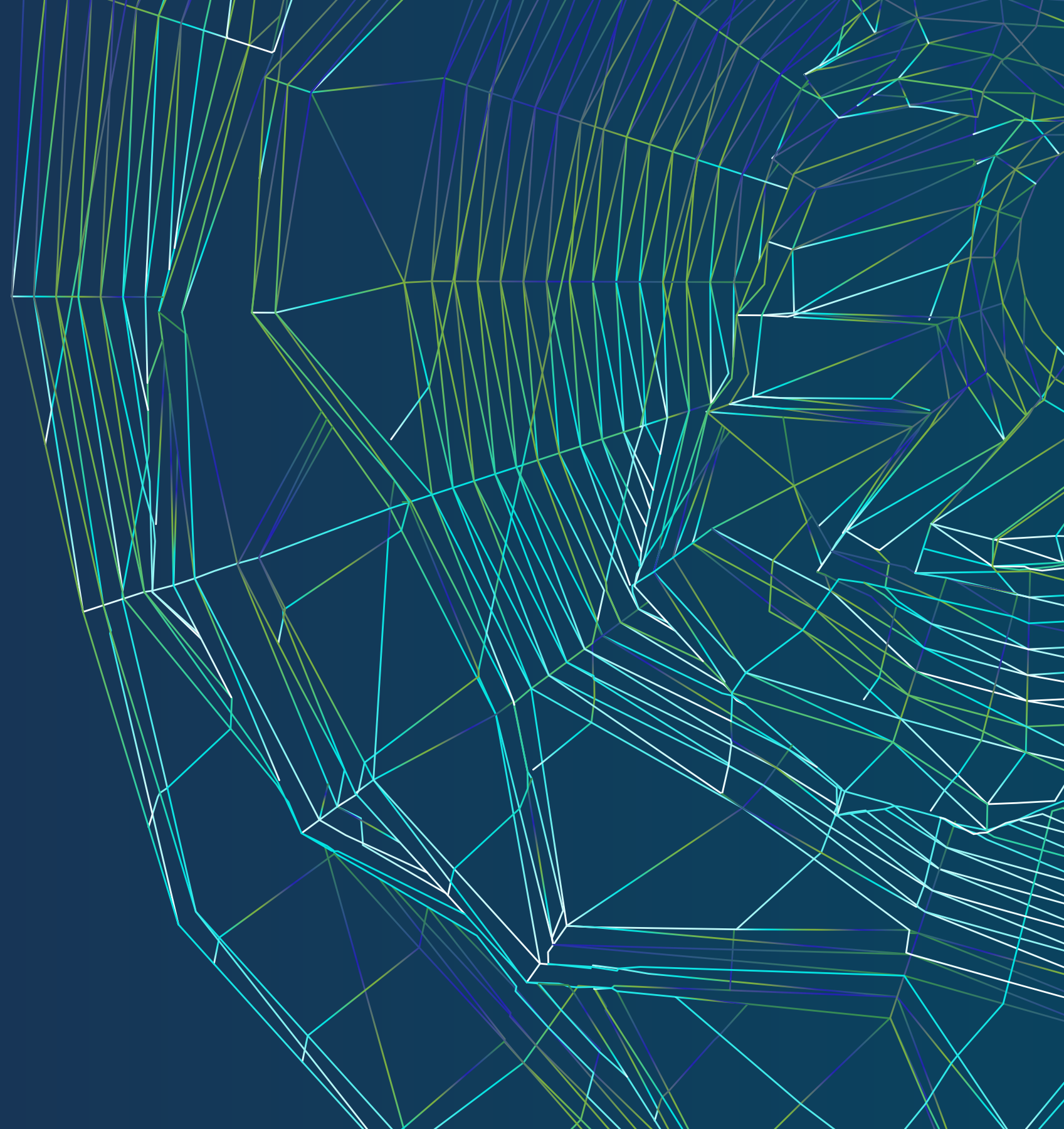


**Baker
McKenzie.**

**Life Sciences Business
Evolution Series**
Shaping Growth —
Supply Chains,
Manufacturing
and Collaboration



Foreword

The life sciences industry is one of the largest and fastest-growing in the world.

Understanding supply chain and manufacturing trajectories; the landscape for therapies, modalities and indications; and how companies can grow through collaboration will be paramount for grasping the opportunities that come with the evolution of this industry.

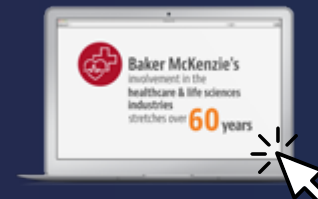
The third and final report of our **Life Sciences Business Evolution Series** explores how pharmaceutical, biotechnology, medical device and medtech companies will continue to leverage new and existing sources of growth over the next decade. The survey of 250 respondents was conducted in partnership with Informa Pharma Intelligence.



Vanina Caniza
Global Head of Healthcare
& Life Sciences
Buenos Aires

Key Findings

- 1 Companies looking at new destinations for manufacturing and supply chain operations rank the United States, Mainland China and Japan as the top three jurisdictions of interest. Respondents indicate their key motivations for seeking out new destinations for manufacturing and supply chain operations are: 1) established regulatory and compliance frameworks, 2) proximity to geographies in line with go-to-market strategies, and 3) clear guidelines on antitrust, competition, tax, bidding and pricing.
- 2 Despite new opportunities for supply chain expansion, one-third of North American and European respondents indicate they are not considering new operation destinations, which affirms the existing, robust frameworks many life sciences companies already have in place. It also suggests future opportunities to potentially optimize and restructure supply chains for greater efficiencies.
- 3 As business evolution continues in the industry, pursuit of up-and-coming areas such as women's health/femtech and neurological diseases/psychiatric disorders will garner as much attention and resources as more traditional therapy areas like cardiovascular diseases, oncology and diabetes. New products like cell and gene therapies, radiology/imaging and hybrid devices and therapies show great promise for better and more targeted patient care.
- 4 Life sciences companies are increasingly looking to grow through collaborations and partnerships with other life sciences and technology companies. Many will look for legal advice in these areas over the next 1 to 2 years.



Baker McKenzie's expertise in the life sciences industry stretches over 60 years. We have been at the forefront of advising our clients in this rapidly evolving sector, propelling commercial opportunities and global expansion while also helping to navigate various areas of risk and legal challenges.

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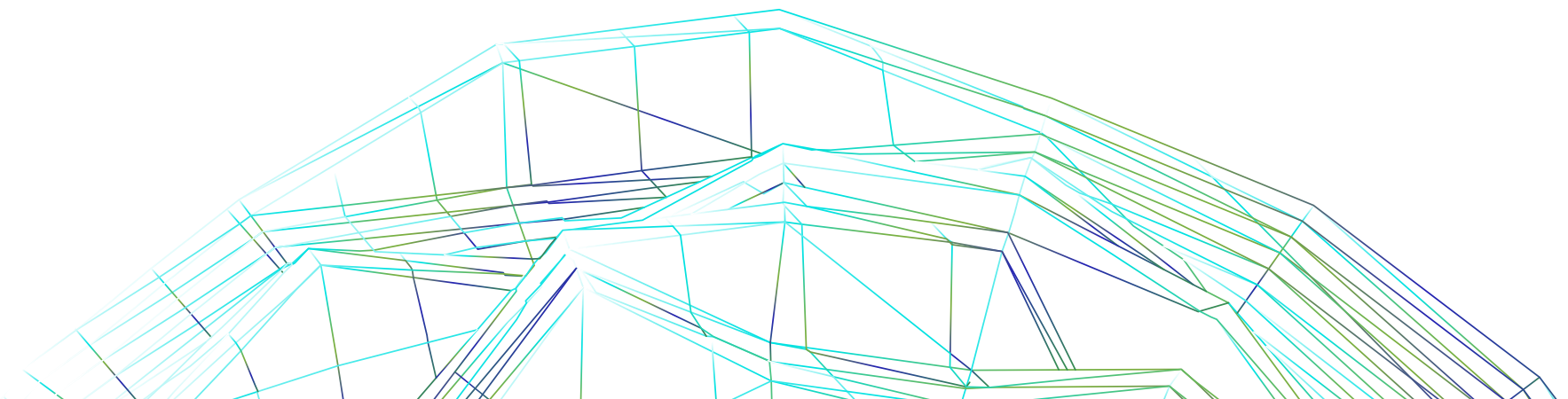


Methodology

All findings across three flagship reports in the Life Sciences Business Evolution Series are gleaned from a custom survey conducted by Baker McKenzie in collaboration with Informa Pharma Intelligence in late 2021.

Over 250 life sciences respondents from North America, Latin America, Europe and Asia Pacific were consulted on their thoughts relating to the changing market conditions, challenges and opportunities affecting life sciences business models, growth patterns, funding and shifting operational dynamics.

Respondents include executives C-suite, EVP/SVP, Head of, Director, Manager, General Counsel, Assistant General Counsel in various business functions including clinical operations, business development, IT, clinical research, strategic operations, quality, R&D, regulatory, commercialization, digital transformation, market access, medical affairs, operations, sustainability and legal.

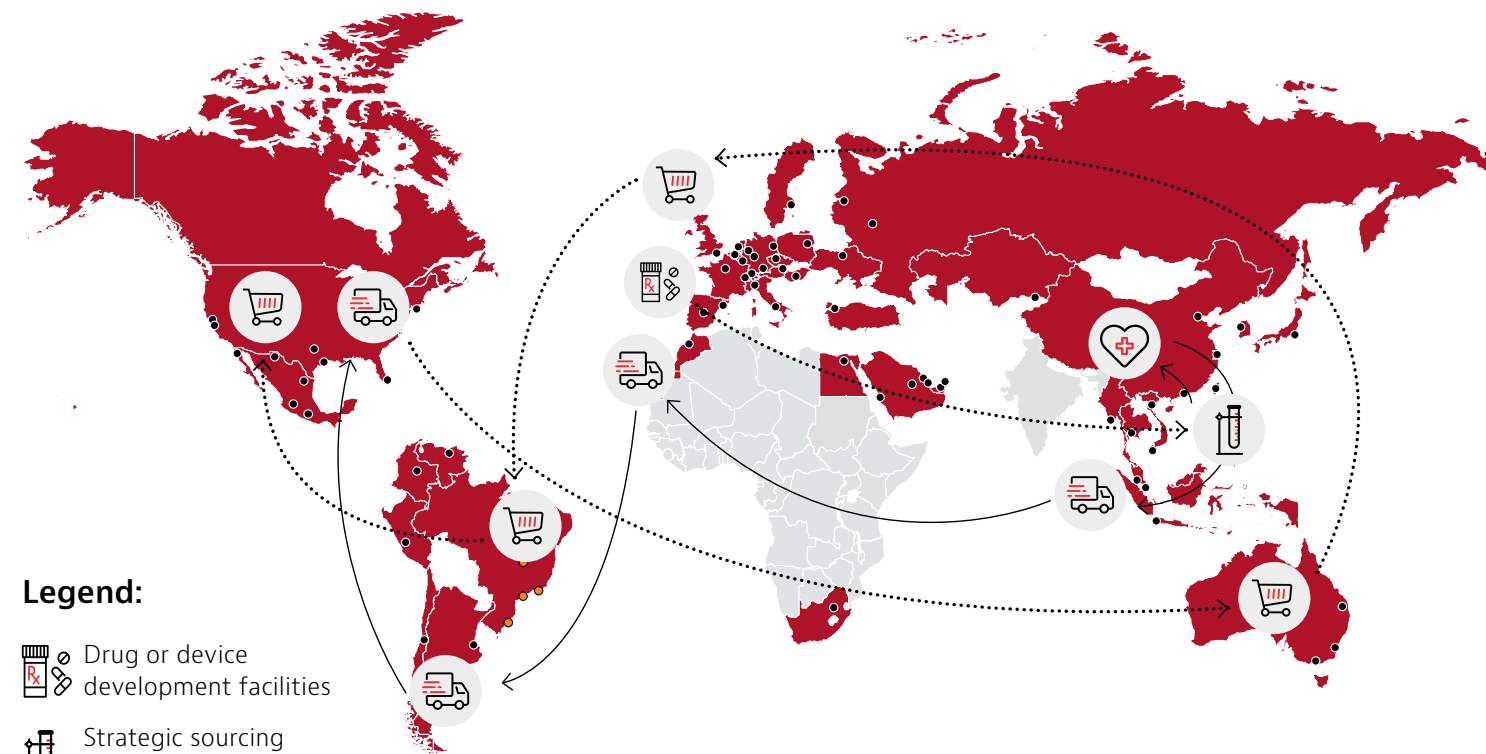




1 Supply Chain and Manufacturing Trajectories

1.1 The Interdependence of Supply Chains

The Interdependence of the Supply Chain:
 A healthcare and life sciences view



Legend:

- Drug or device development facilities
- Strategic sourcing operations
- Smart manufacturing plants
- Distribution centers
- Retail and advertising units

Above illustrates the complexity and connectedness of the supply chain for a global healthcare and life sciences company.

- Location of Baker McKenzie offices
- Baker McKenzie geographic initiatives
- In cooperation agreement with Trench Rossi Watanabe



“The complex interdependencies of life sciences supply chains have never been more apparent than with the COVID-19 global pandemic. Companies need to find cost-effective and low-risk ways to develop, test, manufacture and distribute the products whilst navigating logistic, regulatory, tax, market access and compliance issues across borders. Additionally, businesses need to seek legal advice on issues such as downstream compliance and ESG mandates for life sciences supply chains.”

Cecilia Pastor
 Partner, Madrid

“When discussing what the future looks like for supply chains, many industry clients’ mindsets are focused on reshaping cost, risk, geographical proximity, alternative sources of supplies, stable (and modern) regulatory frameworks and digital solutions. To streamline operations and seek business transformation, life sciences companies may pursue M&A activity to divest existing manufacturing or supply chain operation sites as a way to channel resources into other avenues of growth including investment in digitalization. Being ready to rapidly adapt is important in every region but even more so in Latin America, where the pandemic opened a new dimension on how companies conceive supply chains following two very challenging years.”

Vanina Caniza
 Global Head of Healthcare & Life Sciences, Buenos Aires

Explore more in our [Healthcare & Life Sciences Supply Chain Webinar Series](#)



1.2

1.2 New Manufacturing and Supply Chain Destinations

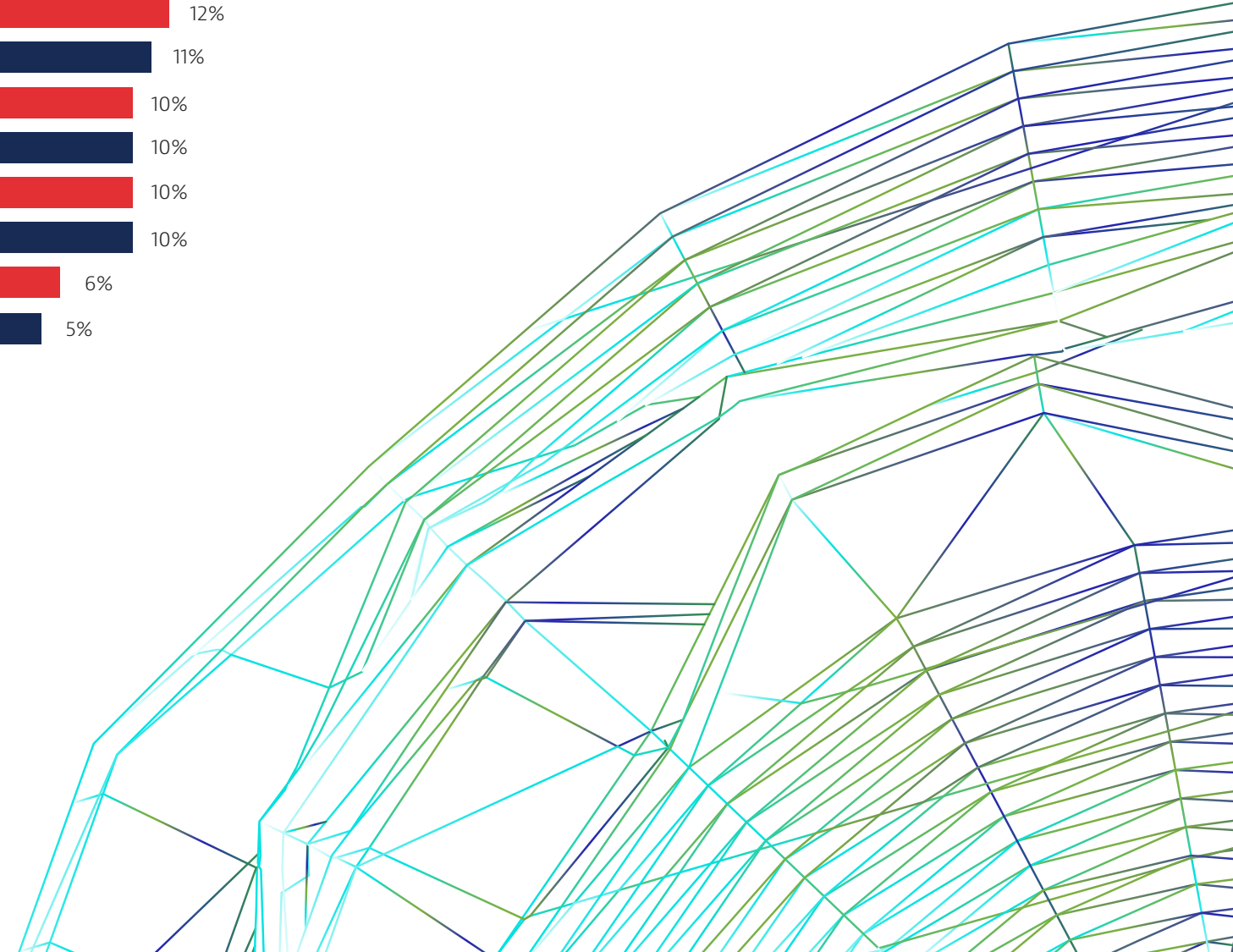
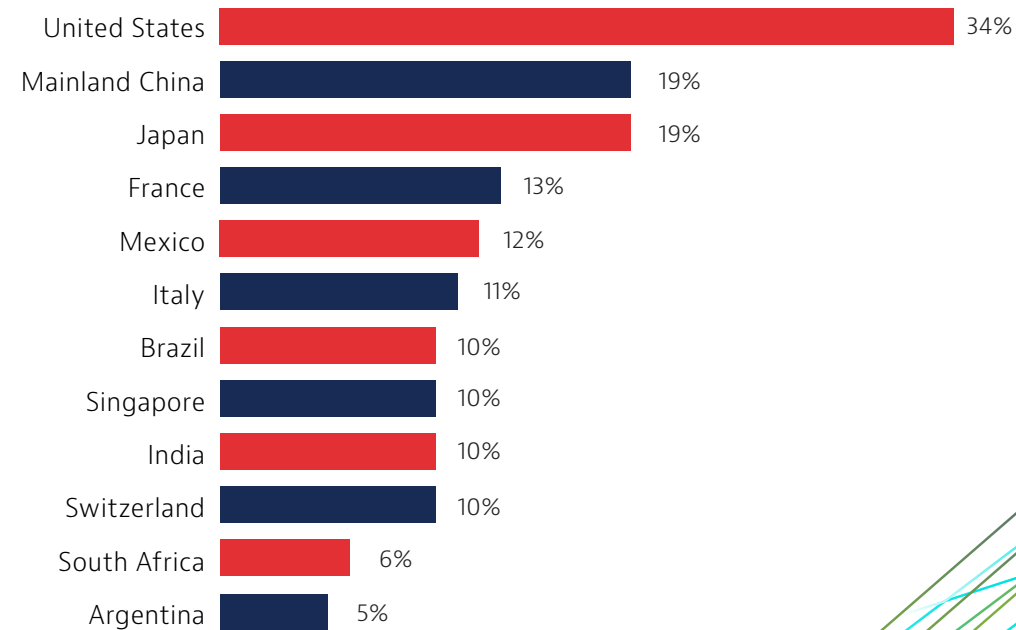
Respondents were asked to identify new potential manufacturing and supply chain destinations.

The United States (34%), Mainland China (19%) and Japan (19%) were chosen as the leading destinations for manufacturing and supply chain operations. Given the size of the United States and Mainland China markets, it is unsurprising that these countries were named as top destinations. In fact, 47% of respondents from Asia Pacific cited Mainland China as a key destination choice.

Intraregional preference also surfaced in the findings within all four regions captured in the respondent demographics. Aside from considerations such as cost and supply chain future-proofing, destination choices also reveal the increasingly complex landscape for manufacturing, owing to a response in demand for therapies related to vaccines and infectious diseases.

Interestingly, almost one-third of respondents globally, particularly from the United States and Europe, also indicated they are not looking for new destinations, which may indicate a potential ramp-up in M&A and divestiture activity from large and established companies. In fact, 21% of global respondents indicated that they would seek legal advice for M&A, including growth via acquisition, carve-outs and specific subsector divestitures.

FIGURE 1. Jurisdictions Considered for New Manufacturing or Supply Chain Destinations (% respondents selected)





1.3

1.3 Regional Lens and Considerations



North America



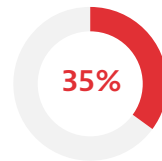
of Americas respondents (38% of North American respondents) picked the United States as a key destination for manufacturing and supply

1/5

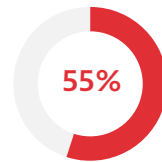
North American respondents also stated that they are not considering new destinations at all, which suggests that they are already established in diverse destinations or are looking to build out domestically



Latin America



Notably, only 35% of Latin American respondents picked the United States as a key destination for manufacturing and supply. 37% picked Brazil, followed by 33% selecting Mexico and 24% opting for Argentina

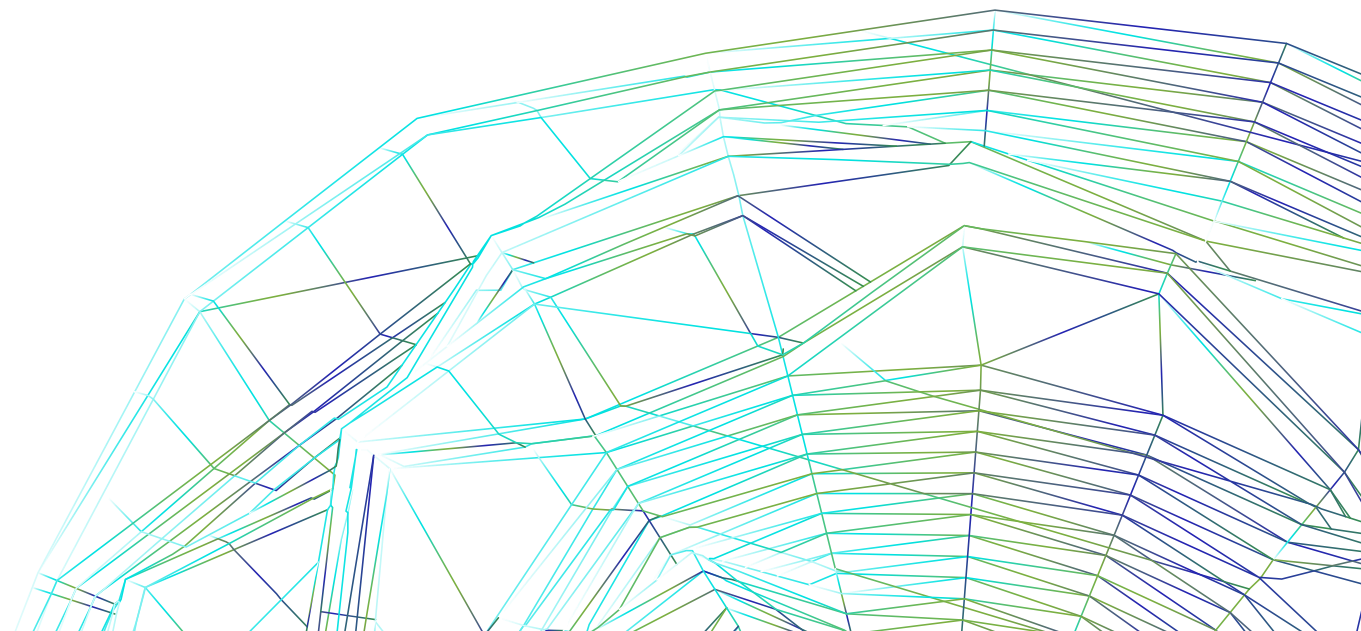


This aligns with data from 55% of Latin American respondents, who cited proximity to geographies in line with go-to-market strategies as a key consideration for new manufacturing and supply chain destinations



“In the United States, the Biden Administration has been focusing on policies to encourage onshoring, nearshoring, and even ‘allyshoring’ of pharma and medical supply chains. The goal is to increase resilience and minimize disruptions by reducing what the Administration views as overreliance on foreign countries, especially Mainland China, for these critical supply chains. But these supply chains are incredibly complex and deeply global, and making dramatic changes is often easier said than done.”

Kerry Contini
Partner, Washington, DC





1.3

1.3 Regional Lens and Considerations



Europe



of European respondents say they are not considering new manufacturing or supply chain destinations. In the face of increased manufacturing complexity, big pharma companies may be considering manufacturing site divestitures in order to streamline operations

1/5

of European respondents are looking at the United States and just 13% are considering Mainland China and India

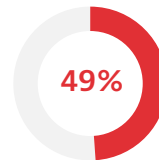


“A global pandemic and geopolitical crises have exposed the vulnerabilities of complex global supply chains. Companies today are faced with a challenging environment in which they have to ensure regulatory and ESG compliance of their supply chains. It is no surprise that they look for established regulatory and compliance frameworks when choosing new destinations for their manufacturing and supply chain operations. The European Union (EU) welcomes this development by increasing regulatory harmonization and stepping up incentives for innovation and re-shoring. Its pharmaceutical strategy and overhaul of basic pharmaceutical legislation follow the revision of the framework governing medical devices and in vitro diagnostics. Whereas policy will need to be closely monitored in Brussels and EU capitals, companies should also remain focused on improving the resilience of their existing supply chains through appropriate contractual safeguards and risk-based compliance systems.”

Martin Altschwager, Partner, Frankfurt
Els Janssens, Counsel, Brussels



Asia Pacific



of Asia Pacific respondents picked Japan as a preferred destination for manufacturing and supply; 47% chose Mainland China



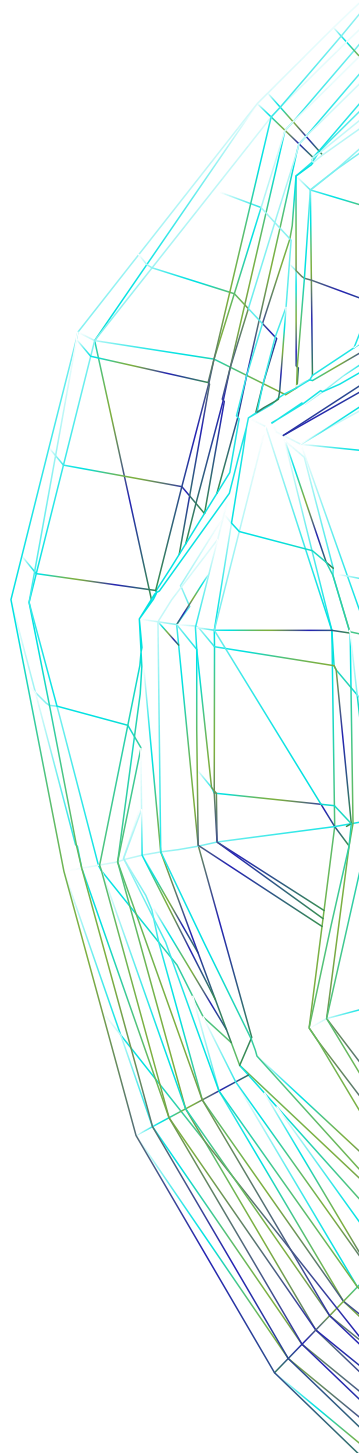
Other key jurisdictions chosen by respondents in Asia Pacific were Singapore (21%) and India (14%). The United States was chosen by 19% of respondents



“In the Asia Pacific region, supply chain risk areas include trade disputes and rising protectionism creating barriers, which can often lead to supply chain disruptions. Additionally, given the diverse make-up of geographies and economies in the region, life sciences companies working in Asia Pacific need to navigate disparate and developing compliance and regulatory laws at times, particularly when considering destinations for new supply chain or manufacturing operations. A jurisdiction-specific approach is therefore a key consideration in Asia Pacific. Given the size of demand in markets such as Mainland China and Japan, it is unsurprising that they are destinations of choice for manufacturing and supply chain operations. This is complemented by life sciences companies looking to expand where barriers to investment remain lower, such as Japan and Singapore, in order to mitigate risks.”

Celeste Ang, Principal, Singapore
Ryosuke Tateishi, Partner, Tokyo
Vivian Wu, Partner, FenXun*, Beijing

*FenXun established a joint operation office with Baker McKenzie in China as Baker McKenzie FenXun, which was approved by the Shanghai Justice Bureau in 2015





1.4

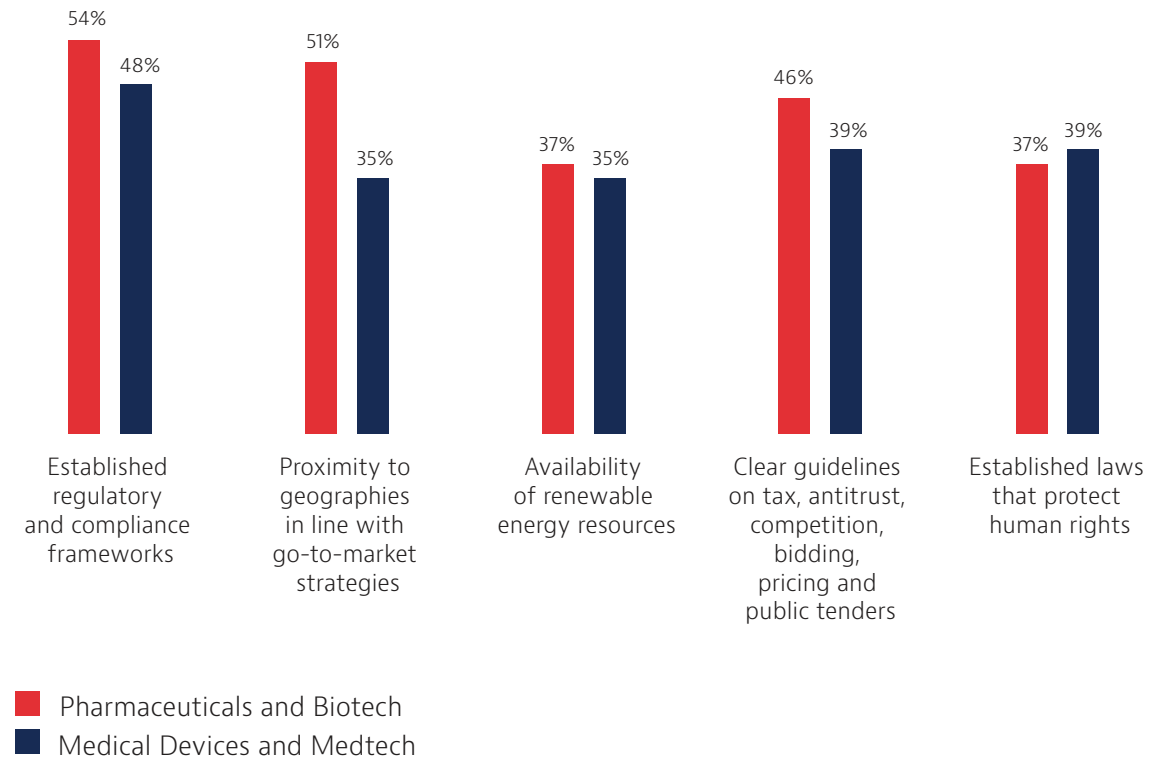
1.4 Motivations for New Manufacturing or Supply Chain Destinations

We asked respondents what considerations they have when choosing new destinations for manufacturing or supply chain operations.

Respondents shared these key insights:



FIGURE 2. Key Considerations for Manufacturing or Supply Chain Destinations (% respondents from all subsectors)



Subsector Trend Overview

Supply chain continuity remains a key risk area for life sciences companies. Thirty-five percent of medical device and medtech respondents indicate that supply chain continuity was an area of legal risk that concerns them, and 29% of pharmaceutical and biotech respondents indicate the same sentiment. The graph above depicts the top five areas of consideration based on a subsector view.



1.5

1.5.1 Clear Tax Guidelines Are Imperative

Respondents share that having clear guidelines on tax implications affects where they decide to build new manufacturing sites or supply chain operations, with 28% of respondents intending to seek legal advice within the next 1 to 2 years on tax matters.

Concerns include potential tax controversies that may arise in regard to where R&D is performed during complex cross-border operations; tax controversies associated with the location of manufacturing operations; and issues related to the attribution of value (and therefore taxable income) assigned to different market jurisdictions.



“Complex supply chains in the life sciences industry mean that companies need to consider how they are driving shareholder value throughout the end-to-end process of product/service development, delivery and post-sale measurement. Tax is an inextricable component in many parts of this process, from manufacturing licensing to import/export or cross-border transit considerations, as well as downstream distribution, logistics and sales. At each of these junctures, tax implications and risk management — particularly in the area of transfer pricing — affect the pricing and profit models as they do operational costs, commercial compliance, risk and in some cases, having to navigate potential contract disruption and tax disputes.”

Julia Skubis
Partner, Chicago

1.5.2 ESG and Sustainability Are Powering Shifts in Manufacturing and Supply Chains

Life sciences businesses are increasingly exploring renewable energy to power operations, save on electricity costs and deliver on decarbonization goals with long-term corporate purchase power agreements (PPAs) or renewable energy contracting structures. As explored in the **second report of this series**, corporate and virtual (synthetic) PPAs have become a popular mechanism to directly source renewable energy for a business and/or to offset emissions via renewable energy certificates, which facilitate the addition of renewable generation capacity to the grid.

Human Rights

Almost one-third of respondents from Europe indicate that having established laws that protect human rights is a key consideration for where they look to set up new manufacturing or supply chain operations. Indeed, as companies look to build inclusive supply chains, workforce safety and ethics considerations remain top of mind, with 27% of respondents citing that they intend to seek legal advice in the next 1 to 2 years for supply chain issues, including managing downstream supply risks.



“Even as businesses transform supply chain operations to ensure business continuity, the focus on mitigating downstream supply chain management risks is key. This includes the ability to build in checks and balances vis-à-vis human rights due diligence throughout manufacturing and supply chain streams, particularly for products that involve chemical compounds and Active Pharmaceutical Ingredients (APIs).”

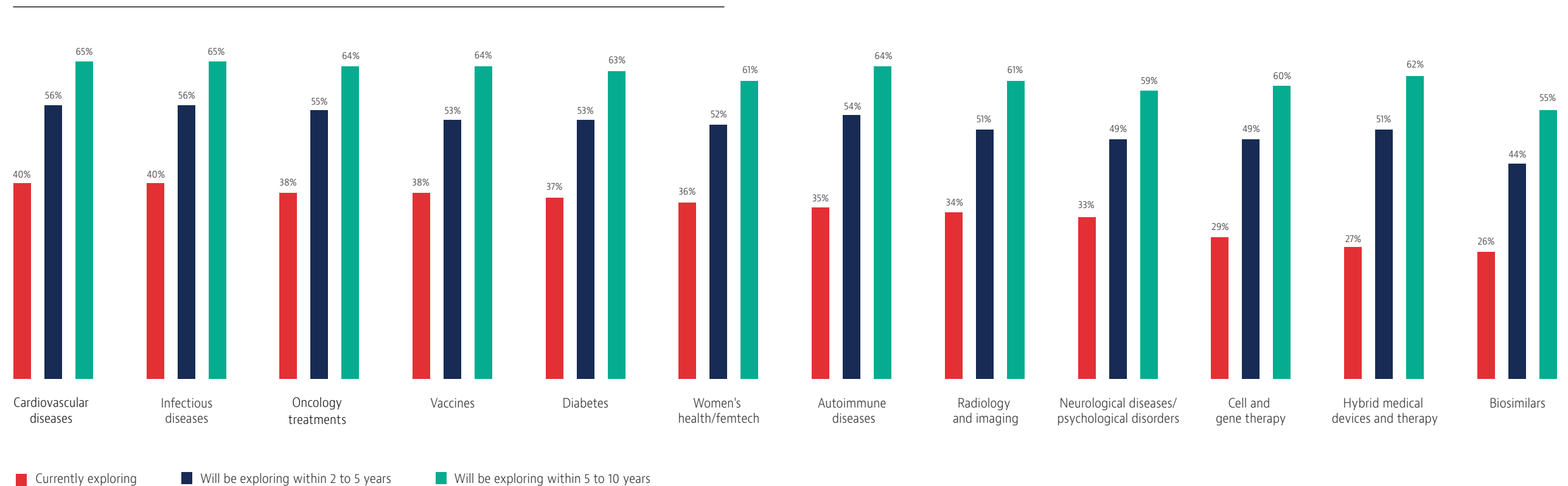
Mirjam A. de Blécourt
Partner, Amsterdam

2 Landscape for Therapies, Product Modalities and Indications

Thirty-eight percent of respondents indicate that their organization has experienced changing demand patterns, and about one-third of respondents have experienced the need for quick product/service development.

Life sciences growth depends intrinsically on global patterns of disease and therapeutic need. Despite major therapeutic advances against conditions such as HIV, tuberculosis and malaria, infectious diseases remain a significant threat to health, aggravated by climate change, globalization and new pandemics. In parallel, population aging and changing lifestyles exacerbate the global burden of non-communicable diseases such as cancer or heart conditions.

FIGURE 3. Areas of Exploration for Therapies
 (% respondents from all subsectors)





2.1

2.1 Key Trends on the Horizon

Current and future trends reflect the always adaptive and innovative nature of the life sciences industry. In the medium to long term, there will be a shift from the current priorities that address urgent pandemic-related needs in addition to prevalent conditions such as cancer, cardiovascular diseases and diabetes. Respondents indicate that they will double down on exploring still-nascent areas of treatment of women’s health, neurological diseases/psychiatric disorders and hybrid therapies in response to the growing needs of society.



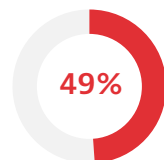
Currently and in the Next 2 to 5 Years

Life sciences companies are primarily focused on **cardiovascular diseases** (40%), **infectious diseases** (40%), **oncology treatments** (38%), **vaccines** (38%) and **diabetes** (37%). These preferences reflect prevalence of diseases, products and current scientific and commercial realities.

Other burgeoning areas for growth in the next 2-5 years include treatments and products for: **autoimmune diseases** and **radiology and imaging**.

Almost one-third of respondents are most drawn to exploring **hybrid medical devices and therapies**.

SUBSECTOR SPOTLIGHT



Pharmaceutical and biotech companies are overwhelmingly focused on **oncology treatments** (49%).



Medical device and medtech companies are focused on products to treat **cardiovascular diseases** (51%).

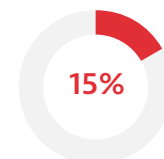


Over the Next 5 to 10 Years

Over 75% of respondents indicate strong interest in **women’s health/femtech**. This reflects ongoing cultural change and a heightened awareness of women’s needs related to fertility, menstruation, menopause and more.

Cell and gene therapies and products related to **neurological diseases/psychiatric disorders** show the most promise for growth in the next 5 to 10 years, based on the survey responses.

SUBSECTOR SPOTLIGHT



Pharmaceutical and biotech companies continue to show an interest in entering spaces such as **cell and gene therapies** (15%), as well as **biosimilars** (13%), and **vaccines** (13%), within this time frame.

1/5

Around 1 in 5 medical device and medtech companies are likely to expand their focus on **neurological diseases/psychiatric disorders** (20%) and **hybrid devices and therapies** (18%), reflecting interest in exploring the new frontier of technology use for mental health support and treatments.



2.2

2.2 Spotlight on Biologics/Biosimilars

Biosimilars in emerging markets

In Latin America, biosimilars (41%) ranked highly in areas of interest. With the uptick in biologics and biosimilars, companies must now manage higher-cost manufacturing and new regulatory frameworks. The Latin America region has responded to demand for lower-cost biologics by establishing flourishing biosimilar industries in countries such as Brazil and Mexico.

Life sciences companies are shifting from small molecule, generic drug development toward the increased use of complex, live-cell biologics and biosimilars. These include the manufacture and supply of vaccines, blood products, and cell and gene therapies for treatment of autoimmune disorders, cancer and other more chronic conditions. Thirty-eight percent of life sciences respondents indicate that improving patient outcomes is their primary motivation for exploring biologic or biosimilar modalities; more than one-third mention that they want increased access for patients; and almost 1 in 5 indicate they want to diversify their portfolio.



“Companies in Latin America, especially within Brazil, Argentina and Mexico, have shown an increasing interest in the biosimilars landscape. Regulatory discussions in the region continue to be influenced by the EU and US, which have enhanced existing regulatory frameworks to better balance innovation and accessibility.”

Christian Lopez-Silva
Head of Mexico Healthcare & Life Sciences, Mexico City





2.3

2.3 Spotlight on Women’s Health/FemTech

The potential for innovation and impact in the women’s health space is immense. Life sciences companies are ramping up the exploration of conditions affecting women, including endometriosis, HPV-related diseases, and perimenopause and menopause, with deals and regulatory discussions reflecting this momentum.



Over the next 2 to 5 years, companies indicate their focus on women’s health and femtech will increase from 36% to 63%. Over the next decade, 80% of life sciences companies will be engaged in women’s health/femtech.



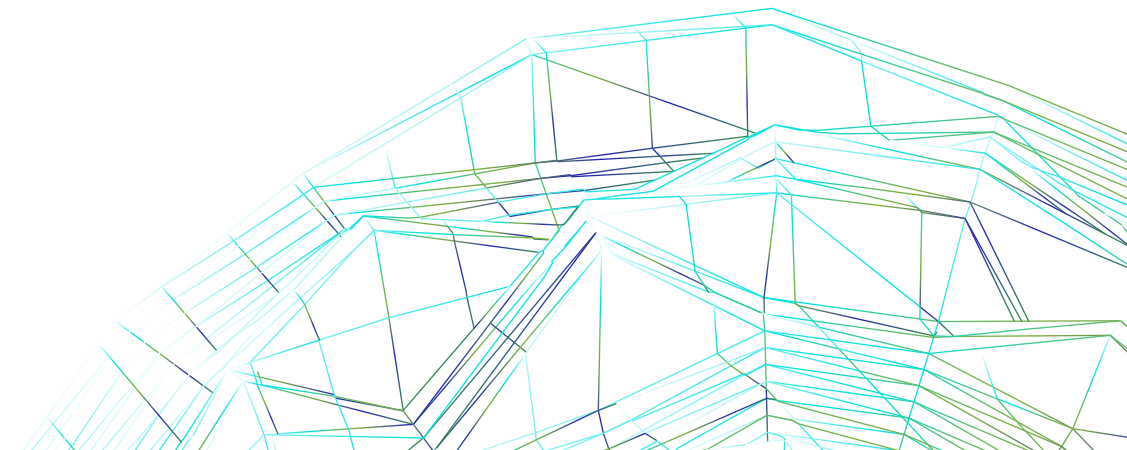
Deal Spotlights

- Advised Merck on the spin-off of its women’s health business, legacy brands and biosimilars unit into an independent, publicly traded company, Organon & Co.
- Advised Mithra Pharmaceuticals, a Belgian biotech specializing in women’s health, on its EUR 100 million equity funding from Goldman Sachs; its landmark license and supply agreement with Mayne Pharma Group to commercialize Estelle, Mithra’s novel combined oral contraceptive product candidate, in the United States; and its EUR 77.5 million capital raising through an exempt accelerated book build private placement of new shares with listing on Euronext Brussels.



“Women experience unique healthcare challenges, yet women’s health remains globally under-researched and under-funded. Healthcare and life sciences companies, investors and digital health start-ups are increasingly recognizing the untapped potential of approaching women’s health holistically, identifying significant opportunities in better supporting the health needs of the world’s nearly 4 billion women. We are beginning to see increased investment and femtech innovation focused upon specific female health issues, as well as broader health services focused upon mental health and wellbeing.”

Elisabeth White
 Asia Pacific Head of Healthcare & Life Sciences
 Sydney





2.4

2.4 Spotlight on Nutraceuticals and Cosmeceuticals

Over the next decade, respondents indicate exponential interest in pursuing nutraceuticals (more than double) and cosmeceuticals (almost triple). The increasing focus on hybrid wellness or beauty products suggests a shift in consumer focus and go-to-market strategies on the part of life sciences companies.

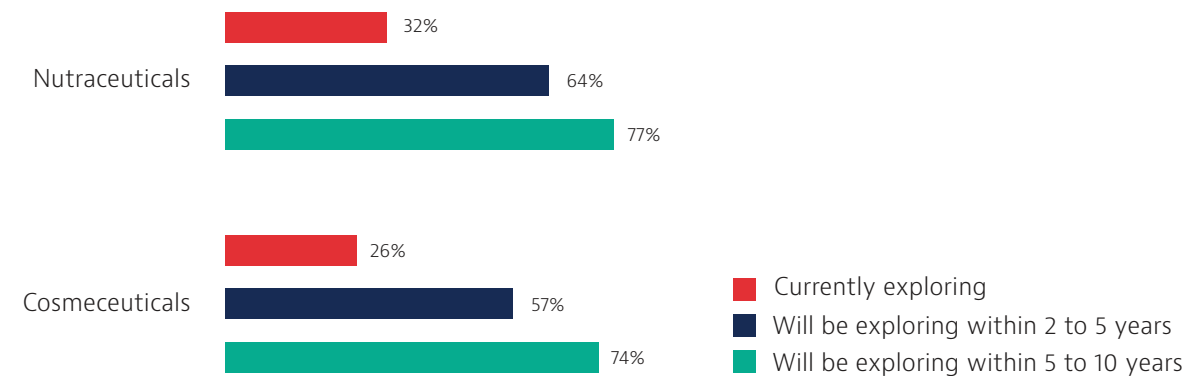
In Europe, over the next 5 to 10 years, respondents emphasized diversifying from more traditional areas into more specialized areas and neighboring sectors: nutraceuticals (33%), and cosmeceuticals (27%). In the Americas, almost 1 in 5 respondents indicate an interest in exploring nutraceuticals and cosmeceuticals.

2.5 Spotlight on Cannabis

The life sciences industry increasingly recognizes the potential for new and innovative medications and treatments derived from cannabis and cannabis-based compounds. In Western Europe and North America, the cannabis industry is on the rise, with cannabis-derived products in increasing demand by consumers looking for alternative health and wellness applications.

Baker McKenzie's **Global Cannabis Dashboard** outlines opportunities for marketing medical cannabis, permissibility of medical cannabis in its raw form and in pharmaceuticals, clinical trials, export/import, recreational use, hemp definitions and private sector involvement for each jurisdiction.

FIGURE 4. Spotlight Trends on Nutraceuticals and Cosmeceuticals (% respondents)



“Given the history of cannabis being illegal in most jurisdictions, what increasing liberalization in each country means for healthcare and life sciences is that it has opened up a market for new products based on compounds that were never commercialized or fully researched — the opportunity this presents is potentially market changing for the industry. What this also means, however, is that there will be various country-specific hurdles in the laws and regulations that companies will have to overcome when thinking about product development, clinical trials, marketing authorization, promotion and trade compliance in this industry.”

Kamleh Nicola, Partner, Toronto

Panyavith (Taro) Preechabhan, Partner, Bangkok

Juan Pablo Concha, Partner, Bogotá

Julia Gillert, Of Counsel, London



Explore our **Global Cannabis Dashboard**, which provides an overview of cannabis regulation in over 110 jurisdictions. Please contact **Lilli Meldrum** to request access to the dashboard.



2.5



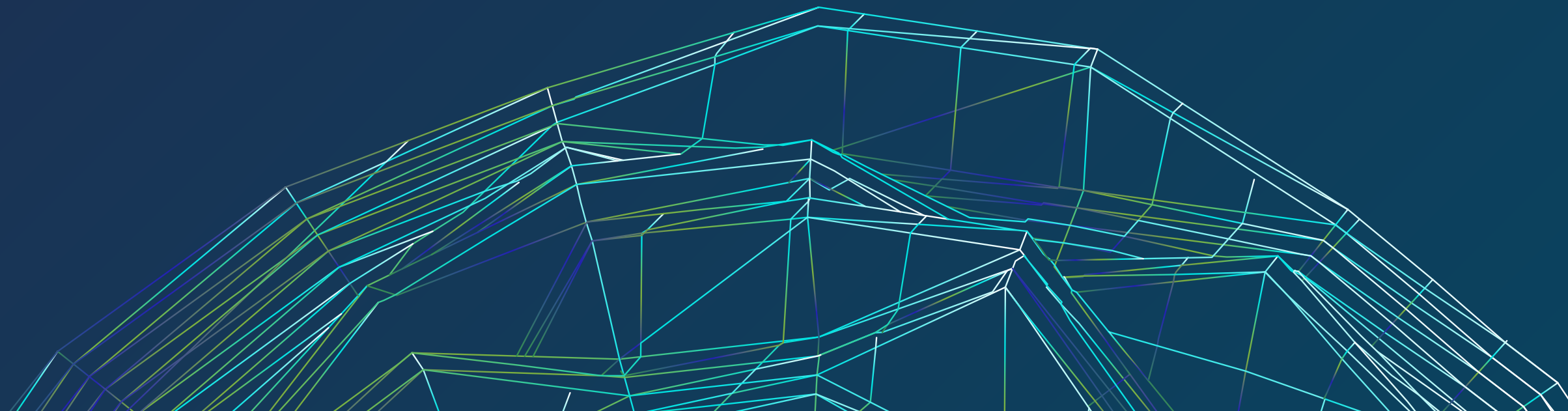
Deal Spotlights

- 1** Advised Phalanx, the sole shareholder of NYSK Holdings, in a roll-up transaction consisting of contribution of NYSK shares into Pharmacann Polska, in exchange for shareholding stake issued to Phalanx. Pharmacann Polska is a Polish pharmaceutical company aiming to become Europe's biggest manufacturer and distributor of cannabis products.

This first-of-its kind transaction occurred following the legalization of cannabis products for medical use in Poland and resulted in the first Polish pharmaceutical entity indirectly owning a cannabis manufacturing plant.

- 2** Advised one of Thailand's largest conglomerates on the establishment of a joint venture to engage in the medical cannabis business in Thailand, including providing advice on the R&D and investment agreement with relevant Thai governmental organizations, advice on the joint venture and partnership with a leading multinational cannabis company and analysis of the regulatory and investment landscape and framework for medical cannabis and hemp in Thailand.

- 3** Advised a major e-cigarette brand on disputes in Canada involving the sale of non-compliant third party vaping products and the sale of cannabis products intended to be used with its products, which has been a matter of significant public interest. Most recently, filed a Federal Court trademark infringement action on that client's behalf relating to the misuse of its intellectual property in connection with cannabis products.





3

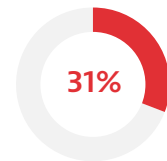
Growth Through Collaboration — Bridging Resource and Funding Gaps

As business models shift in response to changing tides of demand, resource and funding, life sciences businesses continue to look at collaboration as the way forward.

While traditional partnerships are still a mainstay of the life sciences industry, **there is an increase in collaborations beyond the life sciences sector** in light of the need to develop more complex therapies and products such as biosimilars, cell and gene therapies, vaccines, hybrid medical devices, gamification therapeutics and other mobile health (mHealth) solutions.

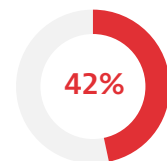
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of respondents said they formed newly structured partnerships across sectors (i.e., public-private partnerships or partnerships with technology companies)



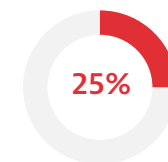
31%

of all respondents indicate they intend to seek legal advice about collaboration and partnerships with other life sciences companies



42%

of medical device and medtech respondents also shared that they have seen the need to shift from product-only to product-service hybrid development

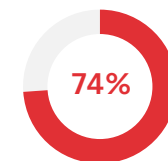


25%

of respondents say they intend to seek legal advice about collaboration and partnerships with other sectors (e.g., technology, PE, VC)

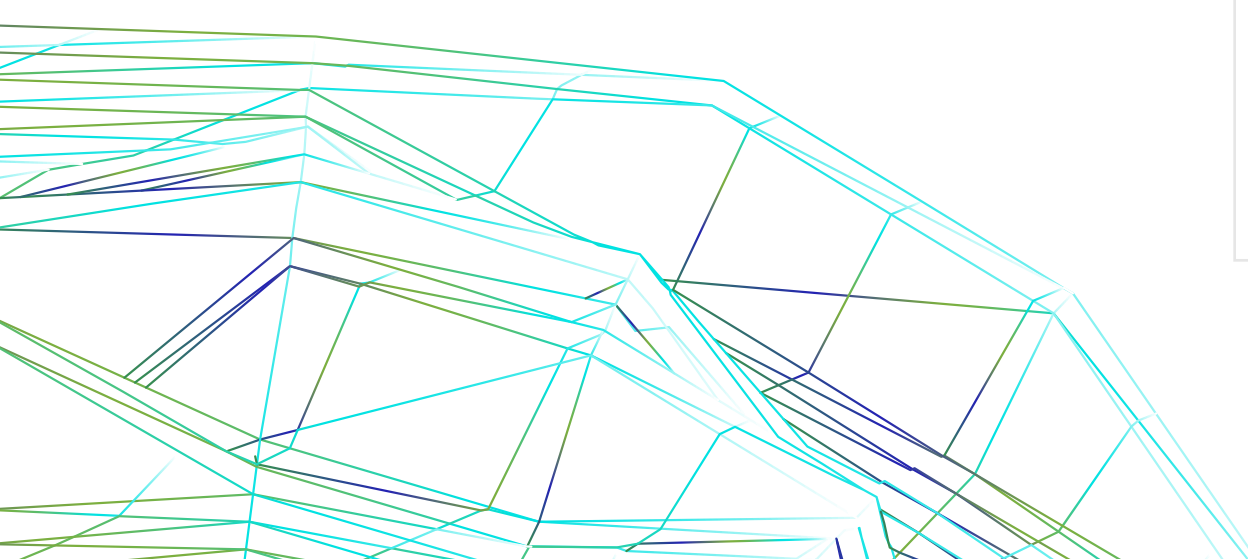
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of pharma biotech respondents say that are implementing data analytics and solutions as sources of new revenue streams



74%

of **digital health players** suggest greater collaboration across the healthcare ecosystem would significantly accelerate progress





3



“The life sciences industry has not fallen behind other industries in adapting to new business models and service offerings through innovation. What underpins the transformation of the industry are partnerships with technology companies — combining data access, app development, cloud computing and other capabilities, life sciences and tech are coming together to churn out new offerings, alternative treatments and therapies that are changing the face of patient care. This pace of collaboration is not likely to slow in the coming years. Through M&A transactions as well as other standalone partnerships, we can expect closer cooperation between tech and life sciences to become the new imperative to industry success.”

Marcela Robledo
Partner, San Francisco

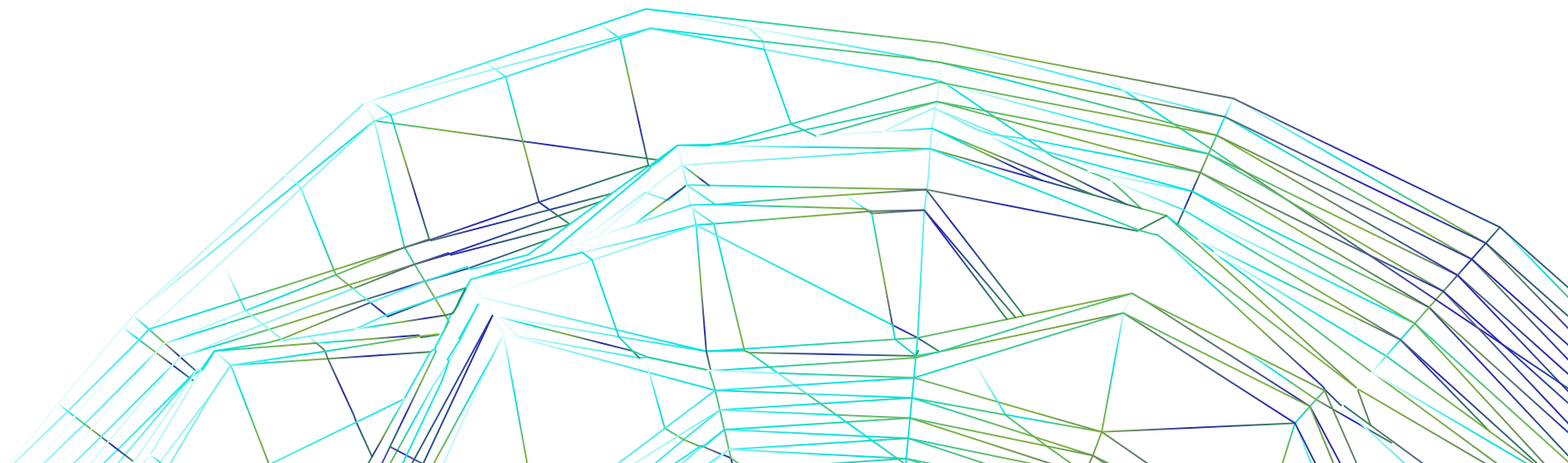
3.1 Tech’s Impact on Partnerships and Collaborations

Tech is propelling change in the industry, and tech collaborations are changing the landscape for life sciences. In the absence of time, resources and knowhow, accessing expertise and technology through partnerships with technology companies is becoming a viable option for growth. The access to digital tools and solutions — particularly related to cloud and cybersecurity needs — to manage, store and monetize data is becoming integral to life sciences business models.



Subsector Spotlight

- For medical device and medtech companies considering the integration of tech/data to offer product-service hybrids as a source of new revenue, more than half of respondents (56%) say partnerships, and 1 in 2 respondents cite that investments, have affected their organization’s management of patient data.
- The majority of pharmaceutical and biotech companies indicate they are already exploring the use of apps, monitoring and business support platforms for operations (i.e., cloud technology, data storage, etc.). Most intend to pursue the application of 5G in the next 2 to 5 years and the use of artificial intelligence and/or automation in the next 5 to 10 years.





4 Conclusion

As the life sciences industry evolves to meet new realities and the changing demands of the market, companies are addressing evolving patterns of growth, funding, supply, manufacturing and collaboration.

Such trends, when combined with a rapid rise in digitalization and myriad transactional routes to funding, are poised to influence the industry's growth trajectory in the next decade.

In terms of how companies make decisions on where, when and how to expand to new locations and explore new areas of research, the following findings are key:



Regional Trends Shape Global State of Play

Many life sciences companies in the United States and Europe are not looking for new destinations for supply chain and manufacturing operations, indicating they are well established in their markets or that they are looking to expand domestically.

Companies may be looking for future opportunities to potentially optimize and restructure supply chains for greater efficiencies, especially as data and technology transform and streamline operations.

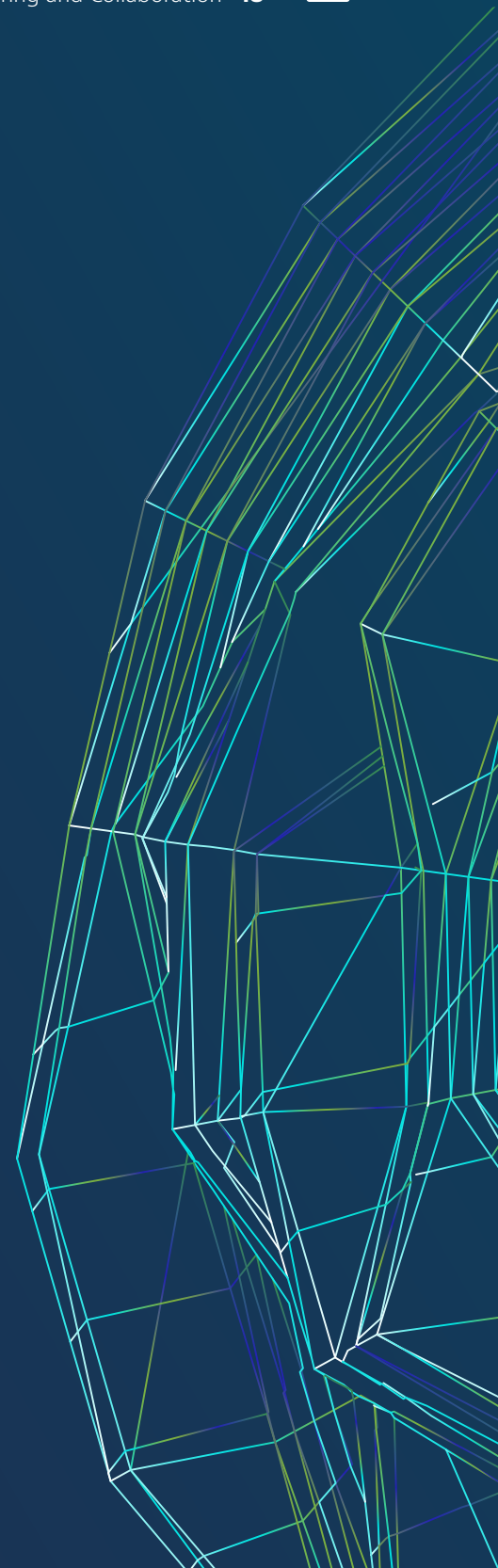
Clear legal guidance on matters such as tax, antitrust, competition, bidding and pricing is important. Trade sanctions and disputes grow in importance as geopolitical crises have a huge impact on the global economy. ESG considerations demand forward-looking legal advice, especially with respect to decarbonization targets and PPAs.



Critical Areas of Legal Insight

New manufacturing and supply chain destinations bring a myriad of complex legal issues. While many issues must be considered before new destinations are decided upon, life sciences players must also anticipate future areas of legal concern which could arise once operations begin. A new destination does not sit as a legal island, rather it is a new link in the existing supply chain so the legal issues across the entire supply chain must be analyzed.

Future-proofing the supply chain requires legal counsel with a global perspective across many areas of law. Counsel must also have deep industry knowledge to navigate legal issues and communicate effectively with the different divisions and departments within a specific industry player.





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Burgeoning Areas for Life Sciences Growth

As business evolution continues in the industry, pursuit of up-and-coming areas such as women's health/femtech and neurological diseases/psychiatric disorders will garner as much attention and resources as more traditional therapy areas like cardiovascular diseases, oncology and diabetes.

A surge of innovative products like cell and gene therapies, radiology/imaging and hybrid devices and therapies show great promise for better and more targeted patient care.

With an abundance of these types of products set to enter the market, legal advice on regulatory and compliance frameworks is essential. Having a legal advisor that understands the jurisdictional nuances of drug/device classifications, privacy implications from devices/software collecting more data, how to properly manage big data sets, liability and contractual issues for drug-device combination products and compliance with new rules and regulations around the promotion and advertising of such products will be more important than ever.

Changing Nature of Partnerships and Collaboration

Increasingly, companies are looking to partner outside of their industry to gain access to the proper digital tools and expertise that enable effective management, storage and monetization of data in the face of current limitations around time, resources and knowhow.

Corporate and cultural clashes among diverse partners cannot be underestimated since they can lead to legal conflicts and eventual project failures if not dealt with quickly and effectively. Diverse partners by nature have different priorities. These differences are an advantage for an effective partnership but also risky when issues such as regulatory compliance are not top of mind for both parties.

Inconsistent legal frameworks and law lag across jurisdictions covered by the collaboration can also strain partnerships in absence of sound legal advice.

Key Resources

- Healthcare & Life Sciences Hub
- Hyper-Hybridity
- Corporate PPA Hub
- The Health Pod

CANNABIS

- Global Cannabis Dashboard (please contact Lilli Meldrum to request access to the dashboard)
- Global Cannabis Compliance Blog
- Cannabis Webinar Series

TRANSACTIONS

- Guide to IPOs for Biotech and Pharma Companies
- Asia Pacific DealSCAPE: Healthcare & Life Sciences

SUPPLY CHAIN

- Healthcare & Life Sciences Supply Chain Series
- Managing the Healthcare & Life Sciences Supply Chain
- Global Supply Chain Compliance Blog
- Tax and Legal Implications of New Supply Chain Challenges
- Biden Supply Chain Policy Video Series

OTHER RESOURCES

- 2021/2022 Digital Transformation and Cloud Survey
- The Year Ahead: Global Disputes Forecast 2022
- Risk Reshaped: Tax Disputes Outlook 2022–2025
- Litigation Intelligence Tool
- Connected Compliance

Findings from Baker McKenzie's three-part **Life Sciences Business Evolution Series** define a new era for one of the fastest-growing and most promising industries in the market. Over the next decade, life sciences businesses are poised to mold their business models to address data-related issues, the impact of government actions, new opportunities for growth through acquisitions, a rising focus on sustainability goals and the changing nature of supply and manufacturing.

In meeting the challenges of today and tomorrow head on, businesses must continuously adapt and seek out legal counsel that leverages expertise in sectors such as data and technology, life sciences transactions, mergers and acquisitions, pharmaceuticals and biotech, sustainability, commerce and trade, and more.





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*Trench Rossi Watanabe and Baker McKenzie have executed a strategic cooperation agreement for consulting on foreign law.

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*FenXun established a joint operation office with Baker McKenzie in China as Baker McKenzie FenXun, which was approved by the Shanghai Justice Bureau in 2015.

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