

Trade compliance challenges and in-house training in export operations: a case study of a multinational biopharmaceutical company

Lora A.K. Sinyangwe, Joana Koci,** Fatih Cura****

Abstract

Trade compliance has become increasingly complex for multinational firms as export controls, sanctions, customs requirements, and other regulations change across jurisdictions. While existing research has examined regulatory frameworks and compliance systems, less attention has been paid to how trade compliance challenges, knowledge gaps, and training needs vary across organizational functions. This study examines how trade compliance challenges and knowledge gaps vary across organizational functions and how in-house training and knowledge-sharing practices are organized within a global biopharmaceutical company. Using a qualitative single-case study design, 21 semi-structured interviews were conducted across trade compliance, logistics, customer service, classification, research and development, and related functions, supported by internal training and audit materials. The findings show that regulatory complexity is closely connected with internal challenges involving product information, classification, documentation, responsibilities, and information flows.

* Lora A. K. Sinyangwe holds a Master's degree in International Logistics and Supply Chain Management from Jönköping International Business School (JIBS), Sweden. She has expertise in trade compliance, export/import operations, procurement, distribution, and retailing. She is passionate about sustainable and technology-driven supply chains, with knowledge of artificial intelligence, blockchain, machine learning, and Industry 4.0 applications.

** Joana Koci holds a Master's degree in International Logistics and Supply Chain Management from Jönköping International Business School (JIBS), Sweden. Her expertise includes supply chain integration and international logistics, with a strong interest in global trade. She is passionate about improving cross-border logistics operations and enhancing supply chain efficiency in international business environments.

*** Fatih Cura is an Assistant Professor in Business Administration at Jönköping International Business School (JIBS), Jönköping University, Sweden. He is also affiliated with the Media, Management and Transformation Centre (MMTC) at JIBS. His research focuses on the activities of logistics service providers, visualizing trade data on international markets, export performance and export competencies of SMEs.

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Rather than representing purely regulatory issues, many compliance challenges emerged at the intersection of regulatory requirements and organizational processes. Compliance knowledge was also unevenly distributed across functions, making access to specialist expertise and cross-functional coordination important when cross-functional decisions were required. Training practices varied considerably across functions and included e-learning, role-specific training, cross-training, certification, and external learning. Participants identified more practical and role-relevant training as useful, particularly through scenario-based and function-specific approaches. However, the findings also show that training constitutes only one element of a broader compliance system involving clear responsibilities, procedures, systems, monitoring, and specialist knowledge. The study contributes to the trade compliance literature by providing a cross-functional perspective on how compliance knowledge is distributed, shared, and applied within a highly regulated multinational organization.

Keywords

Trade compliance; trade regulations; export controls; dual-use regulations; knowledge sharing; export operations; in-house training.

1. Introduction

The biopharmaceutical industry operates within one of the most highly regulated environments in international trade. Companies must comply with a broad range of export controls, customs procedures, sanctions regulations, and health and environmental requirements to ensure both product safety and legal conformity. As global operations expand, managing compliance across multiple jurisdictions has become increasingly difficult.¹ Over the past decade the biopharmaceutical market has experienced significant growth due to increased investment and global demand within the pharmaceutical sector. The industry focuses on creating medicines through a comprehensive process of product and process development.² Because of the sensitive nature of its products, it operates under strict regulations to ensure safety and compliance with the law. To avoid violations and disruptions in international markets, companies must adhere to trade regulations, particularly those concerning export controls and supply chain security.³

The globalization of biopharmaceutical markets has increased regulatory and operational complexity, requiring companies to manage various international regulatory requirements and global standards. Compliance also extends to how products are classified, licensed, and transported across borders, making trade compliance a crucial part of the overall regulatory framework. To prevent unauthorized exports, companies must accurately classify their goods and obtain the necessary licenses. Cross-border compliance is shaped by regulatory frameworks administered by authorities such as the Bureau of Industry and Security (BIS) in the U.S. and by the European Union trade and export-control regulations implemented through EU and national authorities.⁴

¹ Benjamin van Rooij and D. Daniel Sokol, "Introduction: Compliance as the Interaction between Rules and Behavior," in *The Cambridge Handbook of Compliance*, ed. Benjamin van Rooij and D. Daniel Sokol (Cambridge: Cambridge University Press, 2021), pp. 1–10.

² Su Young Lim and Minsuk Suh, "Product and Process Innovation in the Development Cycle of Biopharmaceuticals," *Journal of Pharmaceutical Innovation* 10, no. 2 (2015), pp. 156–165.

³ Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items (recast), 2021 O.J. (L 206), pp. 1–461; Robert Beeres, Jeroen Klomp, Job Timmermans, Robert Bertrand, and Joop Voetelink, "Introduction," in *NL ARMS Netherlands Annual Review of Military Studies 2021: Compliance and Integrity in International Military Trade*, ed. Robert Beeres et al. (The Hague: T.M.C. Asser Press, 2021), pp. 1–11.

⁴ Guilherme Schneider Rasador and André Moreira Cunha, "The New Security Grey Zone: Export Controls, Emerging Technologies and US-China Technological Rivalry," *The Pacific Review* 38, no. 6 (2025), pp. 1020–1048; Bureau of Industry and Security (BIS), Export Administration Regulations (EAR) Guidelines on Dual-Use Exports, Washington, DC: U.S. Department of Commerce, 2023.

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Moreover, organizations such as the World Customs Organization (WCO) and the World Trade Organization (WTO) are vital for shaping global trade and compliance structures. Non-compliance may restrict a company's market access and disrupt its supply chain, leading to additional delays. Often, these delays are caused by operational and regulatory problems within the company, like inadequate documentation, rather than issues with the actual production or formulation of the product.⁵ This shows that companies need strong internal systems and qualified employees who can effectively manage the ever-evolving regulatory environment.

Given the scale, complexity, and regulatory sensitivity of international trade in the biopharmaceutical industry, companies must ensure not only that compliance systems are in place, but that employees across departments understand how to implement them.

Regulations differ significantly among major markets, thereby complicating the environment in which biopharmaceutical companies operate. In addition, the international markets are constantly changing and becoming more unpredictable, making it more challenging for companies to manage export regulations. To respond to geopolitical risks, governments are continuously revising export control policies, thus requiring companies to stay updated to avoid potential violations.⁶ The diversity of regulations across markets and the rapid pace of regulatory change highlight the need for specialized compliance knowledge to effectively navigate the complex international regulations.

Geopolitical tensions and rapidly changing regulatory environments further intensify compliance challenges. As a result, companies face difficulties in implementing structured in-house training programs across departments involved in international trade.⁷ Internal training is often ineffective as many companies adopt the "Read and Understood" modules, which leaves employees unmotivated, thus leading to knowledge gaps. Although trade compliance is seen as a critical tool, many companies still lack a structured in-house training program. Compliance errors frequently arise from insufficient knowledge sharing between departments and employees who are unaware of the regulatory updates. In the biopharmaceutical industry, where controlled and

⁵ Melvin P. Fisher and Virginia L. Pascucci, "Regulatory Reflections Concerning the State of Biotechnology Progress," *Drug Information Journal* 30, no. 1 (1996), pp. 41–46.

⁶ Vahid Jafari Sadeghi, Paolo Pietro Biancone, Charles Giacomini, and Silvana Secinaro, "How Does Export Compliance Influence the Internationalization of Firms: Is It a Threat or an Opportunity?," *Journal of Global Entrepreneurship Research* 8, art. 3 (2018), pp. 1–15.

⁷ Tanaka, Alexei. "Regulatory Frameworks for Biopharmaceutical Exports: Comparative Analysis Across Major Markets," *Journal of Commercial Biotechnology* 29.5 (2024), pp. 95–104.

sensitive products are handled, knowledge gaps can disrupt supply chains thereby causing delays in deliveries and exposing the company to legal penalties. Typically, employees are responsible for their own professional development. However, in the highly regulated biopharmaceutical industry, when regulatory requirements are involved, the responsibility falls on the entire organization, as non-compliance risks affect all operations.⁸

The existing research on the biopharmaceutical industry thoroughly explores regulatory and economic aspects, including pricing and market entry, risk management, data integrity, and the changing regulatory environment, along with manufacturing practices and regulatory compliance regarding product quality and safety.⁹ Studies also examine the impact of in-house training on employees, with an emphasis on improving organizational innovation performance.¹⁰ One study in particular emphasizes the advantages of in-house training within the biotech sector, with the focus on employees' technical skills rather than trade compliance-related expertise.¹¹ Many other studies emphasize the benefits of outsourcing, including cost efficiency and access to specialized knowledge.¹² However, existing studies provide less insight into how trade compliance challenges and knowledge gaps vary across organizational functions within highly regulated firms. There is also limited practical understanding of how in-house trade compliance training and knowledge-sharing practices are organized across functions and aligned with operational needs in the biopharmaceutical industry. To address this gap, this study examines how trade compliance challenges and knowledge gaps are experienced across functions and how current training and knowledge-sharing practices are organized within a multinational biopharmaceutical company.

⁸ Stefanie Götze, Debora Jeske, and Karolina Benters, "Training Challenges in Regulated Industries: Making It Work," *Strategic HR Review* 17, no. 3 (2018), pp. 155–159.

⁹ Judith Nwoke, "Regulatory Compliance and Risk Management in Pharmaceuticals and Healthcare," *International Journal of Health Sciences* 7, no. 6 (2024), pp. 60–88; Niharika Sahoo, Koel Choudhury, and Padmavati Manchikanti, "Manufacturing of Biodrugs: Need for Harmonization in Regulatory Standards," *BioDrugs* 23, no. 4 (2009), pp. 217–229.

¹⁰ Jinliang Chen, Yaxin Zhao, Yu Wang, and Tao Jia, "How Boundary-Spanning Search Brings About Innovation Performance: The Contingent Effects of In House Training of Employees and Communication Investment," *Technology Analysis & Strategic Management* 36, no. 11 (2024), pp. 3757–3771.

¹¹ Amit Kumar, Sudhir Kumar Singh, and Govinder Kumar, "Effectiveness of In-House Training on Technical Employees in Biotech Industry," *Journal of Technical Education and Training* 9, no. 1 (2017), pp. 113–124.

¹² Oscar F. Bustinza, Luis M. Molina, and Leopoldo J. Gutierrez-Gutierrez, "Outsourcing as Seen from the Perspective of Knowledge Management," *Journal of Supply Chain Management* 46, no. 3 (2010), pp. 23–39; Lam, Wing, and Alton YK Chua. "Knowledge outsourcing: an alternative strategy for knowledge management." *Journal of knowledge management* 13.3 (2009), pp. 28–43.

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Accordingly, the study addresses the following research questions (RQs): RQ1: How do trade compliance challenges and knowledge gaps vary across organizational functions within a multinational biopharmaceutical company?; RQ2: How are trade compliance training and knowledge-sharing practices organized within a multinational biopharmaceutical company, and what improvements do participants identify as useful for addressing compliance challenges?

2. Literature review

Trade compliance has become increasingly important in international business due to the expansion of global supply chains, the intensification of geopolitical tensions, and the growing complexity of export control systems. Companies operating internationally are required to comply with a broad range of regulations governing customs procedures, sanctions, export licensing, dual-use controls, and supply chain security. In highly regulated sectors such as the biopharmaceutical industry, trade compliance extends beyond administrative obligations and increasingly represents a strategic capability that influences operational continuity, market access, and organizational reputation.

The concept of compliance generally refers to organizational adherence to legal rules, regulatory expectations, and internal procedures.¹³ In international trade, compliance specifically concerns the systems and processes firms use to ensure that imports and exports conform to applicable laws and regulatory frameworks. Export control systems represent a critical component of trade compliance because they regulate the movement of sensitive products, technologies, and information that may have military or dual-use applications.¹⁴ Strategic trade controls therefore seek to prevent the proliferation of weapons and unauthorized technology transfers while simultaneously allowing legitimate international trade to continue.

Within the biopharmaceutical industry, compliance requirements are especially demanding due to the sensitive nature of products and technologies involved. Companies frequently handle biological materials, laboratory technologies, filtration systems, software, and chemicals that may fall under export control or dual-use regulations. In addition, firms must comply with customs procedures, environmental rules, sanctions

¹³ Van Rooij and Sokol, "Introduction: Compliance as the Interaction between Rules and Behavior," pp. 1-10.

¹⁴ Philippe Achilleas, "Introduction Export Control," in *Theory and Practice of Export Control: Balancing International Security and International Economic Relations*, ed. Dai Tamada and Philippe Achilleas (Singapore: Springer, 2017), pp. 3–16.

regimes, and health-related regulations across multiple jurisdictions.¹⁵ The globalization of production and distribution further complicates these obligations because companies often coordinate exports across several countries with differing legal frameworks and enforcement practices.

2.1. Trade compliance challenges in multinational operations

Existing literature consistently highlights regulatory complexity as one of the central challenges affecting export operations. Firms must continuously adapt their operational processes to changing international market conditions and evolving regulatory requirements in order to sustain export effectiveness.¹⁶ Previous studies also argue that export controls create substantial administrative and operational burdens for firms because firms must continuously interpret and apply changing regulations across multiple markets.¹⁷ Similarly, export compliance has become increasingly important for internationally active firms due to heightened geopolitical uncertainty, sanctions enforcement, and security concerns.¹⁸ Organizations must therefore maintain systems capable of managing licensing requirements, denied-party screening, customs declarations, tariff classifications, and country-specific restrictions.

The geopolitical environment has intensified many of these compliance pressures. Recent studies note that technological competition between major economies, particularly the United States and China, has contributed to stricter export control policies and more aggressive enforcement mechanisms.¹⁹ Sanctions regimes targeting Russia and other jurisdictions have also expanded significantly, creating additional compliance obligations for multinational firms. Such developments increase operational uncertainty because regulatory requirements may change rapidly in response to political events.

¹⁵ Alexei, "Regulatory Frameworks for Biopharmaceutical Exports: Comparative Analysis Across Major Markets," pp. 95-104.

¹⁶ Fatih Cura, "Marketing Orientation Components and Their Effects on Export Competencies," *International Academic Social Resources Journal* 6, no. 25 (2021), pp. 928-937.

¹⁷ Seyoum, Belay. "Export Controls and International Business: A Study with Special Emphasis on Dual-Use Export Controls and Their Impact on Firms in the US." *Journal of Economic Issues* 51, no. 1 (2017), pp. 45-72.

¹⁸ Sadeghi, Biancone, Giacomini, and Secinaro, "How Does Export Compliance Influence the Internationalization of Firms: Is It a Threat or an Opportunity?," pp. 1-15

¹⁹ Schneider Rasador and Cunha, "The New Security Grey Zone: Export Controls, Emerging Technologies and US-China Technological Rivalry," pp. 1020-1048.

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In addition to regulatory complexity, another major challenge identified in the literature concerns product classification and export documentation. Accurate classification under tariff schedules and export control lists is critical because incorrect classifications can lead to shipment delays, customs penalties, or export violations.²⁰ In practice, classification processes often require coordination across departments including logistics, sourcing, engineering, and regulatory affairs. In industries involving highly technical products, employees may struggle to determine whether products fall under dual-use regulations or require export licenses.

Research also highlights the organizational consequences of compliance failures. Non-compliance can result in financial penalties, reputational damage, shipment delays, and restrictions on market access.²¹ For multinational organizations operating in highly regulated sectors, even minor documentation errors may interrupt supply chain continuity and reduce customer trust. Consequently, companies increasingly recognize trade compliance as a core operational function rather than solely a legal or administrative responsibility.

Despite the growing importance of regulatory compliance, existing research suggests that many organizations continue to experience deficiencies in internal regulatory understanding. Employees outside specialized compliance departments frequently possess limited understanding of export regulations, sanctions requirements, or customs procedures.²² These deficiencies are particularly problematic because export operations rely heavily on cross-functional collaboration. Customer service teams, sourcing specialists, finance departments, logistics personnel, and research units all contribute to export processes and may influence compliance outcomes.

These regulatory challenges do not create the same knowledge needs in every function. Their practical impact depends partly on employees' responsibilities and on whether they know when specialist compliance input is needed. In-house training can help translate changing regulatory

²⁰ Shaik Maideen M. G., P. Sudha, and V. Pradeep, "A Study on Export Documentation and Clearance Process at Logistics Company," *Central Asian Journal of Innovations on Tourism Management and Finance* 4, no. 10 (2023), pp. 165–182; Fatih Cura, "Uluslararası Ticarete İhracat ve İthalat Kavramları ve Süreçleri [Export/Import Concepts and Processes in International Trade]," in *Uluslararası Ticaret ve Lojistik 4.0: Güncel Trend ve Uygulamalar* [International Trade and Logistics 4.0: Current Trends and Applications], ed. Gökhan Akandere and Fatih Cura (Konya: Eğitim Yayınevi, 2022), pp. 7–24.

²¹ Daniel Salisbury, "Trade Controls and Non-Proliferation: Compliance Costs, Drivers and Challenges," *Business and Politics* 15, no. 4 (2013).

²² Malouke Esra Kuiper et al., "A Network Approach to Compliance: A Complexity Science Understanding of How Rules Shape Behavior," *Journal of Business Ethics* 184, no. 2 (2023), pp. 479–504.

requirements into role-relevant knowledge and clarify employees' responsibilities in export processes. However, training is only one part of this response and must work alongside clear procedures, systems, responsibilities, and access to specialist expertise.

2.2. In-house training within trade compliance programs

These challenges have increased scholarly interest in organizational learning and compliance training. Within a broader internal compliance program, training is one mechanism for developing the knowledge required by employees involved in trade compliance activities. Training is generally understood as a formal and planned effort to develop job-relevant knowledge and skills.²³ Within regulated industries, compliance training aims to ensure that employees understand legal requirements, internal procedures, and operational responsibilities.

In the context of trade compliance, training is particularly important because regulations frequently change and require ongoing interpretation. Employees involved in relevant trade compliance activities must therefore maintain up-to-date understanding of export controls, sanctions, customs procedures, and licensing obligations.

Recent strategic trade control literature emphasizes that training and awareness-raising are essential components of effective export control and non-proliferation systems. Internal compliance programs increasingly rely on training to ensure that employees understand export control requirements, dual-use risks, and risk management procedures associated with sensitive transfers.²⁴ Beyond regulatory compliance, educational initiatives also play a critical role in fostering awareness of dual-use concerns and developing an organizational culture capable of identifying and mitigating security risks associated with sensitive products, technologies, and knowledge.²⁵ These perspectives suggest that trade compliance training should be viewed not merely as an administrative requirement but as a strategic mechanism that supports export control effectiveness and broader security objectives.

²³ Irwin L. Goldstein and J. Kevin Ford, *Training in Organizations: Needs Assessment, Development, and Evaluation*, 4th ed. (Belmont, CA: Wadsworth, 2002).

²⁴ Tatyana Novossiolova, Tom De Schryver "Editorial: Training on the mitigation of biological and chemical proliferation risks: insights into effective design, delivery, and implementation", *Journal of Strategic Trade Control*, Special Issue, Vol. 2, (September 2024), pp. 1-7.

²⁵ Lijun Shang, Weiwen Zhang, and Malcolm Dando, "Addressing the biological security educational gap", *Journal of Strategic Trade Control*, Special Issue, Vol. 2, (September 2024), pp. 1-8.

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The literature distinguishes between outsourced training approaches and internally developed in-house training programs. Outsourcing may provide access to specialized expertise and reduce administrative burden.²⁶ However, several scholars argue that in-house training offers important strategic advantages because programs can be tailored to company-specific operations, products, and compliance risks.²⁷ Internal training also enables organizations to integrate practical scenarios, department-specific examples, and organization-wide knowledge sharing into learning activities.

Within the biotechnology and pharmaceutical sectors, studies examining in-house training primarily focus on technical competencies, innovation performance, and manufacturing quality rather than trade compliance expertise. Some studies have found that in-house training improves technical employee performance and operational understanding in biotechnology organizations.²⁸ Similarly, other studies demonstrate that internal training supports organizational innovation by strengthening communication and knowledge integration across departments. However, limited research specifically examines how in-house trade compliance training is organized and experienced within highly regulated export operations.²⁹

The compliance literature further suggests that passive training approaches often produce limited learning outcomes. Generic e-learning modules and “read-and-understood” systems may satisfy formal compliance requirements while failing to develop practical competence.³⁰ Effective compliance training instead requires interactive and role-specific learning methods that reflect employees’ operational realities. Scenario-based learning, cross-functional workshops, and practical case discussions are frequently recommended because they improve employee engagement and strengthen knowledge retention.³¹

²⁶ Bustinza, Molina, and Gutierrez-Gutierrez, “Outsourcing as Seen from the Perspective of Knowledge Management,” pp. 23–39.

²⁷ Ingi Runar Edvardsson and Susanne Durst, “Outsourcing of Knowledge Processes: A Literature Review,” *Journal of Knowledge Management* 18, no. 4 (2014), pp. 795–811.

²⁸ Kumar, Kumar Singh, and Kumar, “Effectiveness of In-House Training on Technical Employees in Biotech Industry,” pp. 113–124.

²⁹ Chen, Zhao, Wang, and Jia, “How Boundary-Spanning Search Brings About Innovation Performance: The Contingent Effects of In House Training of Employees and Communication Investment,” pp. 3757–3771.

³⁰ Kfir Manor, “Is a Compliance Training Program Effective? A Comparison Analysis of Compliance Officers’ Perceptions and Recommended Practices in Multinational Corporations Regarding Compliance eTraining Program Effectiveness,” *Journal of Legal, Ethical and Regulatory Issues* 28, Special Issue 2 (2025), pp. 1–18.

³¹ Gordon Haines and Marcus Spreen, “Why Training Matters,” *Pharmaceutical Technology Europe* 27, no. 12 (2015), pp. 10–12.

2.3. Organizational knowledge and the analytical role of Resource-Based View and Knowledge-Based View

The Resource-Based View (RBV) and Knowledge-Based View (KBV) provide a complementary perspective for interpreting how trade compliance knowledge is developed and retained within the organization. The RBV emphasizes the value of firm-specific resources and capabilities, while the KBV focuses more specifically on the creation, transfer, and integration of organizational knowledge.³² In the context of trade compliance, these perspectives are useful for considering whether compliance knowledge remains concentrated within specialist functions or is shared more broadly across departments involved in export operations.

In this study, RBV and KBV are used as interpretive lenses rather than as frameworks for developing hypotheses or testing the effectiveness of particular training methods. The analysis is primarily inductive, and the themes are derived from the empirical data. RBV and KBV are therefore used in the Discussion to interpret how in-house training, knowledge sharing, and cross-functional learning may contribute to the development of organizational compliance capability.

Although previous studies provide valuable insights into trade compliance, export controls, and organizational training, limited research examines how in-house trade compliance training is implemented operationally within the biopharmaceutical industry. Existing literature pays considerable attention to legal frameworks and compliance systems. However, less attention has been given to how employees across departments develop and apply compliance knowledge in practice. This study addresses this gap by examining how in-house trade compliance training and compliance knowledge are currently organized and experienced across functions within a multinational biopharmaceutical company.

3. Method

This study adopts a qualitative single-case study design using semi-structured interviews. This design was appropriate because both

³² Vijay Pereira and Umesh Bamel, "Extending the Resource and Knowledge Based View: A Critical Analysis into Its Theoretical Evolution and Future Research Directions," *Journal of Business Research* 132 (2021), pp. 557–570; Navaneethakrishnan Kengatharan, "A Knowledge-Based Theory of the Firm: Nexus of Intellectual Capital, Productivity and Firms' Performance," *International Journal of Manpower* 40, no. 6 (2019), pp. 1056–1074.

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research questions concern how trade compliance challenges, knowledge, and training practices are experienced and organized within a specific organizational setting rather than testing causal relationships or estimating their prevalence. RQ1 requires cross-functional accounts that show how trade compliance challenges and knowledge gaps vary across organizational functions, while RQ2 requires detailed descriptions of current training and knowledge-sharing practices and participants' views on possible improvements. Semi-structured interviews therefore allowed participants to explain role-specific and regional experiences while providing sufficient consistency to compare patterns across functions.

The case was selected purposively for both substantive and access-related reasons. Substantively, the company is a multinational life-science and biopharmaceutical manufacturer exposed to diverse customs, sanctions, export-control, and dual-use requirements across multiple jurisdictions. Access to internal stakeholders and company data was also a practical consideration in the case selection. One of the thesis authors had previously completed an internship at the case company, providing an existing organizational connection that facilitated access to relevant participants and company information. The company is not treated as statistically representative of the biopharmaceutical industry. Rather, it is examined as a case of how a large multinational organization operating in a complex regulatory environment organizes and experiences trade compliance across geographically and functionally dispersed operations.³³

Our case study company is a life-science and biopharmaceutical manufacturing company operating in more than 40 countries, with a strong presence in North America, Europe, and Asia-Pacific. Its activities include bioprocessing, cell and gene therapy, diagnostics and genomics, chromatography and filtration, vaccines, and related applications. The company operates through a geographically dispersed network of manufacturing, research and development, commercial, logistics, and specialist trade compliance functions. As a result, international trade activities often require information and coordination across several organizational functions and regions. This organizational setting makes the company particularly relevant for examining how trade compliance knowledge, responsibilities, and training are distributed across functions. This combination of a tightly regulated product portfolio, international operations, and complex cross-border supply chains creates substantial exposure to customs, sanctions, export-control, classification, licensing, and dual-use requirements. The case evidence also indicates that training operates within a wider compliance infrastructure. Participants and

³³ Christian Lund, "Of What Is This a Case? Analytical Movements in Qualitative Social Science Research," *Human Organization* 73, no. 3 (2014), pp. 224–234.

internal materials referred to written policies and standard operating procedures, formal workflows, internal trade-compliance platforms and databases, specialist trade and classification teams, common communication and escalation channels, internal checks, and post-import/export audits. Training is therefore only one element within a broader set of organizational controls used to manage trade compliance. The study did not systematically audit every component of the company's formal internal compliance program, and it therefore does not claim to provide a complete assessment of all program elements.

Purposive sampling was used to select participants whose roles provided direct experience of trade compliance, export operations, or functions providing information required for compliant trade decisions. The sample included trade compliance specialists and leaders as well as employees from customer service, logistics, classification, sourcing/customer support, site services, and research and development. The purpose of this cross-functional sampling was to capture variation in compliance responsibilities, knowledge needs, and regulatory exposure rather than to estimate the prevalence of particular views across the company.

The main dataset comprised 21 semi-structured interviews with 21 participants. Participants had between two and forty years of professional experience, and interviews lasted between 23 and 60 minutes. Table 1 provides further information on their roles, functions, experience, and interview duration. To preserve anonymity, participants are identified using participant codes (P1-P21) throughout the article.

Table 1. Participants of the case company. Source: authors' compilation based on interview data.

Participants	Role	Department	Years of experience	Interview duration
P1	Customs Operations and Regulatory Affairs specialist	Global TC Team	10	52 minutes
P2	Order Management Specialist	Customer Service	2	41 minutes
P3	UK Trade Operations Leader	Global TC Team	14	54 minutes
P4	Director of the Trade Centre Excellence	Classification Team	40	57 minutes
P5*	Asia Trade Operations Manager	Global TC Team	20	49 minutes
P6	Trade operation specialist EMEA	Global TC Team	15	32 minutes
P7*	UK Trade Operations Leader	Global TC Team	15	53 minutes

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P8*	Senior Order Management Specialist	Customer Service	10	47 minutes
P9	Senior Customer Service Administrator	Customer Service	17	60 minutes
P10*	Global Trade Manager, Americas	Global TC Team	20	41 minutes
P11	Global Customs Valuation Leader	Global TC Team	13	35 minutes
P12	Logistics Specialist	Logistics Team	20	30 minutes
P13	Custom Parts Specialist	Customer Support / Sourcing	3	46 minutes
P14	Site Service Coordinator	Site Service	9	40 minutes
P15*	EMEA Trade Operations Leader	Global TC Team	10	23 minutes
P16	Portfolio Manager	Research and Development	25	30 minutes
P17	Global Export Operations Leader	Global TC Team	12	37 minutes
P18*	EMEA Trade Operations Leader	Global TC Team	20	37 minutes
P19	Global Classification Manager	Classification Team	18	46 minutes
P20	Export Customer Service	Customer Support	2	35 minutes
P21	Logistics Specialist	Logistics Team	7	46 minutes
Total minutes				854 minutes

Participants also differed in their involvement in training. Some primarily reported their experiences as training recipients, while several trade compliance specialists and leaders also reported delivering, coordinating, or arranging training for colleagues. Training responsibility was not, however, a formal sampling criterion, and participants were therefore not classified exclusively as trainers or trainees.

Before the main interviews, preliminary scoping discussions were conducted with six participants (P5, P7, P8, P10, P15, and P18), representing trade compliance roles across different regions. These discussions introduced the research topic and supported referrals for the main interviews; the main analytical dataset nevertheless comprised 21 semi-structured interviews with 21 distinct participants.

The interview data were complemented by internal company documents and operational material. These included materials relating to current and previous training practices, post-import and export audits, and additional documents provided by participants after the interviews. The documentary material was used to contextualize and compare participants' accounts of current compliance and training practices rather than as evidence that a particular training approach was effective.

The interview data were analyzed using a primarily inductive thematic-analysis approach. The research questions guided the broad areas covered by the interview guide, including trade compliance challenges, training and knowledge gaps, knowledge sharing, assessment practices, and possible improvements (see Appendix A). However, RBV and KBV were not used to predetermine interview responses, coding categories, or themes. The analysis remained open to recurring patterns and contrasting perspectives emerging from the interview data. RBV and KBV are therefore used subsequently in the discussion as interpretive lenses rather than as deductive coding frameworks.

All interviews were conducted through Microsoft Teams and always recorded with the participant's consent. The recordings were subsequently uploaded to TurboScribe for transcription. To ensure transcription accuracy, each audio recording was reviewed alongside the transcript line by line. This process enabled us to become more familiar with the dataset, and we noted early patterns, such as regulatory complexity, trade compliance challenges, basic training across most departments, and the need for greater awareness and improvements to the company's current training programs, such as the request for real-life scenarios and more interactive training sessions.

Manual coding was conducted line by line across all transcripts, identifying key data that were relevant to the research questions. Relevant excerpts addressing the research questions were first identified and then assigned descriptive codes. All 21 transcripts were coded systematically, while recognizing that individual interviews varied in the amount and relevance of evidence they contributed to particular themes. For instance, the statement "we have very basic compliance regulations covered. So, very basic knowledge will be delivered in that training" was coded as "Basic knowledge from training". These codes allowed us to see patterns in the data that reflected common experiences or challenges across departments. At this stage, the related codes were grouped into broader categories. We reviewed codes across all 21 transcripts and merged codes with similar meanings into broader categories. The thematic analysis generated nine themes reflecting recurring patterns across the interview data. For presentation, these nine themes were subsequently grouped under broader headings linked to the research questions and the

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main topics covered in the interviews. This grouping did not change the themes generated through the coding process. To increase transparency in theme development, Table 2 links illustrative empirical evidence from a wider range of participants to the descriptive codes/categories and the nine themes generated through thematic analysis. The table follows the data-structure logic advocated in inductive qualitative research, while the analytical procedure itself remains thematic analysis.³⁴

Table 2. Data structure linking empirical evidence, codes, and themes. Source: authors' analysis of interview data.

Illustrative empirical evidence	Descriptive codes/categories	Theme
P1: Regulations differ across countries where the company operates. P5: Trade compliance involves "quite a lot" of different regulations.	Multi-jurisdictional requirements; export controls; sanctions; customs requirements	1. Global Trade Compliance Landscape and Its Complexity
P17 identified China as difficult because of export-classification requirements. P3 reported that missing tariff classifications can delay goods already at the border.	Regional complexity; classification and licensing; procedural delays	2. Export Compliance Challenges
P8 recalled that the last relevant training was about two years earlier. P17 reported conducting two update sessions annually.	Uneven training frequency; regulatory-update practices	3. Regulatory Change and Organizational Training Responsiveness
P12 identified incorrect documentation as a common problem. P15 linked limited knowledge with incorrect classification and documentation.	Documentation errors; classification problems; knowledge-related operational issues	4. Prevalence of Compliance Issues, Common Challenges, and Organizational Impacts
P9 reported limited classification knowledge in customer service. In contrast, P10 reported no major knowledge gaps within his team.	Uneven departmental knowledge; specialist expertise; contrasting perceptions	5. Departmental Understanding of Compliance
P18 described SharePoint and internal resources for sharing compliance information. P4 explained that knowledge is often shared when an issue is being discussed.	Digital knowledge platforms; reactive knowledge sharing; issue-driven communication	6. Mechanisms for Knowledge Sharing

³⁴ Dennis A. Gioia, Kevin G. Corley, and Aimee L. Hamilton, "Seeking Qualitative Rigor in Inductive Research: Notes on the Gioia Methodology," *Organizational Research Methods* 16, no. 1 (2013), pp. 15–31.

P15 described new-joiner and project-specific training. P6 described an area with no standardized training process.	Role-specific training; targeted training; variation in standardization	7. Training Approaches and Knowledge Gaps
P17 described sample-based audits of completed orders. P19 described bi-monthly audits followed by training and corrective action.	Audit-based assessment; corrective action; structured assessment in some functions	8. Assessing Compliance Understanding
P19 recommended real compliance cases for scenario-based training. P5 argued that training is only “a small, very small portion” of the wider compliance program.	Scenario-based learning; practical training; limits of training; wider compliance controls	9. Participant-Identified Improvements to Training and Compliance Practices

Several measures were used to strengthen the trustworthiness of our findings. First, participants were drawn from specialist and non-specialist functions and from different operational contexts. Second, interview accounts were compared with available internal training and audit material. Third, contrasting perspectives were retained in the analysis rather than treating participants’ accounts as uniform. Finally, the link between empirical evidence, descriptive codes, and themes is made more explicit through the data-structure table. The study did not involve prolonged ethnographic engagement or sustained participant observation, and this limitation is acknowledged when assessing the transferability of the findings.³⁵

4. Findings

The thematic analysis generated nine themes, as shown in Table 2. For clarity, the findings are presented below under three broader sections that follow the research questions and the main topics covered in the interviews. The nine themes remain the empirical themes generated from the coding process; the broader sections are used only to organize their presentation. Section 4.1 addresses RQ1 by bringing together findings on regulatory complexity, export challenges, operational impacts, and differences in compliance knowledge across functions. Section 4.2 examines current training, knowledge-sharing, and assessment practices, mainly in relation to RQ2. Section 4.3 presents participants’ suggestions for improving training and compliance practices.

³⁵ Yvonna S. Lincoln and Egon G. Guba, “But Is It Rigorous? Trustworthiness and Authenticity in Naturalistic Evaluation,” *New Directions for Program Evaluation* 1986, no. 30 (1986), pp. 73–84.

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Table 3. Organization of findings by research question. Source: authors' own elaboration.

Findings section	Empirical themes	Research question
4.1 Trade compliance challenges and cross-functional knowledge	Regulatory complexity; export compliance challenges; organizational impacts; departmental understanding	RQ1
4.2 Current training, knowledge sharing, and assessment	Training responsiveness; knowledge sharing; training approaches and knowledge gaps; assessment	Primarily addresses RQ2, while informing RQ1
4.3 Participant-Identified Improvements to Training and Compliance Practices	Suggested improvements to training and compliance practices	RQ2

4.1. Trade compliance challenges and cross-functional knowledge

4.1.1. Global trade compliance landscape and its complexity

Participants described the company as operating under EU regulations, U.S. export control requirements where a U.S. jurisdictional nexus exists, and national regulations in countries where the company maintains legal entities or conducts trade activities, including China, Singapore, India, and Australia. Several interviewees highlighted the breadth of this environment, with one noting that “we are following the regulations in other countries where we have legal entities like China, Singapore, like New Zealand, Australia as they have their own trade compliance regulations” (P1) and another participant indicating that trade compliance is “not relevant to one regulation or two... there’s really quite a lot” (P5). Participants’ accounts indicate that differences in export control obligations, sanctions requirements, and dual-use regulations across jurisdictions require employees to interpret and apply compliance requirements in different national and regional contexts.

Export controls and dual-use regulations emerged as central issues in participants’ accounts because of the nature of the company’s products. P4 described the purpose of these controls as ensuring that sensitive items do not fall “into the wrong hands.” Participants also identified sanctions and embargoes as important considerations in the company’s international trade operations. In addition, customs acts, tariff classification, and preferential trade agreements were frequently mentioned as additional layers shaping day-to-day operations.

Respondents also identified environmental and health regulations as additional sources of complexity in day-to-day trade operations.

4.1.2. Export compliance challenges

The second theme shows that participants perceived export-related challenges as strongly region-specific. Participants consistently pointed to Asia, particularly China and India, as the most difficult regions. These markets were described as having strict or unclear requirements, long lead times, and limited guidance. As one participant stated, “Countries like China, India have very difficult export regimes... Asia is the most challenging” (P4).

The United States was also perceived as challenging due to rapidly changing tariffs, classifications, and political influences. Participants also described sanctioned markets, especially Russia, as requiring heightened checks and extensive screening.

In addition to regional differences, participants described challenges associated with the technical characteristics of the company's products. Participants associated dual-use classification, incomplete product data, and lengthy licensing processes with delays in export activities. One participant noted the operational consequences of missing product classification: “items are often already at the border... and the tariff is not in place” (P3). Participants' accounts indicate that incomplete product data, incorrect classifications, and delays in licensing determinations can disrupt export operations.

Participants also identified internal procedural issues, including manual approval layers, unclear responsibilities, and slow information flows, as factors that complicate the export process.

4.1.3. Prevalence of compliance issues, common challenges, and organizational impacts

The fourth theme describes how participants reported recurring compliance issues across operations, although their frequency varied by department. Incorrect documentation, incomplete license texts, misclassifications, and valuation errors were repeatedly cited as common problems. As one participant explained, such issues are “a part of the life of the supply chain” (P4).

Participants associated these issues with several forms of organizational impact. Participants described operational delays when documentation

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had to be reworked or shipments were held by customs. Participants also reported financial consequences, including unnecessary duty payments and potential penalties associated with misclassifications or incorrect declarations. P4 illustrated the financial impact with a concrete example, explaining that “We are unnecessarily paying” when goods are misclassified into tariff categories with higher duties.

Participants also raised concerns about reputational risk, particularly when customs authorities repeatedly identify errors. Participants associated logistics delays with effects on customer satisfaction, internal planning, and supply chain continuity.

4.1.4. Departmental understanding of compliance

The fifth theme shows that participants perceived uneven levels of trade compliance understanding across departments. Participants described significant differences in awareness between departments. Some highlighted that colleagues “act... without knowledge” (P1), while others stated that beyond the trade compliance team, “not many people understand at all” (P4).

Participants described some experienced teams, including logistics, regulatory affairs, and certain customer service units, as having stronger compliance knowledge due to more frequent exposure to trade-related processes. Other participants described more limited compliance understanding among some employees in functions such as finance, R&D, and sales, as well as among new joiners.

Not all participants perceived significant knowledge gaps. P7 reported no major gaps within an experienced team whose members engaged in continuous professional development and shared learning from conferences. P10 similarly stated that his team was “in pretty good shape,” while P3 identified the greater challenge as staying current with continuously changing regulations rather than a lack of existing knowledge. These contrasting accounts indicate that perceived knowledge gaps vary across functions and levels of experience rather than being uniform across the organization.

As a whole, these accounts suggest that trade compliance knowledge may be more concentrated within specialist functions than across the wider organization. This concentration is not necessarily problematic, since employees in other functions do not need the same level of specialist knowledge. Difficulties may arise, however, when compliance decisions require specialist input but responsibilities, communication routes, or access to that expertise are unclear.

Participants also referred to individual attitudes and willingness to engage with compliance topics as additional challenges. Some participants perceived limited willingness among certain employees to engage with trade compliance learning or apply compliance knowledge in practice. As P7 noted, some employees adopt an attitude of “it’s not my job, I’m not going to do it.”

4.2. Current training, knowledge sharing, and assessment

4.2.1. Regulatory change and organizational training responsiveness

The third theme highlights a perceived mismatch between the pace of regulatory change and the organization’s training responses. Sanctions, in particular, were described as dynamic and frequently updated. As one participant stated, sanctions regulations are “evolving and changing every month” (P1).

In contrast, several participants reported that training did not always keep pace with regulatory changes. Several participants indicated that they had not received formal training updates on regulatory changes and instead relied on self-monitoring, external sources, or informal discussions. While some functions reported periodic refresh sessions, the training approach described across participants appeared uneven and decentralized.

Participants’ experiences illustrate this variation. P8, from customer service, recalled that the last relevant training had been approximately two years earlier, whereas P17 reported conducting two update sessions each year. P19 described training the team when regulatory changes occurred, while P5 expected specialist staff to monitor regulatory changes as part of their professional responsibilities rather than relying on formal update training.

4.2.2. Mechanisms for knowledge sharing

The sixth theme examines how trade compliance knowledge is shared across the organization. Participants described trade compliance information as being shared across departments through online platforms and internal tools. Participants described these systems as useful archives containing documentation, regulatory links, and process guidance. However, participants described much of the knowledge sharing as reactive and issue-driven rather than proactive. Several participants explained that learning often occurs during problem-solving meetings or through direct communication triggered by shipment issues.

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One participant summarized this dynamic: knowledge is often shared only “when we are discussing an issue” (P4). These accounts suggest that, while knowledge-sharing tools are available, their use is uneven and knowledge sharing is not always embedded in a systematic organizational learning process.

4.2.3. Training approaches and knowledge gaps

The seventh theme concerns the organization’s training practices and remaining gaps. Participants described current training offerings as including annual e-learning modules, certification programs, cross-training initiatives, and external learning through conferences and webinars. Participants also reported certification-based learning through the company’s learning hub and, in some functions, external certification. Targeted approaches included new-joiner training, project-specific training for particular groups, and different training levels according to employees’ experience and responsibilities.

The level of targeting also differed across functions. P15 described new-joiner export-control training and project-specific training for selected groups, P8 described basic, intermediate, and experienced training levels in customer service, and P5 reported cross-training between trade, FTA, and classification teams.

Despite these training activities, participants continued to identify knowledge gaps across some functions and processes. Several participants identified gaps in cross-departmental understanding, process awareness, and access to timely regulatory updates. As P1 explained, trade teams sometimes “figure out issues alone,” reflecting that participant’s concern about limited compliance knowledge in other departments.

Participants identified a need for more practice-oriented and role-relevant training, with training frequency and content adapted to the needs of different functions and linked more closely to real compliance scenarios. At the same time, training practices were not uniform across the organization; one participant described an area with no standardized training process, where learning was mainly based on experience, presentations, and meetings (P6).

4.2.4. Assessing compliance understanding

The eighth theme indicates that participants did not describe a consistent formal system across the organization for assessing whether employees understand and correctly apply compliance procedures. Instead, escalations serve as the primary indicator of compliance performance. As one participant put it: “We can measure it on the numbers of escalations” (P1).

Some teams use informal peer checks, daily discussions, or second opinions to verify decisions. More structured mechanisms were also reported in some functions. P17 described auditing samples of completed orders to assess whether they had been processed correctly, while P19 reported bi-monthly audits in which findings were shared with the team and followed by training and corrective action. P9 also described an internal assessment process using structured templates. Overall, participants’ accounts suggest that assessment is often reactive, with problems and escalations providing feedback after issues have occurred rather than through systematic evaluation of learning outcomes.

4.3. Participant-identified improvements to training and compliance practices

The final theme presents participants’ suggestions for improving current trade compliance training practices. Several participants called for scenario-based, practical, and interactive training formats that reflect actual compliance challenges. P4 recommended using “in-depth and focused, real-time case studies” to make training more closely connected to practical compliance situations. P19 expressed a similar preference, suggesting that actual compliance cases could be used to demonstrate the consequences of decisions in real-world situations.

Some participants viewed in-person training as more engaging than passive e-learning and considered regular updates important for keeping pace with regulatory change. Participants also emphasized the need to raise awareness of the organizational and individual consequences of non-compliance. Some participants believed that improved training could support faster problem-solving and better coordination across teams. These views represent participants’ expectations based on their experience with current practices; the study did not evaluate whether the proposed training approaches produced these outcomes.

Participants also emphasized that training must be complemented by stronger systems and internal controls, reflecting the view that training alone cannot guarantee compliance. P5 expressed this point particularly strongly, describing training as “a small, very small portion of the trade

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compliance program” and emphasizing greater reliance on systems for monitoring procedures.

5. Discussion

The findings show that trade compliance challenges in the case company are shaped not only by regulatory complexity but also by how compliance knowledge, responsibilities, and training are distributed across organizational functions. Rather than discussing the nine empirical themes separately, this section considers three broader issues emerging from the case: regulatory complexity and cross-functional compliance knowledge, the organization of training and knowledge sharing, and the role of training within the wider compliance program.

5.1. Regulatory complexity and cross-functional compliance knowledge

The case findings support previous research showing that internationally active firms face substantial compliance complexity arising from export controls, sanctions, customs requirements, classification, licensing, and differences between national regulatory systems. Previous studies have similarly shown that export control requirements create administrative and operational burdens for firms operating across jurisdictions and that geopolitical developments can further increase regulatory uncertainty.³⁶ The case adds a more operational perspective by showing how these pressures are experienced across different organizational functions in a multinational biopharmaceutical company. Participants did not describe regulatory complexity only as an external legal problem; they connected it with incomplete product information, classification difficulties, documentation problems, licensing delays, and internal information flows.

A particularly important finding is that compliance knowledge was not perceived as equally distributed across the organization. Specialist and experienced functions were generally described as having stronger knowledge, while participants identified more limited understanding in

³⁶ Belay, "Export controls and international business: a study with special emphasis on dual-use export controls and their impact on firms in the US," pp. 45-72; Sadeghi, V. J., P. P. Biancone, C. Giacomini, and S. Secinaro. "How Does Export Compliance Influence the Internationalization of Firms: Is It a Threat or an Opportunity?"; Schneider Rasador and Cunha. "The new security grey zone: export controls, emerging technologies and US-China technological rivalry," pp. 1020-1048; Salisbury "Trade controls and non-proliferation: compliance costs, drivers and challenges," pp. 529-551.

some other functions and among employees with less exposure to trade compliance activities. This suggests that the relevant problem is not simply whether the company possesses compliance expertise, but where that expertise is located and whether it can be accessed when cross-functional decisions are required. This is especially important for classification, documentation, screening, and licensing processes, which often require information from several organizational functions.

This finding is relevant to the Knowledge-Based View because the challenge appears to concern not only the possession of specialist knowledge but also its transfer and integration across organizational boundaries. The KBV emphasizes the importance of creating, sharing, and integrating organizational knowledge.³⁷ In the present case, compliance expertise concentrated within specialist functions may be valuable, but its organizational usefulness also depends on whether other functions can access and apply the knowledge required for their own compliance-related responsibilities. The findings therefore suggest that cross-functional knowledge integration, rather than uniformly increasing compliance knowledge among all employees, is a notable issue for multinational trade compliance.

The distribution of specialist knowledge should also be considered in relation to organizational structure. Compliance expertise is normally assigned to particular roles and functions rather than distributed evenly across the organization.³⁸ The issue is therefore not that every employee should possess the same level of compliance knowledge, but whether responsibilities are clearly allocated and employees know when and how to involve specialists. Clear responsibilities are also important for ensuring that specialist knowledge is kept up to date and shared when other functions need it. From this perspective, organizational arrangements that connect specialist expertise with operational functions are important for ensuring that compliance knowledge is available when cross-functional decisions are made.

A related concern is knowledge continuity: when important compliance knowledge is concentrated in a small number of specialists, organizations also need mechanisms for retaining and transferring that knowledge

³⁷ Kengatharan, "A Knowledge-Based Theory of the Firm: Nexus of Intellectual Capital, Productivity and Firms' Performance," pp. 1056-1074.

³⁸ Christopher Gresov and Robert Drazin, "Equifinality: Functional Equivalence in Organization Design," *Academy of Management Review* 22, no. 2 (1997), pp. 403-428; Carolin Baier, Markus Beckmann, and Jens Heidingsfelder, "Hidden Allies for Value Chain Responsibility? A System Theory Perspective on Aligning Sustainable Supply Chain Management and Trade Compliance," *International Journal of Physical Distribution & Logistics Management* 50, no. 4 (2020), pp. 439-456.

when responsibilities change or employees leave. This issue was not directly examined in the present study but warrants further research.

5.2. Current training and knowledge-sharing practices

The case also shows that in-house trade compliance training should not be understood as a single organizational program delivered uniformly across the company. Participants described a mixture of annual mandatory e-learning, certification-based learning, new-joiner and project-specific training, cross-training between specialist teams, external webinars and conferences, and learning through internal meetings and experience. At the same time, the degree of standardization differed across functions. This variation is a significant empirical finding because it shows that training practices within the same multinational organization can differ considerably according to employees' responsibilities, experience, and operational context.

This variation partly supports existing guidance that compliance training should be adapted to employees' level of involvement in trade compliance rather than delivered through a uniform approach. The literature emphasizes the use of different training methods, role-specific content, regular updating, and appropriate documentation of training as well.³⁹ Previous research also questions whether passive or generic e-learning alone is sufficient for developing practical compliance competence.⁴⁰ The case findings add nuance to this literature: the issue is not simply a choice between e-learning and more interactive training, because several forms of training already coexist within the organization. The more significant challenge appears to be whether the content, frequency, and method of training correspond to the particular compliance responsibilities and regulatory exposure of different functions.

The case further indicates that formal training is only one way through which compliance knowledge is developed. Participants described internal platforms, documentation, direct communication, meetings, peer checks, and problem-solving as important knowledge-sharing mechanisms. However, much of this learning was described as reactive, occurring when a shipment or compliance issue had already arisen. A similar pattern was observed in assessment practices. Operational

³⁹ Torres Law, "Fundamental Elements of Effective Trade Compliance Programs." Torres Law, 2020. accessed September 27, 2026, <<https://torrestradeadvisory.com/fundamental-elements-of-effective-trade-compliance-programs/>>.

⁴⁰ Manor, "Is a Compliance Training Program Effective? A Comparison Analysis of Compliance Officers' Perceptions and Recommended Practices in Multinational Corporations Regarding Compliance eTraining Program Effectiveness," pp. 1–18.

escalations, peer review, and audits provide information about compliance performance, but they do not necessarily constitute direct measures of whether employees have learned from training. This distinction is important because the number of escalations cannot by itself establish whether a particular training approach is effective. More structured evaluation could provide better information about learning, but the present study does not find such mechanisms.

5.3. Training as one element of a broader compliance program

Participants identified several possible ways to improve current training practices, including greater use of real cases, scenario-based learning, role-relevant content, regular regulatory updates, and more interactive formats. These preferences are broadly consistent with strategic trade control literature emphasizing practical and active approaches to awareness and training.⁴¹ However, this convergence with the literature should not be interpreted as evidence that these approaches were shown to reduce compliance errors in the case company. The study did not introduce a new training program or compare training formats, and the suggested improvements therefore represent participants' experience-based views rather than evaluated interventions.

At the same time, the findings do not support treating training as the primary solution to compliance problems. One participant explicitly challenged this view, describing training as only "a small, very small portion of the trade compliance program" and emphasizing the importance of systems that allow procedures and activities to be monitored. This contrasting perspective is notable because many of the problems identified in the case, such as incomplete data, unclear responsibilities, approval processes, information flows, and documentation problems, cannot necessarily be resolved through additional training. Training must therefore be considered alongside management commitment, clear responsibilities, procedures, monitoring, auditing, escalation mechanisms, information systems, and other elements of the wider internal compliance program.

This broader interpretation also clarifies the relevance of RBV and KBV to the study. From a KBV perspective, the evidence indicates that the central issue is not simply whether compliance knowledge exists, but how it is distributed, transferred, and applied across functions. A related risk arises

⁴¹ Novossiolova and De Schryver, "Editorial: Training on the mitigation of biological and chemical proliferation risks: insights into effective design, delivery, and implementation", pp. 1-7

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when important compliance knowledge is concentrated in a small number of specialists. If these employees leave or change roles, organizations need mechanisms to retain and transfer that knowledge. This issue was not directly examined in the present study but deserves attention in future research. From an RBV perspective, specialist compliance knowledge is more likely to constitute an organizational capability when it is embedded in repeatable processes, systems, routines, and cross-functional practices rather than residing mainly with individual experts.⁴² Training may contribute to this process, but it is only one mechanism through which organizational compliance capability is developed. The case therefore supports a broader view of compliance capability in which employee knowledge, organizational processes, systems, and management arrangements operate together.

The contribution of the case is not to propose a new model of internal compliance or to show that more training improves export performance. Existing compliance guidance already recognizes management commitment, risk assessment, authorization procedures, recordkeeping, training, audits, and procedures for addressing violations as interconnected elements of an effective internal compliance program.⁴³ Rather, this study provides an empirical account of how trade compliance challenges, specialist knowledge, training practices, and knowledge-sharing mechanisms are experienced across different functions within one multinational biopharmaceutical company. In particular, the findings show that compliance knowledge is unevenly distributed, training practices differ across functions, and some knowledge sharing and assessment take place only after operational problems arise. The case therefore adds an organizational and operational perspective by showing how these established compliance mechanisms are experienced and connected in day-to-day export operations. The case also illustrates the practical difficulty of translating complex trade compliance requirements into coordinated work across functions, regions, systems, and areas of specialist knowledge. Training and management support are therefore better viewed as parts of a wider compliance system rather than as stand-alone solutions.⁴⁴

⁴² Pereira and Bamel, "Extending the Resource and Knowledge Based View: A Critical Analysis into Its Theoretical Evolution and Future Research Directions," pp. 557–570; Kengatharan, "A Knowledge-Based Theory of the Firm: Nexus of Intellectual Capital, Productivity and Firms' Performance," pp. 1056–1074 .

⁴³ Hauser, Christian. "Trade-Control Compliance in SMEs: Do Decision-Makers and Supply Chain Position Make a Difference?" *Journal of Business Ethics* 179, no. 2 (2022), pp. 473–493; Bureau of Industry and Security, Export Compliance Guidelines (U.S. Department of Commerce, 2017).

⁴⁴ Wolfgang Amann, Christian Hauser, Matthias Kleinhempel, Raul Saccani, Agata Stachowicz-Stanusch, and Shiv Tripathi, eds., *The Changing Role of the Chief Compliance Officer* (Abingdon: Routledge, 2026).

6. Limitations of the study and areas for further research

This study examines a single multinational biopharmaceutical company and is intended for analytical rather than statistical generalization. The transferability of the findings therefore depends on the similarity of other organizational and regulatory contexts. Although the interviews were complemented by internal company materials, the study did not involve prolonged ethnographic engagement nor sustained participant observation. In addition, the interviews were conducted online because participants were geographically dispersed, which limited access to non-verbal communication. The prior organizational connection of one researcher, who had previously completed an internship at the case company, facilitated access but may also have influenced the research process or interpretation. Finally, several participants had substantial professional experience, which provided valuable insights but may also have affected how critically they assessed established company practices. Future research should include multi-case studies to validate and extend the results across diverse organizations. Also, exploring the effectiveness of emerging digital training tools, such as AI-driven platforms, in comparison to traditional face-to-face or hybrid training methods could provide valuable guidance for organizations seeking to optimize their compliance training strategies.

7. Conclusion

This study explored trade compliance challenges and in-house training within a global biopharmaceutical company. Using a single-case study supported by 21 semi-structured interviews and thematic analysis, the research provides an in-depth view of how employees experience trade compliance challenges and current in-house training practices within the case company. Training should therefore be understood as one component of a broader internal compliance program, alongside clear responsibilities, procedures, systems, monitoring, auditing, escalation mechanisms, and management support.

Regarding RQ1, “How do trade compliance challenges and knowledge gaps vary across organizational functions in the case company?”, participants reported a complex and fragmented regulatory landscape involving overlapping EU, U.S., and national requirements, including dual-use controls, sanctions, customs procedures, tariff classifications, and environmental and health requirements.

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Internally, vital challenges concern incorrect or incomplete documentation, misclassification of products, valuation errors and inconsistent recordkeeping. These issues result in shipment holds, operational delays, unnecessary duties and penalties, and reputational risks with authorities and customers. Across departments, understanding of trade compliance is generally basic and uneven. Outside the dedicated trade compliance and logistics teams, many employees lack clarity about product classification, licensing requirements, the allocation of responsibilities in international shipments, and their own compliance obligations. Human factors, such as low motivation and reliance on others to resolve compliance-related issues, further elevate the problem. Existing knowledge-sharing mechanisms and training efforts are often reactive, fragmented and only loosely connected to day-to-day export operations. These results imply that uneven compliance knowledge and training practices form part of a broader set of organizational factors associated with these challenges, alongside responsibilities, information quality, procedures, systems, monitoring, and cross-functional coordination.

With respect to RQ2, participants identified several areas they believed could improve current in-house training practices. These suggestions reflect participants' experiences with current compliance work and training practices; the study did not introduce or evaluate a new training program and therefore cannot establish the effectiveness of the proposed approaches.

First, training content needs to move beyond generic e-learning and one-off modules towards scenario-based, practical and role-specific learning that reflects real export cases, dual-use decisions, documentation requirements and sanctions screening. Participants repeatedly requested in-depth and focused, real-time case studies and interactive formats that help them understand both what to do and why it matters.

Second, the frequency and content of training should reflect employees' roles, level of involvement in trade compliance, and exposure to regulatory change, especially in areas such as sanctions and dual-use rules.

Third, the findings highlight the importance of cross-functional training and knowledge sharing. Since export compliance is a cross-departmental responsibility, training should target not only trade compliance specialists but also customer service, logistics, finance, sourcing and R&D, clarifying how each department affects classification, documentation and licensing. This cross-functional perspective is consistent with both the Knowledge-Based View and Resource-Based View, which emphasize knowledge as a strategic resource and internal capabilities as a source of competitive advantage.

Fourth, assessment of compliance understanding in the case company appears to rely heavily on escalations and shipment problems. Participants suggested that this could be complemented by pre- and post-training checks, periodic audits focused on learning outcomes, and clearer performance indicators. The study contributes an empirical, cross-functional view of trade compliance within a multinational biopharmaceutical company. Rather than presenting compliance as solely a regulatory or specialist concern, the findings show how compliance outcomes are shaped by the interaction of regulatory requirements, information flows, responsibilities, training practices, and access to specialist expertise across organizational functions. The findings further suggest that the central organizational challenge is not necessarily whether all employees possess specialist compliance knowledge, but whether that knowledge can be effectively accessed, shared, and applied when cross-functional decisions are required. From a practical standpoint, managers should view in-house trade compliance training as one element of a broader compliance program rather than as a stand-alone solution. Training should reflect employees' roles and level of involvement in trade compliance activities. In the case company, participants also pointed to the importance of clear responsibilities, reliable information, monitoring, audits, escalation mechanisms, and systems that support compliant decisions. Preventive mechanisms, such as clear procedures and role-specific guidance, therefore need to operate alongside detective mechanisms that identify problems and support corrective action. Ultimately, the case suggests that effective trade compliance is not simply a matter of regulatory knowledge or training provision, but of ensuring that the right expertise, information, and organizational support are available when cross-functional compliance decisions must be made.

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8. Appendix

Appendix A. Semi-structured interview questions

Background & role in compliance

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1. Can you describe your role in managing trade compliance within the company? (years of experience in the industry)
2. Which trade compliance regulations are most relevant to your department?
3. How often do these regulations change? And how frequently is training updated to reflect new or changing regulations?
4. How often do compliance issues (e.g., incorrect documentation, export violations) occur in your department?
Trade Compliance Challenges
5. What are the most common trade compliance violations or challenges you face? (Can you share a specific example?)
6. How do these challenges impact business operations (e.g., delays, penalties, lost revenue)?
7. How well do employees across different departments understand compliance regulations?
8. How is compliance knowledge currently shared across departments (ex. Online/in person meetings, sharing documents, training sessions, workshops etc.)?
9. Are there particular export regions or product classifications that present more compliance difficulties?
Training & Knowledge Gaps
10. What kind of trade compliance training is currently provided? Are there any certifications, or benchmarks that you follow for training standards?
11. What knowledge gaps do you see in your team or department regarding trade compliance?
12. How do you assess whether staff fully understand and apply compliance regulations in practice?
Improving Training & Compliance Efficiency
13. What improvements would you suggest for in-house compliance training programs?
14. In what ways do you think better training could enhance compliance efficiency and reduce risks?