

TradeWatch

EY Global Trade

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Insights

Insights

Global

Electronic customs filing

1

Recent trends in life sciences – impact
on the global trade function

5

Life sciences: Addressing the impact of
evolving export controls and sanctions

13

Insights from EY.com

18

Our Global Trade webcasts and podcasts

19

Electronic customs filing

This article deals with real-world considerations for designing and implementing a leading-class solution for electronic customs filing, often referred to as e-customs filing. E-filing is evolving and continuing to replace traditional paper-based filing around the world. Many customs agencies have implemented electronic filing systems to streamline the process and enhance efficiency, making it easier to conduct business in their countries.

Benefits of e-customs filing

E-customs filing offers significant financial and operational benefits for businesses, including:

- **Reduced processing times and delays:** Electronic filing reduces the time needed to prepare and process customs declarations manually by automating the process, leading to faster clearance of shipments by customs agencies.
- **Cost savings:** Automating customs filing reduces or eliminates the need to manually generate paper-based declarations, which allows businesses to save on administrative, printing and document storage costs. Companies can also reduce brokerage fees by automating the process and sending data to service providers electronically vs. having them perform the entire process using their own people and technology resources.
- **Improved accuracy:** Manually generated paper-based declarations are resource intensive, time consuming and error prone. By automating customs filing processes companies reduce the time and risk of human error in data entry, ensuring more accurate and reliable information is submitted to customs agencies. This accuracy element also may aid the use of duty-reduction mechanisms. For example, errors in import or export declaration can impact the use of duty drawback or free trade agreement preferences.



Removing human error, whether within the company or with the customs broker, provides a better foundation for tariff planning. E-filing may also facilitate post-entry corrections and reconciliation of transfer pricing adjustments.

- **Streamlined compliance:** Electronic customs systems and processes often include capabilities that help businesses comply with various international regulations, such as automating the calculation of duties and integrating screening for export and import controls, licenses, sanctioned parties, and embargoes.
- **Better data management:** Electronic filing creates a data trail for internal and external auditing, making it easier for companies to track and manage customs documentation and associated revisions and resubmissions. E-filing also aggregates data to perform data analytics identifying risks and opportunities as well as enabling use of key performance indicators (KPIs) and metrics.

These benefits and others make e-customs filing a viable option for businesses looking to streamline and optimize their import and export processes.

Challenges

While e-customs filing offers many benefits, it also comes with challenges:

- **Technical issues to consider:** Implementing and maintaining e-customs filing systems and processes can be complex and costly. Technical issues or system outages can disrupt the filing process. Therefore, companies should thoroughly and methodically plan their implementation projects and develop contingency plans for systems outages as part of their cutover and post-go-live plans.
- **Process standardization:** Countries have varying standards and requirements for e-customs filing, making it difficult for businesses to comply with multiple agency and system requirements. Companies should take a global template approach that allows them to standardize their filing program and processes as much as possible, while recognizing there may be a need to localize a standard process for a specific region or country.
- **Training and solution adoption:** Adapting to new technologies can be challenging, especially for smaller businesses. Businesses need proper training and knowledge transfer to use automated customs filing systems effectively. Having an effective change management strategy and plan is critical for a successful launch, adoption, and sustainable program and processes.
- **Integration with other systems:** Integration of data from multiple sources, sometimes including parallel legacy systems, is one of the biggest challenges in implementing e-customs filing systems. Business systems such as procurement and transportation management need to integrate seamlessly with enterprise resource planning (ERP) and global trade management systems. Lack of integration and timeliness of data availability can lead to inefficiencies and processing errors. It is also important to ensure that the master and transactional data required for e-customs filing is available, accurate and retrievable from source systems so businesses can aggregate the data into their customs filing system.
- **Regulatory compliance:** Keeping up with changing rules and regulations that drive customs filing requirements while maintaining compliance can be challenging, especially when dealing with multiple jurisdictions. To deal with this, companies should develop a sustainment plan and checklist to identify and schedule periodic maintenance and review of their filing system and processes.

Options for incorporating into the plan include, but are not limited to, customs rules and regulations review; third-party customs and content updates, if used as part of your filing process; product attributes (e.g., export control classification number (ECCN), harmonized tariff schedule (HTS); certificate of origin (COO)); and software updates, patches, and fixes to keep the system performing at its optimal pace.

Despite these challenges, the benefits of e-customs filing, such as cost savings, faster processing times and reduced paperwork, usually outweigh the difficulties.

Preparing for a project

Preparing for e-customs filing implementation involves several key steps to ensure a smooth transition and compliance with varying rules and regulations:

- **Understand the business requirements:** Be familiar with the specific e-customs requirements of the countries the business trades with. Each country may have different standards and regulations that will impact the global template and localization approach.
- **Invest in technology:** Implement the necessary software and hardware to handle e-customs filing. This might include global trade management or customs management software that integrates with existing systems. A best practice is to leverage investment in global trade management (GTM) software to enable this process if it includes e-customs filing functionality.
- **Change management and training:** Ensure that staff are well-trained in using the new systems. This includes understanding how to submit electronic declarations and how to troubleshoot common issues. Also, create and use business process documentation and desktop reference materials to help system users adapt to the system to perform their day-to-day job and responsibilities.
- **Data management and reporting:** Maintain accurate and up-to-date records of all transactions. Good master data governance is crucial for compliance and efficient processing. Having operational reports, metrics and KPIs on system and process performance is also important to provide visibility into operations and processes, and it can help sustain the system and continuously improve the filing program.



- **Engage with customs authorities:** Establish a good relationship with customs authorities. They can provide guidance and support during the transition and will play a key role in the testing of your system as the business implements and deploys it.
- **Pilot testing:** Conduct pilot tests to identify and resolve any issues before fully implementing the system. This helps ensure that everything works smoothly when it goes live.
- **Stay updated:** Keep abreast of any changes in customs regulations and technology. This will help the business remain compliant and take advantage of new opportunities.

By following these steps, businesses can better prepare for the shift to e-customs filing and enjoy the benefits of a more efficient and streamlined process.

Reducing risk

Implementing an e-customs filing system and program can be a complex process, and there are several common risk factors to avoid in order to have a smooth transition:

- **Inadequate planning:** Failing to plan thoroughly can lead to unexpected issues. It's crucial to have a detailed implementation plan that includes timelines, milestones, responsibilities and contingency measures.
- **Poor data quality:** Inaccurate, incomplete or untimely data can cause delays and compliance issues. Ensure that all data entered into the system is accurate and up-to-date. Also, design and implement a system that maximizes default data that flows into a customs filing transaction to minimize or eliminate the need for manual data entry by system users.
- **Lack of training:** Without proper training, staff may have challenges to use the new system effectively. Invest in comprehensive training programs to ensure everyone is comfortable with the new processes.

- **Resistance to change:** System users may resist new systems due to fear of the unknown or comfort with processes to which they've become accustomed. Address their concerns through transparency, clear communication, use of standard operating procedures and desktop reference materials. Highlighting the benefits of the new system and how it will make their job more efficient and effective will also help users throughout the cutover to a new system.
- **Insufficient or inadequate testing:** Eliminating or speeding through the testing phase of your project can lead to catastrophic results once the business operationalizes and goes live with the program and processes. Perform thorough testing to identify and resolve critical defects and issues before full implementation. Develop test scenarios and scripts that are based on real-world scenarios and incorporate positive and negative tests into test plans.
- **Failing to identify or ignoring regulatory changes:** Customs regulations can change frequently. Stay informed about any updates to ensure ongoing compliance.
- **Integration issues:** Ensure that the electronic filing system integrates seamlessly with other internal systems, such as ERP, transportation management, inventory management and other business systems needed to enable the filing processes.

By being aware of these pitfalls and taking proactive steps to address them, businesses can better navigate the complexities of an e-customs filing implementation.

Change management

Implementing e-customs involves significant changes, and effective change management is crucial for a smooth transition. Here are some practices to consider:

- **Engage stakeholders early:** Engage key stakeholders early and often to gain their support and address their concerns. This includes management, employees and external partners, such as customs brokers. This should include the tax department, due to the potential impact on customs valuation.

Ensure customs brokers are involved in the project planning process so that they have the resources, bandwidth and commitment to meeting the dates and milestones laid out in the project timeline.

- **Clear communication:** Maintain open and transparent communication throughout the process. Regular updates on progress, challenges and successes help keep everyone informed and engaged.
- **Training and support:** Provide comprehensive training and ongoing support to ensure everyone is comfortable with the new system. This can include workshops, online tutorials and help desks.
- **Pilot testing:** Conducting pilot tests to identify and resolve any issues before full-scale implementation is beneficial to confirming that there is a fully enabled and working system prior to full go-live across the technology and business landscape. This helps ensure that the system works as expected and allows for adjustments based on feedback.
- **Monitor and adjust:** Stay in touch with the project team and continuously monitor the implementation process. Be prepared to make adjustments to maximize the system's potential. This includes gathering feedback and addressing any issues that arise promptly.
- **Celebrate successes:** Recognize and celebrate milestones and successes to maintain momentum and to uplift stakeholder morale. This reinforces the positive aspects of the change and encourages continued support for the initiative.

By following these practices, businesses can navigate the complexities of e-customs implementation more effectively and promote a smoother transition. ■

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Recent trends in life sciences – impact on the global trade function

Over the last decade, there has been a shift away from the relaxation of global trade barriers toward the re-imposition of higher import taxes (including imposition of additional duties and taxes to counter trade disputes between countries) and an increasingly complex regulatory framework at import (due to factors including heightened geopolitical tensions and the implementation of sustainability measures). This shift has led to a rise in the significance and complexity of how companies operate to manage import duties and other indirect taxes that are collected at international borders, as well as satisfy increased regulatory and other governmental agency requirements.

Our EY Global Trade team in Ireland has led a Global Life Science Strategic Trade Forum since 2006 that has, at the heart of its objectives, the goal to bring together trade experts from leading companies in the sector to collaborate and foster insightful dialogues. The forum has created a platform to drive conversations around compliance, strategy and the impact of geopolitical trends on the life sciences industry. This article aims to share some of those key insights and trends, drawing from recent discussions, think tanks, and benchmarking outputs gathered from this community's collaborative efforts.

For the life sciences industry specifically, there has been a noticeable increased focus on the substance and structure of the global trade function, with a primary emphasis on safeguarding compliance with regulations to help ensure timely delivery of products to patients, while at the same time reflecting the need to manage international trade costs due to an increased focus on margins amid financial pressures in the sector. We explore below the scope and breadth of the trade function globally, its broader organizational impact, and the primary objectives that it should aim to achieve.

Recently, global trade teams in life sciences companies have shifted much of their resources toward navigating increasingly complex, fast moving and stringent export controls. These controls are a central aspect of a broader regulatory framework that includes ensuring compliance with health and safety standards, obtaining necessary product licenses, and screening of suppliers and goods. Companies must navigate these complexities while also adhering to environmental, social and governance (ESG) principles, including sustainability measures like the Carbon Border Adjustment Mechanism (CBAM)¹ and the [European Union \(EU\) Deforestation Regulation \(EUDR\)](#).

¹ For further information on CBAM, please refer to articles in previous edition of *TradeWatch*. [Find them here](#).



Impact on the global trade function

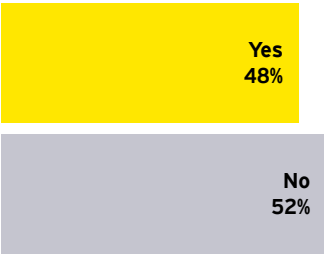
The reporting structure of the global trade function within life sciences organizations is a topic of ongoing debate. There are no one-size-fits-all conclusions. Key trade policy developments (ESG initiatives, increased tariff barrier disputes (US-China, EU-China), geopolitical tensions) have prompted companies to reassess the optimum placement for the trade function in their organization (e.g., tax, supply chain, legal, finance).

Benchmarking within the life sciences sector, based on an analysis of 30 top companies located around the globe, indicates a consistent level of dedicated trade personnel, with most companies maintaining a team of up to 50 individuals. Compliance is the cornerstone of the trade function, with management of export controls and sanctions requirements emerging as critical areas due to the impact of events such as the Russia-Ukraine war. While cost savings are considered, the primary emphasis is on achieving operational excellence and efficiency, ensuring that products meet quality standards and reach the market without delays.

In the past, it is fair to say that many global trade functions within the sector may have been characterized as reactive, focusing on battling fires rather than focusing on processes and strategic planning. Our most recent benchmarking results indicate a shift in focus, with activities now split between tactical and strategic. The trade function is increasingly tasked with operating on a global scale having dedicated regional trade leaders to enhance global trade outcomes and ensure efficient resource utilization as well as carrying out efficient

operational activities at site level. Our latest benchmarking data reveals that more than half of the life sciences companies employ regional trade leaders, and a significant 93% believe it is a best practice for these regional leaders to report directly into the global trade team leader. Additionally, there is wide recognition of the importance for a global trade team leader to be operating at the level of director or above to be most impactful in their activities.

Do you have regional trade leaders in the four main regions (i.e., Americas, EMEA, APAC and LATAM)?



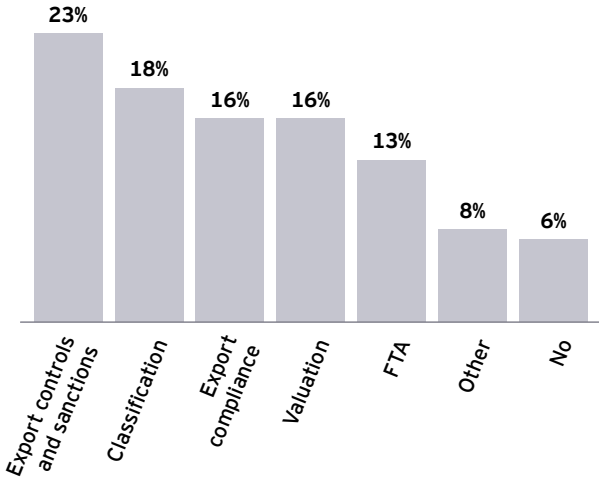
Do these regional trade leads report directly to you?



Do you think it's best practice to have regional leads as direct reports?



Do you have individuals in your global team focused on specific subject matter areas?



Based on a survey of 29 companies who attended the Global Life Science Strategic Trade Forum in Dublin on 14 and 15 September 2023.

Sanctions and export control

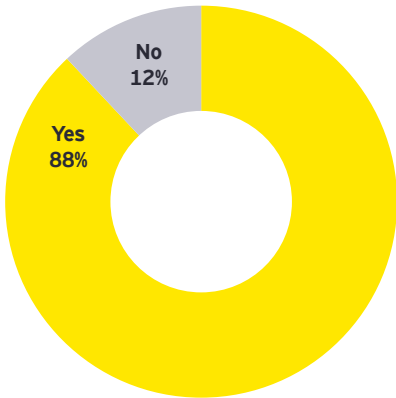
The sanctions imposed on Russia have placed significant strain on trade teams within the life sciences industry, requiring swift adjustments to new regulations and a shift in resource allocation. Trade professionals, including those without prior experience in export controls, have had to rapidly familiarize themselves with the latest requirements to support their organizations. Those without specialized export control personnel have had to invest time and resources to understand these regulations. Consequently, there is an increased emphasis on export controls and sanctions within trade teams.

Previously, businesses in this sector were mainly focused on adhering to US export control and economic sanctions regulations, but now they must strategically reassess their approach due to the growing complexity of EU and international sanctions. The industry recognizes that these measures are likely to remain and become more intricate amidst ongoing geopolitical tensions. This evolving scenario necessitates a more comprehensive and specialized expertise to mitigate all associated risks effectively.

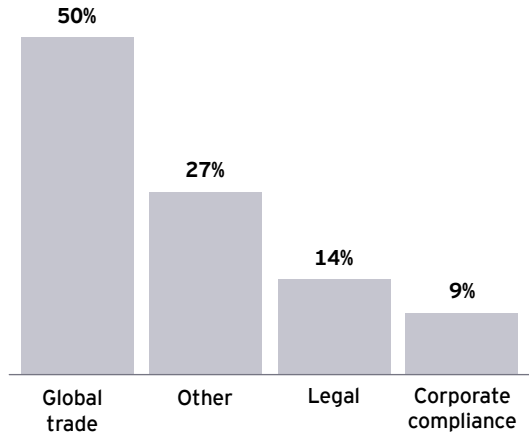
The recent enforcement of EU Directive (EU) 2024/1226,² which imposes criminal penalties for sanctions violations, has triggered an urgent recruitment of qualified personnel, especially within the EU. Yet, the market faces a notable scarcity of individuals with the requisite experience to satisfy the increasing demand.

Benchmarking insights indicate that companies with dedicated export control personnel are confident in their expertise and are focusing on trade automation as a strategic component in their export control and screening management processes.

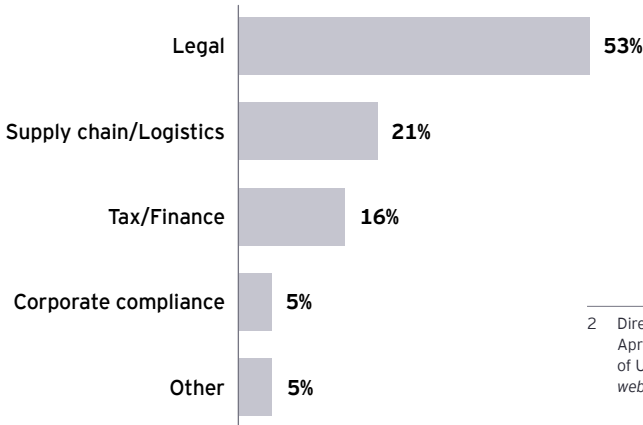
Do you have a dedicated function/person(s) responsible for export controls?



Which function within your organization is responsible for monitoring changes related to sanctions and export controls regulations?



Do you have a touch point/escalation for changes related to sanctions and export controls regulations into other departments?



² Directive (EU) 2024/1226 of the European Parliament and of the Council of 24 April 2024 on the definition of criminal offences and penalties for the violation of Union restrictive measures and amending Directive (EU) 2018/1673, *EUR-Lex website*. [Find it here](#).

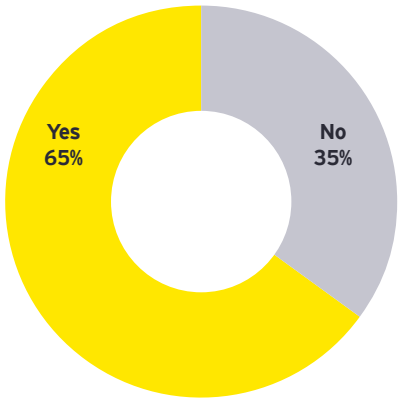
New licensing requirements

With the introduction of new sanctions and regulatory measures, companies have experienced a surge in the number of licenses they need to acquire, particularly for exporting medical products to Russia. This increase in license applications is a direct response to the tighter controls imposed by governments to regulate trade with Russia more strictly.

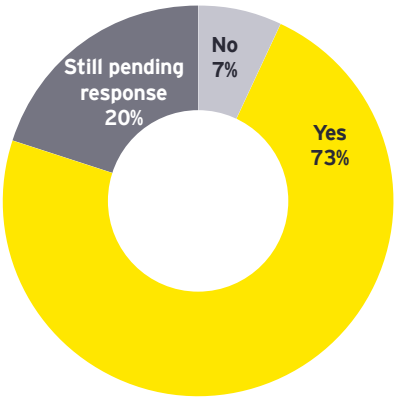
The process of obtaining these licenses has become more complex and time-consuming, as companies must navigate through an expanded set of requirements and provide detailed documentation to justify their export activities. As a result, companies have had to allocate more resources to ensure compliance with these new licensing requirements. This includes dedicating staff to manage the application process, investing in compliance training, and sometimes seeking external expertise to navigate the complexities of the regulatory environment.

The heightened scrutiny on exports to Russia means that companies must also be prepared for potential delays in obtaining licenses, which can impact their operations and lead to increased costs. This has made it essential for companies to plan ahead and incorporate these considerations into their trade strategies to minimize disruptions to their business.

Has your organization applied for licences or authorizations from the appropriate regulatory agency to export goods to Russia?



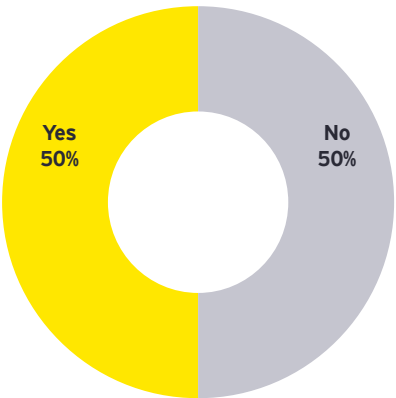
Were those licences/authorizations to export to Russia granted to your organization?



Is your organization aware of procedures to obtain licences/authorizations to export goods to Russia?



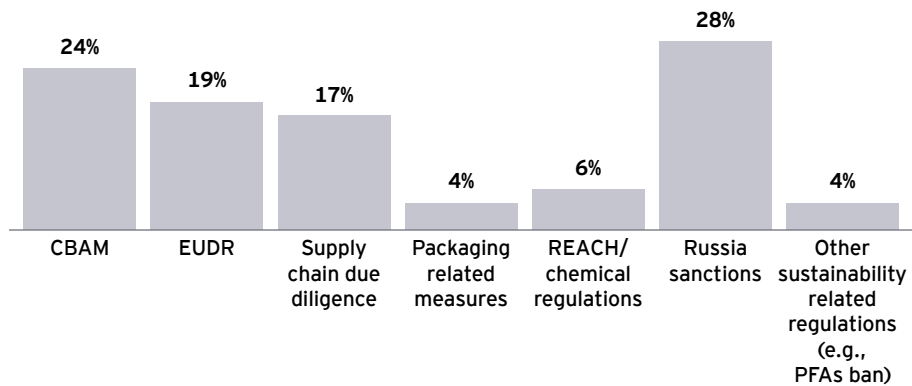
Were any of those licences/authorizations rejected/returned for additional information?



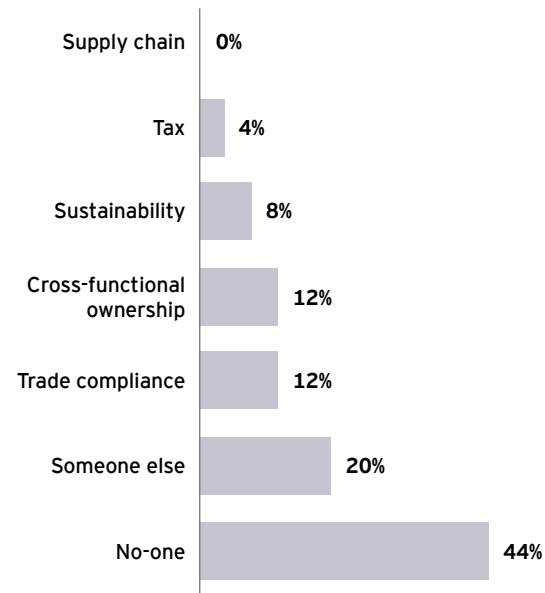
Sustainability

Global trade in life sciences is increasingly influenced by sustainability regulations, with CBAM, Forced Labor, and EUDR initiatives posing significant challenges for companies in the sector. The uncertainty surrounding the ownership of compliance responsibilities within organizations is a primary concern. Traditionally, departments such as environmental health and safety (EHS), sustainability, compliance, or supply chain might be considered for this role. However, the complexity of these regulations requires a more integrated approach, often involving multiple departments and the trade function serving as a subject- matter expert due to its understanding of import and export flows.

What are the biggest sustainability-related concerns for you at present? (3 max)



Which department in your business is responsible for CBAM?



CBAM

For the life sciences industry, the current scope of CBAM affects aluminum films, which are commonly used in packaging and equipment. Additionally, manufacturers need to be aware that machinery may also fall under CBAM regulations. The scope of covered goods is expected to expand by 2026 to potentially include plastics and polymers, with the aim of aligning with the European Union's Emissions Trading System (ETS) and bringing all relevant goods into scope by the end of 2030.³

With companies already having submitted their first three quarterly CBAM reports, life sciences companies must focus on the next steps in their sustainability compliance journey. The ultimate goal that will require companies to report on the actual embedded emissions of imported goods (including calculations based on a comprehensive account of both direct and indirect emissions, as well as any carbon costs incurred in third countries) will be a significant additional reporting obligation. Data gathering for compliance has already been highlighted as a key requirement but it may be difficult to source. Such data is required for accurate tracking of emissions and supply chain practices. Building a dedicated team or enhancing the capabilities of existing teams to manage these data requirements is essential for compliance and for making informed decisions on sustainability.

EUDR

EUDR represents a significant step in the EU's commitment to combating climate change and promoting sustainable trade practices. This regulation aims to minimize the EU's contribution to global deforestation by ensuring that products entering the EU market have not been produced on deforested or degraded land after 31 December 2020. It requires companies to exercise due diligence in their supply chains to verify the legality and deforestation-free status of commodities and products such as soy, beef, palm oil, wood, cocoa, rubber and coffee, as well as derived products.

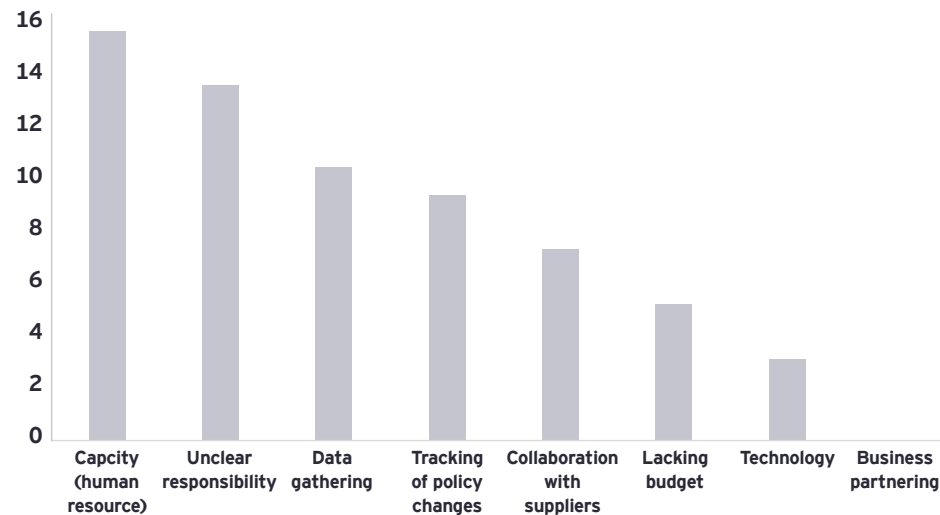
For global trade professionals, EUDR introduces an additional layer of scrutiny and responsibility. While the direct impact on the sector may seem limited at first glance, as the primary commodities listed are not typically associated with pharmaceuticals or medical devices, the regulation's broader implications cannot be ignored. Life sciences companies often rely on a diverse range of raw materials and derivatives, some of which may be subject to the regulation either directly or through their supply chain connections. For instance, palm oil derivatives are commonly used in the production of some medications and personal care products, which could fall under the scope of the regulation.

³ "EU: Final regulations published for new CBAM and ETS revisions", *TradeWatch* Issue 2 2023, page 36. [Find it here.](#)

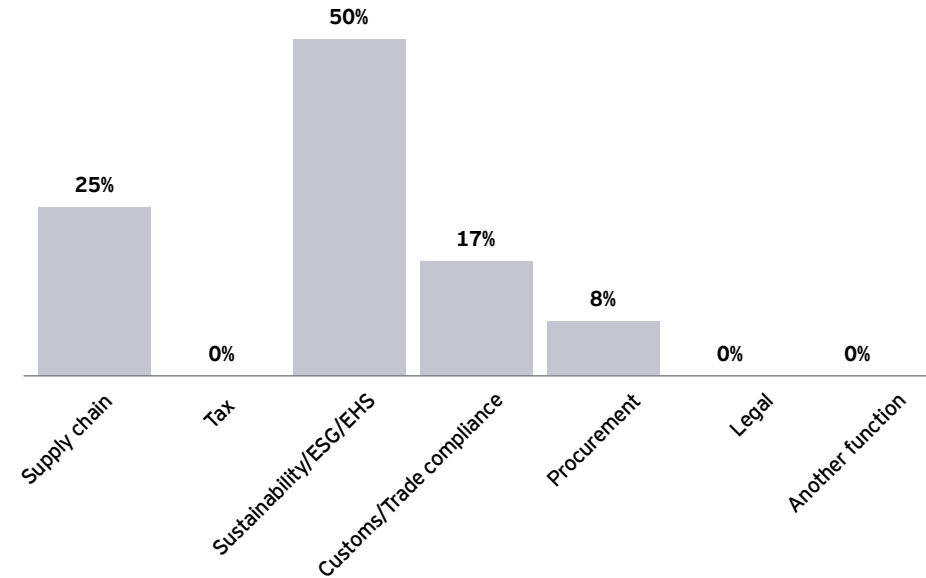
Our recent poll identified the top three concerns about the EUDR:

- 1. **Lack of capacity:** This limits companies from performing the necessary impact assessments to monitor transactions potentially affected by the regulation and, more importantly, the ongoing need to complete due diligence statements for each relevant commodity traded. This step is crucial for life sciences companies, as these statements are mandatory for import and export activities. Failure to provide them could result in goods being stopped at borders, a critical issue for certain products, e.g., those that are temperature sensitive. Moreover, there will be a need for qualified personnel to conduct due diligence to assert a “negligible risk” in these statements, which is a requirement set by this regulation.
- 2. **Unclear responsibility:** 75% of respondents in our latest poll indicated sustainability or supply chain as the function responsible for EUDR compliance. In practice though, it often falls to global trade teams to prevent goods from being detained at customs.
- 3. **Challenge of data gathering:** Particularly acquiring specific geolocation coordinates where commodities were harvested or produced, which is also a requirement set by this Regulation.

Which of the following are the key challenges for you? (3 max)



What business function owns EUDR?



The regulation thus compels life sciences companies to conduct thorough assessments of their supply chains, ensuring that their sourcing practices do not contribute to deforestation. This may involve re-evaluating supplier relationships, investing in traceability technologies, and potentially restructuring supply chains to meet the EU's stringent standards. As a result, EUDR not only affects trade dynamics by imposing new compliance requirements but also encourages the life sciences sector to adopt more sustainable and transparent business practices, aligning with broader ESG objectives.

Summary

The global trade environment for the life sciences sector is rapidly changing due to geopolitical shifts, tougher regulations and a stronger focus on ESG responsibilities. The complexity of new rules has made it crucial for businesses to carefully manage their trade practices and comply with regulations. The collective insights as summarized above illuminate the path ahead and play a key role in helping companies navigate these challenges by sharing insights and best practices. The industry is moving toward a more strategic approach to trade, with a focus on compliance, efficiency and sustainability. As companies face new regulations, complexities of export controls and sanctions and strive to meet sustainability goals such as CBAM and EUDR, the role of the global trade function has never been more important. As the sector evolves to meet the demands of an ever-changing global landscape, the commitment to compliance, operational effectiveness and supply chain integrity remains steadfast. ■



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Life sciences: Addressing the impact of evolving export controls and sanctions



The life sciences industry is a complex and dynamic sector, encompassing pharmaceutical, biotechnology, medical and other companies related to health care and biological sciences.¹ As technological advancements and increasingly sophisticated global supply chains characterize this dynamic industry, risks related to global export controls and sanctions are increasingly in play, creating new challenges and risks in a field that has historically been less impacted relative to the technology, aerospace and defense, and advanced manufacturing sectors.

Around the world, trade compliance risks have never been higher. The start of the Russia-Ukraine war in February 2022 triggered massive changes in export controls and economic sanctions rulemaking and enforcement in the US and abroad. The original focus was Russia, but it quickly broadened. Waves of escalating regulatory changes, in parallel with coordinated enforcement, impact all industry sectors. Some have been specifically targeted, such as semiconductors and advanced computing. But for other sectors, including life sciences, the challenges stem from the interplay between such changing trade rules, supply chains established before the abrupt shift from globalization to quasi-polarization, and industry advances in technology.

Trade compliance programs should be fit for risk. The higher the risk – likelihood of impact, magnitude of consequences – the greater the need to verify that the trade compliance function has the right people, processes, systems and governance model to achieve corporate objectives. Companies with adequate trade compliance programs for their risk profile in 2021 now find their programs are no longer sufficient to maintain supply chain continuity, ensure business right-to-operate, reduce customs duties and taxes, and foster compliance.

This article covers how industry changes and evolving export control, economic sanctions and other trade rules have increased risks in the life sciences sector – and what companies can do about it. While the focus is on pharmaceutical, biotechnology, medical and other companies related to health care and biological sciences, many of the challenges and responses will resonate with trade practitioners in every sector.

Evolving export control risks

Export controls have always been relevant to life sciences companies. Export control restrictions have longstanding application to certain human, animal

¹ Please also refer to our article "Recent trends in life sciences – impact on the global trade function" on [page 7](#) in this edition.

and plant pathogens and agents (US export control classification numbers (ECCNs) 1C351, 1C352 and 1C354), related genetic elements (US ECCNs 1C351-4), related vaccines and testing kits (US ECCNs 1C395 and 1C991), biological processing equipment (e.g., US ECCN 2B352),² and related technology (e.g., US ECCNs 1E001, 2E001, 2E002 and 2E301).

These historical export control risks have expanded due to recent industry and regulatory changes that increasingly impact the entire product lifecycle.

Increased use of export-controlled materials as part of drug products impacting the entire product lifecycle

Advances in technology have led to new therapeutic modalities where a late-stage component used in creating, or as part of, the active pharmaceutical ingredient (API) is export controlled. Similar concerns apply to medical devices.

For example, pharmaceutical companies may have APIs that are export controlled across numerous therapeutic areas:

- **Small molecules:** With some modern medicines the API itself may be export controlled. A particularly interesting example is the use of export-controlled deuterium in producing deuterated medicines (explored in the case study opposite).

- **Biologicals and large molecules:** Export-controlled genetic sequences, plasmids and vectors related to controlled pathogens are being used to fashion treatments for uncontrolled pathogens. While the finished drug product may not be controlled, all earlier stages of development and product manufacture may be subject to stringent export controls.

- **Radiological components:** There are both historical and emerging treatment modalities that involve the application of radiation. Here, too, the finished drug or device may be subject to complicated regulatory controls spanning the entire supply chain.

In such cases, export controls are relevant at every stage of the product lifecycle –research, development, clinical studies, manufacturing and distribution. A failure to identify and resolve export controls risk at any stage impacts all subsequent business operations and even patient outcomes.

For example, clinical trials may pose export control and sanctions risks due to the global nature of their administration and footprint: A single clinical trial may span dozens of countries, each with its own export control and licensing requirements applying not only to the end product itself but to kits, samples, and the equipment and technology used to administer the trials and record data. A failure to identify export-controlled goods, software and technology may lead to unexpected delays or even complete stoppage.

Case study – deuterated compounds

Deuterium is a chemical element that can be used for many purposes, from nuclear to medicinal uses. A stable isotope of hydrogen with a neutron in its nucleus, deuterium is a key material in nuclear applications, specifically as a neutron moderator in nuclear reactors and as a fuel in nuclear fusion. While deuterium itself can be associated with nuclear power or nuclear weapons production, it is not itself radioactive.

Medical applications of deuterium or deuterated compounds have exploded with technological advances in medicine and pharmaceuticals. Deuterium can be used to create deuterated versions of existing drugs and pharmaceuticals, increasing the effectiveness of certain medications by enhancing the drug's metabolic stability and pharmacokinetic properties (i.e., the drug's absorption and distribution within the body).

Due to historic and existing nuclear applications of deuterium, the element and its compounds have been highly controlled for nuclear end uses in support of nuclear nonproliferation. Since 2021, the US has bifurcated two different sets of export control rules for civilian-used deuterium: Deuterium and deuterium compounds for use in a nuclear reactor are controlled by the US Nuclear Regulatory Commission (NRC), while deuterium and deuterium compounds used for civilian non-nuclear reactor end uses are controlled by the US Department of Commerce Bureau of Industry and Security (BIS). Depending on facts and

² Examples of biological processing equipment controlled under US ECCN 2B352 may include centrifugal separators, clean rooms, cross-flow filtration, freeze-drying and spray-drying equipment, fermenters, positive-pressure protective suits, aerosol challenge chambers, and Class III safety cabinets.

circumstances, an export license may be required by either agency. Many other countries follow a similar model.

Deuterated medicines are, technically, compounds featuring deuterium. Even though they are not readily capable of nuclear end use like other deuterated compounds (such as heavy water), the regulatory framework employed by most countries was not designed with such a distinction. So far, regulatory and licensing carve-outs for medical end uses of deuterated compounds have been slow to manifest in most countries, including the US, making the finished drug product potentially subject to import and export controls.

China is a notable exception. China has specific medical-use classification for certain deuterium compounds used for treating certain diseases, such as Huntington's disease. As advances in medical uses for deuterium and other highly controlled compounds accelerates, other countries may see this trend as jurisdictions and regulatory frameworks keep pace with emerging technologies.

Increased export control risks for life sciences R&D

Research and development (R&D) in the pharmaceutical and life sciences industries often involve highly controlled toxins, viruses, chemicals, equipment and technology that are subject to strict licensing requirements for export to most countries. Life sciences companies should be aware that in many cases, it is not just the specific virus, toxin or biologic that is controlled and thus requires a license;

related technology, and certain types of discrete lab equipment, software and technology, may also be controlled.

Due to national security concerns, controls on life sciences technology are subject to current regulatory focus. For example, in early 2023, BIS expanded controls under US ECCN 1E001 to include technology for the development or production of specific marine toxins controlled under US ECCN 1C351.d.

Changes in export controls may be aligned with more universal research, discovery and development and not just specific pathogens, agents or toxins. Recent unilateral (e.g., US Section 1758) and multilateral (e.g., Wassenaar Arrangement) inquiry or rulemaking areas have included nucleic acid assembler and synthesizer software that is capable of designing and building functional genetic elements from digital sequence data, instruments for the automated chemical synthesis of peptides, and certain brain-computer interface technologies.

Export-controlled technologies impact research, discovery and development. Increased international collaboration and offshoring R&D activities result in employees from different countries sharing and exchanging information or technology that may be controlled. Additionally, shipments and exchanges between countries of export-controlled samples, prototypes and the like may run the risk of going undetected by companies as they are viewed as noncommercial shipments. Collaboration in international environments poses deemed export risks, where a license is required to share information or software related to a controlled item to a foreign national in the same way a license would be required to physically ship a controlled item to another country.

Any multinational R&D operation in any sector may face these types of risks, but life sciences companies in particular face a further complication. At most life sciences companies, research, discovery and development activities typically rely on isolated



systems and processes that make it hard to deploy traditional trade compliance controls, whether automated or manual. In addition, laboratory procurement and shipping often does not occur on the primary enterprise management systems. The processes and systems used may vary by lab or therapeutic area. This makes implementing effective internal controls harder than in most other industries.

Increased economic sanctions and other trade risks due to geopolitics

Economic sanctions are restrictive measures imposed by governments to advance foreign policy and national security goals. While export controls are generally focused on movement of goods, software and technology, economic sanctions generally restrict interactions with countries, their governments, targeted sectors and/or their entities.

Unlike most industries, life sciences companies enjoy the possibility of obtaining general or specific export control and/or economic sanctions authorizations to sell and support non-controlled medicines and medical devices even to comprehensively sanctioned countries (assuming that they have adequate trade resources for licensing and transaction diligence).

Even so, life sciences companies are impacted by evolving sanctions and geopolitics. Pharmaceutical companies performing clinical studies in Russia during 2022 would have been impacted by iterative

export controls and economic sanctions issued on short notice. Medical device providers selling to Russia would have had to quickly respond to successive rounds of new regulations impacting each area of the lead-to-cash pathway.

Similarly, life sciences companies operating in China face new and future geopolitical risks.

China plays a prominent role in biotech and API production, meaning that further geopolitical tensions between the US and China could disrupt supply chains. For example, in 2024, US lawmakers have considered a bill restricting business with certain Chinese biotech companies on alleged national security grounds. As another example, in September 2024, the US significantly raised current and/or prospective tariffs on face masks, medical gloves, syringes and needles sourced from China. The US Trade Representative opined that “increasing Section 301 duties on certain personal protective equipment will help protect recent investments in increasing domestic production and in US preparedness.”³ Two months prior, in July 2024, BIS⁴ announced that it will be conducting a comprehensive assessment of the US API industrial base that will ultimately be used “to help ensure the availability and security of the API supply chain and to raise awareness of current limited domestic manufacturing capabilities, among other potential issues.”

The above examples are merely illustrative and do not fully reflect the complicated intersection of the life sciences industry with economic sanctions or geopolitics in general, or with Russia or China in particular. Nonetheless, they demonstrate why

economic sanctions, geopolitics and trade remedies are an important aspect of supply chain planning.

Increased export controls and economic sanctions risks due to increased enforcement

In recent years, the US and other governments have significantly ramped up enforcement of export controls and economic sanctions, reflecting a strategic shift toward tighter regulation of export controls and sanctions as matters of national security. This new enforcement trend includes coordinated investigations, higher civil penalties and more criminal prosecutions. In 2023, the US Departments of Justice and Commerce, working in collaboration with the Federal Bureau of Investigation and Homeland Security Investigations,



³ “Notice of Modification: China’s Acts, Policies and Practices Related to Technology Transfer, Intellectual Property and Innovation,” Office of the United States Trade Representative, 89 Fed. Reg. 76581, 76585, 18 September 2024. [Find it here.](#)

⁴ “BIS To Conduct Assessment Of U.S. Active Pharmaceutical Ingredient Industrial Base,” BIS website, 9 July 2024. [Find it here.](#)

launched the Disruptive Technology Strike Force to investigate and prosecute export control, economic sanctions and espionage matters. US regulators began aggregating their data to target investigations. Similar coordinated investigation and enforcement activity is already occurring between the US and its allies. In September 2024, BIS created a new Chief of Corporate Enforcement role foreshadowing future enforcement activities.⁵

Enforcement efforts have begun to impact the life sciences sector in interesting ways. A 2023 resolution involving Iran sanctions featured a USD175,000 settlement with an individual former senior executive in addition to the corporate settlement. In 2024, the US Department of Justice declined criminal prosecution of export control violations by a pharmaceutical company based on the actions of internal trade compliance personnel. A 2024 settlement with a US university involved a suspended one-year loss of export control privileges for controlled biologicals pending remedial activities. Failure to comply would effectively shut down international research involving controlled biologicals for a year. This would be unfortunate for a university but crushing to many life sciences companies.

Actions for businesses

Maintaining a robust compliance and risk assessment program is vital not only for ensuring compliance but also for ensuring sustainable business operations that can directly impact customers and patient outcomes globally.

- **Risk assessments:** Frequent enterprise-wide risk assessments facilitate the identification of controlled items or technology as well as associated risk factors related to supply chains and the involvement of third parties or sensitive, high-risk jurisdictions. Risk assessments allow organizations to keep a steady pulse on their risks and opportunities for improvement and prioritization of internal controls to manage risks. For life sciences companies, this risk assessment should recognize the impact of evolving export controls, economic sanctions, geopolitics and trade remedies across the entirety of operations, including sources of API, clinical research organizations and locations, contract management operations and locations, and distribution.
- **Internal controls:** Developing and maintaining robust internal controls relative to enterprise risk is vital for ensuring compliance across large organizations. Documented procedures and integrated steps to check and manage risks for controlled items, including software and technology, can prevent violations before they occur. For life sciences companies there may be a particular need to separately address controls for research, development and clinical operations from commercial manufacturing and distribution activities.
- **Training:** Frequent enterprise-wide and targeted role-based trainings are essential for a strengthened compliance program, cultivating awareness of risks associated with export controls and sanctions relative to their daily tasks and

responsibilities. Risks related to laboratory and clinical settings may benefit from integrating export controls content into existing targeted laboratory trainings (biosafety, radiation safety, etc.).

- **Monitoring and auditing:** Monitoring is crucial for a robust compliance program, as it provides insights into the business, its operations and associated risks, which can then be used to strengthen policies, procedures and internal controls. Data analytics and technology-driven solutions can assist in monitoring and auditing compliance programs, which is useful for spotting risk gaps and opportunities for improvements to internal controls and enterprise operations to manage risks. Executives need to recognize that including the trade function in strategic enablement (business and supply chain planning, acquisition due diligence, government relations) is absolutely necessary to ensure supply chain continuity and maintain business right-to-operate in this geopolitical era. ■

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⁵ "Commerce Implements Regulatory Changes to Voluntary Self-Disclosure Process and Penalty Guidelines; Names Raj Parekh as First-Ever Chief of Corporate Enforcement," *BIS website*, 12 September 2024. [Find it here](#).

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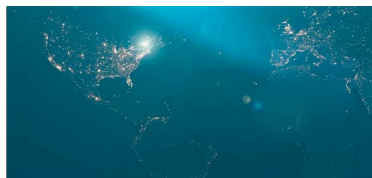
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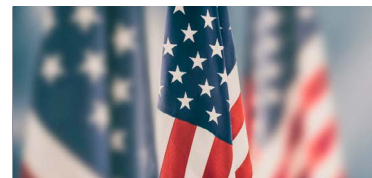
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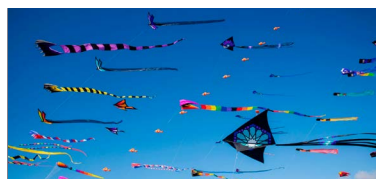
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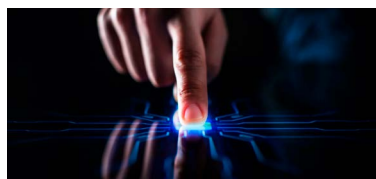
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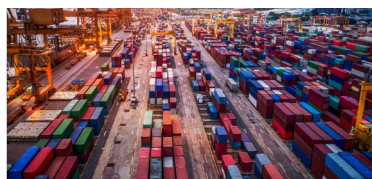
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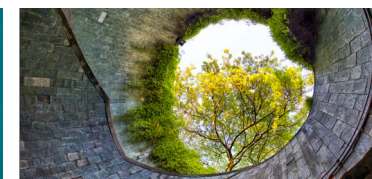
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- Brazil moves major VAT reform bill to Senate for consideration (05 August 2024)

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- Colombian 2024 Tax reform bill submitted to Congress, would affect corporate and capital gains rates, among others (13 September 2024)
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- US White House publishes Fact Sheet outlining proposed changes to de minimis shipments exemption (19 September 2024)
- USTR publishes final Notice of modification of actions on impacted Chinese origin products subject to increase in additional Section 301 tariffs and applicable exclusions (17 September 2024)

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- Initial Digital Platform Information reporting due in early 2025
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- Danish Government plans to introduce a new agriculture CO2 tax (06 August 2024)
- Danish Parliament introduces CO2 tax on fuels and CO2-emission tax on industry from 2025 (06 August 2024)

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- European Court of Justice holds relocating production won't enable company to escape additional duties unless relocation is economically justified (03 December 2024)
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- Poland presents framework for National e-Invoicing System (05 November 2024)

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- Saudi Arabia announces 18th wave of Phase 2 e-invoicing integration (03 December 2024)

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- Saudi Arabia announces 14th wave of Phase 2 e-invoicing integration (05 August 2024)

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- Slovakia introduces tax on sweetened nonalcoholic beverages (20 September 2024)

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- South Africa publishes amendments to customs duties on lead-acid batteries (13 August 2024)

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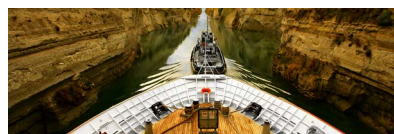
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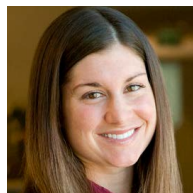
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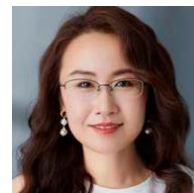
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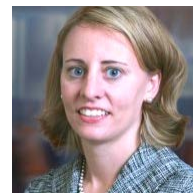
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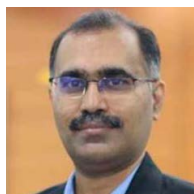
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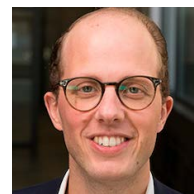
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