

Case Study

How Septodont turned a quality software into a company-wide EDMS and workflow solution, maximizing its ROI.

Challenge and Need: Starting Over a Bad Experience

- Being ISO and GxP compliant is mandatory
- Compelling need to monitor and manage quality documentation already identified => INQA (a quality software on the market) was implemented
- Too stiff, not fully 21CFR compliant, it was not being used as it should be => a double workload for Quality people: administering the software + dealing with paper in parallel
- As a consequence, costs were increasing, not decreasing
- Urgent need to find a long-term solution



ABOUT SEPTODONT

Since its inception in 1932 Septodont has developed, manufactured and distributed a wide range of high quality products for dental professionals. Today, the company employs over 1,000 people. It has six manufacturing plants in France, North America and India, and an international distribution network that is dedicated to serving the needs of dental professionals in more than 150 countries.

Project: EDMS, Workflows, Regulatory documentation

- **Quality documentation** management quickly reached complete user adoption: 7 years after implementation, Ennov manages over 12 500 documents in the different sites and languages.
- Septodont then automated the **Change Control process**, which entirely freed the dedicated staff from quality that dealt with the sequential paper process validations.
- Configuring Change Control was very easy. The real challenge was change management. It took time and energy to have people understand the real benefits of BPM, but resulted in a flood of needs that could not all be handled.
- When a project to electronically manage and submit **MAA dossiers** emerged, Ennov was the obvious solution, as many documents involved were already managed within the EDMS. The resulting solution is « so obvious » that users just love it and spend half the time assembling and publishing a dossier.

Within a year, a single person, with no IT background, implemented a company-wide EDMS and workflow system

Conclusion

- **#1** An excellent ROI: the Quality team **saves a full-time job**. All employees save at least 1 hour a week, just because they find information a lot more easily.
- **#2** Risk reduction is highly appreciated: paper losses were experienced from time to time (once a complete batch of commercial documentation has been lost between two sites). **Processes are secured**: one knows exactly who is doing what.
- **#3** Operational efficiency has dramatically improved thanks to deadline control: average change control process duration **dropped from several weeks to a couple of days**.
- **#4** **Personal productivity has risen significantly**: submission related paper work is growing on average at 20% a year, while staff count has remained constant for 3 years.

« With more than 1 500 MAA in 150 countries, we face a real productivity challenge. **With Ennov We have been able to issue 400 dossiers in 18 months.** Our users experience for the first time tremendous time-savings in looking for documents. »

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