

Associate Director, Trade Compliance & International Logistics

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Sunovion Pharmaceuticals is looking for an Associate Director, Trade Compliance & International Logistics to join our Distribution group in Marlborough, MA.

The Associate Director of Trade Compliance and International Logistics will have a primary role to ensure company compliance with US customs and associated trade regulatory agencies. Responsibilities include establishment, maintenance, education, and enforcement of trade compliance policies and procedures in cooperation with corporate and external counsel. Responsible for the compliant, expeditious and efficient flow of imports and exports. Additionally, this role will have responsibilities in key logistics and distribution activities. Role will drive continuous improvement, ensure scalability, and manage related systems and information in a GxP environment. Position will be the Sunovion SME on import and export trade compliance activities.

Essential Functions:

Trade Compliance

- Support the international movement of company materials by ensuring compliance with the requirements of customs authorities and other agencies that regulate imports and exports, including but not limited to CBP, FDA, USDA, CDC, BIS, Census, EPA, and F&W. Movements will include activities related to commercial, clinical, R&D and other programs.
- Responsible for US trade compliance systems, policies, processes, and relationships, both internal and external.
- Develop, implement, and maintain programs, policies, procedures, and controls to ensure company-wide compliance in accordance with guidelines of the U.S. Customs and Border Protection (CBP) and other relevant agencies.
- Evaluate new US Government regulations and ensure that import and export activities remain in compliance with changes. As necessary, incorporate changes into day to day operations and standard operating procedures. Provide updates to management.
- Perform regular internal import and export audits; assist in regulatory post entry audits; resolve discrepancies, request and drive appropriate corrections, reconcile or protest as appropriate; verify valuation methodology including adjustments such as assists and royalties. Ensure recordkeeping practices as maintained.
- Provide mechanisms for trade compliance general awareness across organization as well as detailed operational training sessions.
- Assess and report out on transaction testing for compliance and improvement opportunities.
- Facilitate customs releases on new and escalated entries.
- Maintain trade classifications and country of origin determinations.
- Conduct and coordinate annual Customs Reconciliation activities.
- Oversee and maintain import/export security programs (e.g. CTPAT).
- Provide updates to management on new trade developments for opportunities and risk impacts.
- Identify and lead continuous improvements related to import and export activities. Ensure all documentation is sufficient and contemporary. Provide recommendations to senior leadership on cost avoidance, best practices on duty mitigation strategies, and proactively suggest areas of required improvement.
- Serve as SME on trade issues including, but not limited to, HTS classification, country of origin determination, valuation, denied parties, embargoed countries, duty and tax reduction programs and red flag issues.

- Ability to analyze and interpret complex issues and data gathered from a variety of sources and, through effective decision-making and planning, deliver high-performing business solutions relative to trade compliance.

Logistics and International Transport Management

- Manage, select, and improve international transportation operations to efficiently move materials between CMO's, CPO's, 3PL's, Clinical Operations and Distribution Centers.
- Proactively manage international transportation risks including development of risk mitigation strategies.
- Develop and maintain compliance to international transportation regulations and pharmaceutical cold chain requirements where required.
- Facilitate shipment coordination of materials (API, Intermediates and finished goods).
- Promote and maintain GxP compliance throughout Sunovion's network.

Minimum Education, Experience, Knowledge and Skills Required:

- Bachelors Degree in Business or related field.
- 5-7 years' experience of logistics and trade compliance experience with 2-3 years in the Pharmaceutical or related industry.
- Knowledge of US customs regulations preferably with products under FDA authority.
- Experience with product HTS and ECCN classifications, valuation, and Country of Origin determinations for pharmaceutical products. Familiarity with CBP ACE portal.
- Experience with Customs Reconciliation process, Royalties, True-ups, and Assists preferred.
- Experience with the CBP CTPAT program.
- Ability to lead external partners including Customs Brokers, Customs Attorney, freight forwarders, and parcel/courier providers.
- Working knowledge of GxP principals.
- Working knowledge of Free Trade Agreements, Foreign Trade Zones, and VAT mitigation/recovery strategies.
- Experience in developing procedures and providing education/workshops to others.
- Ability to interact with other departments and communicate at a high level.
- Experience in International freight management preferably in Pharma environment. Knowledge of validated cold chain transport.
- Ability to read and interpret government regulations.
- Ability to work independently.
- Well organized – a natural ability to be organized in how you think, communicate and conduct your work.
- Ability to manage multiple projects and priorities.
- A curious mindset that allows you to constantly learn and challenge the status quo.
- Participation in industry groups (e.g. ICPA, AAEL).
- NCBFAA Certified Customs Specialist (CCS) preferred.
- *This is an individual contributor position.*
- Work hours may include meetings scheduled outside of normal working hours. Demands during peak times may require work hours outside of normal working hours. Occasional travel (~5% Domestically) may be required.