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CASE STUDY

Implementing an electronic document, business process and training management solution to increase efficiency across the organization

Accessing the correct information and harmonizing processes at a corporate level while ensuring ISO and GxP compliance is a priority for Septodont. Faced with the challenges of international regulatory alignment and the inefficiencies associated with a paper-based quality system, Septodont recognized the need for an electronic Quality Management solution. Automating the system would allow the company to manage publications, approval cycles and document sharing while streamlining processes. Septodont selected commercial, off-the-shelf Quality Management software that appeared to be easy to implement, simple to use and cost effective. However, the system they selected proved to be the complete opposite and was not flexible enough to meet the company's requirements. If fact, the workload of the quality team had doubled as they struggled to manage the software implementation while continuing to deal with their paper system. This resulted in increased costs and underscored the need for a long-term solution that was much easier to deploy while still ensuring compliance with all requisite regulations.

About Septodont

Septodont is an independent French pharmaceutical and medical device company that is recognized as the world leader in Dental Pain Management. Since its inception in 1932, Septodont has developed, manufactured and distributed a wide range of high quality dental products. With over 1,700 employees, Septodont is dedicated to serving the pain control, endodontics, restorative dentistry and infection control needs of dental professionals in more than 150 countries.

Project: Implement a single solution to support both Quality and Regulatory operations

Following the failed QMS project, Septodont evaluated several different alternatives for managing Quality documentation and processes. After much analysis, they selected Ennov due to its elegant and intuitive user interface, comprehensive functionality, support for regulatory requirements (i.e. FDA's 21 CFR Part 11) and ease of configuration. The choice, in hindsight, was a very wise one. Within one year, a single Septodont employee, with no IT skills, successfully implemented Ennov's electronic document and business process management software for their Quality organization. Soon after, at the request of their CEO, Septodont embarked on additional projects to implement Ennov's training module for Quality documentation and the automation of the Change Control process. User adoption of the system was rapid and complete. Ennov now manages over 12,500 Quality documents across multiple geographies and languages and has been instrumental in the elimination of paper documents and the thousands of hours of effort required to manually manage and track them. The success of the Quality Management project caught the attention of Septodont's Regulatory organization who were looking for a solution to help manage submission related documents and Marketing Authorization Application (MAA) dossiers. Ennov is now used across the company to help Septodont get their products to market faster and ensure regulatory compliance while saving time, effort and money.

"With more than 1,500 MAAs in 150 countries, we face a real productivity challenge. With Ennov we have been able to issue 400 dossiers in just 18 months. For the first time, our users are experiencing tremendous time savings when locating documents."

Aurélie Becquet
Regulatory Affairs
Septodont

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Within a year, a single person with no IT background implemented a company-wide electronic document and business process management system.

Conclusion

- **Return on Investment:** The work of the Quality team was extended to the Regulatory organization to improve operational efficiency and increase productivity.
- **Risk mitigation:** Physically routing paper docu-ments between sites introduced the potential of loss or damage to critical records. Electronic doc-uments and workflow processes are more secure and easily tracked.
- **Operational efficiency:** Timeline control has streamlined processes with the average change control duration reduced from weeks to days.
- **Personal productivity:** Submission related docu-mentation is growing on average at 20% a year, while staff count has remained constant for 3 years.