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The New Ice Age:

Creating a flexible, intelligent pharmaceutical cold chain

Rosa watches the clock as the nurse takes her blood. The doctor said it was late-stage cancer. Every day counts. Right now, time is of the essence for getting her immune cells to the facility. At the site, her cells will be genetically modified to fight the cancer then returned to her for treatment—all within three days.

When the doctor comes in, Rosa asks: "**Are you sure we'll get it back in time?**"

The doctor reassures her: "**Don't worry**," she says. "**Millions of people have this kind of therapy now. We'll track your medical bag from here to the lab and back again. The operators can see everything in real time. If there's a temperature or delivery time deviation, they can intervene. Simulations can even test the best possible rerouting options. You can even use an app to monitor progress.**"

Over the next two days, Rosa logs into the app—at her daughter's birthday and other hospital appointments—to follow her treatment's journey back to her. When her appointment time pops up well within the 72-hour window, the weight in Rosa's chest lifts a little. More time.

New science, new approaches

In the future, such scenarios won't be the exception, they'll be the norm—and not only in developed countries. In fact, from 2018 to 2024, such therapies, which are reliant on cold chain capabilities, are expected to grow **48% globally**, outpacing growth for non-cold chain therapies by 21 percentage points.[1] This means cold chain capabilities would need to grow in parallel with therapeutic innovations to satisfy patient demand.

The total market value of pharmaceutical products is expected to be $1.7 trillion by 2024, with 30% representing the cold chain portfolio.[2]

New Science and cold chain

New Science is expected to drive 81% of biopharma revenue growth but is more expensive to develop and deliver.

The shift away from traditional small molecule products to rare disease, orphan drug, and personalized medicines brings new, unconventional supply chain requirements from the manufacturing process, through storage and eventual last mile delivery.

While complex, these delivery models will need to be flexible and adaptable to changing product characteristics and supply chain disruption.

As a result, cold chain participants will be more successful if they don't try to do it alone, but rather engage in partnerships with vendors and subject matter experts.

Between 2020 and 2024, biopharma cold chain logistics expenditure is expected to grow at a 5.5% compound annual growth rate on the heels of increased demand.[3]

Although cold chain logistics in the pharmaceutical industry aren't a new development, the growing complexity and demand are. As a result, life sciences companies, distributors, and carriers—cold chain participants—are under pressure to scale delivery and storage capabilities, support and monitor variable temperature ranges in real time, and offer services like predictive and dynamic estimated time of arrival tracking. These changes are driving new-ways of working, as companies innovate at speed to create sustainable growth.

Cold chain capabilities need to mature and scale at the speed of the industry. But how?

To understand the key challenges life sciences professionals experience in building and managing a cold chain in this new landscape, Accenture recently conducted a survey of 200 industry executives from Europe and North America. These insights shed light on how life sciences companies can work with partners to incorporate a patient-centric cold chain into their overarching supply chain operating model.

Those who make the right investment with the right ecosystem partners stand to gain both patient trust and a competitive edge.

Struggling to scale

While cold chain products are growing steadily, current capabilities and operational insights are insufficient to meet future needs—and patient demands—for consistent visibility, quality assurance, flexibility, and agile execution. Life sciences companies, however, cannot just lift and shift old ways of operating to serve new needs. They require new capabilities and agile operating models that can ship 100,000 doses of traditional medicines as effectively as one dose of a personalized therapy.

Pressure is mounting on cold chain participants to deliver on this potential at scale. Accenture research, however, revealed that life sciences companies, particularly those who didn't take part in the COVID-19 vaccine rollout, are acutely aware that their operating models may become uncompetitive in the evolving biopharma landscape. Approximately 70% of respondents identified the gap, saying they lack efficient logistics cold chain capabilities at scale.

They face significant operational hurdles in each of the following areas.
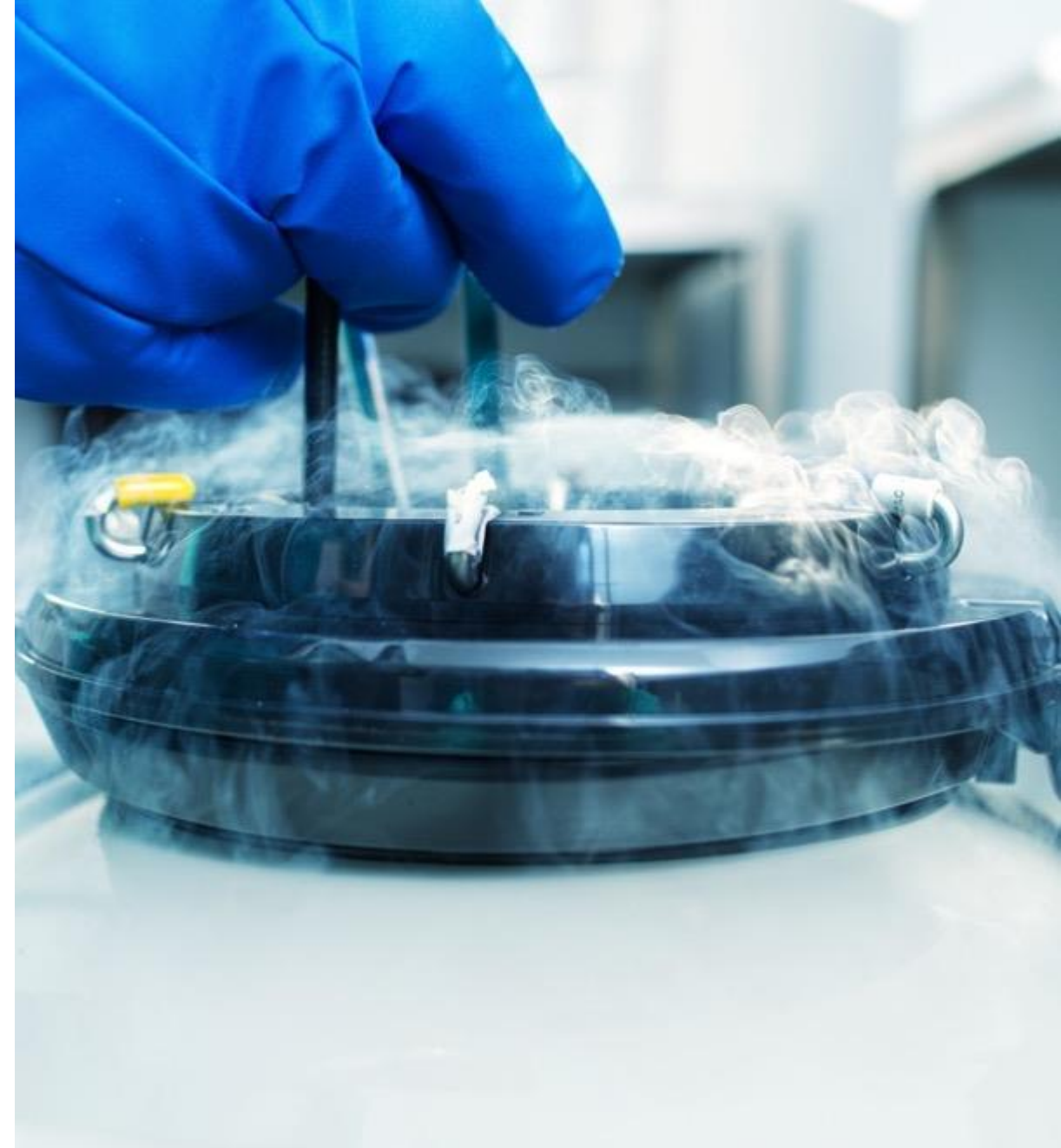
Fragmented infrastructure networks and evolving requirements

Cold chain infrastructure involves physical and logistics capabilities, such as automated, high-density storage warehouses and thermal shippers for ultra-low and cryogenic temperatures to no more than 2-8˚C. The infrastructure is supported by Internet of Things solutions that collect and transmit environmental monitoring data in real time. The cold chain infrastructure landscape, however, is in flux and demand is increasing.

New, nontraditional vendors and shippers coming into the marketplace means there are no dominant players, and many of the solutions are maturing.

In recent years, the focus on speed to market of complex disease-fighting therapies that are dependent on cold chains has reshaped the expectations of healthcare supply chains, globally. Flexibility is paramount, as cold chain participants will need to enable infrastructure that can manage a range of temperature profiles as the product undergoes stability changes over time or at different stages of the logistics lifecycle.

In 2020, the business of delivering cold chain pharmaceuticals reached $17.2 billion.[4]

Many life sciences companies find such complex demands difficult to navigate. Our research shows that 31% are looking for better equipped internal/external logistics networks, particularly those investing in automation and multi-chamber storage/transportation for different temperature requirements. Quality management, tracking capabilities, and eco-friendly options are also highly sought after.

Lack of end-to-end insights

Logistics service provider fragmentation means that many participants struggle to deliver the experience that such sensitive products and their recipients need. Approximately 90% of our research respondents say their companies are using multiple disconnected solutions to collect data across the cold chain. As a result, the lack of coherent real-time environmental monitoring makes it difficult to gain visibility into the product while in transit, risking ETA management, security & document compliance, and continuous temperature monitoring across multiple logistics legs. The lack of insight exacerbates functional organizational siloes.

Automated data collection and contextualization with user-friendly dashboards can help teams quickly identify and proactively respond to delivery issues regardless of data/IT skills.

About 56% of survey respondents are using visibility tools in the cold chain but find them unsatisfactory. There's little automation, and some still use manual processes to identify actionable business insights from data. This suggests that many respondents had little understanding of their future cold chain requirements when initially building capabilities.
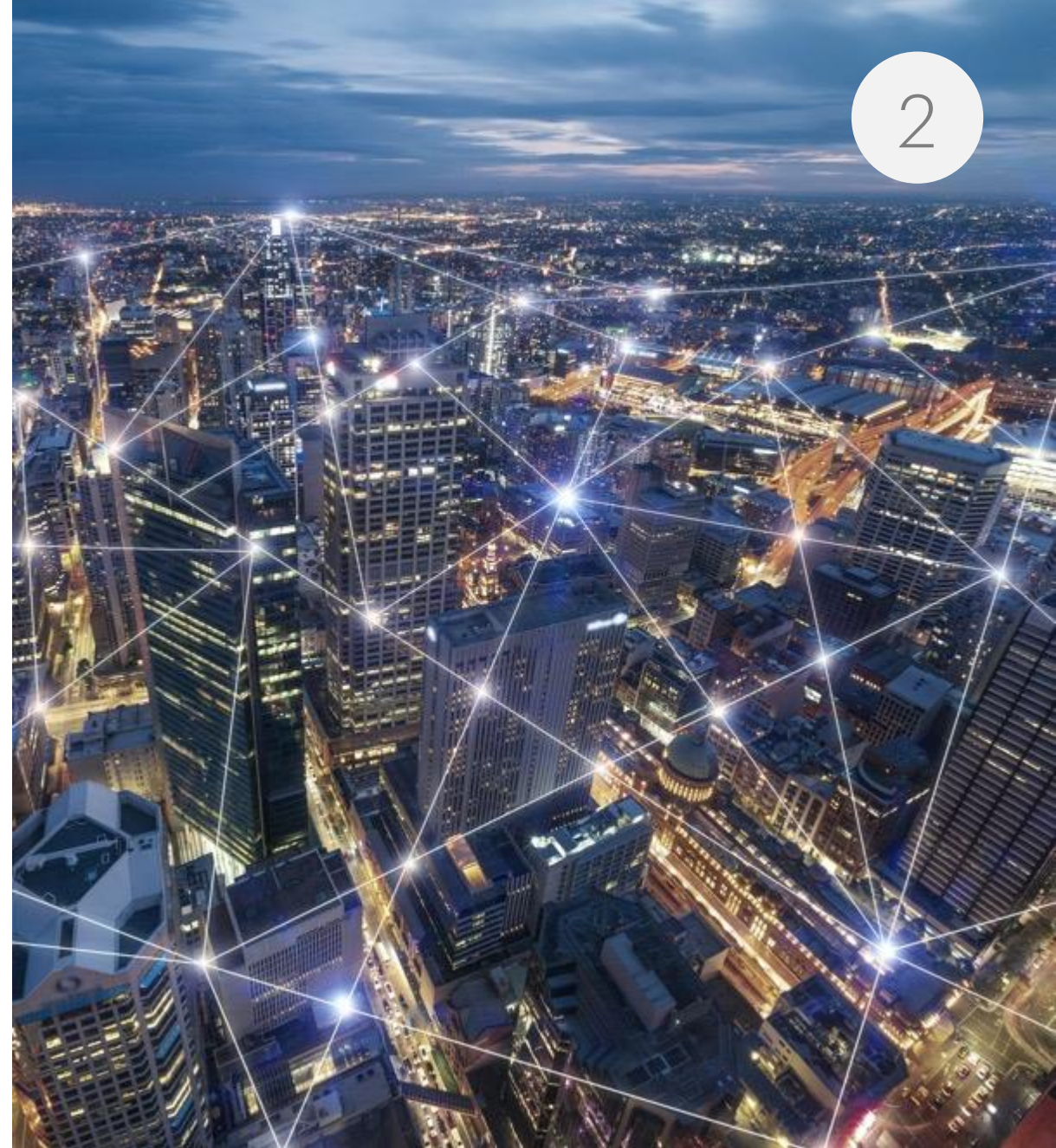
Cold chain capability gap

To facilitate future cold chain initiatives and the use of sophisticated solutions, companies are looking for skills in artificial intelligence (AI), IT automation, analytical skills, engineering, and geopolitical awareness. For instance, life sciences professionals may need to be trained to handle new cross-border processes and solutions that support direct shipping to the patient. Or they may need to completely change their way of thinking from resolving to preventing problems.

The required skills, however, are in short supply.

2/3 About two-thirds of life sciences companies report a significant workforce capability gap, according to our research.

Creating an intelligent patient-centric cold chain

Balancing traditional supply chain needs with new cold chain demands is not straightforward. Adding automation or other technical solutions alone won't be enough. Supply chains need to become technology agnostic, weaving cold chains into the existing digital network to reduce solution and organizational redundancies. Cold chain participants require a holistic strategy to address specific needs and answer important questions like:

- "Do I modify my existing supply chain operating model or start from scratch?"

- "What kind of functional and technical skills do we need?"

- "How do we move from being reactive to proactive?"

They also need a roadmap to help navigate their journey and change management solutions to acclimate the workforce to new ways of working.

Making the right first-time investment requires gaining a big picture overview while considering multiple possible pathways. Taking a holistic approach and working hand-in-hand with an ecosystem of partners, can prevent time-consuming U-turns later.

What's clear is that any lasting and robust cold chain strategy will require a patient-centric cold chain operating model supported by innovative infrastructure, digital capabilities, and talent with the right skills.

Patient-centric operating model

Within a patient-centric operating model, cold chain participants will be expected to handle a range of product specifications and temperature profiles, deliver on short lead times direct to the customer/patient, serve one or many patients in each shipment, and provide continuous order visibility.

It also involves moving from siloed to collaborative decision-making and reaching underserved patients. How can cold chain participants make the right first-time investment to acquire those new capabilities and skills?

They would first need to collaborate on an end-to-end framework to understand, define, plan for, and implement future cold chain needs.

Define the vision

Evaluate your products and determine what your cold chain will require given the products' unique environmental demands and the customer experience you seek to deliver (think direct to point of use).

Segment products

Identify and prioritize the factors (disease burden, product type, etc.) most pertinent to your business. Create more than one framework for each segment so cold chain capabilities can be categorized according to specific use cases.

Set your north star

Assess your product portfolio. Map and further segment the products on the framework(s) to discern nuances. Decide how you will stand up capabilities and change your organization over time toward new ways of working.
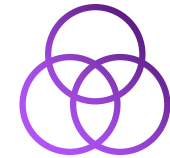
Determine desired capabilities

What capabilities/skills does your cold chain require? How should they be arranged? How can your cold chain operating model flexibly support your product portfolio?

Select the right framework(s)

Identify common capabilities across major segments for all frameworks under consideration. Pick the best framework(s) that represents your current and anticipated product portfolios.

Implement and continuously improve

Acquire agnostic solutions and capabilities that can serve all product segments across a rapidly changing landscape as well as niche capabilities to support strategic areas. Pick a solution that supports all products but launch with one.

Cold chain participants won't necessarily need to revamp their entire supply chain.

Creating a strategy and roadmap, however, are critical first steps to successfully scale at speed while avoiding ill-considered investments.

Smart infrastructure

Patients and customers increasingly demand an Amazon-like fulfillment model. To comply, the cold chain infrastructure and delivery network will need to be constructed around the patient experience. Standing up end-to-end delivery models and new infrastructure, like warehousing or packaging solutions, requires considerable investment.

Partnering with leaders in the field will allow participating companies to access the best capabilities in a complex, maturing environment.

Life sciences companies and distributors should determine which type of providers and vendors are up to the task, as well as available solutions and potential use cases. Do partners have relevant experience, storage and packaging solutions or agnostic digital technology to integrate with yours? For instance, large-scale cold chain storage facilities supporting temperatures ranging from ultra low temperature to 2-8°C don't exist at scale and are expensive to build.

Cold chain participants will need to think carefully about how they collaborate on such critical infrastructure development and maintenance.

Depending on circumstances, life sciences companies may also need to evaluate whether it makes sense to ship direct to consumer, continue using delivery partners or both. New requirements and new market entrants can change historic relationships. For instance, the startup Now Rx has teamed with Hyundai on last-mile medication deliveries using autonomous vehicles, potentially bypassing traditional logistics service providers or pharmacies & treatment centers.

While life sciences companies may have deeper pockets and desire to change, their partners will need to understand the future landscape to mature at the speed of industry innovation.

Those partners who provide the right skills and infrastructure technology, whether it's packaging, storage or environmental sensors, are likely to be more attractive for collaborative ventures.

Digital capabilities

Real-time technology promises to make cold chain safer and reduce waste, as well as provide new ways to manage the business. But much of the enabling cold chain technology hasn't existed until recently and, like infrastructure, is still maturing. How can cold chain participants use digital technologies and the Internet of Things to support enhanced data requirements?

Participants can re-define their end-to-end operating model by leveraging more artificial intelligence, machine learning, automation, and virtual reality-based digital capabilities such as data insights, predictive alerts, and digital twins.

● **End-to-end data insights**

Predictive alerts

Digital Twins

01
End-to-end data insights

An effective cold chain should multiply the data requirements by using environmental monitoring devices across the supply chain that transmit real-time data (such as environmental conditions and in-transit events) from manufacturer through delivery to patient. A centralized data platform helps cold chain participants make timely, intelligent decisions and mitigate risk. For example, Cardinal Health teamed up with Ember Technologies to offer a self-refrigerated shipping box (the Ember Cube) that ensures product integrity and security while reducing waste. The temperature tracking and transportation track and trace are supported by a cloud-based dashboard that allows for data insights and precision control.[6]

02
Predictive alerts

Alerts indicate if medicines or medical samples have suffered environmental exposure, such as going out of temperature, rough handling, or light degradation. Analytics can also track when and where these exceptions occurred to prevent them from happening again. Amelioration can even be automated; if damage is registered, the system can ship a replacement.

End-to-end data insights

Predictive alerts

● **Digital Twins**

03
Digital Twins

Digital twins use a framework of digital solutions to model the cold chain in planning scenarios or when moving materials. They mine data to anticipate interruptions, simulate possible solutions, predict the impact of decisions, and select the best alternative to support real-time decision-making. For instance, at a cold chain warehouse with a parking lot for 1,000 shipments and constrained put-away capacity, digital twins can give logistics and quality teams visibility into all shippers and predict the consequences of moving them. Operational teams can see when the contents of one shipment will go out of temperature and what the ripple effect might be if they prioritize it in the schedule and correct course. The simulation data is then used to further improve responses next time.

Training and recruitment

Industry changes demand new talent and skills, which form the lifeblood of any organization. Life sciences companies will need to reconsider how they design their organizations and talent strategies. Achieving "operational readiness" within the cold chain requires new ways of working—not business as usual.

Prime talent is critical in supporting a new operating model, digital solutions, and infrastructure.

To understand recent trends in New Science and manage cold chain implications, life sciences companies need to recruit and train high performing individuals who can think strategically, lead global projects, and develop new talent. Companies expanding into new markets also require individuals with cultural training and a knowledge of diverse regulatory environments.

Right investment, right outcomes

Those who adopt innovative cold chain solutions quickly and make the right investments the first time stand to benefit significantly, as do their patients. They will be in a position to outmaneuver competitors with benefits in these areas:

Improved outcomes

An effective cold chain offers better outcomes for patients with more reliable and effective therapies.

Greater access

Cold chain efficiencies mean that patients in rural areas or developing nations can benefit from better geographic reach.

Enhanced cost efficiency

Cold chains may cost more, but efficiency can save money by reducing wastage. The UN reported that during the COVID-19 pandemic, vaccine waste rates were estimated to be as high as 50%. As many as 1 billion vaccines could have been saved with more effective cold chain management practices.[7]

Investing in the right cold chain operating model and tools the first time avoids wasting money on multiple iterations.

Product development

Companies without end-to-end cold chain visibility cannot release new therapies unless they can be safely delivered to patients. In addition, extensive monitoring of product and storage data over multiple legs of the journey helps manufacturers understand how temperatures and storage conditions could be flexed without damaging the product. For instance, a year's worth of post-launch vaccine monitoring may reveal that longer periods out of temperature have less of an impact on effectiveness than originally anticipated.

A critical link in the supply chain

As life sciences companies and their partners plan for their future success, an intelligent, patient-centric cold chain will be an essential component to deliver the personalized experiences patient's desire. It's as central as innovating new therapies because what good will innovative treatments be if they can't reach a broad base of patients or are rendered ineffective in their delivery?

In terms of speed to market and cost-savings, getting the strategy and partnering right the first time is critical.

Cold chain participants need to be ready to act, whatever their role is in the ecosystem, and they will need to think through the broad implications for their needs now and in the future. Making the system technologically agnostic and flexible enough to accommodate what lies ahead will be a payoff in and of itself.

Like in Rosa's case, the escalation of pharma cold chains can positively impact millions of patients, their families, and communities. This will not only improve survival rates and quality of life, but also launch a new era of revenue and possibility for the intelligent pharmaceutical industry.

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About the research

In August 2021, Accenture conducted an online survey with 200 life sciences professionals from Europe and North America. We surveyed a range of levels, from managers to C-suite executives across quality, IT, manufacturing and supply chain. The companies are based in the United States, United Kingdom, Ireland, Germany, France, Belgium and the Netherlands.

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