
Papers

Export compliance for life sciences

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Abstract

Long before worrying about US Food and Drug Administration compliance, organisations that work with foreign employees, contractors, vendors or partners need to be concerned with the importation and exportation of technological knowledge – the so-called ‘deemed exports’. This is particularly apt for executives in the biopharmaceutical, biotechnology and medical device fields who outsource research and development overseas or who hire non-US citizens. US export regulations have strict guidelines on the types of knowledge that cannot be shared with non-US citizens and carry harsh penalties for non-compliance that fall equally on the organisation in question and its executives who ought to have known better. This paper presents an eight-step strategy to develop a regulatory compliance programme that meets US export compliance regulations.

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INTRODUCTION

The United States Bureau of Industry and Security (BIS) sent 31 people to jail, fined 69 individuals and companies, and collected \$14.6m in penalties in 2005 alone. For many, the BIS (under the Department of Commerce) is the most worrisome compliance agency to deal with.

US-based pharmaceutical, biotechnology and medical device companies that work with offshore partners, that ship equipment out of the US or that re-export combination products with internal technology need to have a defined and well-tended export compliance programme covering both tangibles and intangibles.

Here are eight steps to building a good programme.

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BOARD APPROVAL

The first step is to obtain approval from the governance board and the senior management

team to establish an export compliance programme under three conditions:

1. Senior management and the board of directors must be knowledgeable about the programme and its business impact.
2. Senior staff and the directors must recognise their personal liability under the BIS and US sentencing guidelines.
3. The board and senior management will need to push for both compliance and business progress.

Recognise that an overly conservative compliance programme that hampers legitimate business progress will have a compounding negative bottom line impact. As appropriate, consider asking an outside independent advisor for help.

GAP ANALYSIS

Conduct a compliance gap analysis on your current processes, from hiring of employees and contractors to your supply chain – each of these is a link in the chain of export compliance. Assess how you store and secure records that prove your compliance.

Focus on reasonable gaps that the ‘man in the street’ or ‘joe cubicle’ would be able to identify, and you will be on the way to a good balance.

SCREENING

Review names of individuals and firms on the government-restricted lists. Your procurement process and your hiring process need to incorporate this in an ongoing basis. The government makes thousands of changes to the lists yearly, so consider an annual review of your vendors, partners and contract personnel. To an auditor, out-of-date programmes will equate to programme ineffectiveness.

END USE QUESTIONS

For any product developer and marketer, the export compliance rules require you to

provide a level of assurance that your product is not falling into the wrong hands.

As part of the sales process, as well as evaluating your suppliers and distributors, be certain that your product is being purchased for its intended use:

- Ask about the intended usage of the product by those who buy it.
- Assess whether your product or service is consistent with the business of the potential buyer.
- As appropriate, ask the distributor or the purchaser if they will be selling or sending your product to embargoed countries.

If you typically perform due diligence audits on potential distributors or partners, incorporate these questions into your audit.

WRITE AND IMPLEMENT PROCESSES

Each component of the product chain in your company should have a set of processes to ensure the proper measures are taken to control export compliance risks. Pay particular attention to ‘deemed export’ (or knowledge transfers) controls.

Procedures, flowcharts and/or checklists should be in place for information technology, purchasing, human resources, engineering, manufacturing, sales, order fulfilment, shipping and customer service.

One organisation I worked with established a Compliance Export Team comprised of key, cross-functional individuals – IT, HR and purchasing, plus finance and regulatory affairs. This team was able to quickly flowchart and identify checkpoints across all core company activities used to conduct day-to-day business.

TRAIN AND REVIEW

It is almost cliché to recommend training for any compliance-based programme, so focus on training that allows individuals to make good decisions without direct review of

policies. If nothing else, the fall-back should always be to ask for help.

Several years ago, the management team of an organisation brought in a mix of outside lawyers and consultants to run a dual-purpose training: the lawyers handled the legal aspects of compliance while the independent consultants worked the company staff through 'what if' examples and provided basic flowcharts upon which the company then built its compliance programme.

COMBINE CONTROLS

Leverage your other organisational controls and security. If you are ISO compliant or deal with the US Drug Enforcement Agency, you can often combine control points. Do not take the position of a regulatory affairs officer I recently worked with, who said, 'If I combine everything, people will get confused!'

Avoiding combined controls is akin to having three passwords just to log onto your computer: one to do FDA work, another for DEA activities and a third for BIS work. Do not make things more difficult for yourself.

RECOGNISE THE NEED FOR HELP

Do not lose sight of the fact that regulations are meant for the broad base of companies. They are *not intended* to deal specifically with your company and how it evolves over time in the market.

If you are not certain where to start, or want a sounding board for your strategy, consider asking for independent advice. Search professional associations such as the Regulatory Affairs Professional Society, the Institute of Management Consultants or the Independent Computer Consultants Association for 'export' or 'export compliance'.

And ask if they know the 'deemed export' provision of the rules; if they give you a blank stare, you are missing half the picture.

FINAL THOUGHTS

Many executives privately admit to being a little uncertain about the export compliance rules, much less being aware of the BIS. Just make sure that your uncertainty does not land you in trouble. As lawyers in the BIS are quick to remind, ignorance of the law is no excuse.

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