why It Matters: The Strategic Value of Patient-Centric Supplies

CTS are often the first and most frequent touchpoint between a patient and the clinical study. Poorly designed kits, confusing instructions, or inconvenient delivery methods can lead to:

- Non-compliance with dosing schedules
- Increased site burden due to patient queries and protocol deviations
- Higher dropout rates
- Delays in data collection and trial timelines

For CTS professionals, this means that supply design is no longer just operational—it's strategic.

Key Pillars of Patient-Centric Supply Strategy

1. Co-Design with Patients and Sites

Engaging patients and site staff in the design of clinical supplies is one of the most effective ways to ensure usability. This can encompass

- Conducting feasibility assessments to understand patient routines, needs, and limitations. This can be done with the help of patient experts and patient associations like The European Patients' Academy (EUPATI).
- Running pilot tests of new packaging or delivery formats.

- Gathering feedback through site closure surveys or post-trial interviews.

By involving end users early, CTS teams can identify pain points and opportunities that internal teams' stakeholders might overlook.

2. Simplification and Accessibility

Supplies and training materials should be intuitive and inclusive. When creating them it is important to consider:

- Using plain language and avoiding medical jargon in instructions.
- Including visual aids, such as diagrams or QR-linked videos (present on labels).
- Offering materials and formats accessible to patients with disabilities and patients from all educational and cultural backgrounds.

Replacing dense IFUs with one-pager guides or video walkthroughs can significantly reduce confusion and improve compliance.

3. Flexible Delivery Models

As decentralized trials become more common, CTS teams must adapt to new delivery paradigms like Direct-to-Patient (DTP) shipping, which reduces the need for site visits and supports remote participation.
These models require robust logistics and regulatory planning but could potentially offer significant benefits in terms of patient convenience.

4. Digital Integration and Support

Technology can enhance the patient experience and streamline supply management:

- Mobile apps can provide dosing reminders, shipment tracking, and feedback collection.
- Smart packaging and adherence devices can monitor treatment adherence and send alerts for missed doses.
- Virtual help desks or chatbots can assist patients with supply-related questions.

CTS professionals should collaborate with digital teams to ensure these tools are integrated into the supply strategy.

5. Training and Enablement

Patient-centric supplies require training — not just for patients, but for site staff and internal teams:

- Onboarding modules for patients can explain how to use supplies correctly.
- Quick-reference guides for sites can reduce support calls and errors.
- Internal workshops can help CTS teams understand patient-centric principles and apply them to their work.

Training ensures consistency and builds confidence across all stakeholders.

6. Understanding patients and understanding that not all patients are the same

In clinical trials, it's crucial to recognize that not all patients are the same. This understanding helps in designing more effective and patient-centric clinical trials. One way to achieve this is by using patient archetypes. They are a simple tool that several organizations like Amazon, Google, and Apple use every day to get into the shoes of their consumers.

Patient Archetypes

Archetypes are summaries of raw insights that focus on behavioral characteristics rather than demographic ones. They help us understand patients' thoughts, feelings, and motivations around the clinical trial. By outlining the future state experience journey and suggesting solutions, archetypes bring the patient experience to life; which could potentially aid in designing supplies and processes that cater to the diverse needs of patients

Industry Trends Driving Change

Several macro trends are accelerating the shift toward patient-centric supplies:

- **Decentralized Clinical Trials (DCTs):** With patients participating from home or local clinics, supply strategies must support remote engagement and flexible logistics.
- **Diversity and Inclusion:** Trials must accommodate a wide range of patient backgrounds, languages, and abilities—requiring adaptable and inclusive supply formats.

- **Regulatory Expectations:** Agencies are increasingly emphasizing patient involvement and usability in trial design, including supply components.
- **Sustainability:** Eco-friendly packaging and reduced waste are becoming priorities, aligning with patient values and corporate responsibility goals.
-

CTS professionals must stay ahead of these trends to remain competitive and compliant.

Challenges and Considerations

Implementing patient-centric supply strategies doesn't come without hurdles:

- Customization vs. Scalability: Tailoring supplies for individual needs can strain resources and complicate logistics.
- Regulatory Compliance: Changes to packaging, labelling, or delivery methods must meet strict guidelines across regions.
- Finding the right balance: Patient centricity needs to be a priority but this needs to be also outweighed and find the right balance with other important factors like study timelines, budget, and environmental impact.
- Cross-Functional Collaboration: Success requires alignment between several stakeholders: CTS, clinical operations, regulatory, digital, and patient advocacy teams.

Overcoming these challenges demands strategic planning, stakeholder engagement, and a commitment to innovation.

Conclusion: A Call to Action

Patient centricity is reshaping the clinical trial landscape, and CTS professionals need to be at the forefront of this transformation. By embracing patient-centric principles, supply managers can:

- Enhance trial efficiency and data quality.
- Improve patient satisfaction and retention.
- Increase patient's involvement in study and clinical trial supply planning and development.
- Elevate the strategic value of the CTS function.

The success of our trials depends not only on the timely and efficient delivery of supplies but also on how these supplies influence the patient experience . The future of clinical trial supplies is not just about delivering products, it's about delivering care, compassion, and connection. For those in the CTS world, now is the time to lead the change.

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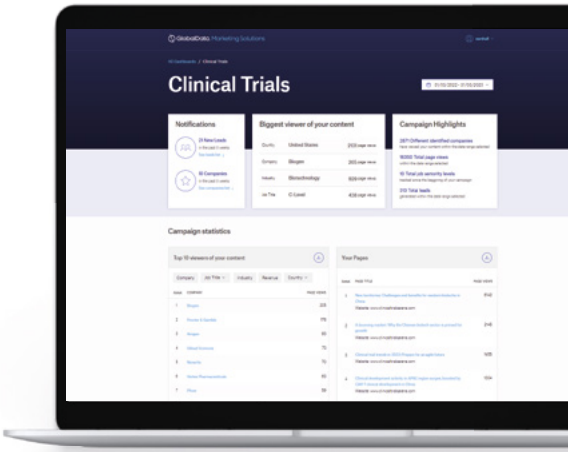

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Are European biopharma manufacturers 'nearshoring'?

Experts debate whether European manufacturers are preferring domestic operations as the continent competes with Asia and the US.

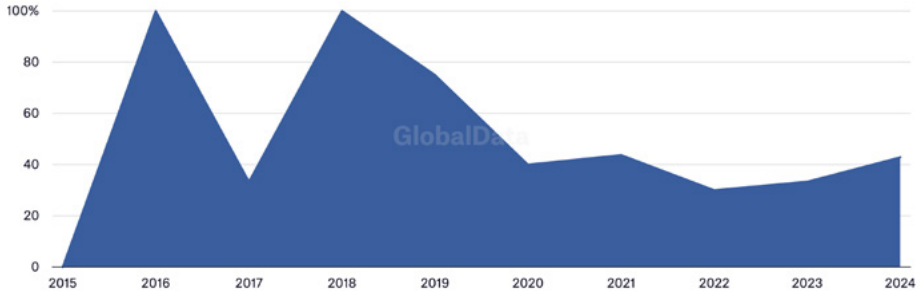
Credit: Shutterstock.com

In step with international news in recent times, European pharma and biotech are leaning towards 'nearshoring', preferring domestic operations to outsourcing abroad, experts say. But regionally focussed sentiment is to be limited and short-lived, they state, faced with globally cooperative markets and supply chains.

"Firms are moving towards nearshoring," says Dr. Pooja Thakur-Wernz, assistant professor of business administration at Washington and Lee University in Lexington, Virginia. However, having interviewed pharmaceutical executives, Thakur-Wernz said she finds that much of the rationale for offshoring clinical operations in regions such as India, high speed and low cost, has been overshadowed by concerns about the subpar quality of clinical work.

affirm or discount nearshoring as a trend. Rather, Natz says 20 years of contract tendering by European pharma has given lower-priced Indian and Chinese CDMOs a decisive advantage in generics manufacturing over European counterparts.

However, Natz does note that differences in the production of generics and innovative compounds could be driving nearshoring for certain drugs. He maintains the low labour cost in Asian markets is one factor encouraging European companies to offshore manufacturing in those regions, but that these same economic incentives are less prevalent for newer therapies. Seán Byrne, a senior manager at EUCOPE, points to Europe's prolific vaccine exports during the Covid-19 pandemic; "We were able to do that because for the most



Outsourced manufacturing 'nearshored' in Europe
The percentage of commercial manufacturing deals signed by European biotech/pharma each year to be outsourced within Europe

Offshored generics vs nearshored innovative medicines

Later stage manufacturing also seems to be increasingly nearshored according to Dr. Michael Quirmbach, CEO of Swiss-based CDMO CordenPharma. "In particular you see a strong [nearshoring] trend when it comes to the commercialisation of new chemical entities – API (active pharmaceutical ingredient) and drug product manufacturing".

Alexander Natz, secretary general of the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), is less sure, as EUCOPE does not have the necessary data to

innovative medicines, we do still have manufacturing capabilities in Europe, and part of the reason is the expertise needed [for that]".

This distinction between generic and innovative drugs is also emphasised by Anne-Sophie Deman, managing director in healthcare and life sciences at FTI Consulting. "It's these older products, many of which are also generics or critical medicines, where price competition is very intense and that's where it's a challenging business case to bring manufacturing back to Europe", she says.

European policy impact

According to Deman, the Covid-19 pandemic made clear the pitfalls of Europe's reliance on Asian manufacturers for much of its critical medicine supply. "This has led to a conversation around strategic autonomy in the EU and the health and life sciences sector under the mandate of the new European Commission (EC) following the elections last year."

Since the pandemic, the EC has set its sights on 'competitiveness' on the global biopharma stage. This involves initiatives such as the Competitiveness Compass, following the recommendation of former European Central Bank head Mario Draghi to focus on innovation in biopharmaceuticals, and the proposed EU Competitiveness Fund, a scheme from EC President Ursula von der Leyen to centralise clinical research funding.

While originally motivated by drug shortages during the pandemic, Deman argues that nearshoring is now further spurred by a broader ambition for European strategic autonomy and security concerns under mounting geopolitical tensions. She cites the EUFAB initiative, as an example of initiatives reflecting nearshoring under these priorities. EUFAB is to reserve production capacities and organise prioritised manufacturing of vaccines in case of public health emergencies, thereby keeping a facility 'ever warm' for manufacturing.

However, as Quirmbach states, "to stay competitive, it requires a unified European way". Growing nationalist sentiment among resurgent right-leaning parties in many EU member states, as seen with France's Rassemblement National and Germany's AfD, could threaten this unity if countries abandon unified manufacturing regulation, says Quirmbach, but he states that from a CDMO perspective, he is not particularly concerned by these developments.

Opportunity for Europe

With the US Trump administration signalling tariffs for several countries and curtailing international aid, European manufacturers could play a key role. Quirmbach sees opportunity for those in Europe, particularly with regards to the BIOSECURE Act, which could hamper China-US biopharma trade if passed, leaving a void Europe might fill.

Natz notes positive developments in this direction with moves made by the EC, most notably in the proposed Critical Medicines Act and EU Biotech Act. These are aimed at addressing critical medicines shortages by addressing supply chain dependencies and vulnerabilities and at fostering biotechnological innovation in Europe, respectively.

For Natz, a reform to the tendering mechanisms by which EU pharma contracts CDMOs could also be key to seeing manufacturing return from Asian countries. He points to tendering lots implemented by some German payers for antimicrobial resistance products, which stipulate a portion of contracts must go to European manufacturers. He also notes the ALBVVG law passed in Germany in 2023 allowing drug makers to increase prices, lessening manufacturing price competition for generics.

Beyond serving its own manufacturing needs, Europe may also seek to increase biopharma exports to the UK. Though home to a number of innovative biotechs, Quirmbach says, "the UK has not been a manufacturing hub", leaving a high-demand biotech market in close proximity to the EU in need of biopharma imports. Many of these imports would concern innovative pharma products such as sensitive cell and gene therapies for which quick transport is crucial, making EU manufacturers an ideal supplier if they can prove themselves competitive.

The limits of nearshoring

For the time being, Thakur-Wernz expects some level of nearshoring in biopharma production to continue but says underlying globalisation and deglobalisation trends come in waves, and eventually, "people realise that free markets are the best way to go".

"I think it would be rather foolish for Europe to say, 'we're just going to have one big European

market", she says. Manufacturers will need to look outward for populations to which they can sell their products.

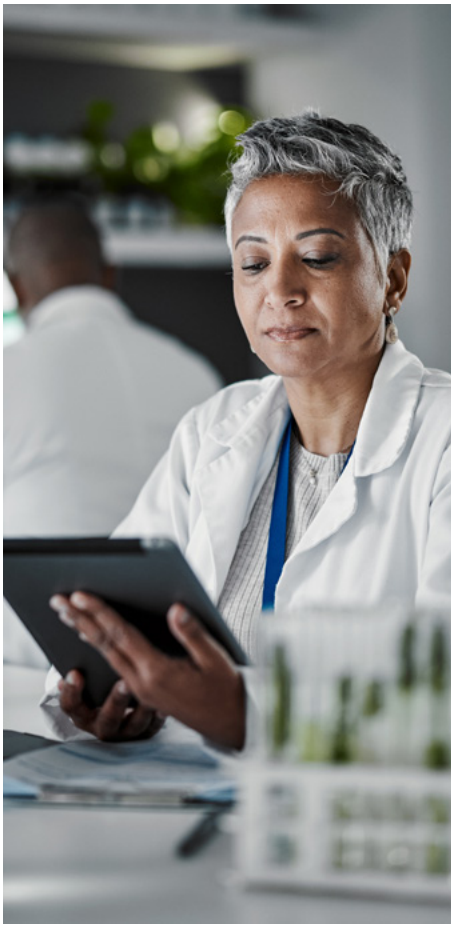
Further, as Quirmbach notes, "you can't nearshore everything. There are significant raw materials, certain parts, which maybe today are only available from the far East". In radiopharmaceuticals, for example, certain necessary isotopes or their precursors can only be sourced at scale from regions like the South China Sea or Russia, precluding outright regionalisation.

Outside manufacturing, Deman also points out that clinical trials take place across several jurisdictions. Beyond the question of finding large populations to support trial enrolment, Thakur-Wernz says, "if you're trying to sell a drug in Africa or Asia, you want to have it tested on the demographics of Africa and Asia."

With cheap labour key to the competitiveness of Indian and Chinese generics manufacturing over their European counterparts, increasing automation and artificial intelligence (AI) might shift this equation. But Quirmbach says it may be challenging to integrate new technologies with existing manufacturing infrastructures and practices. He says many pharmaceutical plants in Europe still rely on older pen-and-paper methods rather than purely electronical ones for batch records and other functions.

To introduce AI systems would require a massive overhaul to much of European manufacturing at large. The same is true for clinical trials, says Thakur-Wernz. "You still need people to administer [the treatments] – you still need technicians and doctors to take readings afterwards, so I'm not sure how much technology and AI will help reduce cost", she states. Moreover, Quirmbach notes that Europe's own innovation trails that of Asia, exemplified in the recent breakout success of China's AI developer DeepSeek, leaving little hope for AI as the route to European competitiveness.

"To introduce AI systems would require a massive overhaul to much of European manufacturing at large. The same is true for clinical trials."



Can You Rely on the Results from Your Clinical Trials?

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The success of a clinical trial depends on the reliability of its data. Many investigational drugs are sensitive to temperature, and any temperature deviation can affect their quality and, in the worst case, patient safety. Automated and integrated temperature monitoring solutions help secure data quality, support compliance, and speed up the delivery of new medicines to patients.

Most clinical trial drugs must stay within a specific temperature range to remain effective. Even a minor deviation can alter a compound's chemical stability, leading to inaccurate trial results and potential safety concerns.

The consequences are costly: compromised efficacy data, extended timelines due to re-testing, potential rejection from regulatory authorities such as the FDA or EMA, and ultimately, delayed access to life-saving treatments for patients.

At the same time, trial sponsors face financial risk and reputational damage when results are questioned. Reliability and validity of data are therefore non-negotiable—not only for regulatory approval, but for scientific credibility and patient trust.

Regulatory agencies continue to cite data integrity and environmental control as leading GCP deficiencies.

According to a recent study analyzing inspection findings from both the FDA and EMA, deficiencies in Good Clinical Practice (GCP) compliance and data integrity remain among the most frequent issues observed in

clinical trials. This underscores the need for stronger quality assurance and traceability mechanisms throughout the trial lifecycle—particularly in areas such as environmental control and temperature management.

The Complexity of Clinical Supply Chains

Clinical supply chains have become more global, digital, and complex. Materials move through many locations and climate zones before reaching sites or patients. Each transport step increases the risk of temperature deviations and data loss.

Maintaining GxP compliance throughout this network requires robust data management and quality assurance. Yet, traditional manual monitoring systems remain common. They are prone to human error, data gaps, and disconnected reporting—issues that make it increasingly difficult to achieve traceability and regulatory confidence.

As the clinical trial landscape evolves—with direct-to-patient logistics, decentralized trials, and temperature-sensitive biologics—the complexity of managing environmental data

“In clinical trials, every degree matters. Automation ensures that your data—and your trial results—can be trusted.”

increases exponentially. Many studies and publications have highlighted how the evolving nature of the clinical supply chain demands new approaches to temperature monitoring, emphasizing the importance of end-to-end visibility and proactive risk management.

The Case for Automation

Automated, end-to-end temperature monitoring provides a clear path toward greater reliability and efficiency in clinical trials. By integrating fully with existing trial technologies—such as IRT, RTSM, or CTMS systems—automation ensures that temperature data is continuously captured, validated, and accessible in real-time. Any deviation is instantly evaluated against the stability budget and the total time out of storage conditions (TOS), providing a complete overview of the remaining stability budget (RSB) for dispense to the patient.

The benefits of automation extend well beyond trial efficiency. First, it enables full traceability and compliance, with every temperature reading securely logged and automatically linked to shipment and site data. This creates complete, auditable records that satisfy even the most stringent regulatory requirements. Second, automation significantly reduces manual error by minimizing user interaction, eliminating data gaps and inconsistencies that can compromise quality assurance.

In clinical trials, every degree matters. Automation ensures that your data—and your trial results—can be trusted.

Another major advantage is the ability to perform instant temperature budget analysis.

Automated systems can evaluate temperature excursions the moment they occur, providing immediate insight into whether a drug shipment remains within acceptable limits. This accelerates decision-making, prevents unnecessary delays, and ensures that investigational products reach patients on time.

Ultimately, this efficiency contributes directly to faster time-to-market—a crucial competitive edge in the life sciences industry.

Strengthening Reliability Across the Trial Lifecycle

Reliable clinical trial data begins with strong quality management and a GxP-compliant digital infrastructure. Integrating automated temperature monitoring into the broader quality framework supports:

- Better communication between sponsors, sites, and patients.
- Faster, data-driven insights into drug safety and efficacy.
- Confident and faster regulatory approvals.

In essence, automation is not just about technology—it’s about building trust in your trial outcomes. When your temperature monitoring and data management processes are automated, validated, and compliant, you can focus on what truly matters: advancing science, protecting patients, and accelerating innovation.

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WEST COAST

22 - 23 SEPTEMBER | BARCELONA , SPAIN

CLINICAL TRIAL SUPPLY
NORDICS

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CLINICAL TRIAL SUPPLY
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1 - 2 DECEMBER | SEOUL, SOUTH KOREA

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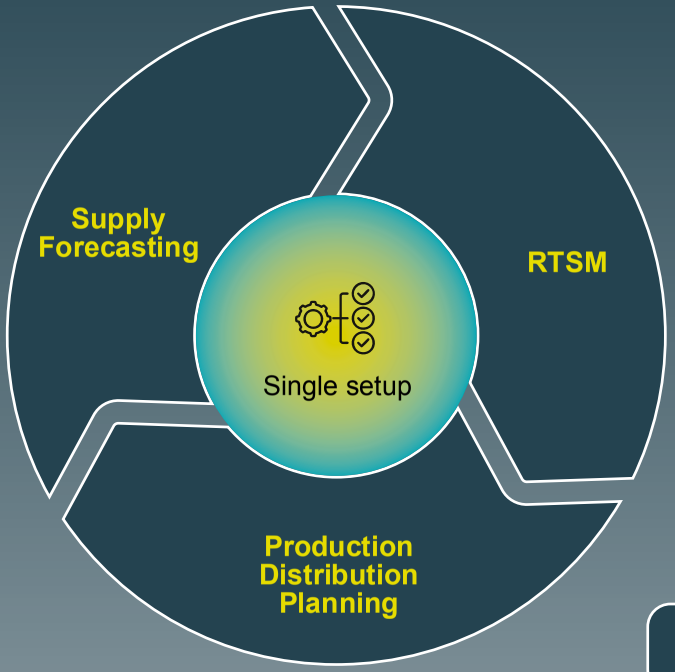

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