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Case Study

Challenge and Need: Aligning regulatory activities to strengthen Aguettant's competitive position

Fast growth and increasing complexity in the regulatory environments gears Aguettant toward to actively seeking for a Regulatory Information Management System.

Although a comparatively small piece in the pharmaceutical field, Aguettant provides a wide and deep mix of 250 essential hospital medicines in over 60 countries, for a total portfolio of 300 marketing authorizations. Agility and responsiveness and operational efficiency are increasingly vital factors to the competitiveness of the company on all markets.

Missing an MA renewal or retaining a batch for a lack of information about its regulatory status is not an option. Through major studies in the field, Aguettant noticed that setting up a RIM system might pay up to 7 times for itself in terms of time savings on various types of activities. As a result, it urged the company to seek and select the most appropriate solution.

Project: After a first rewarding experience, Ennov is the choice of trust and flexibility

Aguettant had three main objectives:

1. **Provide a structured, complete and centralized repository for product information;**
2. **Plan, track and analyze all regulatory, market-access, pharmacovigilance and advertising activities in order to effectively streamline the whole life-cycle of medical specialties; and**
3. **Be IDMP ready.**

Major RIM softwares on the market offered adequate coverage but none offered the flexibility in data modeling or workflow that was necessary to match the company's current and future challenges: What if we want to delegate part of the follow-up features to an external regulatory partner? or to offer local control to a subsidiary, in respect of global policies? Flexibility was a critical success factor. Moreover, this was obviously too challenging for solutions that have been designed with only central control over the activities in mind.

A year before Aguettant completed its roll-out of the Ennov solution, implementing EDMS, workflow and eCTD publishing tools worldwide. Very quickly the system was configured to fit Aguettant's needs and organization. Within two years it helped day-to-day compliance through efficient monitoring of documents, CAPAs, customer claims, audits and change controls. A real hit, that led Aguettant considering the possibility of collaborating with Ennov in the RIM project.

AGUETTANT
ESSENTIAL
MEDICINES

ABOUT Aguettant SAS

Laboratoire Aguettant SAS is a pharmaceutical company dedicated to the development, manufacturing and commercialization of essential hospital medicines. Its expertise in developing innovative injectable drugs makes Aguettant a duly recognized player in critical care, anesthesiology, micronutrients and neurology.

The company has a strong commercial infrastructure in Europe through its subsidiaries and operates in 60 countries through its international distributors. Aguettant employs more than 500 people for an approximate $110M turnover, that has experienced a 26% growth over the three last years.

Partnering efficiently in a win-win project

Even if the RIM solution was on Ennov's roadmap it was not ready yet by that time. Nonetheless the guiding principles of the whole Ennov suite, ie open standards, no IT skills needed to configure and implement the software, true flexibility to fit any company's organization and needs, were so convincing to Aguettant that both companies agreed to enter into a co-development project of the RIM solution.

Aguettant committed to provide business input and feedback, Ennov committed to design an off-the shelf solution that would be supported as a new module of the Ennov suite. Thanks to a close collaboration the Aguettant Project Leader, Cyrille Jeune, and the Ennov Product Manager Pierre Stanislawski, succeeded in getting the RIM solution ready for launch within a year.

Within two years, 14 workflows have been implemented, more than 50,000 forms initiated, 23,500 documents made accessible in their up-to-date version to 400 employees worldwide, and 300 marketing authorizations dossiers published on each year.

Conclusion

- **#1 Increased Global Productivity**
  40 participants in the regulatory process and 360 read-only users have an easy access to relevant and valid information, resulting into tremendous time savings.

- **#2 Heightened Compliance**
  Data governance is clarified as one modification is reflected in all associated documents and activities. The system is IDMP ready: whenever the new ISO Identification of Medicinal Product standard is released, Aguettant will be able to export its product portfolio in an adequate format.

- **#3 Secured Market Opportunities**
  Planning is under control, deadlines managed, and MAA secured. Reporting can easily be performed, allowing real-time overview of risky areas, unfulfilled market opportunities or compliance gaps.

- **#4 Optimized Time-to-Market**
  Quick and easy re-use of approved contents make Regulatory Affairs teams significantly lower their time-to-submit. Immediate access to trustable regulatory information enables subsidiaries, manufacturing departments or even commercial agents activate their daily operations. Eliminating bottlenecks accelerates the overall time-to-market.

« It's really nice to work with a software publisher that shows a great deal of innovative spirit, has great ambitions and is proactive. Above all, I really appreciate Ennov placing particular emphasis on the listening experience of the customer.»

Cyrille JEUNE,
Aguettant Project Leader

Cloud-based or On Site

Multi-Platform

ISO IDMP ready