

InSite Vision: “Process productivity driven by an innovative partnership”



“The electronic submission represented a significant challenge for InSite. We needed to formalize processes and project timelines and bring in specific expertise to augment our internal skill sets. This submission was a major milestone for InSite so we minimized our risk by partnering with Octagon.”

William Smith III, Ph.D.
Regulatory Affairs Sr. Manager
InSite Vision, Inc.

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InSite Vision is a San Francisco Bay Area-based ophthalmic company focused on developing therapies that treat ocular infection, glaucoma, and retinal disease. InSite Vision’s lead product is AzaSite™, which targets infections of the eye. AzaSite contains the drug azithromycin, a broad-spectrum antibiotic formulated with DuraSite™, InSite Vision’s patented drug-delivery vehicle, which offers the benefit of a low-dosing regimen, attractive to both the eye-care patient and physician.

Leading the electronic transformation of Clinical R&D

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The small but focused pharmaceutical development company employs only about 50 people, which often requires outsourcing key elements of their development process. So it came as no surprise that when they were faced with the daunting task of compiling their first new drug application, they took the same pioneering attitude toward developing a cross-functional strategy to complete the regulatory submission and submit in electronic format to the U.S. Food and Drug Administration.

William Smith III, Ph.D., InSite’s Regulatory Department Head, was tasked with developing and executing the strategy to support a tight submission deadline. Dr. Smith consulted with his project team and assessed the organization’s resources and submission experience.

Since InSite traditionally out-licensed products prior to completion of Phase III studies, the organization had never been

through the exercise of compiling all of the required documentation to support a new drug application. They did not have the internal resources to review, compile, publish, and quality check hundreds of documents and data. Dr. Smith quickly came to the conclusion that InSite would benefit from an outsourcing partnership to facilitate the submission process.

InSite chose to partner with Octagon Research Solutions, Inc. to provide Regulatory Operations, Regulatory Affairs and Quality Assurance support throughout the submission creation process. They also chose to submit the application electronically in order to reduce initial production costs and gain efficiencies inherent in storing, accessing and navigating an electronic submission.

InSite faced the traditional small company challenges of limited resources. In addition, the product development team was managing documents and data from multiple Contract Research Organizations as well as numerous geographically dispersed contract medical writers. The submission date demanded accelerated processing timelines. Issue identification and resolution became paramount to this process. Octagon’s Regulatory Operations group utilized ViewPoint®, Octagon’s enterprise submission process management solution, to manage the entire issue lifecycle and ensure accurate and timely reporting of all issues and project status updates. **Dr. Smith noted, “The issue management process was speedy and enabled us to save time and prioritize critical activities. In the end, this gave us flexibility to reallocate resources and work more efficiently. We were able to**

focus our efforts on executing the strategy, because we knew Octagon was continually reviewing, processing and quality checking deliverables.”

The final submission also included content of labeling in which the highlights section was submitted in Physician Labeling Rule format. This was another first for the small organization with only three regulatory resources. InSite and Octagon team members collaborated to produce compliant submission components. **“It didn’t matter that we were on different sides of the country”, noted Dr. Smith. “In fact, we worked as a cohesive team and it seemed like the Octagon team members were just down the hall. Their responsiveness wasn’t limited by their time zone.”**

The final hybrid electronic new drug application was submitted in a modified Common Technical Document (CTD) format. It included over 42,000 navigation items (bookmarks and hyperlinks) that spanned over 37,000 pages. This milestone achievement represented InSite’s first new drug application and first electronic submission. The success of this project enhances InSite’s product portfolio and is a source of pride for the combined InSite/Octagon team members.



For more information, please contact Octagon Research Solutions, Inc. or visit our website at www.octagonresearch.com

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