



Platina QMS

by Formpipe

Enhanced efficiency with Platina QMS



"We saw that we could streamline the paper-based process by making it electronic."

Kemwell

KEMWELL

The benefits for Kemwell of working with Platina QMS

- More efficient and improved processes and documentation management.
- Electronic quality processes allow users to quickly identify who has the authority to do what and to determine whether documents have been read and electronically signed.
- Simplified prioritisation and shorter processing times, thanks to an improved overview of the matter at hand.
- Quick administration of management documents.

Kemwell offers contract manufacturing of pharmaceutical products for global distribution. The company manufactures pharmaceuticals for five of the world's ten largest pharmaceutical companies, including GlaxoSmithKline, Johnson & Johnson, Novartis and Pfizer. The Group has more than 1,000 employees and seven production facilities, of which five are in India and two in Sweden (Uppsala). Kemwell is an approved pharmaceutical manufacturer for countries over the entire globe, including the American, European, Japanese and Indian markets. Kemwell has implemented Platina QMS in order to improve its documentation and case administration.

Within the pharmaceuticals industry, a large number of written instructions are used to describe how the various work stages and processes are to be executed in a uniform manner. The purpose of these instructions is to facilitate management and monitoring, and to ensure that the quality of the production is sustained. There are, for example, processes for handling deviations and for ensuring that preventative measures are implemented to avoid the repetition of such deviations. Kemwell previously used a number of entirely separate systems for quality control, both IT-based and manual, paper-based systems.

The handling of these types of processes takes a long time and cGMP (Current Good Manufacturing Practice) regulations place increasingly high demands. In order to improve the efficiency of the processes, Kemwell decided to automate the documentation management and work processes. Kemwell wanted an IT system that could manage documents and work flows and which would be easy for everyone in the organization to use. Furthermore, the company required that the system was to comply with cGMP regulations, including the demand for electronic signatures. Yet another requirement was that the system should be able to support other, future processes, for example, incident reporting, suppliers' contracts, help desk functions and project documentation.

"We understood that we could improve the efficiency of our administration by moving from a paper-based system to an electronic system. In doing so, we would have, for example, immediate access to documentation of equipment and processes, and we would be able to further develop our improvement activities with the possibility to quickly identify deviations in a particular machine, or by producing key ratios for our quality processes," states Katarina Holmström, Senior Quality Professional at Kemwell.

Formpipe.

About Kemwell

Kemwell is a leading provider of contract manufacturing and development services for pharmaceutical products globally.

The company was founded in 1980 and has its corporate headquarters in Bangalore, India.

With operations in India, USA, and Sweden, Kemwell supports companies from early drug development through commercialization, and delivers to over 80 countries worldwide.

The company manufactures pharmaceuticals for five of the world's ten largest pharmaceutical companies, including GlaxoSmithKline, Johnson & Johnson, Novartis and Pfizer.



Formpipe.

Swedish Office
+46 70 515 30 56
info.se@formpipe.com

UK Office
+44 78668 42978
info.uk@formpipe.com

US Office
+1 678 938 0957
info.us@formpipe.com

www.formpipe.com/lifescience



that the personnel concerned have either read the instructions, or have received training in the work processes, including the instructions. This is traditionally a time-consuming activity, time which could be better spent elsewhere in the business.

The solution

Platina QMS proved to be a system which met Kemwell's requirements and wishes in full. By conducting the quality processes electronically, it is possible, for example, to immediately identify who has the authority to do what and to determine whether documents and instructions have been read and electronically signed, with full traceability. During 2011, Kemwell has worked to complete the final stages of the implementation of Formpipe's product, which has been specially developed to meet the requirements of life science.

"All in all, a good IT support system means we can quickly and easily produce information which fully indicates that we have control over our processes and that our personnel have the right training for their duties, regardless of whether the request for information comes from us, our clients or a supervisory authority. Not only that, but we are also able to access, update and administer management documents much more quickly," concludes Katarina.

Control of specialist skills

Many activities in work processes require specialist skills, which need to be documented. These include instructions for everything from how to clean a particular machine to a list of all of the steps which need to be controlled before a product leaves the factory and is released on to the open market. Instructions must be kept up to date and, to ensure the proper execution of the activities, there must be confirmation

Formpipe.