ONE OF AUSTRALIA'S LARGEST PHARMACEUTICAL GROUPS PHEBRA CHOSE MAINPAC FOR ITS ASSET MANAGEMENT REQUIREMENTS

Overview

Phebra is one of Australia's largest privately-owned pharmaceutical groups, with a manufacturing facility in Sydney which develops, produces, and markets critical medicines in Australia and across the world. Since 1993, Phebra has built a reputation for innovation, product development, and manufacture of over 65 medicines in critical therapeutic disease areas such as cystic fibrosis, antidotes, diagnostics, oncology, and pain. Being dynamic and innovative, Phebra collaborates with healthcare providers to research, develop and produce critical medicines to meet unmet needs.

Challenge

Phebra was previously using a scheduling tool for managing maintenance of operational assets but required a more effective overall package offering greater functionality that met 21 CFR Part 11 compliance.

This compliance is part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) in regulations on electronic records and electronic signatures. The term "Part 11" applies to records in electronic form that are created, modified, maintained, archived, retrieved, transmitted, or submitted, under any records requirements set forth by the FDA regulations/predicate rules.

Life science organizations and device manufacturers including Phebra, regulated by the FDA are required to follow the Code of Federal Regulations Title 21 Part 11.

Solution

Mainpac offered a solution that met the Goods Manufacturing Practice (GMP) requirements offering security features, audit trails, safe storage of historical data, and reporting features. This included capabilities designed for documents and approvals regulated by 21 CFR Part 11. In addition, Mainpac provided ongoing support throughout the validation process. Phebra chose Mainpac EAM to manage operational assets, maintenance scheduling, ad hoc work orders, and external work requests generated from other departments internally.

Results

Phebra now has a GMP compliant software package to manage scheduled maintenance and work orders in a secure environment with the ability to run various reports and track maintenance history of individual assets.

"We chose Mainpac because they could provide an overall solution to meet our GMP requirements. Competitive ongoing costs and local support were also a deciding factor." Phebra stated.

In the future, Phebra plans to expand the use of Mainpac solutions to utilize the spare parts module and work order workbench.
Pharmaceutical manufacturers can make technology investments that support their current workflow and set them up for future growth—while choosing tools meeting requirements for regulatory compliance.

Contact us!

Ready to improve the reliability and performance of your assets? Stop wasting time and money on an asset management. Let's get started, talk to a solution specialist today

info@mainpac.com