

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.



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 since the client was anticipating a quick launch in fifteen global markets covering North America, Europe, and the Middle East. In addition to time constraints being a major concern, the client was working with a limited budget and a small medical affairs team.

Solution

Medical Information Call Center

Leveraging Med Communications' hubs in U.S. and Portugal, and multi-lingual healthcare providers located around the world, Med Communications leaders quickly scaled-up to provide a shared-service contact center model comprising of live-phone agents, adverse event and product complaint intake agents, as well as email and webform coverage during local business hours for the fifteen global markets in North America, Europe, Middle East, and Asia. The Med Communications IT team acquired new local phone numbers in the global markets and created custom telephony messaging in the local language(s)

SUMMARY

Client

Top 10 pharmaceutical manufacturer

Challenges

Client required a partnership that offered considerable scalability, fluctuating staff levels, new product support, and ability to handle a varied workload due to growing pipeline.

Solution

Med Communications exceeded needs of client by providing flexible staffing models and diversified solutions.

Impact

The client reported increased efficiency in its medical information contact center and medical writing activities during a period of significant product growth.

for each market. Med Communications worked with the client’s outsourced website developer to integrate the client’s Adverse Event Reporting Webform with the Med Communications Adverse Event system. Staffing and call routing was setup for a Med Communications’ pharmacist, fluent in the local language, to answer customer calls in each country. During weekdays, the Med Communications Contact Center “followed the sun” across Asia, Middle East, Europe, and the Americas.

End-to-End Pharmacovigilance

The Med Communications’ Pharmacovigilance team immediately appointed a dedicated implementation group to act as a flexible, yet highly specialized partner, able to streamline the communication, assemble the necessary resources quickly and integrate them with the client’s team or act as stand-alone 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 QPPVs and LPPVs, prepared global and local PSMFs, Risk Management Plans, completed all preparatory activities for aggregate safety reporting and signal management, and set up of literature search expressions and PV agreements with local partners.

The client was able to effectively address the complexity of regulatory requirements, meet internal timelines and achieve cost targets, by leveraging Med Communications’ expertise, established process frameworks, business accelerators, as well as its hosted cloud based safety database, easily scalable with the client’s growth, and allowing for simplified global submissions across various regions.

Scientific Content Development

The 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 nineteen 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 launch efforts.



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About Med Communications

Med Communications is a premier resource for global medical affairs services. We are trusted by the world’s leading pharmaceutical, biotech, and medical device manufacturers for comprehensive, high-quality scientific resources and information. Our global services include medical information, scientific content development, pharmacovigilance, and commercial.