

Case Study: DTP Program Review and Evaluation

THE CLIENT

The client is a mid-sized pharmaceutical manufacturer that is engaged in the promotion and sampling of prescription drugs across multiple product lines. The client contracted QPharma to evaluate its Direct-to-Practitioner (DTP) program for compliance with the Prescription Drug Marketing Act (PDMA), and to identify any program deficiencies.

THE CONCERNS

- The client had a program in place for several years, and felt it was necessary to conduct a re-evaluation of the program documentation.
- Internal policies and procedures were established by the client, but audits of the actual processes had not been performed.
- QPharma made the assessment that the client's compliance with requirements for documented signed sample receipts or Acknowledgement of Contents (AOCs) was in need of tighter controls. This concern was that growing enforcement of the Affordable Care Act (ACA) would result in increased scrutiny of sampling data.



BACKGROUND

The DTP program was initially established with PDMA-compliant policies and procedures, and implemented with the objective of following these requirements. Since the launch of the client's DTP program, staffing as well as vendors who were assisting with the program management had undergone constant changes, which was disruptive and negatively impacted success.

Following internal investigations and discovery efforts, the client acknowledged the need to have QPharma perform a thorough review of its documentation and processes. Additionally, the client desired insight into industry best practices as a means to explore program options in order to improve costs and efficiencies.

DTP REVIEW AND EVALUATION METHODOLOGY

QPharma's approach and methodology is based on more than two decades of applicable experience as an industry leader in sampling compliance, including DTP programs. QPharma employs industry subject matter experts specializing in PDMA compliance and DTP programs who have been recognized as thought leaders in the health and life sciences vertical.

QPharma's project methodology for this effort included the following key components:

- Kick-off meeting with key stakeholders to confirm project scope and timelines;
- Discovery sessions that included the collection of pertinent documents and data along with interviews conducted with key stakeholders to confirm processes;
- Facilitation of weekly status meetings to align communications, developments, and updates with the project plan, objectives, and goals, as well as to clarify documentation as needed;
- Drafting of a Recommendations Report, which allowed the client to respond to observations and recommendations, ultimately leading to the identification of potential risks as well as areas in need of process improvement;
- Build-out of a road map for the implementation of recommendations; and
- Creation of a final report incorporating feedback and responses from the client.

CONCLUSION

The client was able to address potential compliance concerns through a revision of several internal policies, procedures, and work instructions. With minimal process change, QPharma assisted the client in aligning DTP processes under a more effective model while anticipating that these efficiencies would ultimately prove to be cost-effective.

With the guidance of QPharma, the client has implemented several tracking disciplines, which have yielded a 95% success rate on AOC follow-ups; paralleled with corrective measures in place for non-compliance.

Lastly, the client successfully fulfilled all sample transparency reporting requirements in compliance with §6004 of the Affordable Care Act, under the navigational direction of the draft guidance by the FDA. Today, they have renewed confidence effected by the successful efforts of QPharma's commercial and compliance subject matter experts.

