Pharma & Life Sciences

BlueCielo ECM SOLUTIONS

Industry ECM Solutions

Companies in the pharmaceutical, biotech, and medical device industries are continually looking for innovative ways to bring new products to market faster. It is critical to maximize market success and lower product liabilities by reducing the risk through validation and maintaining compliance with government regulations. By keeping track of accurate engineering information throughout the organization and by making it accessible to the appropriate people, production flaws can easily be avoided.

InnoCielo Meridian Enterprise

The mission of BlueCielo ECM Solutions (formerly Cyco Software) is to provide technology, integration, applications, and services that will help organizations leverage engineering information throughout the enterprise.

BlueCielo offers best-of-class solutions for engineering, provides tight integration with related business applications (including maintenance management systems such as Maximo, Datastream, and SAP PM), and connects to enterprise systems such as Microsoft SharePoint and SAP.

InnoCielo Meridian Enterprise (formerly AutoManager Meridian) with the FDA Module is an out-of-the-box business solution that manages current good manufacturing practices (cGMP) engineering documentation throughout the enterprise. The module also adds specific features to the core data management engine that help minimize risk, ensure compliance, and avoid costly recalls.

The module was developed using standard IT practices and is based on integration with leading technology platforms. BlueCielo's engineering content management (ECM) solution supports regulations such as FDA 21 CFR Part 11, European Annex 11 of the EU Guide, and the Sarbanes-Oxley Act.

Industry-Specific Advantages

FDA 21 CFR Part 11 Compliance

InnoCielo Meridian Enterprise and the FDA Module fully support 21 CFR Part 11 by providing the necessary technical controls.

Part 11 enables pharmaceutical companies to handle electronic records equivalent to paper records and handwritten signatures. The rule applies to all industry segments regulated by the US Food and Drug Administration and includes good laboratory practices (GLP), good clinical practices (GCP), and current good manufacturing practices (cGMP).

The regulation establishes requirements to ensure that electronic records and signatures are trustworthy, reliable, and generally equivalent substitutes for paper records and traditional handwritten signatures.

Secure Access to Engineering Information

The development of new pharmaceutical products is an intricate process that needs to be secure from prying eyes and malicious activity. InnoCielo also provides a "single source of truth" – a central, secure repository with exact roles and privileges for authorized users.

All security rules, such as notification, inactivity period, separate application login and electronic signature passwords, password length, rotation, expiration, and number of retries can be configured and are audited.

Lifecycle and Validation Documentation

It is mandatory in a highly-regulated environment to validate your IT systems and provide the appropriate documentation indicating that the system was tested and meets user requirements as well as the system specifications.



Electronic Signatures

InnoCielo Meridian Enterprise with the FDA Module provides the ability to configure the types of documents and workflow transitions that require electronic signatures from authorized users.

The user is prompted for the required username and password, and the action is logged to the application's audit trail. Users can delegate the signing task to other authorized users. Invalid signing attempts are logged to the audit trail and the system administrator is subsequently notified. Document status is automatically tracked as well as signature approvals.

Upon a successful signing, the appropriate metadata is updated, and the signature information, including the user's full name, current date and time, and reason for the signature are embedded within a PDF rendition of the document. Additionally, a signature page can be configured with the same information.

Controlled Printing

InnoCielo Meridian Enterprise offers organizations that follow cGMP practices a way of controlling printed documentation. Printed documents contain clearly visible banners that indicate the restrictions on the use of the document. The banners can be placed within the headers or footers of documents.

What Customers Say

PDL BioPharma, Inc (PDL) chose to implement the InnoCielo Meridian Enterprise pharmaceutical module. Based in Fremont, California, PDL is a biopharmaceutical company focused on the research, development, and commercialization of novel therapies for inflammation and autoimmune diseases, acute cardiac conditions and cancer. The company selected InnoCielo Meridian Enterprise with the FDA Module from BlueCielo as the best solution to help them achieve FDA compliance with 21 CFR Part 11.

Major Benefits

InnoCielo Meridian Enterprise's integrated solution for pharmaceutical companies provides the following benefits:

Improve Compliance Effectiveness

When using engineering content management solutions by BlueCielo, companies can automatically incorporate greater control in their document handling and administration, minimizing risk and reducing the number of errors.

Reduce Validation Effort

Based on experience and implementations around the world, InnoCielo's out-of-the-box, industry-specific FDA Module includes features that are proven and tested.

Improve Document Workflow Throughout the Enterprise

InnoCielo Meridian Enterprise provides secure access to current (as-built) engineering data and other technical documentation throughout the enterprise. By enforcing an automatic workflow, efficiency of design, production, and maintenance operations is increased.

Lower Cost of Ownership

By using InnoCielo you can dramatically enhance the return on investment of your existing IT infrastructure.

Your Bottom Line

With InnoCielo and the FDA Module industry template for the pharmaceutical, biotech and medical device industries, companies can bring products to market faster. This will boost revenue and reduce costly errors while fully complying with FDA 21 CFR Part 11 and other governmental regulations.

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