

Customer & Market Due Diligence Of FDA Compliance Services Provider: Establishing Competitive Positioning And Growth Outlook

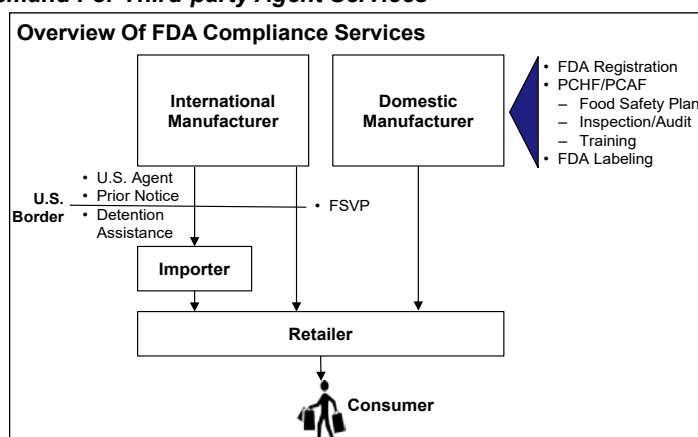
The Challenge: One of our PE clients was considering acquisition of an FDA supply chain compliance solutions provider serving a diverse array of end-users involved in the import of food, drugs, medical devices, and cosmetic ingredients. From its beginning of providing niche compliance services, the target had grown both organically and through acquisitions to expand its service offering and become a market leader. Our client was excited by the target's services given growing food safety regulations and by its extensive long-standing customer base but needed a clear view of the target's opportunity to leverage this customer base with additional service offerings, as well as the risk of companies bringing these services in house. Accordingly, the client asked Gotham to conduct a 2-week customer & market due diligence to establish: (1) the supply chain compliance services map/market size; (2) an understanding of the target's value proposition/competitive positioning; and (3) the target's growth opportunity.

Niche Compliance Services Market Assessment: To deliver a fact-based view of the market and competitive dynamics, Gotham:

- Reviewed food safety regulations issued by various agencies (e.g., FDA, USDA, CBP), conducted interviews with FDA officials, and reviewed service offerings of key compliance services providers to develop an FDA supply chain compliance services map
- Conducted interviews with food importers and exporters to gain insights into: their supply chain compliance needs and how they are evolving; their approach to meeting these compliance requirements; the competitive landscape; and the target's reputation
- Analyzed import trends and modeled the size of the FDA supply chain compliance services market in order to: provide a view of services by end-user type; establish service volume and pricing; and estimate the target's market share by service line
- Established the competitive landscape, including player segments offering U.S. Agent services (e.g., customs brokers, importers, consultants, lawyers), direct competitors offering FDA supply chain compliance services, and new entrants.

Perceived Increase In U.S. Agent Liability Driving The Demand For Third-party Agent Services

With the introduction of the Bioterrorism Act of 2002, regulations were established requiring food importers to register with the FDA and have a U.S. Agent who acts as a domestic communications link with the FDA. Gotham's research indicated that the third-party agent services only accounted for ~40% of the U.S. Agents, with 20% of importers having physical presence in the U.S., and the remaining 40% fulfilled by customs brokers, importers, lawyers, etc. However, the Food Safety and Modernization Act (FSMA) tightened the regulation for importers by requiring biennial registration of foreign food facilities and making the U.S. Agent liable for cost of reinspection. Our interviews with customs brokers and importers indicated that they were becoming reluctant to take on U.S. Agent roles due to this shifting liability, thus driving the use of third-party U.S. Agent services.



FSMA's Provision Of Making Importers Liable For Food Safety Driving Demand For Supply Chain Compliance Services

In 2011, FSMA imposed cGMP regulations – a foreign supplier must produce food in compliance with processes that provide the same level of public health protection as those required of domestic manufacturers. To meet these regulations, FDA implemented the Foreign Supplier Verification Program (FSVP), requiring importers to certify food safety plans (e.g., hazard analysis, prevention control, recall plan) for each imported food and requiring a Prevention Control Qualified Inspector (PCQI) to sign off on these plans. Our interviews with importers established that a large number of foreign suppliers tend to use an in-house PCQI due to the overall outsourced cost of supplier verification, while other importers rely on third-party services and FDA consultants to serve as their PCQI. We also found that importers are not clear on the exact requirements for monitoring safety of imported foods. As such, FDA's posture had been "educate while we regulate", so audits had been more lenient. However, FDA is now shifting its posture towards more enforcements, which will likely lead to increased use of third-party services.

Target Is A Clear Market Leader In This Niche Market With An Opportunity To Create A Cloud-based Food Import Ecosystem

Beyond the target, FDA compliance services providers tend to be small companies, and the target has a lion's share of the market. Its market-leading brand presence was built through active involvement in food shows/trade events and its active marketing campaigns. But, there are new entrants in the target's market as established players from other parts of the supply chain services ecosystem are now moving into the FSMA compliance space (e.g., pharma compliance, USDA compliance services companies).

The target's existing customer base is composed of a large portion of food exporters, and we determined that target has an opportunity to build a SaaS platform to provide comprehensive food supply chain compliance functionality by connecting importers and exporters to facilitate communications, document sharing, auditing, and paperwork generation for FDA audits. This platform could be further enhanced to include a marketplace to facilitate commerce. Once this platform achieved scale, there would be an opportunity to leverage the data to offer insights through analytics and AI/machine learning.

The Outcome: Gotham's assessment provided clarity on the FDA supply chain compliance services and market size, uncovered how stricter regulations are forcing the market to evolve, and established the target's value proposition. Armed with a solid understanding of the market, the competitive dynamics, and the target's growth opportunities, our client aggressively pursued the target.