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CASE STUDY

Effectively Managing Regulatory Information for a Growing Global Product Portfolio

Fast growth and increasing complexity in the regulatory environment were the catalyst behind Aguettant's search for a Regulatory Information Management (RIM) solution. Although they are a relatively small company, Aguettant markets a broad portfolio of over 250 essential medicines in over 60 countries with a corresponding inventory of over 300 marketing authorizations. Because of their size, agility, responsiveness and operational efficiency had become increasingly important to remain competitive in the markets they serve.

Aguettant recognized that implementing a RIM solution would save a significant amount of time and resources required to perform various Regulatory activities and could result in a return on investment of over 700%. As a result, the company embarked on a project to identify and select the most appropriate solution to help them achieve their three primary objectives:

- Provide a comprehensive, structured and centralized repository for product registration information.
- Plan, track and analyze all regulatory, market access, pharmacovigilance and advertising activities to effectively streamline the lifecycle management of their products.
- Prepare the organization for ISO IDMP.

AGUETTANT
MÉDICAMENTS
ESSENTIELS

About Aguettant

Laboratoire Aguettant is an independent French pharmaceutical company dedicated to the development, industrial production and distribution of innovative injectable pharmaceutical specialty products. They are dedicated to the development and the commercialization of essential hospital medicines mainly in movement disorder & Parkinson disease, critical care, anesthesiology and parenteral micronutrients. Aguettant operates in 60 countries and employs more than 500 people.

The Solution: Joint Development of Ennov RIM

Commercially available RIM software offered adequate coverage of Aguettant's requirements but none offered the flexibility in data modeling or workflow necessary to meet the company's current and future needs—specifically the ability to delegate part of the follow-up activities to an external regulatory partner or offer control to a subsidiary to better address local regulatory requirements. For Aguettant, this flexibility was seen as a critical success factor—but one that presented a challenge for solutions designed with only central control over the activities in mind.

A year before initiating their RIM project, Aguettant completed its roll-out of their Ennov Regulatory solution, implementing Ennov Doc, Ennov Process and Ennov Dossier worldwide. The system was quickly configured to meet Aguettant's requirements and support their organizational structure. Two years later, the system was ensuring day-to-day regulatory compliance through efficient management of documents, CAPAs, customer claims, audits and change controls. It was this initial success that led Aguettant to consider the possibility of collaborating with Ennov in the co-development of their RIM solution.

In this unique partnership, Aguettant committed to provide business expertise and design feedback while Ennov committed to developing an off-the-shelf RIM solution that would be supported as a new module in the Ennov Regulatory suite. As a result, Aguettant and Ennov succeeded in getting the solution ready for launch in less than one year. The system is now being used by more than 400 employees worldwide to manage Aguettant's expanding product portfolio.

Aguettant's co-development partnership with Ennov resulted in a win-win scenario for both companies

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Conclusion

- **Increased Productivity:** 400 global users have easy access to relevant and up-to-date regulatory information resulting in tremendous time and cost savings.
- **Enhanced Compliance:** Data integrity is enforced as relevant changes are cascaded throughout the system. The system is ISO IDMP ready.
- **Secure Market Opportunities:** Planning is controlled, deadlines managed and the Market Authorization is secured. Easy reporting provides visibility into risk areas, unfulfilled obligations and possible compliance gaps.
- **Optimized Time to Market:** Quick and easy reuse of approved documents decreases submission cycle times. Immediate access to trustworthy information helps subsidiaries, manufacturing and commercial operations eliminate bottlenecks and accelerate overall time to market.