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Implementing a Total Quality Management Solution to Become Paperless and Unify the Organization

Pharmacosmos, like many companies, were relying on manual, paperbased systems to manage GxP and non-GxP documentation, training records and Quality processes including Change Control, Deviations, CAPAs, Product Complaints and Audits. In an effort to modernize, they embarked on an initiative to identify and implement a single electronic system that would address all of their needs while providing global visibility into the status of their Quality program.

Pharmacosmos felt the new system had to be comprehensive—it must support the management of both Quality documentation and processes. The system must fulfill GxP requirements as well as those of FDA 21 CFR Part 11 while providing fully compliant electronic signatures. Data integrity, security and access control were also considered key capabilities of the system. Finally the system had to be highly configurable and easy to implement and validate. Pharmacosmos was looking for a software vendor with deep pharmaceutical industry experience, a history of fulfilling customer requirements, an efficient professional services organization and a robust technical support staff. Following the issuance of an RFP and a vendor evaluation period, Pharmacosmos selected the Ennov Quality Suite consisting of Ennov Doc, Ennov Training and Ennov QMS to achieve the digital transformation of their GxP compliance organization.

PHARMACOSMOS

About Pharmacosmos

Headquartered in Denmark, Pharmacosmos is a family-owned, international healthcare pharmaceutical company with more than 50 years of innovation and leadership in iron and carbohydrate-based solutions and treatments for animal and human patients suffering from iron deficiency and anemia.

Pharmacosmos has subsidiaries in US, UK, Ireland, Germany, China, Sweden and Norway and its products are marketed in more than 80 countries around the world. Its manufacturing facilities are approved, among others, by the Danish Medicines Agency and the US FDA.

> ❯ More than 300 Life Sciences companies around the world are powered by **Ennov**

The Solution: The Ennov Quality Suite

Pharmacosmos identified three primary criteria that would determine whether the implementation of their new QMS would be a success. First, the software must be capable of fulfilling all of their user requirements. Secondly, the software must be accepted by the users and the organization had to demonstrate a willingness to use the system. Finally, the system had to be successfully validated while maintaining the implementation schedule. Ennov was able to meet all of these criteria through a combination of clearly defined customer requirements, a well prepared system design and configuration and a skilled and experienced implementation team.

Pharmacosmos now has a common eDMS (Ennov Doc for Quality) for SOPs and other types of GxP-related documentation with easy versioning and electronic signatures. They also have a common global training system (Ennov Training) for SOPs training where it is now possible to have full visibility into the training status of all employees.

"The old manual training system consisted of various paper or Microsoft Excel/Word forms with handwritten signatures," says Flemmimg Simonson, Director, GxP System Compliance at Pharmacosmos. "Compared with similar implementations at other companies, Pharmacosmos is the first company where colleagues were excited about the new electronic system before it was even in use. Even after go-live the excitement remains, as we now have the ability to do everything fully electronically."

> *"We are very excited having implemented our new electronic document and quality management system using Ennov throughout Pharmacosmos. It makes our daily handling and signing of documents much faster, reduces the use of paper and eliminates signing documents by hand."*

Flemming Simonsen
Director, GxP System Compliance
Pharmacosmos

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The Ennov Quality Suite provides Pharmacosmos with a global, modern and fully electronic Quality Management solution that meets all of their key requirements

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Conclusion

› **Fully Paperless Process:** Ennov's Quality Suite replaced a manual process that relied on paper, MS Word and Excel forms that required handwritten signatures and hardcopy archives.

› **Global Visibility:** Ennov Doc for Quality and Ennov Training are used in combination to control SOPs and manage training records globally—increasing visibility and reducing the risk of non-compliance.

› **Fulfilled Customer Requirements:** Ennov's ease of configuration combined with an experienced and skilled project team ensured all user requirements were considered and implemented as specified.

› **High User Adoption:** Pharmacosmos' user community are very enthusiastic about replacing their old manual process with their new fully electronic QMS.