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Mainpac Pharma Module

Painless support for FDA-compliant maintenance practices in the pharmaceutical industry



Pharma continues Mainpac's commitment

Mainpac Pharma is designed to support growing globalisation in the pharmaceutical manufacturing industry by ensuring maintenance and asset management functions meet the stringent requirements set by the world's leading regulatory bodies. Mainpac Pharma reflects Mainpac's long-standing commitment to leading pharmaceutical manufacturers. The module embodies the functionality deemed essential by the pharmaceutical industry's leading consultants and is based on a resilient and solid technology platform. In the hands of your operations and maintenance staff, Mainpac Pharma simply extends the range of benefits that our customers have come to associate with the Mainpac product suite over many years, adding to these benefits to address the challenges of today's pharmaceutical manufacturing industry.

Meeting the demands of a global market

The growing pace of globalisation and international trade has focused the regulatory spotlight on the pharmaceutical manufacturing industry like no other. Many countries require pharmaceutical manufacturing facilities to be approved before allowing product from those facilities to enter their country. Major approval authorities include the FDA (USA), the MCA (United Kingdom), the HPFB (Canada) and the TGA (Australia).

In the past manufacturers relied on paper records documenting the processes, testing methods, training

and related issues surrounding and including the Good Manufacturing Practice (GMP). From now on, manufacturers that operate under such authorities must meet requirements defined in the FDA's benchmark Code of Federal Regulations (CFR) Part 11, where computer systems are used to maintain records.

Documentation of all processes that support the manufacturing of the product, specifically the maintenance of electronic records and validation of electronic signatures, is a key aspect of the CFR Part 11 and derivatives thereof in other countries.



Benefits in Three Key Areas

Compliance with enhanced security provisions and the authentication of changes to records that effect the Good Manufacturing Practice (GMP) are key requirements of the Part 11 regulations.

This means that additional system controls are required when making changes to the planning and scheduling of maintenance and calibration activities.

The objective is to ensure the consistency of the manufacturing process in the interest of public health and safety.

Mainpac's Pharma module overcomes the need for time-consuming, error prone manual procedures to deliver benefits in three key areas

- greater security meaning better control of user access to the system
- authentication of changes to GMP
- audit trail – online saving of changes to records and no need to manually keep a record of how maintenance is being managed

Current users of Mainpac will enjoy the same look and feel with Mainpac Pharma without the need to re-train staff. Those new to Mainpac can look forward to significant streamlining of maintenance practices and reporting.

Designed by experts to underpin the industry standard

Mainpac's Pharma module was developed to underpin our long-standing reputation as the 'industry standard' maintenance system for pharmaceutical companies.

Mainpac engaged the skills of the industry's leading specialists in regulatory requirements and information systems as a precursor to designing the module to meet, if not exceed the requirements of CFR Part 11. They defined these requirements which were then engineered into a powerful solution by Mainpac's design and development team.

A separate but integrated module of Mainpac, the Pharma module is not only supported under a standard maintenance agreement but upgrades to Mainpac will be incorporated into the Pharma module.

Mainpac Pharma is designed for the .NET environment and is strong testimony to the well-defined Mainpac development roadmap.

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Satisfying the Regulations

The Pharma module's comprehensive features can be divided under general, electronic record and electronic signature headings.

Electronic record features to satisfy the regulations include: record retention, audit trails, authority checks and operation checks.

Electronic signature features ensure that e-signatures are as secure as handwritten ones, that an electronic signature cannot be divorced from the record to which it was originally attached and that every e-signature must be accompanied by the full name of the signatory, the date and time of signing and the reason or purpose of the signing.

General features include: comprehensive system, code and password security; facilities to manage code and password maintenance; parameters for non-biometric security; and access to and security of the data to ensure its authenticity, integrity and confidentiality.

Your prescription for painless compliance

Find out more about Mainpac's Pharma module and you'll be taking the first step to streamlining the maintenance practices that support your company's global marketing objectives.

