

Full service Post-Marketing Pharmacovigilance and Medical Information Services for large nutritional health company



On behalf of {our company}, I want to say a big THANK YOU for all your support on this. Your lead and courage were fundamental for the success of this project. Please share my comments with the whole PharmaLex team as well for all their efforts to make this happen. - Head of US Regulatory Affairs

Challenge



Rapid set up and go live for PV and Med Info Services

- Large nutritional health company with newly acquired Rx products in US and Canada required urgent full support with all PV activities, Medical Information contact center services, as well as data migration of cases from prior MAH
- New to prescription drug market with 3-week timeline to take over PV and Call Center responsibilities
- Need of additional support for NDA maintenance support, promotional materials development and review, and product complaint management

Solution



Provision end-to-end PV services tailored to company's needs

- Thorough analysis of the company's individual situation and needs
- Setup of a global PharmaLex team with PV experts both in the US and Europe, with a single point of contact overseeing all activities
- Critical timelines met to ensure set up of Medical Information intake, data capture, and triage as well as PV case processing, literature review, signal detection, aggregate report systems
- Prioritization of tasks, teamwork and transparency with client allowed PharmaLex to tailor set up to company's established processes and procedures

Outcome



Timely provision of services ensuring compliance with regulatory requirements

- Successful go-live: on time, comprehensive system with fully trained team
- End-to-end PV services provided by PharmaLex, including medical information call center
- Database set up for medical information and case processing, including PV case migration
- Through global reach and local presence PharmaLex covers medical information and PV support on a multinational scale
- Extensive PharmaLex service portfolio allows company to outsource various activities (including PV, Regulatory and Quality Management and Compliance) to one preferred provider