Export compliance in the Life Sciences: Keys to international growth

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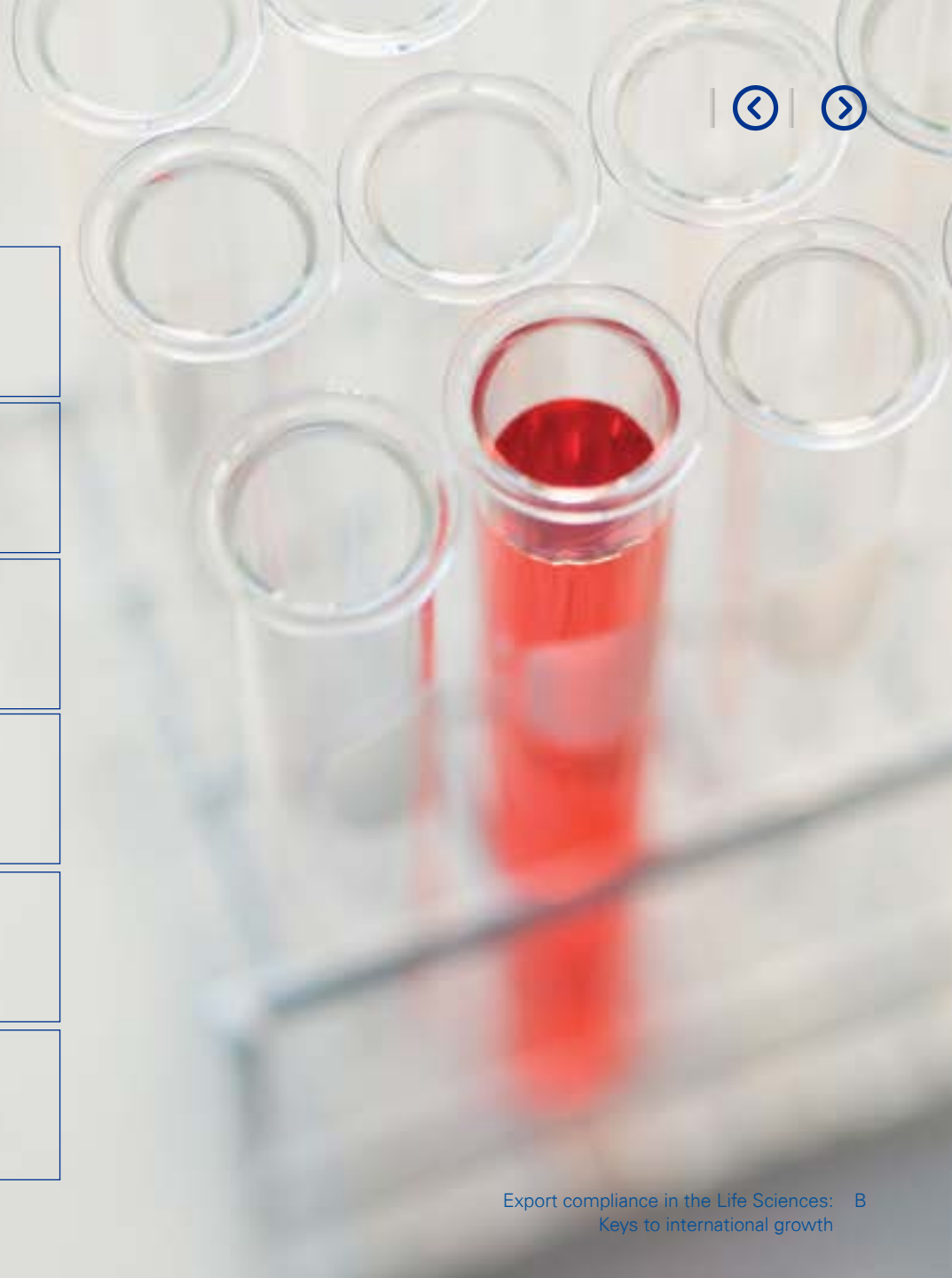


Introduction

As sophisticated new technologies drive growth for pharmaceutical, medical, and biotech companies, historical and new U.S. export controls in the life sciences space create a challenging environment for aligning export compliance with business goals.

The complexity of pharmaceutical and life sciences supply chains gives rise to inherent export control and sanctions related risks. Supply chains may involve research and development (R&D), clinical trials, production, and sales and marketing activities in numerous jurisdictions. Commercial and non-commercial shipments are often recorded in separate systems, making them harder to monitor, and IP and technology transfers to partners abroad create new requirements requiring close management.

Additionally, the life sciences industry is subject to stringent licensing requirements relative to other industries, with certain toxins, viruses, and equipment used in R&D activities often requiring an export license to every country. Equipment for the handling and monitoring of toxins and biological materials, for example, are stringently controlled under ECCNS 2B351 and 2B352, requiring licenses to many countries even when shipped intra-company.

Software and technology controls are also a key consideration. The Australia Group and the U.S. Bureau of Industry and Security (BIS) recently instituted new controls on software designed for nucleic acid assemblers under ECCN 2B352, and additional software that could be used to develop sensitive materials may become controlled. Regulators are taking steps to identify and control other emerging technologies, such as gene sequencing, genomic and genetic engineering, and certain biotechnology items.

In this environment, it is vital for Life Sciences companies to understand the business activities that involve exports and that expose them to risks, and how to mitigate those risks with an effective internal compliance program.

Export controls & sanctions trends in the Life Sciences

- Evolving risks and opportunities
- Product controls
- Sanctions regimes management challenges
- Increased enforcement

Export compliance touchpoints in the Life Sciences

Research and development

Research in the pharmaceuticals and life sciences industries often involves toxins, viruses, and other materials that are highly controlled and that require an export license to every country. Licensing requirements can be intensive given that R&D activities are increasingly conducted in international environments, with employees in different countries frequently initiating non-commercial shipments that fly under the radar of current compliance processes and systems. Additionally, relying on the best global talent to develop new products may introduce "deemed export" licensing requirements for foreign national employees, contractors, and third parties working in the U.S.

Contract development and manufacturing

The growth of contract service relationships in Life Sciences has led to an increase in import/export activity for many companies, including shipments of sample materials, chemicals, and equipment to laboratories abroad and transfer of production information and technology to contract development and manufacturing organizations (CDMOs) and other affiliates.

Clinical trials

Many items used to conduct clinical trials may be subject to export control restrictions—for example, electronic devices used for data collection, biological agents, and laboratory equipment. A single clinical trial may have trial sites in multiple foreign countries, each with its own export control regimes and requirements. Additionally, companies may be required to provide export-controlled technology to foreign regulatory agencies prior to clinical trials, creating export licensing requirements.

International sales

Expanding sales to countries such as India, China, and others is critical for business growth in the Life Sciences. It also introduces export compliance risks. The export licensing requirements can be complex, requiring companies to have a deep understanding of their products, end-uses, and end-users.

Tools for managing risk

Applying a strong risk-management framework will not only reduce the likelihood of export controls and sanctions violations but enable business. Although a specific compliance plan will be driven by each company's unique needs, there are a few critical steps most companies should take:

Entity-wide risk assessment: A risk assessment identifies the specific risk drivers based on products, supply chains, business procedures, and third parties. Following this assessment, the export compliance team will be able to prioritize its risks and identify where enhanced procedures and systems would be beneficial.

Key control identification: Key control management is imperative to a healthy export controls and sanctions program. When a key control fails, it may lead to a significant failure in the compliance program. Identifying, testing and modifying these processes will be crucial in preventing large-scale violations.

Monitoring: Compliance programs are strengthened by insight into business teams and their activities. Designing effective controls requires understanding which teams work with controlled items, identifying where and why exports are occurring, and ensuring the right data feeds are in place.

Training: Entity-wide training should be developed to sensitize employees, regardless of location, to their responsibilities in facilitating compliant transactions.

How KPMG can help

The KPMG Trade & Customs practice has extensive experience working with Life Science companies on the full range of export controls and sanctions matters, including thorough risk assessments, product classification, key control identification and management, risk monitoring and reporting, Restricted Party List (RPL) Screening, and more. Our recent industry experience is detailed below.

Case study #1

- A client in the life sciences industry was prepared to invest in its export compliance program but lacked insight into the key risks that should drive the program's design. Business teams in multiple locations and departments were making exports of a wide variety of items, but the procedures and systems used by the teams were fractured and inconsistent. Compliance personnel needed additional visibility into the business in order to tailor a program and organization around the key risks.
- To address these issues, KPMG analyzed data from several systems and provided a report with analytics on the company's export/import flows, key shipping stakeholders, controlled items and technology, and regulatory requirements across the data sources. Following the report, KPMG designed and rolled out a custom survey to business stakeholders to obtain further information on the company's inventory of controlled items. The company plans to use the survey as a regular monitoring mechanism, with KPMG data analysis and reporting providing an ongoing data feed to compliance personnel.

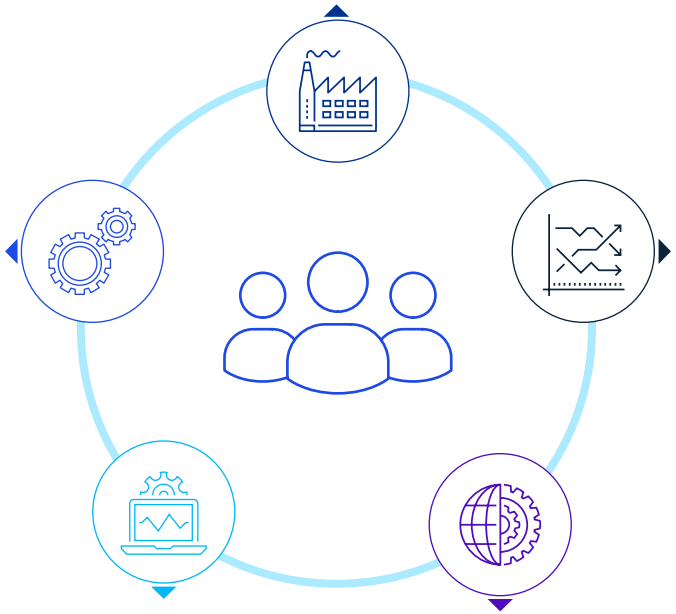
Case study #2

- A global biopharmaceutical company confronting increased compliance requirements related to its core product line required a global risk assessment and reconsideration of its compliance operating model.
- KPMG provided the company with an organizational and resource model and global risk assessment, as well as assistance with development of a target operating model (TOM) to support the implementation of the new organization, systems, and processes, which included comprehensive review of the company's global trade profile and developing shared services, centers of excellence, and local entity resources, defining geographic and functional roles and conducting detailed resource analysis to adequately staff the model, and design of a global risk assessment covering 40 countries and 50 sites to obtain in-depth visibility into potential global risks. This work included reviewing controlled technology management procedures to identify gaps, then establishing a robust program to compliantly facilitate business needs.

KPMG's differentiators

Deep industry knowledge: Our global team not only understands export controls and sanctions requirements but has significant experience in the life sciences industry. We know the challenges that the industry is facing and have developed customized approaches for evaluating risks in the life sciences environment. Our experience in working with emerging technologies reduces our learning curve and enables us to hit the ground running.

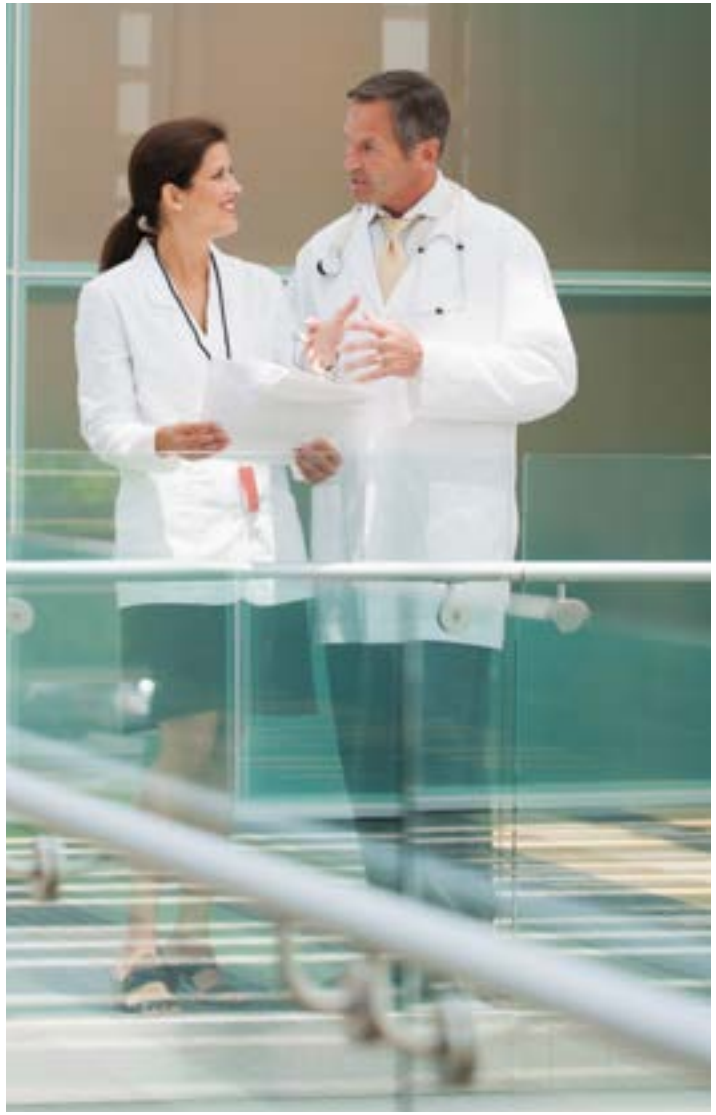
Automated tools: We have developed automated survey and monitoring tools specific to life sciences clients, whereas competitors often use manual approaches. Our toolbox allows us to quickly identify activities, materials, equipment, software, and technology subject to export control regulations. Our automation and data analysis tools enable us to quickly gather and analyze information to help bring visibility into the global compliance posture.



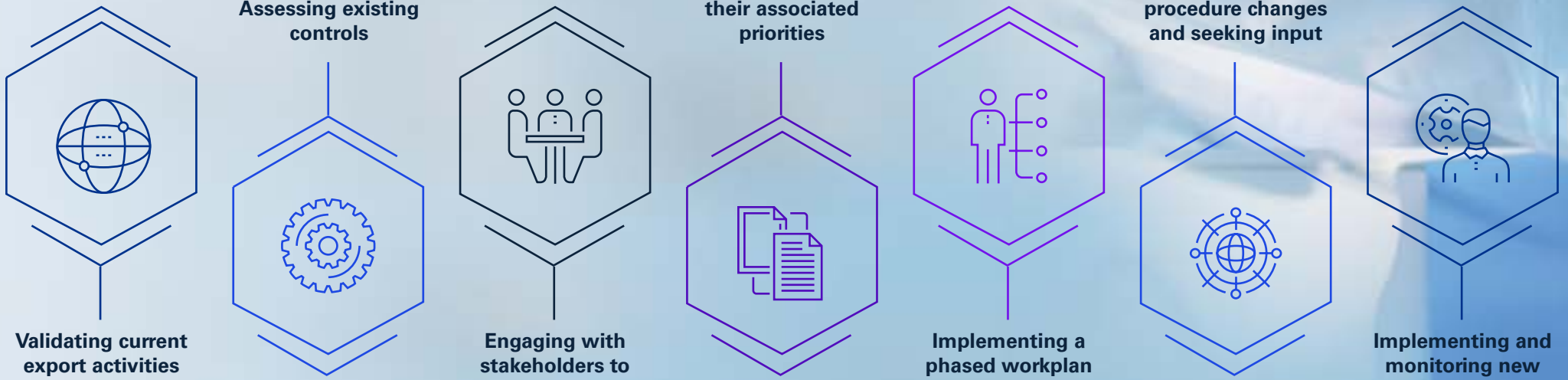
Industry benchmarking and publications: We have an extensive library of publications on export controls and sanctions compliance, and recently conducted a benchmarking survey of multinational companies in various industries including life sciences to gain insights into their export control programs and organizational structure.

One firm approach: Teaming with the industry-leading KPMG Cyber Security practice enables us to design effective technology and technical data controls.

Wide-ranging suite of services: The KPMG Trade and Customs practice provides services related to a full range of regulatory requirements impacting the life sciences space. We provide a single team that can address export and import compliance, design and implement GTM solutions, identify opportunities for duty savings, and assess risks and opportunities throughout the supply chain.



KPMG applies a proven methodology to identifying and developing a strategy for managing risks. This includes:



Validating current export activities

Assessing existing controls

Engaging with stakeholders to understand their current and future activities that may have an export nexus

Identifying action plans and their associated priorities

Implementing a phased workplan

Educating stakeholders on policy and procedure changes and seeking input

Implementing and monitoring new procedures for effectiveness

Contact us

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