Insight Brief

Mergers and Acquisitions

How to manage regulatory risk and avoid issues

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Introduction

Mergers and acquisitions (M&As) have long been a vehicle for life sciences industry growth. They allow major pharma and MedTech players to rapidly expand their R&D pipelines and grow their portfolios into new therapeutic areas, while giving emerging biotech companies a quick and profitable exit or the opportunity to become part of a larger brand.

This trend has only increased in recent years as companies are looking for new sources of revenue. With blockbuster drugs reaching their patent cliffs, biopharmas are looking for proven marketed drugs and new breakthrough therapies and devices to expand their portfolios.

In 2019, the industry saw a record breaking 1,276 M&A deals totaling $411 billion and, despite the global pandemic, deals in 2020 continue to close.

But often, deal makers fail to anticipate the deep operational complexities surrounding ownership transfer of such highly regulated drugs and medical devices—which can take months to complete with many pitfalls encountered along the way. When they don't factor in all of the cross-functional and regulatory activities required to successfully transfer marketed products, it can add months-long delays, lead to hefty fines for missed acquisition milestones and regulatory deadlines, and prevent acquirers from generating revenue from their newly acquired products.

It's a common mistake.

EARLIER REGULATORY FOCUS NEEDED

M&A decision-makers focus primarily on the legal and financial aspects of the deal, and they limit the number of stakeholders involved in pre-deal discussions to maintain confidentiality until the contracts are signed and the antitrust period ends. They typically don't have anyone at the table to advise them on the regulatory challenges of completing the assets transfer. As a result, they are unaware of how seemingly benign decisions can result in huge losses of time and revenue.

Potential complications can arise if regulatory and compliance teams are left out of pre-deal

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decision-making discussions. At the pre-deal stage, a few key stakeholders—typically lacking a regulatory background—conduct the negotiations. Regulatory and compliance teams are often only provided with details at the time of signing which makes for very tight deadlines. They have little to no time to go through deal parameters, check for issues and adjust their schedules. Additionally, they must quickly collect regulatory intelligence, prepare a global regulatory strategic transfer plan, develop detailed plans for each in-scope country and ensure acquirer readiness. This is outside of many employees' need to digest the fact that their life's work is about to be handed over to another company.

Deadlines are most frequently unrealistic given the regulatory complexities of assets transfer, including the transfer of product licenses – also known as Marketing Authorization Transfers (MAT). Decision-makers often assume the licenses transfer will require little more than a pile of paperwork, and thus can easily be completed in a few months. In reality, a large global project – with 30-80 countries in scope – can take, on average, one to five years to complete.

Even when given sufficient time, internal regulatory and compliance professionals may lack experience in MAT processes. MAT is less about preparing the regulatory submission package and more about regulatory and cross-functional readiness to take over the responsibilities that come with the products' ownership transition. The existing regulatory department is often expected to assume a leadership role on these transactions while continuing to fulfill their regular day-to-day responsibilities such as regulatory support of products in development and marketed product regulatory maintenance. This approach can set up regulatory and other functional teams for failure, putting a company at risk of non-compliance which can result in fines, cost overruns, inability to meet product demand, lost revenues, and reputational damage affecting investor confidence.

DIVESTMENTS AND TRANSFERRING LICENSES FOR ONLY SOME COUNTRIES

At times, companies make major strategic deals and regional or national anti-trust laws require the acquiring entity to divest some of the resultant portfolio. This generates an entirely new set of required regulatory asset transfer steps which adds time, cost and risk to the process.

In our experience, splitting a product portfolio in a divestiture could cause serious issues unless properly assessed, especially if there are Reference markets. If it is necessary to transfer markets which are a Reference to other markets being retained, companies will have to identity a new Reference, rework reference materials, product supply chain, labeling and packaging. Maintaining those licenses after the divestiture costs so much time and money that transferring all markets to the acquirer may be a more effective solution.

UNDERSTANDING THE MAT PROCESS

While technically "transfer of a marketing authorization" in most countries is an administrative procedure, a MAT accomplishes a transfer of ownership of an asset, formalizing the fact that the new Marketing Authorization Holder (MAH) now has regulatory and legal responsibilities over the product. However, prior to the transfer, the acquiring company must have systems and processes in place to comply with all relevant laws and regulations in each market involved in the acquisition and/or divestment – including pharmacovigilance requirements.

Often, new biopharma companies, seeking to increase their global footprint, acquire global portfolios, only to find that, at post-deal close, they do not have the necessary internal expertise and/or appropriate systems and platforms set up to comply with all the legal obligations in any given territory.

MAT processes will vary with every deal and must take into account the type and number of assets transferred, acquirer readiness, the countries/territories in scope,

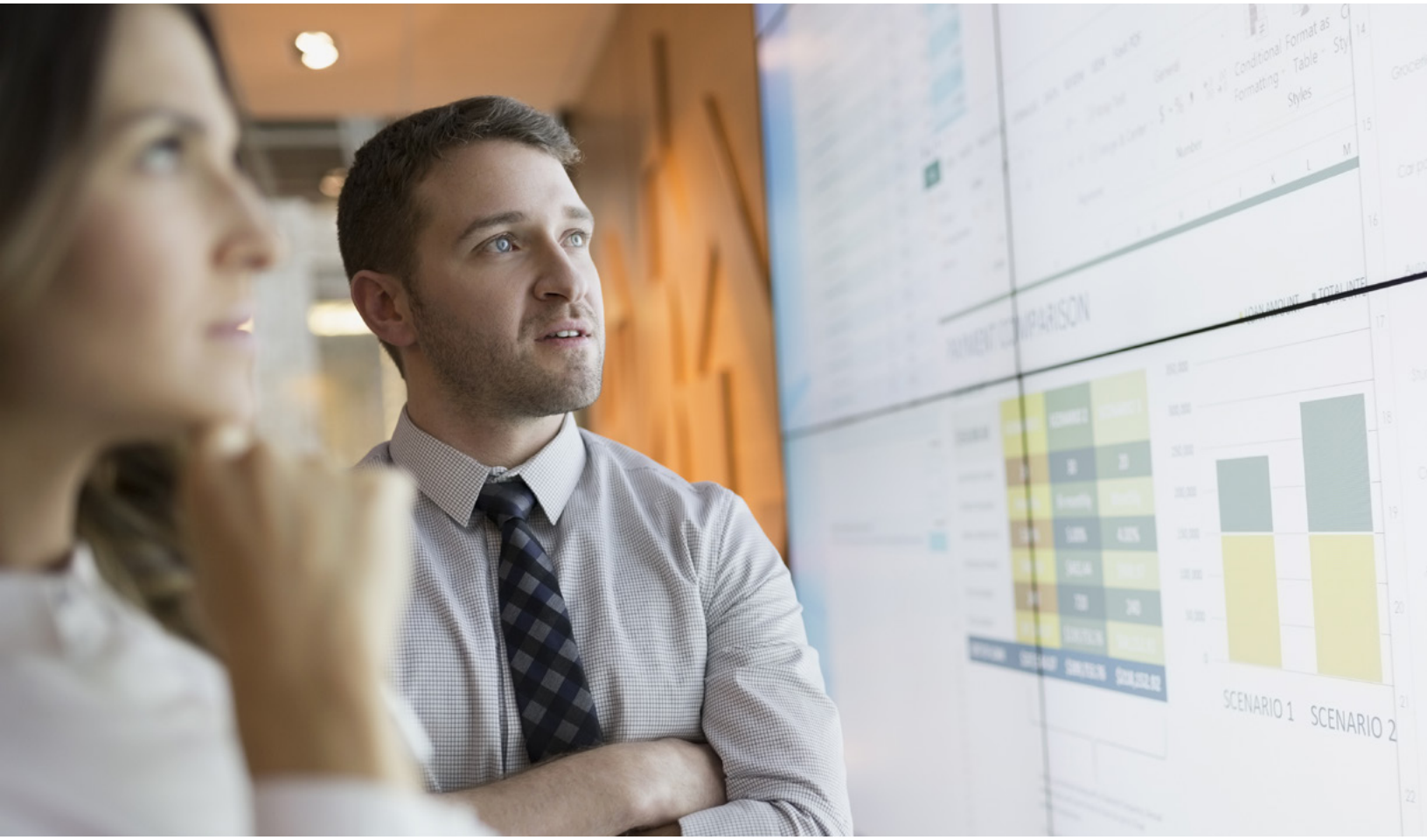
supply chain factors, product regulatory status, and compliance requirements in every market, to name just a few. Companies also need to consider technical issues related to data transfer and the likelihood that incompatible platforms will require added steps to proceed. These are all regulated activities, subject to compliance oversight, and must be conducted in coordination with other functions e.g. quality, safety, manufacturing, supply and commercial.

The time and cost of the MAT will depend on all of these factors and can only be adequately determined if regulatory and compliance experts are part of the initial due diligence process. Failure to define the MAT workflow, cross-functional dependencies, realistic scheduling and risks before the contracts are signed could put the entire deal in jeopardy. However, when companies make regulatory planning part of the pre-deal due diligence, many of these risks can be mitigated, ensuring a successful outcome for all parties involved.

GOVERNANCE AND RISK MANAGEMENT

In the best scenarios, acquirer and divestor will assemble a cross-functional global governance team to monitor the assets transition and manage risks at every stage. This group should include representatives from finance, legal, regulatory, commercial, safety, manufacturing and quality teams to enable global oversight, coordination of local teams and maintenance of formal communication channels for rapid risk mitigation and issue resolution.

The delivery team should also develop a robust communication plan to keep all relevant stakeholder groups updated on progress, and their evolving role in the MAT. Good, transparent communication is the most effective way to prevent small problems from becoming costly obstacles.



TEN POINTS TO CONSIDER WHEN PLANNING A PORTFOLIO TRANSFERENCE

Regulatory teams should create a roadmap for the asset transfer that takes into account strategic and operational regulatory aspects, some of which are listed below, along with the amount of time needed for a successful transfer of responsibilities. Considerations include:

1. Whether any transfer markets have regulated MAT timelines. For example, in Brazil the MAT submission must be completed within 180 days of the agreement execution date, and several regulated milestones must be met following the MAT approval by ANVISA. In addition, the acquiring company must have the capacity to conduct local quality control before releasing the product to the market which means analytical transfer to a local partner (if applicable) must be completed in a timely manner.

2. Whether any markets require the acquiring company to have a local presence in the country to act as a local distributor and regulatory point of contact. For example, most Gulf Cooperation Council (GCC) countries require a local presence in order for the market authorization holder (MAH) to market their products in the GCC region. Therefore, a local partnership must be established prior to the MAT if the acquiring company does not have local representation, otherwise the transfer cannot be completed.

3. Whether the markets require new Marketing Authorization Holders to have official representation. These include Canada and Australia, for example, where lack of local MAH representation will prevent the product from being transferred successfully to the new MAH.

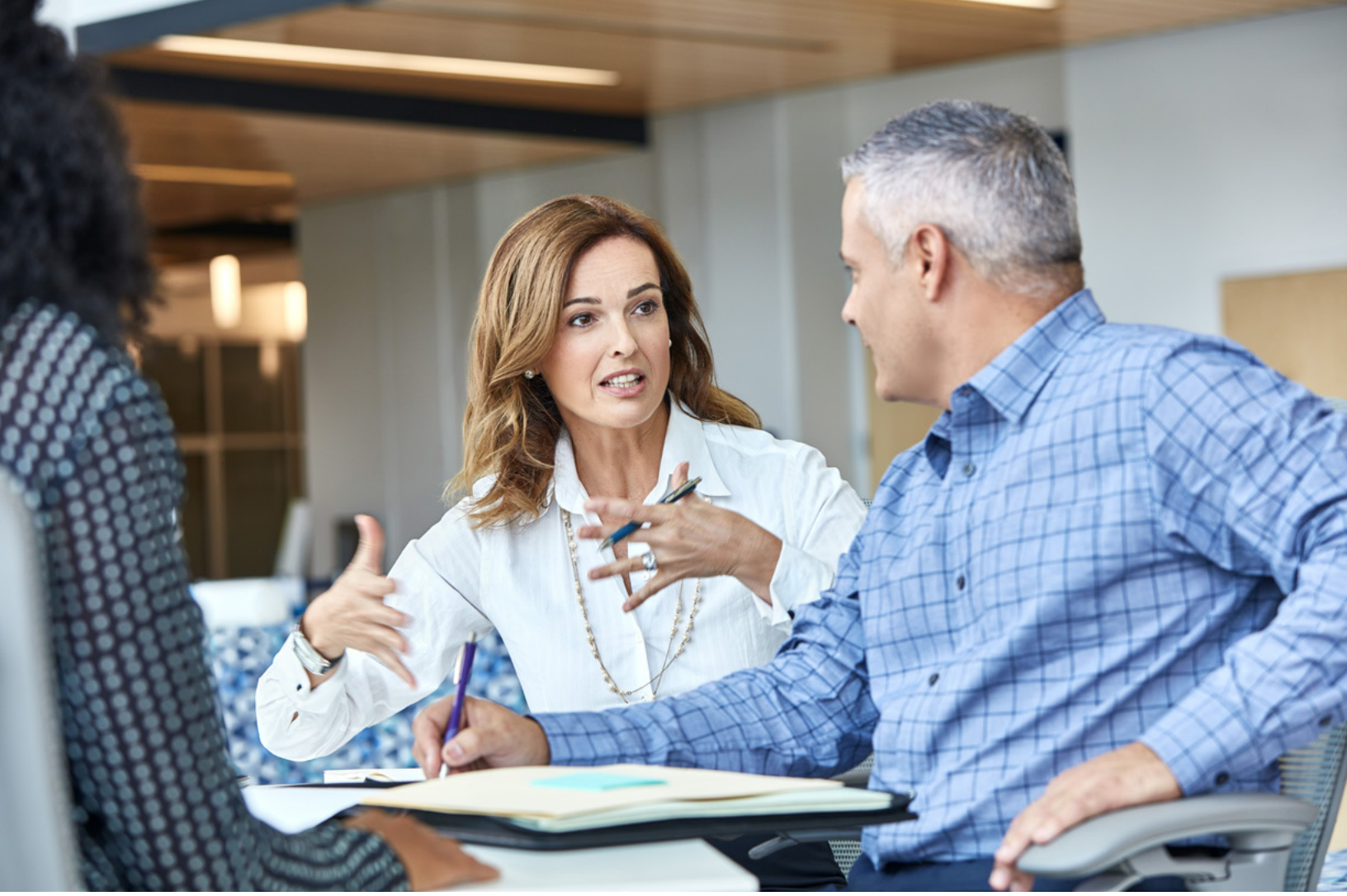
4. Whether a market lacks local registration regulations, and if so, which country will act as a reference market? For example, some African, Asian and Caribbean markets don't have their own stringent safety regulations, therefore these markets rely on the approved safety data from other bigger, more robust markets (such as the US, key European countries and Japan) and use them as "reference" countries to ensure that quality, safety and efficacy of the products to be marketed in their territory is safeguarded.

5. Whether local product release testing is required. Brazil, Argentina, S. Korea and Uruguay, are examples of countries that require analytical methods transfer prior to the asset transfer. Depending upon local analytical site availability and experience level of the acquiring company, this process can take 5-12 months.

6. Whether the regulatory status of the product will impact the MAT. In some cases, the asset will be in the midst of a license renewal or other regulatory procedure that will need to be completed prior to the MAT, adding 1-12 months to the process.

7. What submission documentation is required to complete the MAT? Some documentation, such as regulatory forms and certifications take little time to complete, while, for example, product artwork preparation and Certificates of Pharmaceutical Product, can take 3-5 months.

8. Whether product supply will be available in the new markets once the MAT is complete. Product supply may need to be built up to allow market presence during the time of transition, thus necessitating a grace period for existing product sales in the seller's livery following the transfer. It is not uncommon for acquiring companies to experience a 3-6 month delay or more due to manufacturing schedules, capacity or other issues such as raw materials on back order. Acquiring companies may be able to mitigate these delays by applying strong manufacturing risk management measures or resolving such issues by accessing product inventory shared between markets – e.g. products produced for France sold in other French-speaking countries.



9. What pharmacovigilance (PV) activities need to be addressed and by whom? A comprehensive Pharmacovigilance Agreement must be prepared as soon as possible after deal close. Roles and responsibilities over PV matters must be clearly defined. For example, per EU and US legislation, there must be only one Global Safety Database (GSD) per active substance, therefore during divestment/ acquisition negotiations, decision-makers must define which party will hold and maintain that database to assure compliance continuity. Decision-makers must also review individual case safety reports (ICSRs) exchange conditions. They must also assign responsibilities for overseeing aggregate safety report preparation, review, provision of sales and clinical trial data, and off-label use of data to avoid post-transaction PV issues which may lead to non-compliance, and subsequently to regulatory action and financial impact.

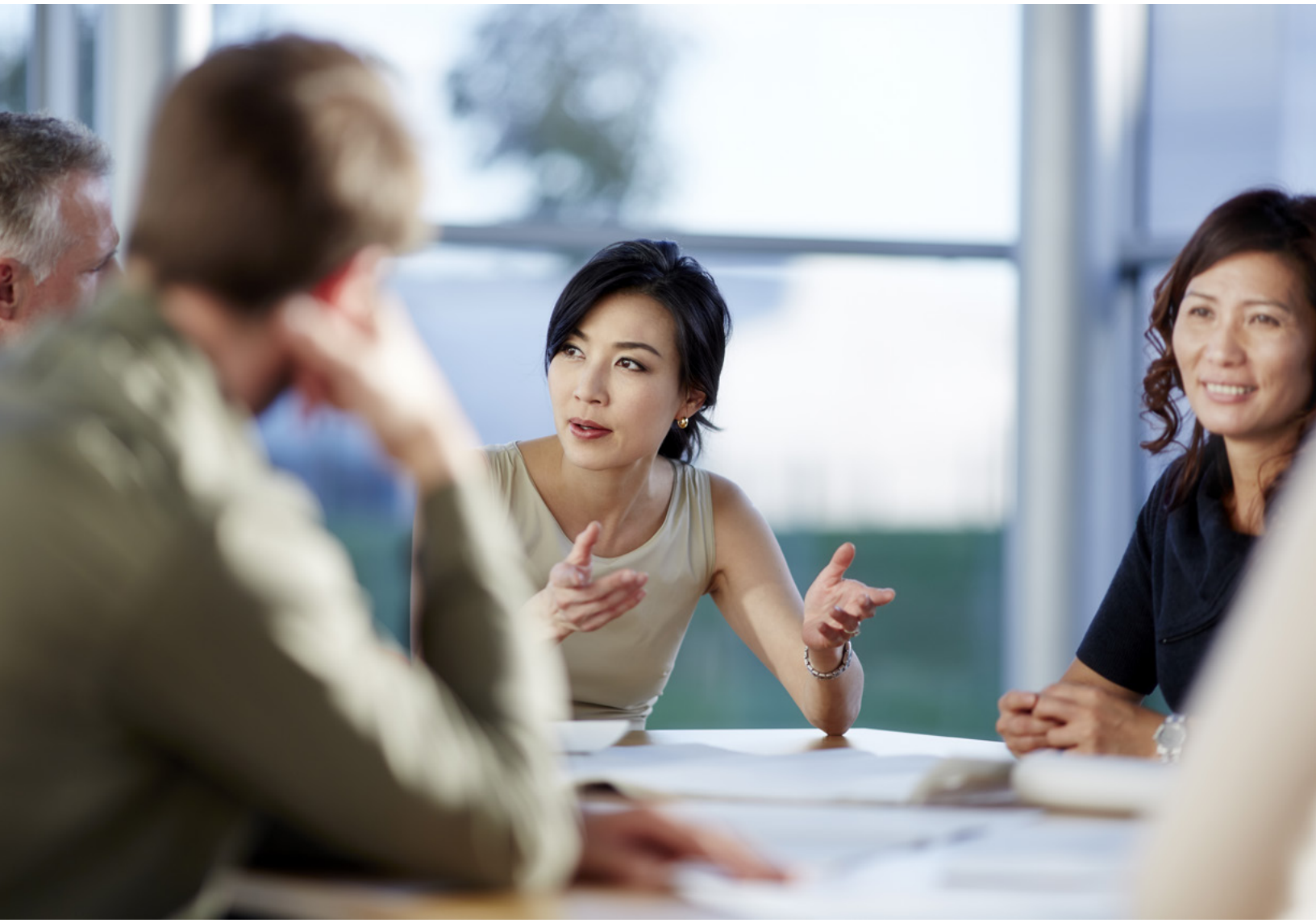
10. Who is in charge of the paperwork? The MAT necessitates the transfer of all product-related documentation and data repositories (e.g. regulatory dossiers, databases, and, sometimes, paper archives), which is a massive, time-consuming and often overlooked step in the MAT process. For mature assets, companies may have thousands of documents, many of which may be in paper format that might need to be scanned and transferred. Subsequently, documentation transfer requirements of all formats and operational aspects should be discussed at the pre-deal stage.

Conclusion

When regulatory experts aren't part of the M&A decision-making process, lucrative deals can quickly go off the rails. Due to the complexity of the tasks involved in a MAT, many companies heading into an M&A will bring in outside regulatory experts to ensure a fast, smooth and compliant transfer. Working with a partner to manage the MAT ensures that the company has experienced professionals overseeing every aspect of the assets transfer, while freeing their regulatory and other functional staff to focus on the existing pipeline development efforts, ensuring minimal impact on day-to-day workflow.

Outsourcing creates a streamlined approach to assets transfer which can mitigate transition-related risk, and ultimately save companies time and money by bringing in the appropriate expertise and staff at the right time.

For information on how IQVIA's end-to-end suite of regulatory services can help support your successful MAT, contact us at: iqvia.com/regulatorycompliance



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Cecile Riboud is currently responsible for IQVIA's Global Integrated Technology and Compliance Solutions in Europe, including safety/ pharmacovigilance, regulatory and quality compliance. She has over 17 years of life sciences experience across Scientific Information Management, Global Regulatory Affairs, Mergers and Acquisitions and Product Development. Having worked for large pharmaceutical groups and companies of all sizes in Europe, Riboud has an excellent understanding of the pharmaceutical and MD-IVD industry. She has held global management leadership positions leading large international programs, projects and teams of experts. Prior to joining IQVIA, Riboud worked at a well-known regulatory consulting firm in Germany, where she served as acting deputy head of an office totaling 60 international consultants and led global project regulatory activities involving 70 consultants worldwide. She was responsible for client delivery and was actively involved in Business Development. Riboud holds a M.Sc. in Analytical Sciences from the University of Strasbourg, France and an Executive MBA from EMLyon Business School, France – Shanghai, China.

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