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Ennov Powers Pharma IT's EDMS+QMS Solution for Life Sciences

Within the Pharma, Biotech and Medical Device industries, implementation and maintenance costs of IT Systems are often overwhelming for small and newly-founded companies (less than 50 employees). Beyond the upfront and recurring costs, companies must also commit to a solution that can evolve in parallel with their business. Specifically, the platform must be able to provide scalable performance with growing quantities of users and data, or allow the adoption of new applications to meet their evolving business needs (EDMS, RIM, etc.).

In addition to the financial and performance considerations, companies must also contemplate data ownership when deciding whether or not to commission a CRO.

Pharma IT

About Pharma IT

Located in Copenhagen, Pharma IT is a consulting firm that acts as a one-stop shop for pharma consulting. Pharma IT serves the Pharmaceutical, Biotech and Medical Device Industry with expertise in: IT consultancy, Drug and Medical Development consultancy, and IT solutions, among others. Founded in 2016, the company has enjoyed rapid growth with over 90 employees and clients across the Nordics.

> More than 450 Life Sciences companies around the world are powered by **Ennov**

The Project: Small Biotech Companies Need a Solution that is Accessible and Scalable

Pharma IT's Founder and Managing Director Jakob Juul Rasmussen had three objectives:

› Offer a service that is accessible to small and mid-size life science companies

› Provide a comprehensive software suite with a single information repository

› Deliver a fully scalable solution with seamless interoperability

For this unique business model to succeed, Jakob needed to not only identify a platform that met these criteria, but also find a company that was flexible and creative enough to see the potential in such a collaboration.

Major software vendors serving the life sciences market offered adequate functional coverage but were either unwilling to see the potential in Jakob's vision, or were unable to supply a solution that leverages a single repository across all domains. Flexibility was a critical success factor. The guiding principles of the Ennov suite were also defining elements, for example: intuitive implementation and configuration, flexibility to quickly fit any company's needs, and state-of-the-art technology that is secure, stable, and remarkably usable. Moreover, a single repository solution was necessary as it allows clients to expand, both in data quantity and functional diversity.

This partnership allows for the Pharma IT Cloud service to implement Ennov's platform and offer clients EDMS and PV systems while assuring GxP compliance. Pharma IT has interpreted the DIA reference model to curate best practices that are easily implemented and adaptable to client needs. Additionally, this service dramatically lowers the upfront software and maintenance costs. While Pharma IT manages initial configuration and onboarding, clients remain the sole owners of their intellectual property, removing the need for third-party data managers. Finally, it enables small and mid-size companies to implement electronic business processes without the risk of non-compliance.

Pharma IT decided to move forward with the Ennov platform in January 2021. The system was swiftly configured to fit Pharma IT's vision and prepare for client onboarding in under three months. In June the platform was live with 3 clients and over 100 users. Beyond cost-efficiency, rapid system deployment and training means clients benefit from a faster return on investment.

> *"What sets Ennov apart is the unified database. You could integrate your eTMF with your clinical database and submission documents because the data is all in one place."*

Find more Case Studies at
www.ennov.com/insider

Ennov Partnership with Pharma IT provides a full pharma-focused solution that responds with a single repository platform. This project resulted in an intuitive and accessible yet scalable path to compliance.

Conclusion

Less than a year into the project, the successes of this partnership speak for themselves. Looking beyond the current network of Ennov users, Pharma IT is preparing to onboard a number of new clients. By offering a service that is preconfigured to industry requirements, Pharma IT directly fulfills a great unmet need in the market.

› **Strategic Partnership:** Choosing to collaborate with Ennov was a strategic decision for Pharma IT as it permitted the service of providing a trustworthy and secure full pharma solution to clients. This allows for efficient and accessible implementation and maintenance.

› **Risk Mitigation:** Clients that benefit from the platform are able to utilize electronic document and workflow processes. Digitization eliminates the loss or damage to critical records.

› **Heightened Compliance:** Data governance is maintained 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 required, users will be able to export its product portfolio in an adequate format.

› **Scalability:** As clients look to expand their product portfolio, the Ennov system is able to expand in parallel to support business growth.

About Ennov

Ennov offers a unified compliance platform to power solutions that span all regulated business areas (Regulatory, Quality, PV, Clinical, Commercial). From leading pharmaceutical companies to start-up biotechs, we proudly serve over 450 companies and 500,000 users worldwide.

For more than 25 years, we have been developing innovative, powerful and easy-to-use software for regulated content, data and process management. Our solutions are designed and built to support the entire Life Sciences R&D continuum. Ennov is ISO 9001 and 27001 certified for all software products and processes, and we boast a 100% success rate in customer audits.

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