CASE STUDY

Expedited Scale-Up To Support Global Launch of New Product

Leveraging staff around the globe helps meet tight timelines even with a small medical affairs team and a limited budget.

Challenges
A biotech client with a small medical affairs team and significant time and budget constraints needed support from Med Communications to successfully execute US and global launch plans for a new product.

Solution
Med Communications provided flexible and easily scalable staffing models and diversified medical information solutions uniquely tailored to meet the clients' needs.

Impact
Partnership with Med Communications provided the guidance, support, and solutions needed for timely and successful execution of the clients' specific launch plans.

Background

Client: Biotech client with US and global launch plans under an Emergency Use Authorization.

Med Communications worked with a new client looking for support with medical information contact center, pharmacovigilance, and medical writing services for a new drug that was under evaluation by several regulatory agencies, including the FDA and the European Medical Agency.

Challenge

With the possibility of regulatory authorization occurring at any time, timelines were exceedingly tight because the client was anticipating a quick launch in 15 global markets covering North America, Europe, and the Middle East. In addition to these time constraints, the client was working with a limited budget and a small medical affairs team.

Solution

Medical Information Call Center
Leveraging our hubs in U.S. and Portugal plus our team of multilingual medical information pharmacists located around the world, Med Communication's leaders quickly scaled up to provide a shared-service contact center model comprising live phone agents, adverse event and product complaint intake agents, as well as email and webform coverage during local business hours for each of the client's 15 target global markets. Our IT team acquired new local phone numbers in the global markets and created custom telephony messaging for each market's local language. Our staff worked with the client's outsourced website developer to integrate the client's Adverse Event Reporting

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Webform with the Med Communications Adverse Event system. Staffing and call routing was set up for a Med Communications' pharmacist who is fluent in the local language to answer customer calls in each country. On weekdays, the Med Communications Contact Center "followed the sun" across Asia, Middle East, Europe, and the Americas.

End-to-End Pharmacovigilance

Our Pharmacovigilance team immediately appointed a dedicated implementation group to act as a flexible yet highly specialized partner, able to streamline communication, assemble the necessary resources quickly, and integrate them with the client's team or act as standalone experts as the project dictated. The PV implementation group provided expert advice on pharmacovigilance global strategic planning activities and reviewed PV requirements in all relevant countries. They also identified, onboarded, and appointed Qualified Person for Pharmacovigilance and Local Person for Pharmacovigilance, prepared global and local Pharmacovigilance System Master File and Risk Management Plans, completed all preparatory activities for aggregate safety reporting and signal management, and set up literature search expressions and PV agreements with local partners.

The client was able to effectively address complex regulatory requirements, meet internal timelines, and achieve cost targets by leveraging Med Communications' expertise, established process frameworks, business accelerators, and hosted cloud-based safety database, all of which are easily scalable with the client's growth and allow for simplified global submissions across various regions.

Scientific Content Development

Med Communications' Scientific Content Development team assessed the client's launch-specific scientific content needs and made appropriate recommendations that were rapidly approved by the client. The experienced team of medical writers swiftly created 19 US-based standard response documents and cover letters for the new product. In addition, global standard response and cover letter templates to be adapted for use in any country upon EUA or regulatory approval were created.

Business Impact

Because of the experience and expertise of the Med Communications team, all steps were completed on time for the client to be ready for global launch. With Med Communications establishing scientific content, contact center, and end-to-end pharmacovigilance services, the client was free to focus on other aspects of the launch. A biotech client with a small medical affairs team and significant time and budget constraints needed support from Med Communications to successfully execute US and global launch plans for a new product.

- **Each step was completed on time for the global launch.**
- **Med Communications' expertise freed the client to focus on the launch.**
- **The US and global launch plans were successfully executed.**