KUEHNE+NAGEL

Healthcare Logistics

Scaling supply chains for rare and ultra-rare therapies

From clinical control to commercial reality

From the desk of
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When a therapy transitions from clinical trials to real-world patients, the supply chain fundamentally changes. Demand becomes unpredictable, regulatory scrutiny intensifies, and processes must shift from flexibility to full validation and precision. For advanced therapies, managing this complexity at scale while maintaining Chain of Identity is significantly more challenging.

In trials, supply chains operate in controlled environments with known patient numbers, locations, and timelines. After commercialisation, demand can arise anywhere, at any time, while stricter regulations and expanding networks of hospitals increase operational and financial risk significantly overall.

Why planning must start early

Planning for life after trials should begin much earlier than regulatory submission. Many therapies start small and highly controlled but waiting too long often creates a commercialisation gap.

Packaging solutions used in trials may not meet global requirements, manual processes may fail to scale, and hospitals may not be prepared. Data systems may also not integrate, leading to delays. These gaps can result in financial losses, delays, or failed launches, making early supply chain design essential.

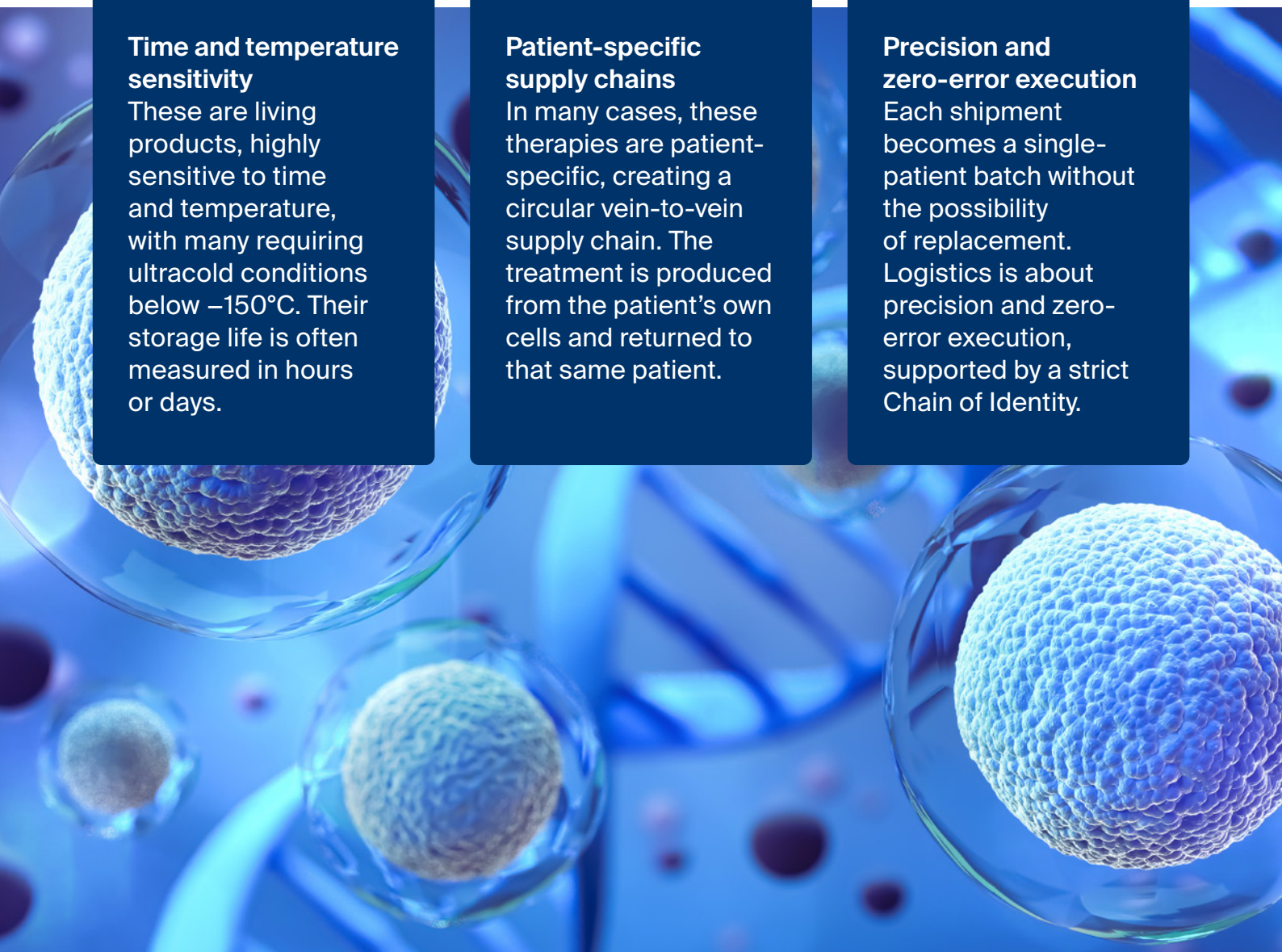
Advanced therapies change the rules

Cell and gene therapies introduce a completely different level of complexity compared to traditional medicines. These are living, patient-specific products with no margin for error. As a result, supply chains must shift from cost efficiency to precision, reliability, and control.

Time and temperature sensitivity
These are living products, highly sensitive to time and temperature, with many requiring ultracold conditions below –150°C. Their storage life is often measured in hours or days.

Patient-specific supply chains
In many cases, these therapies are patient-specific, creating a circular vein-to-vein supply chain. The treatment is produced from the patient's own cells and returned to that same patient.

Precision and zero-error execution
Each shipment becomes a single-patient batch without the possibility of replacement. Logistics is about precision and zero-error execution, supported by a strict Chain of Identity.



Risk shifts as therapies near launch

As therapies approach launch, the perception of risk changes significantly. Here's a breakdown of how risk changes across four key stages of development and how the onus shifts from risk mitigation to risk avoidance, requiring new levels of control and reliability.

From financial to patient-critical risk
Early in development, risk is largely financial or related to data loss. As commercialisation approaches, it becomes clinical, reputational, and patient-critical.

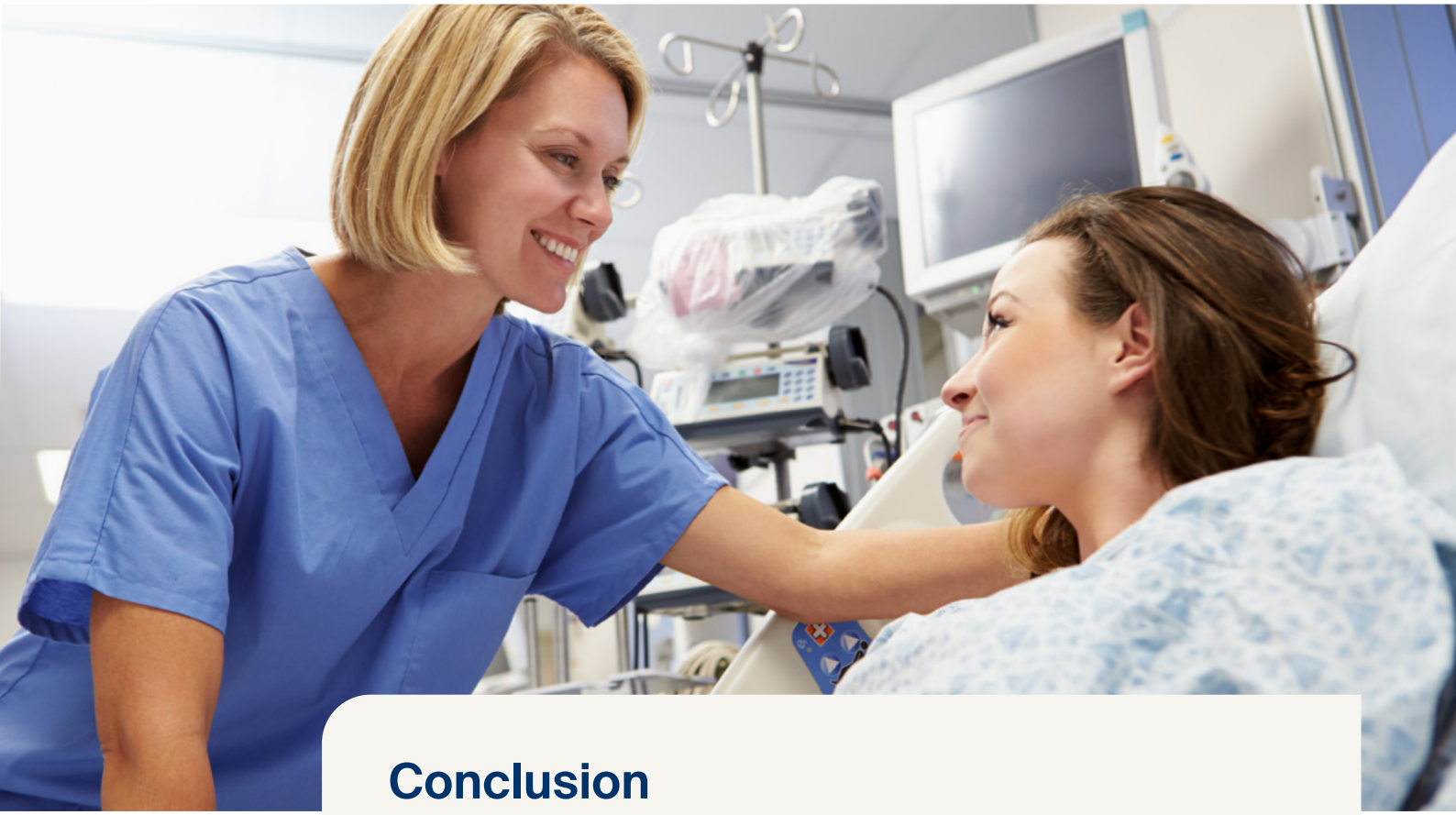
Focus on successful patient infusion
The goal isn't just simple delivery to the hospital but successful patient infusion.

From mitigation to avoidance
The focus shifts from risk mitigation to risk avoidance. Companies introduce reserve capacity, including backup routes and alternative transport solutions.

Operational and administrative risks increase
Risk also extends to hospital readiness and staff availability. Administrative errors, such as documentation issues, become major risk drivers.

Redefining success for ultra-rare therapies

For ultra-rare therapies, volumes may remain low throughout the product lifecycle. In these cases, success is not defined by scale or cost efficiency. Instead, it is defined by precision, reliability, and availability, with a supply chain that must be ready to act at any time, regardless of demand frequency, where speed of activation becomes more important than volume. Each treatment is often a single-patient batch with no alternative or replacement. As a result, the priority is not reducing costs but making them predictable.



Conclusion

Ultimately, success means ensuring every patient can access treatment without delay, with zero errors, waste, and friction. The supply chain must deliver with precision, reliability, and full control, making even the most complex therapies feel consistent, predictable, and dependable.

About us

Kuehne+Nagel is about making logistics work smarter for our customers. With a global network and deep industry expertise, we help businesses navigate complexity and unlock growth through reliable, digital services, advanced technologies and data-driven insights.

As the logistics partner of choice for companies worldwide, we deliver tailored, end-to-end supply chain solutions across Air, Sea, Road, and Contract Logistics.

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