

CASE STUDY: Consultative Expertise for DTP Program Compliance

Background:

A mid-sized pharmaceutical manufacturer with a diverse product portfolio faced challenges with PDMA compliance and the efficiency of their Direct-to-Practitioner (DTP) program amidst increased scrutiny from the Affordable Care Act. Since the DTP program's inception, changes in staffing and vendors had occurred, prompting the client to recognize the need for a thorough review of its documentation and processes. Additionally, the client sought to incorporate industry best practices to enhance the program's efficiency and cost-effectiveness.

Challenge:

- Program Re-evaluation: The client's longstanding program required a thorough review, with established internal policies and procedures needing actual process audits to ensure effectiveness.
- Enhanced Compliance Controls: Compliance with documented signed Sample Receipts or Acknowledgement of Contents (AOCs) was identified as inadequate, necessitating stricter controls due to heightened scrutiny under §6004 of the Affordable Care Act.

This manufacturer needed expert analysis and strategic recommendations to refine and ensure compliance of their DTP program.

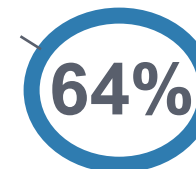
QPharma's Solution:

- Expertise Deployment: QPharma leveraged its recognized industry leadership in sampling compliance and DTP programs, employing subject matter experts to guide the project.
- Methodical Approach: Initiated with a kick-off meeting to define scope and timelines, followed by thorough documentation collection, stakeholder interviews, and weekly status updates to ensure alignment and address emerging issues.
- Strategic Recommendations: Produced a Draft Recommendations Report for client feedback on prioritized risks and process improvements, leading to a strategic roadmap for implementation.
- Final Deliverables: Concluded with a Final Report that incorporated client responses, solidifying the pathway for enhanced program efficiency and compliance.

Titanium® Results:

The client boosted their confidence in meeting PDMA and ACA 6004 compliance. Operational adjustments aligned seamlessly with industry best practices, minimizing disruptions. They achieved full compliance with ACA 6004's sample reporting mandates. Guided by QPharma, the client enhanced their Acknowledgement of Content (AOC) process, achieving a 95 percent success rate in AOC completions, thereby improving overall operational efficiency and compliance tracking.

% of completed AOCs pre-QPharma recommendation



% of completed AOCs post-QPharma recommendation

