

# Building a Compliance Program from the Ground Up

*Pre-commercial pharma company engages IQVIA to provide commercial compliance infrastructure for its first launch*

## Situation

A pre-commercial pharmaceutical company was preparing to introduce its first product in the U.S. following FDA approval. As a pre-commercial company entering a new market, the customer faced significant challenges in establishing the necessary compliance infrastructure to support a successful launch.

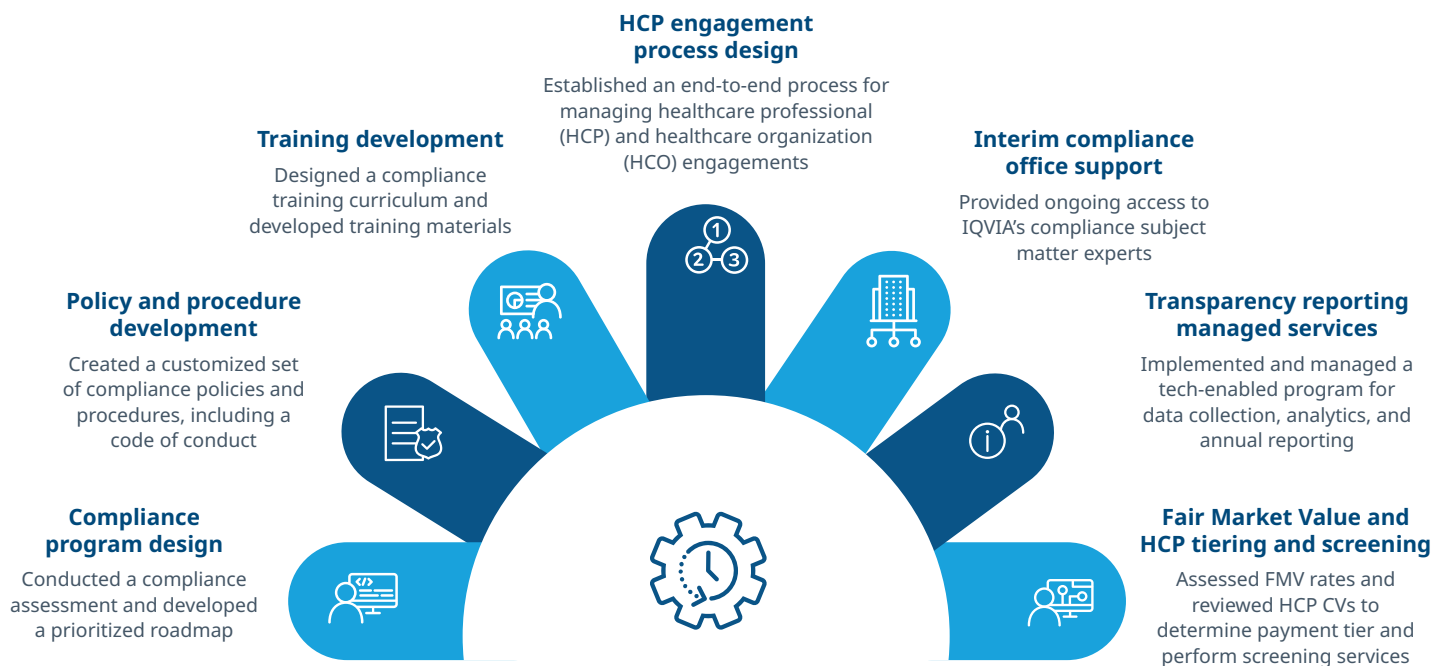
The customer had a small team of consultants, some with limited expertise with the U.S. pharmaceutical commercial compliance requirements. They needed a seasoned industry partner who could provide guidance, oversight, and the development of a commercial compliance program, starting from square one.

## Solution

The customer engaged IQVIA to design and implement a comprehensive commercial compliance program, including services to support a culture of compliance throughout their organization. Our cross-functional team of subject matter experts served as an extension of the customer’s team in daily operations, reducing customer burden and establishing a cadence of proven processes.

IQVIA’s tailored solution encompassed several key areas and was right sized but scalable to grow with the customer’s future expansion.

### Tailored solutions to mitigate risk and drive efficiency and business value



## Results

Within just a few months of engagement, IQVIA successfully delivered a comprehensive compliance program tailored to the customer's needs, serving as a single partner. This led to many positive outcomes.



### Rapid program development

IQVIA successfully delivered critical compliance infrastructure elements under urgent launch time constraints.



### Allowing leaders to focus on leading

Client leaders indicated that IQVIA compliance support exceeded expectations and reduced stress, allowing them to focus on other critical activities with confidence.



### Cost-effective expertise

By leveraging IQVIA's services, the customer gained access to a broad range of compliance expertise without the need to hire multiple full-time employees.



### Seamless integration

IQVIA's compliance services integrated smoothly with other launch support activities, providing a cohesive approach to the customer's market entry.



### Ongoing support

The interim compliance office support model gave the customer flexible access to expert guidance as new compliance questions and challenges arose.

IQVIA's work demonstrates the value of a comprehensive, tailored approach to compliance program development for small and pre-commercial pharmaceutical companies. By leveraging our expertise and tested solutions, the customer was able to rapidly establish a robust compliance infrastructure to support its U.S. launch while maintaining a lean internal organization.



IQVIA offers the technology, consulting and services to drive value across your entire compliance ecosystem.