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**KRISTIN BROOKS**
Managing Editor, Contract Pharma

# EY's Global Pharma Supply Chain Assessment

## The main challenges that persist impacting pharmaceutical supply chains and how to overcome them.

On October 4, 2023, EY released its assessment on the state of global pharmaceutical supply chains, focused on supply chain vulnerabilities, complexity challenges, and the future of supply chain visibility.

With recent global disruptions, there is a need for enhanced resilience in pharmaceutical supply chains. Despite stabilization in the global supply chain environment, challenges persist due to prolonged delivery times and increased costs associated with inflation and interest rates.

The assessment points out the need for improved visibility in the supply chain for efficient response to disruptions and cost management, along with addressing intricacy challenges of the multi-tiered nature of the pharma supply chain.

Companies are increasingly focusing on digital solutions that offer real-time alerts and insights, fostering proactive risk management. EY's Olaf Zweig and Derron Stark provide further context and comment on pharma's global supply chain landscape.

***Contract Pharma:*** *What are the main challenges that persist impacting pharmaceutical supply chains?*

Pharmaceutical supply chains are still affected by high ongoing costs (resulting from high inflation and interest rates driving up the cost of working capital) and have additional cost concerns given the likelihood of upcoming regulatory

changes such as the US Inflation Reduction Act (IRA) cutting drug prices.

The bigger picture is that the global operating environment is still in the midst of a major potential transition, with governments and regional trading blocs increasingly concerned with securing regional supply potentially even at the cost of prioritizing localization over the globalized supply chain model that has evolved in the past three decades. At present, delivery times have yet to return to pre-pandemic levels, with multiple disruptions ongoing, and the overall situation is one of flux and uncertainty which companies are forced to navigate.

***Contract Pharma:*** *How might these challenges be overcome?*

Localization is one possible answer to the challenge of improving supply chain resilience, with the industry looking at a potential pullback from fully globalized supply chains towards more hybrid models involving a mix of local, regional, and global sites. However, onshoring is just one aspect of the range of strategies for boosting resilience.

Interpreting supply chain resilience as a composite of several factors, including better operational efficiency and reliability, agility and speed to market, and greater control over risk exposure, companies and policymakers have several possible levers for improving their performance. Among these possibilities are new supply chain models using some local and some global elements, such as "hub and spoke" models and potential collaborations between companies including initiatives such as joint warehousing or jointly run procurement clearing warehouses.

One of the most promising approaches is to improve supply chain resilience, using digital technologies to enhance companies' visibility into their upstream supplier base and downstream customer base. Better visibility could improve the industry's ability to predict and respond to shocks, disruptions, and changing market signals, anticipate and mitigate delays and price increases and overall better understand and reduce the risk exposure across their supply chains.

***Contract Pharma:*** *What can the pharmaceutical industry learn from other industries?*

Remaining with the subject of supply chain visibility (as noted, only one of many possible levers for enhancing resilience, but nonetheless a relevant and important field), digitally enhanced supply chain visibility is yet to reach its full maturity and potential in any sector, though the consumer retail industry, for example, has long been a leader in the field. More recently, pharmaceutical companies have had the example of peer companies in the aerospace and automotive industries, which have used digital tools for a range of supply chain visibility enhancements, including better supplier screening and due diligence, risk monitoring and management and multi-tier network mapping.

None of these industries have yet to fully resolve the structural challenges of managing highly complex supply networks, and solutions will need to involve not only better data but better analytical tools (including AI) to scan, assess and filter the information and devise possible responses. Companies will also need to establish proper governance around these data to enable faster and more effective decision-making. Initiatives to improve supply chain visibility are in their early stages, but better visibility will ultimately become a keystone of pharmaceutical supply chains of the future, which will incorporate automation, AI, and end-to-end process integration. As such, improving visibility should be a priority for most pharmaceutical companies as they look to create a more resilient future.

*Views expressed in this article are those of the author and do not necessarily represent the views of Ernst & Young LLP or other members of the global EY organization.*

DERRON STARK is the EY-Parthenon Managing Director in Strategy and Transactions. He helps clients build supply chain resiliency to make certain that critical medicine and equipment are always accessible. Derron integrates client perspectives with his relevant experience to deliver success. He strives to demonstrate the strong values and principles that guide scientists in their work.

OLAF ZWEIG, EY-Parthenon Partner, Life Sciences, EY-Parthenon GmbH, leads the health sciences and wellness sector of EY-Parthenon in Europe. He is helping companies to transform within a changing and increasingly digitized health ecosystem. His experience covers strategy-based transformation and improvement programs, supply chain management and resilience, and production network (internal and external) strategies.


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**BRYN JONES**
Senior Category Manager Logistics – EMEA, Marken

# Critical Role of Precision Logistics in Healthcare

In our interconnected world, quality logistics are the foundation of every industry, with a seamless supply chain being paramount. In healthcare, the movement of goods and services transcends mere transactional exchanges—it's a lifeline where precision logistics play a pivotal role. Marken, the clinical precision logistics and advanced therapy subsidiary of UPS Healthcare stands at the forefront of this critical field. By adhering to the stringent standards of current good distribution practices (cGDP), we ensure that every facility, packaging solution, and mode of transport is meticulously planned and tested. Driven by our passion for patients, we are committed to delivering lifesaving biopharmaceutical products with unwavering reliability and transparency.

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The evolution of hyper-sensitive personalized medicines has raised the stakes, necessitating a cold chain with unparalleled precision, expert handling, and a robust infrastructure. At Marken, we approach these challenges head-on, implementing comprehensive risk management and proactive planning to ensure the safe delivery of these vital medicines to patients worldwide.

Digitalization plays a vital role in enhancing the resilience of our logistics operations. By integrating advanced software solutions, we break down silos and foster transparency across the supply chain. Our dedication to quality management and the adoption of cutting-edge technologies ensure our systems remain flexible and responsive to any situation.

Utilizing state-of-the-art passive and active sensor technology, we offer end-to-end visibility and control over the storage and transport of medicines with the ability to pivot shipment strategies instantaneously. By leveraging our central monitoring systems, GPS tracking, temperature-controlled packaging solutions and specialized control towers, we manage the complexities of the most ultra-sensitive advanced therapies to ensure the integrity of these high-value shipments at every step.

With a wealth of data at our fingertips, we continuously evolve

our logistics strategies for maximum efficiency and effectiveness. Our proprietary software systems provide realtime access to critical shipment information, facilitating smart decision-making and enabling continuous improvement across our operations.

As technology advances, so does our ability to predict and manage logistics. Through the integration of AI, machine learning and additional technological breakthroughs, we anticipate even greater levels of visibility, efficiency, and optimization in our future operations. These innovative tools will one day predict and manage the orchestration of healthcare logistics on an unprecedented level previously unimaginable.

## NAVIGATING THE GLOBAL REGULATORY AND COMPLIANCE LANDSCAPE

Understanding the complexities of international logistics is essential for ensuring the rapid and safe delivery of medical products. Marken's regulatory teams navigate the everchanging compliance requirements across borders and through various regulatory environments on a local to global scale. Our proactive approach to customs clearance and vigilance in monitoring geopolitical and environmental factors ensure we can anticipate and mitigate potential disruptions, keeping our supply chain resilient and responsive.

Understanding the time and temperature-critical nature of our shipments, we understand there is no margin for error. Our operational teams employ rigorous corrective and preventive measures to ensure the flawless execution of every delivery. By combining methodologies from different departments, we reach a higher level of best practice, instilling a culture of lean management and continual improvement on every level, which ultimately leads to a flexible and adaptive supply chain responsive to the needs of patients and partners.

## CHARTING THE FUTURE OF PRECISION LOGISTICS

Marken's robust strategic worldwide network continues to grow stronger, extending healthcare access to the most remote corners of the globe. Our unique suite of supply chain solutions, including specialized storage and distribution centers, liquid nitrogen and dry ice fill stations, home healthcare services, advanced therapy logistics and a dedicated fleet of temperature-controlled vehicles, exemplifies our commitment to diverse patient needs. It's not just about moving products; it's about delivering hope and health where needed most.

As we look ahead, Marken will continue to push the boundaries of what's possible in healthcare logistics. Our future-focused supply chain matrix is a testament to our ability to balance logistical efficiency with the intricate demands of the healthcare ecosystem. In an ever-evolving world, Marken is a leader in supply chain resiliency, sustainability, and innovation - dedicated to delivering lifelines and enhancing healthcare equity for all.

BRYN JONES is a chartered manager in logistics and Senior Category Manager for Marken, a leader in delivering pharmaceutical products and the clinical subsidiary of UPS Healthcare. With over three decades of experience in logistics, Bryn uses his knowledge and passion for the supply chain to support colleagues throughout Europe, the Middle East and Africa. His extensive background in logistics began while serving in the military, and among the notable accolades in his career, he is responsible for developing an award-winning 4PL control tower for a major producer of fast-moving consumer goods. As an acclaimed logistician, his immense work ethic drives innovation and technological advancement in delivering what matters.

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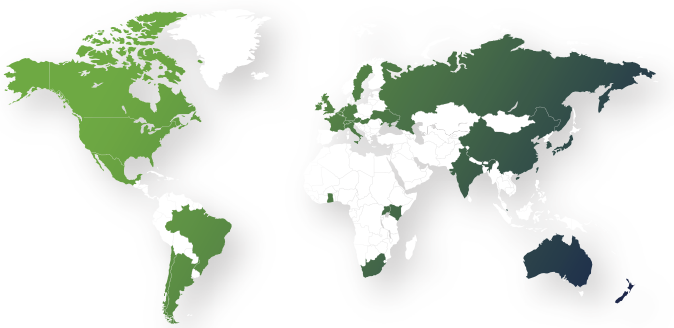

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**EMILY NEWTON**
Contributing Writer, Contract Pharma

# How to Preserve Quality in the Pharma Cold Chain

## Modern technologies are playing an increasing and ever-important role in today's pharmaceutical supply chain.

The cold chain is substantially different from the conventional supply chain. Everything from the packaging of goods to constant refrigeration calls for a much more hands-on approach.

This is especially true for maintaining pharmaceutical quality and the health of related goods. If and when they are exposed to less-than-optimal conditions, bad things can happen. Food can become contaminated, medicine can spoil and become dangerous, and lots of money is lost as a result.

Preserving quality in the pharmaceutical cold chain goes beyond just keeping the goods safe and in optimal condition. People depend on that medicine, and sometimes their life hinges upon its safe arrival. The logistics may be the same, but the consequences can be much more severe.

So, what are some tried-and-true ways to preserve quality in the pharmaceutical cold chain?

### START WITH THE PACKAGING

Pharmaceuticals must be kept at a constant and reliable temperature, including medicine and vaccines. Any failure to maintain the recommended temperatures could mean the medicine spoils.

When temperature readings go outside the intended boundaries, it's called a temperature excursion. According to the U.S. Centers for Disease Control and Prevention (CDC),[1] a temperature excursion is "any temperature reading outside ranges recommended in the manufacturer's package inserts." The best way to deal with them is to "take immediate action" to correct the excursion before the vaccine or medicine goes to waste.

Temperature-controlled packaging can help preserve those boundaries, at least for longer than standard packaging methods. From insulated boxes that expel heat to specially designed coolants for use in shipping and transport, technology plays

a huge role in keeping pharmaceuticals safely stored. It's also being improved constantly with new and innovative solutions, such as cryogenics and biologic therapies.[2]

## EXTENSIVE TESTING IS NECESSARY

As with all things, it's wise to conduct various tests and assessments to understand where things may go wrong and how to improve upon them. However, with the cold chain, once things are in motion, they stay in motion. That's because it involves constantly dealing with vulnerable and easily affected pharmaceuticals, and there's no way to halt operations without potentially damaging those valuable goods. It calls for a new form of dynamic testing and real-time operations, empowered by modern technologies such as IoT (internet of things) and connected devices.

After initial tests, the IoT devices and sensors will constantly report data that can be used to protect the related goods, but also to take immediate action when things go bad. A sudden temperature drop in a cold transport, for example, would result in alerts going out to the driver, support crews, and administrators. That team can then work together to figure out what's happening, and either remedy the situation to continue the transport's journey, or make adjustments to save the inventory—like moving it to another truck or a nearby storage facility.

It's an ongoing level of testing, driven by data and more informed decisions.

## SMARTER OPERATIONS

Artificial intelligence and machine learning tools, such as neural networks, can aid in both cold chain planning and automation tasks. They ingest data, sometimes collected and shared thanks to IoT devices, turning it from passive to active, and creating actionable insights that can improve operations and business processes.

Think shorter routes with more conducive environmental conditions, faster time to market because of process optimizations, and reduced operating costs thanks to more effective strategies. They can also allow predictive modeling to plan ahead for changes in the market, supply shortages, and customer demands. The technologies are designed to parse and analyze information to find hidden patterns, trends, and other flags that can be leveraged in some way. Not only do they do it faster than any human could hope to, but they also make it possible to maintain real-time data solutions.

Even outdated and ineffective payment systems can cause quite the hassle. One estimate says the average business loses over $171K per year[3] on poor or ineffective payment solutions. Nearly 6,500 man-hours are wasted just on chasing purchase order numbers and processing invoices, and responding to supplier inquiries. Many of those processes could be automated with the help of ML and AI platforms.

## SCALABLE SOLUTIONS

It's no surprise that the pandemic called for an unprecedented ramp-up[4] in production for vaccines and pharmaceuticals. But this move would not have been possible without modern technologies, namely automation and advanced robotics. After the research that went into creating these vaccines, automated solutions allow for the true scaling of operations.

That's not to say events can't be challenging. Manufacturers are up against a seemingly limitless demand that continues to grow, as does the urgency of their arrival. The good news is that many of the solutions being implemented right now will hold and improve going forward. The result is a more scalable industry that can meet demands, no matter how insurmountable.

## SMART CONTRACTS FOR TRANSPARENCY

The technology is still relatively new to the field of logistics and the cold chain, but blockchain technologies, like those powering high-profile cryptocurrencies, could potentially revolutionize the transparency of the entire industry.

The blockchain is essentially a digital ledger that contains secure information for all transactions carried out on the platform. Transactions are always conducted by trusted parties with verifiable identities and traceable goods. This helps cut down on theft, fraud, and counterfeit goods, which could wreak havoc in the world of pharmaceuticals.

Pharmaceutical quality benefits as well, and is just as verifiable through blockchain systems. An interested party could follow a specific batch directly to the source, with verifiable data and more detailed insights. This tracing can go in both directions. And in both the food supply chain and pharma chain, it can help identify, track, and deal with contaminated goods that have made it out to the public.

These types of platforms already exist and are being used,[5] but the proper supply chain solution architecture must be in place.

## PRESERVING PHARMACEUTICAL QUALITY IN THE COLD CHAIN

Pharmaceutical quality in the cold chain is of the utmost importance, and that's true whether you're talking about COVID vaccines or diabetic insulin. All forms of medicine must be preserved to the recommended standards, to fend off potential contamination or failure. Many depend on the medicine and its timely, safe arrival.

Luckily, modern technologies are playing an increasing and ever-important role in the field, aiding in everything from general logistics and storage to data-driven market predictions. Temperature-controlled packaging, real-time insights from IoT and smarter operations, scalable automation platforms, and smart contracts via the blockchain are all examples of innovative technologies being put to use in the industry. They're also crucial to maintaining the level of pharmaceutical quality we all need to thrive. **CP**

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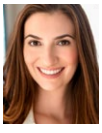

**EMILY NEWTON** is the Editor-in-Chief of Revolutionized. She's always excited to learn how the latest industry trends will improve the world. She has over four years of experience covering stories in the science and tech sectors.

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# Go beyond logistics

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**ROHIN IYER**
Senior Director, Cell and Gene Operations, Marken

**ROBERT BRACKNER**
Global Content Manager, Marken

# Vitality in the Supply Chain:
## The Limitless Potential of ATMPs

In laboratories around the globe, scientists are diligently researching the limitless potential of advanced therapeutic medicinal products (ATMPs). These groundbreaking therapies are changing the face of healthcare by harnessing the potential of the human body for healing. Using cells, proteins, antibodies, tissues, and nucleic acids as "living" therapies is simultaneously promising, but also brings unique challenges from a manufacturing, supply chain, and patient treatment standpoint. The advent of ATMPs is a foundational milestone, the growth of which is comparable to the rise of the microprocessor in terms of its transformative potential for effecting change on humanity. The "holy grail" of ATMP-based treatments is to provide cures for some of the world's most debilitating disease states, but for this to occur, a unified front is needed to democratize these therapies—collaboration from industry, academia, supply chain and, indeed, clinicians and hospitals is paramount to ensuring safe manufacturing and transit.

The reasons for ATMPs garnering huge attention from the scientific community are well justified—ATMPs are now starting to demonstrate curative potential, not just symptomatic treatment, for a litany of rare or intractable diseases. These therapies also come in various forms—some can be classified as cell therapies, others as gene therapies, gene-modified cell therapies, nucleic acid drugs and other therapies including personalized cancer vaccines (PCVs), tissue engineered products, CRISPR-edited therapies and even radioligand therapies, among others.

Still, despite their immense promise, additional research is needed before we fully understand and take advantage of the curative potential conferred by ATMPs.

ATMPs have a long history but were not considered treatments in their earliest forms. In the 1950s, the concept of a "cell therapy" did not exist. Rather, experiments were being conducted to treat radiation victims with bone marrow transplants, but failed due to an unknown reason that we now know to be an immune response-mediated rejection. In 1956, the first ever bone marrow transplant was performed, with surprising results—an identical twin was the key to a successful engraftment, which led soon to the discovery of human leukocyte antigens (HLA), and the understanding that therapies from biological sources needed to match the donor and recipient HLA-type. Around the same time, Canadian researchers Till and McCulloch were performing similar experiments in irradiated mice and found injected bone marrow produces small nodules in the spleen. Since then, an immense body of work has shown that these cells can in fact self-renew and differentiate into multiple lineages, which led to the term "stem" cells, alluding to their being the origin of all tissues in our body.

Today, we have reached new heights in our understanding of the complex signaling pathways and mechanisms of action that contribute to human disease. There are many milestones to speak of in the ATMP space, but most notable among them is a staggering 34,400 chimeric antigen receptor (CAR)-T cell therapies have been delivered to patients as of October 2023. There are now 34 FDA-approved cell or gene therapies in the commercial pipeline, with hundreds more in development. Today, there are six commercially approved CAR-T therapies on the market, and in some countries and regions, they are reimbursed by government health authorities, enabling their use in larger patient populations. Thanks to key pioneers in the field of ATMPs, we can now confidently report that therapies like CAR-T cells are forming a new foundation for cancer treatment.

Of course, the story does not end here. Numerous other ATMPs are now being developed with greater potential for human treatment, such as allogeneic therapies, which can be delivered to an even larger patient population. These require larger bioreactors and healthy donor cell material but offer the promise of lower cost and wider accessibility. Similarly, a large body of work is being done to create therapies for the treatment of rare or orphan diseases. These include gene therapies based on adeno-associated viruses (AAV) that are being developed for both prevalent and rare disease states, such as congenital blindness, sickle cell disease, hemophilia B, dystrophic epidermis bullosa, and even diabetes and spinal muscular atrophy. As examples of commercial successes in this area, Luxturna, Zolgensma, Lyfgenia, and Vyjuvek are approved gene therapies for some of these rarest indications. More recently, new non-viral methods of production are being explored to avoid speculation around the possibility of replication competency that could arise from the use of viral vectors during production.

For example, Vertex Pharmaceuticals and CRISPR Therapeutics made history by gaining the first FDA approval for a CRISPR-based drug, exagamglogene autotemcel (Casgevy) for the treatment of sickle cell disease with vaso-occlusive crisis, coinciding with a record number of 14 review designations awarded by the FDA to CRISPR-based therapies in 2023, according to data and analytics firm GlobalData. In 2023, a record six orphan drug designations, four fast track designations, two regenerative medicine advance therapy designations, and a single rare pediatric disease designation were granted, and priority review was awarded to 10 different CRISPR drugs, representing a 55% increase from 2021 and 2022. These numbers indicate an increased priority and appetite for ATMPs by regulators and manufacturers.

At the end of 2023, there were more than 100 different approved gene, cell, and RNA therapies throughout the world, with over 3,700 more in development. Nucleic acid therapies gained infamy during the pandemic as a rapid and effective way to resolve a key global crisis through mRNA technology, but they also exposed weaknesses and revealed opportunities for new ATMP modalities. In more recent times, mRNA therapies are being used to create personalized cancer vaccines (PCVs), demonstrating their continued usefulness to larger patient populations with severe illnesses in a post-Covid world. Similarly, the advent of nuclear medicines, which has existed for decades, has brought a new contender to the sphere of radioligand therapy (RLT). This therapeutic modality is demonstrating efficacy for some of the most intractable solid tumor cancers, such as metastatic castration-resistant prostate cancer.

While the focus for ATMPs has been on treating cancers like B cell lymphomas and leukemias, as well as rare disease like hemophilia B and sickle cell disease, novel application areas are emerging, such as treatments for diabetes, Alzheimer's, and even cardiovascular disease.

With this excitement comes the realization there is still work to be done to understand the underlying biology behind these ATMPs. As an example, it was recently reported that a small proportion of patients having received CAR-T therapy had also developed secondary cancers in the form of T cell malignancies, which now requires a box label warning. There are also known side effects for CAR-T therapies, which include cytokine release syndrome (CRS)12 and immune effector-cell associated neurotoxicity syndrome (ICANS). Some patients, despite the high levels of response to the therapies broadly seen, do not survive their cancers in the end. Even with these setbacks, it is generally agreed the overall benefits of these ATMPs greatly outweigh their risks. Looking ahead, we must respond to the ever-increasing demand for ATMPs to ensure a consistent supply chain for the patients who require them. **CP**

As Senior Director of Cell and Gene Operations, **DR. ROHIN IYER** leads Marken's advanced therapies division, managing the critical distribution of both clinical and commercial personalized medicines. Leveraging Marken's unique cell and gene therapy (CGT) portfolio, he oversees the complex logistics across a diverse array of advanced therapeutic modalities ranging from nucleic acid therapies to CAR-T therapy, as well as the raw materials used to manufacture them.

**ROBERT BRACKNER** is Global Content Manager at Marken responsible for producing and directing communication with clear, compelling narratives. From articles to website copy, webinars to video scripts, Robert's work connects knowledge and action, driving engagement and understanding in specialty logistics and biopharmaceuticals.

# MARKEN'S RESILIENT SUPPLY CHAIN NETWORK REVOLUTIONIZES HEALTH-CARE ACCESS IN AFRICA

## TRANSFORMATIVE STUDY OFFERS HOPE FOR MALNOURISHED EXPECTING MOTHERS AND THEIR INFANTS IN BURKINA FASO AND THE WORLD

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In today's ever-evolving healthcare landscape, resiliency becomes not just a strategic advantage but a vital necessity to thrive amidst the uncertainties of the future. Marken has an unwavering commitment to deliver lifesaving medicines and treatments to every corner of the world including the most challenging, underdeveloped and remote regions. **By embracing change and mitigating disruption, Marken is able to offer an agile and limitless supply chain network that improves healthcare accessibility and equity globally.** Marken's robust global network, combined with cutting-edge digital tools and a patient-centric mindset, optimizes logistics efficiency and flexibility to ensure the distribution of innovative drugs, treatments and other clinical products to those who need it most. Where there is a need, Marken makes it happen.

## AFRICA STUDY TRANSFORMS LIVES OF EXPECTING MOTHERS AND INFANTS

Burkina Faso, a nation in Africa with severe economic and social instability, has a long-standing history of food insecurity, which presents significant challenges to supply chains in the area. One particular issue is maternal undernutrition, which remains a critical public health concern as achieving nutritional adequacy during pregnancy and lactation is difficult in many areas of this region. This dire situation contributes to poor fetal development and adverse birth outcomes, resulting in a staggering number of small for gestational age (SGA) births annually.

Industry stakeholders across the value chain were determined to do something about this. Led by researchers from Ghent University in Belgium, the MISAME-III trial's primary objective is to assess the effects of a ready-to-use micronutrient-fortified, nutritional supplement on fetal development and infant growth in Burkina Faso. Given the study's scope and duration, researchers needed a specialty logistics company capable of distributing large scalable volumes of study setup materials and ensuring seamless transport of biological samples from thousands of expectant mothers and newborns on a consecutive basis over several years. With an expansive and established ready-to-use operational infrastructure skilled at delivering to remote areas in Africa, Marken was approached by researchers to provide services for this life-changing study.

To add another layer of difficulty - past efforts by other specialty logistic companies to support the study outright failed. Stakeholders were left in turmoil after the original logistics provider lost a vital shipment of nearly 600 blood samples collected over one year — an unquantifiable loss of time and resources. As the leading supply chain solutions provider for clinical trials, Marken stepped up as the exclusive partner to help improve the health and wellness of expectant mothers and infants in the area. The researchers ultimately put trust in Marken as it was the only partner with specialized expertise managing and mitigating logistical adversity to deliver cold chain solutions with the ability to adapt or pivot as needed at lightspeed.

The potential impact of the study's outcome extended beyond the borders of a single country, holding the promise to transform the lives of countless mothers and infants worldwide by significantly reducing infant mortality rates and improving birth outcomes. Research demonstrating that a shelf-stable, micronutrient-rich supplement can provide the essential sustenance needed for a healthy full-term pregnancy could lead to the development of a global strategy. **This strategy would aim to deliver vital nutrition to women, not only in Burkina Faso, but anywhere around the world where food security threatens maternal health.** Further compounding the high-stakes situation, the study's outcome could warrant a substantial, multi-million-dollar investment by policymakers and health authorities to ensure widespread availability, accessibility and distribution of the critical supplement today and in the future.

# STRATEGIC ORCHESTRATION OF TEMP-CRITICAL TRANSIT TO REMOTE REGIONS WITH END-TO-END VISIBILITY

Marken took a proactive and strategic approach to rapidly expedite the transportation of critial ancillaries and medical equipment from Europe to Burkina Faso, streamlining the supply chain process with meticulous planning and state-of-the-art tracking technology. Marken's customer relationship experts worked closely with the dedicated operations teams in the EU, conducting lane mapping, risk assessments, contingency planning and business continuity to effectively manage the collection of materials for every single shipment. Providing end-to-end visibility and track-and-trace oversight, Marken's proprietary software, Maestro™, offered real-time updates, product conditions and shipment milestones to stakeholders during the entire shipment journey.

By putting trust and confidence in Marken, all study teams were able to efficiently orchestrate their respective workflows for a successful and streamlined collaborative environment. Leveraging their logistical strength and resilient global network, Marken ensured the successful delivery of the abundance of supplies, ranging from essential nursing materials to cutting-edge medical devices, flown directly into Burkina Faso's Ouagadougou Airport. Upon immediate arrival, staff stood ready to embark on a six-hour journey to the remote investigator site deep within the Burkina region, ensuring that no precious time was wasted. The high volume of supplies transported was matched by an equally substantial quantity of biospecimen kits, which were vital for the collection of samples required for the study. Once the supplies were delivered, researchers began collecting samples until the necessary quantity was attained for shipment out of Burkina Faso.

Another integral component of the study involved distributing these time and temperature-critical biospecimens to several global universities specializing in various analysis processes. Adding to the complexity, the necessary temperature for sample transit was -80°C which required a very rare and hard to access commodity in Africa – dry ice. Marken customized an integrated supply chain for the rapid import of dry ice, mostly brought from Europe to the Burkina Faso airport and then transferred via ground to the remote study site hundreds of miles into the interior of the country. Along with the constant stream of supplies, Marken delivered a surplus of technologically advanced pre-conditioned packaging to maximize use of dry ice and safeguard sample integrity. After researchers packed a shipment, ground transport moved samples from the investigator site to the airport, where Marken operations had completed lane verification and mapping from Burkina Faso to various university research centers in Canada, the U.S. and Belgium.

In addition to poor and hazardous roadway conditions and treacherous geography, the distance and volume were other barriers that Marken had to overcome. To mitigate adverse challenges and situations, Marken teams responded with hands-on support and end-to-end oversight of the entire value chain process. Adding to the regional difficulties exacerbated by the country's weak infrastructure and social institutions, seasonal catastrophic flooding often prohibits road access, while soaring temperatures require increased precautions for temperature-sensitive materials. Though many specialty logistics companies find these obstacles impossible, **Marken's core strength is to expect the unexpected and remain proactive, anti-fragile and resilient with the ability to consistently adapt to ensure critical deliveries reach their destination.**

## ACCELERATING GLOBAL HEALTHCARE ACCESSIBILITY AND EQUITY FOR HUMANITARIAN CRISIS

Marken's customized solutions are essential to Burkina Faso, a nation at the epicenter of the world's most severe perinatal undernutrition cases. Addressing this humanitarian crisis requires multifaceted global solutions and strategic collaboration involving international academics and national research institutions. **Now actively reaching its fourth year, Marken has completed every study shipment within time and temperature parameters - when other specialty logistics providers failed within weeks.**

**Marken continues to support the growing demands in Africa to make incredible impacts through projects like the MISAME-III study in Burkina Faso.** With dedicated purpose-built facilities in Ghana, Kenya, Uganda, a brand-new facility in Nigeria and more branches planned across the continent, Marken will continue to go beyond, using their logistical strength to expand their global footprint and capabilities to where clinical trials, patient populations and healthcare needs are increasing.

Marken goes beyond logistics, leveraging an unmatched global network that is ready to connect patients to medicines anytime, anywhere. By remaining committed to supporting improved healthcare accessibility and equity around the world, Marken will never stop moving the world forward by delivering what matters.

## WE ARE MARKEN

As the clinical subsidiary of UPS Healthcare, only Marken provides a best-in-class Quality Management System, clinical and commercial cell and gene supply chain solutions, a global GMP depot network, direct-to/from-patient, home healthcare nursing services, and industry-leading expertise all under one roof.

Marken's unique position within the biopharma and life sciences industry is unparalleled. Leveraging our limitless capacity and scalability, Marken manages 180K+ drug product and biological sample shipments every month at all temperature ranges to more than 220 countries and territories and have orchestrated 16K+ home healthcare visits. Our state-of-the-art GMP-compliant depot network and logistics hubs are strategically located in 60 locations worldwide, providing clinical to commercial storage and distribution services, direct-to-patient solutions, home healthcare nursing services, kit production, and cell and gene therapy shipments.

We have the best people and the best tools, and we will continue to operate at the leading edge, investing in new technology, enhancing our global network and lowering our environment footprint to deliver with quality excellence. At the end of the day, we understand that there is a patient who relies on us and our global team will always 'go beyond' to deliver what matters. It is in our Marken DNA.