propharma

CASE STUDY

Program & Project Management: Medical Device Reporting

Challenge

- ProPharma was engaged to temporarily augment the effort to write or update Medical Device Reports (MDRs) and international vigilance reports for medical devices. The client needed to be compliant with US, Asian, and European regulations per regulatory commitments
- Scope: >8000 US, European, and Asian records for processing
- The client was burdened with very tight timelines and was resource-constrained. Estimates to complete the work without enhanced external support were Q1 '2024
- Once involved in the project, further investigation revealed it was a more complex, simple data entry project; it would require a lot more time and investigation of records with the interaction of numerous systems
- Given the number of records, it was also clear that a robust team with a strong project management structure would be needed to achieve a successful outcome and provide proactive, transparent communication

Solution

- Created a project management structure to oversee and execute the project, including the client and ProPharma personnel
- Defined communications/alignment strategy with key project stakeholders
- Developed training and ongoing communications approach and supporting tools
- Quickly staffed (in one week), deployed, trained, and on-boarded 1 Project Manager, 25 technicians, and 6 Pod Leads to complete the project – Daily agile huddle calls to start, then scaled back accordingly
- Remained fully compliant with client CAPA and Change Management processes
- Maintained all applicable project documentation in the client repository

Results

- Developed, prioritized, and completed the global MDRs with close collaboration with the client resources
- Successfully completed the records much earlier than planned (early Q4'2023) with the enhanced resources (Dec 2023) and much earlier than without ProPharma resources (Q1'2024)
- Completed the project 25% under the planned budget
- Introduced daily and weekly tracking of record completion to share with both PPG and the client teams to share weekly reports, review project progress, and escalate/resolve issues
- Freed up client resources to primarily focus on their daily work with time spent on the project to receive ongoing status updates, resolve issues, train the staff, and complete, as needed, tasks
- Successfully pivoted and addressed an unplanned issue; only minimally impacted project completion timing and budget

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

www.ProPharmaGroup.com
Info@ProPharmaGroup.com