

PURDUE PHARMA

QUMAS TAKES THE PAIN OUT OF QUALITY COMPLIANCE FOR PURDUE PHARMA



About Purdue Pharma L.P.

Purdue Pharma, based in Stamford, Connecticut, is a privately held pharmaceutical company founded by physicians and dedicated to finding, developing, and bringing to market new medicines and related products that promote health and healing. The company is known for its pioneering research on persistent pain.

With approximately 900 employees Purdue is a large operation, with many key players and activities located at five different sites. Purdue Pharma is committed to establishing and maintaining an effective quality compliance program – a key component of the Company's commitment to delivering the highest standard of corporate conduct.

Purdue Pharma's Challenges

Like any pharmaceutical firm, Purdue Pharma has an enormous amount of documents it needs to track, maintain, store and circulate for signatures and approvals. These documents, all pertaining to the manufacturing or research of medications, both prescription and over the counter, need to comply with a vast array of regulations from the Food and Drug Administration including GMP –

Good Manufacturing Processes, GLP – Good Laboratory Practices, 21 CFR Part II – Electronic Records and Electronic Signatures, and many more.

With five geographically dispersed manufacturing and research sites, Purdue Pharma sometimes had to resort to sending documents via FedEx® – or even driving them in person between sites – to get the required signatures and approvals. With an estimated 100 Federal Express shipments each month, carrier costs alone rose to \$3,000 some months. According to Herschel Kenney, Sr. Director, Manufacturing and Quality Systems of Purdue Pharma, "Our number one requirement was full electronic document compliance." Essentially Purdue Pharma wanted a software solution that would accelerate and automate document management. The solution needed to be flexible enough to adapt to changing regulations while also adhering to SOP (standard operating procedures) and GMP best practices.

Specifically Purdue Pharma required a solution that would facilitate the electronic routing of documents, providing remote individuals with the ability to review and easily annotate documents. The solution needed to provide a central repository – from which sites could access any specific document or series of documents. The Company also wanted a significant measure of control within the solution – limiting access by individual or role;

tracking workflow, comments and printing; and generating an automatic audit trail for each document. Lastly, Purdue Pharma sought a solution that would identify any deviations from standard procedures.

QUMAS Solution

After researching various options, Purdue Pharma settled on QUMAS DocCompliance™. Based on the DocCompliance features and the QUMAS domain experience in Life Sciences compliance, Purdue Pharma felt the solution would fill its current requirements and be well-positioned to adapt to future and as yet unspecified compliance requirements.

In addition to delivering the "basics" of document compliance – tracking, workflow, version control, approvals and audit trails – QUMAS DocCompliance also delivered some distinct innovations. For example, with QUMAS DocCompliance, Purdue Pharma can track document printing, gain a complete understanding of who printed what when, and use that information to identify deviations in processes. Ultimately, this information helps assure consistent quality.

Using QUMAS, Purdue Pharma can now automate the generation of specific paperwork for the FDA on an as-needed basis, produce validation summaries easily and track approvals, permissions and annotations. Perhaps most importantly, the central repository allows Purdue Pharma



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Herschel Kenney, Sr. Director, Manufacturing and Quality Systems of Purdue Pharma

managers to easily access what they need, review test scripts on-demand and no longer manually route documents. The Company began implementing version 1.1 of QUMAS software. Today, Purdue Pharma is nearing an upgrade to version 4.0 of QUMAS DocCompliance. The software is used at all five sites, with one primary IT person located in Stamford, CT, and one user administrator at each site. With the help of the software, Purdue Pharma's manufacturing sites now have as many as 200+ workflows active at any time, with completion of workflows averaging between one and one and a half months. This equates to the company doing five times as much work as it did previously, without having to increase headcount.

As an added benefit, Purdue Pharma's use of QUMAS completely eliminated the need to ship approval forms via Federal Express, generating an operating cost savings of approximately \$18,000 annually. QUMAS DocCompliance gives Purdue Pharma a Closed-Loop Compliance™ solution, enabling end-to-end compliance with automated document tracking and workflow, and integrating the entire process into other activities vital to meeting regulatory requirements. Kenney comments, "QUMAS DocCompliance ensures a high level of control and understanding over our drug development and manufacturing processes. Our ability to quickly and automatically generate audit trails and other control documents greatly impresses outside auditors."

"Our biggest takeaway," said Kenney, "is the fact that we bought not just what we needed then, but what we anticipate needing in the future. Unlike many software purchases, DocCompliance software won't become obsolete as our requirements change. By combining core functionality with flexibility, we meet today's regulatory requirements and can adapt to tomorrow's changes." Continued Kenney, "There are also a few tactical things to consider. These include the need for an audit trail – does it include a print trail? and the level of granularity you need in your permissions." As other companies are moving towards electronic document compliance, Purdue Pharma is now ahead of the regulatory mandates and confident it can remain compliant while continuing to innovate.

About QUMAS

QUMAS is a leading developer of enterprise compliance management solutions designed to help life sciences organizations meet industry and government standards for 21 CFR Part 11, cGxP, Quality, Regulatory Affairs and Clinical Operations. With over a decade of experience, QUMAS is helping companies accelerate business processes, reduce costs and improve quality. From content lifecycle management, business process and change management to reporting and analysis, QUMAS' Compliance Suite is successfully enabling global life science organizations to proactively manage their regulated content and processes in a secure and compliant way.

For more information visit
<http://www.qumas.com>

NORTH AMERICA

QUMAS

66 York Street
Jersey City NJ 07302

P: 973 805 8600
800 577 1545 [sales]
F: 973 377 8687

EUROPE

QUMAS

Cleve Business Park
Monahan Road
Cork
Ireland

P: +353 21 491 5100
F: +353 21 432 0394

www.qumas.com