Critical Considerations for Outsourcing Medical Writing

As the landscape for drug development and regulatory approval continues to become more complex, the need for experts who can transform large quantities of clinical trial data into accurate, understandable and compliant documents has never been greater. Medical writers who understand the drug development and regulatory strategy, and who are experienced in developing the documents needed for regulatory filings and scientific publications, can be critical members of the project team.

Large pharmaceutical companies may choose to build a medical writing function internally – but for small and mid-sized organizations, outsourcing the medical writing function is often a better choice, enabling the company to access deep expertise while also managing costs.

Pharmaceutical developers who are planning to engage an outsourced partner for medical writing should keep the following three considerations in mind.

1. Depth of Expertise

When it comes to medical writing, it is important that your outsourced team can quickly distill complex data into concise, accurate reports, in formats that comply with regulatory requirements. Each therapeutic area and approval pathway may have its own regulatory nuances and special requirements, so it's important to work with a team that has expertise in your disease area and with products similar to your own. This also leads to a consultative writing approach when you have a skilled writer who is able to draw from previous experience when it comes to either messaging or even filling or bridging gaps. The deeper the expertise of your medical writing team, the more likely they will be to hit the ground running with minimal ramp-up time.

2. Ability to Work as an Extension of Your Team

In the best examples of outsourced medical writing, the supplier's team works in a highly collaborative way with the internal team, enabling the writers to quickly learn, understand and interpret the strategic messaging and scientific aspects of program.

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The ability to attend strategy meetings, participate in comment resolution meetings and even have total access to your company's systems as a credentialed writer can enable the outsourced writer to serve as an extension of your team. Finally, having full access to a medical regulatory writer via an FTE model also helps to ingrain the writer as less of an outsourced supplier and more as part of the team.

3. Capability to Span Regulatory, Scientific, and Commercial Work

It is not uncommon for drug developers to engage different medical writing teams for support with pre-approval regulatory writing, scientific platform and publication planning, and post-approval educational and commercial publications. This multi-vendor model can result in significant inefficiencies for the internal team that has to manage these disconnected teams.

Partnering with a single medical writing supplier with expertise across multiple areas in both pre- and post-approval not only can drive cost savings, but can accelerate deliverables through the gained efficiency of a single team. For example, if the outsourced team that manages the client's scientific publications is also handling the regulatory writing, they will already have a deep knowledge of the product and therapeutic area, and will be able to accelerate timelines by producing the regulatory documents faster.

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