



Artwork Management System

Increasing efficiency and securing quality in the supply chain of printed packaging material.



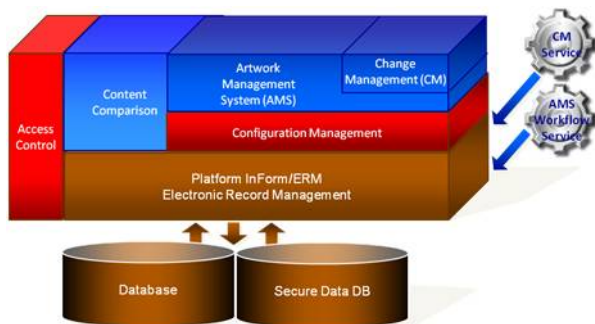
Within the line of artwork management, there are often challenges in setting up a comprehensive environment that will cover various life-cycles which often apply to artworks for printed material. Change review processes, access control and work assignments can be sufficiently different depending on the artwork at hand.

Also in the regulated industry, authorities and quality standards define high demands on how records such as files and information are stored and maintained in electronic archives. The archiving system must comply with requirements for audit trail, electronic signatures, version control etc.

The Artwork Management System developed by InformaIT is a web-based multi-user system with complete features for secure storage, change review procedures, electronic content comparison, and aligned access control, all to be applied on artworks for printed material. Its solution is based on a standardized platform with a globally accessible repository where resources easily can be reached, no paper copies needs to be sent, and all annotations, proofreading and approval is carried out through the electronically stored original. And to meet the demands of the pharmaceutical industry, the system is developed in compliance to GMP standards.

INTEGRATED ARTWORK MANAGEMENT FOR PRINTED PACKAGING MATERIAL

The implementation of an Artwork Management System supports the complete artwork process, from change request and development to print, combining the strength of a standardized platform with powerful tools for review, version control, automated proof-reading functions, structured filing and user access. The system has configurable workflows to map the routines within an organization, speeding up the process for developing new artwork and implementing required changes. The fundamental focus lies in minimizing time to market, providing for a user-friendly well integrated solution and increasing quality within work flows of artwork management.



The AMS platform (InForm/ERM) is based on Microsoft.Net technology to provide for rapid development and low cost of ownership. A selection of several application modules generates a

complete packaged solution for artwork management. The solution is web-based for easy access to the repository regardless of geographical location.

BENEFITS WITH INFORMAIT'S ARTWORK MANAGEMENT SYSTEM

- Web-based
- Instant decision making
- Accurate electronic details
- Part 11 Compliant
- Low cost of ownership
- Faster time to market
- Validation Package included

ARTWORK LIFE-CYCLE WORKFLOW

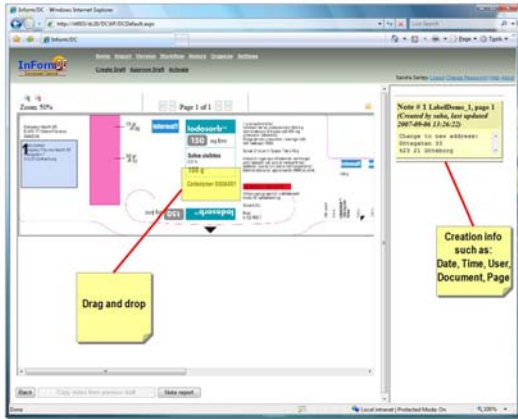
CHANGE MANAGEMENT

With the Change Management module in AMS it is possible to get a better overview of the artwork process from start to end. With the registration of a Change Request and links to related artworks, the User will from one page in the system easy see the current status; displayed with a green-, amber- or red "traffic light". The traffic lights will depend on where in their workflow the related artworks are, and if this is according to specified target dates. From this page it is also possible to run reports, e.g. Workload- and KPI reports.



WORK FILES

Artwork work files can appear in many different formats. Common file types are PDF and Word used for documents, drawings, labels, leaflets, etc. The AMS system however can handle work files of



any kind. All files are imported into the system and marked as the starting point, (manuscript) for a new artwork.

REVIEW PROOF

Somewhere in the organization, or even externally if outsourced, a graphical department is designing or modifying an artwork, creating a "Review Proof" of the new artwork to be. This proof is then reviewed by one or more users through the AMS system where any required changes are described and attached as annotations. The function for adding annotations, also called Notes, is a utility developed by InformaT and completely integrated with the AMS system.

As all annotations are stored attached to each proof, the system can maintain an audit track of all requested changes. For each new review round, new annotations can be added and previous annotations can be copied from the previous proof. All annotations are also marked with date and time of when created and with User ID for a complete trace to the reviewer.

CONTENT CONTROL

How do you know that the requested changes where made correctly, and that nothing else has been changed? For this the AMS system uses the Content Control procedure which is an electronic proofreading utility. As a new proof has been revised, the reviewer has the option of using an automated comparison tool to compare the content of the file with any previous proof or version. The user can select to compare by image, to verify graphics, or as text, to evaluate the content, selectively independent of font and style.

The comparison tool can also be used to read and compare the text from the annotations with the text on the modified artwork. This to verify that the artwork has been changed according to reviewer's notes.

The result of the comparison is displayed both graphically on screen and within a printable report including the artwork file image showing the exact location of all deviations.

VERSION MANAGEMENT

A primary feature of the Artwork Management System is the version handling which keeps track of all created drafts and versions of an artwork file.

The version management also regulates all approvals and authorizations of new artworks. A set of rules controls the flow of approval events, where it is possible to combine different user authorisation depending on the type of artwork.

WORKFLOW

The life cycle for artwork such as labels and leaflets can be complex. There are many instances involved in the process; marketing, regulatory, quality assurance, to mention a few. The traditional time-line from change request to printed material can be time-consuming, especially in global companies serving many markets

With the implementation of a Artwork Management System, the workflow configuration utility, will help you define unique business processes to manage different requirements from markets, customers, regulatory authorities, etc.

Artwork Life-Cycle Management





DELIVERY INSPECTION - RECEIPT CONTROL

As a final measure and to assure correct delivery of the printed artwork, an automated inspection can be carried out by scanning a sample of the printed material and comparing it to the authorised version stored in the electronic archive.

The comparison is performed by a sophisticated software developed by our partner EyeC who is a leading vision technology company focused exclusively on high performance inspection systems.

ORDER HANDLING

To streamline the life-cycle of an artwork even more, an optional order handling can be implemented. An authorized artwork can be linked to bill-of-materials in an ERP system, and when a production order is initiated, the correct artwork is sent from the AMS system to the print shop. The communication is carried out through a standard interface using XML and the system will then keep a history of all artworks ordered from external print shops.

GMP CONSIDERATIONS

The Artwork Management System is designed to comply with general GMP requirements for Good Electronic Record Management, and with CFR 21 Part 11 requirements for electronic signatures.

The standard software system is validated, the **Validation package is included** in the delivery. Additional validation documentation for can be delivered for IQ and customer specific OQ, and our professional services team can help with installations, implementation, validation, training and support.


“Efficient solutions for effective businesses - and the return on investments you seek,,

ABOUT US

InformaIT is a software company that combines specialist competence, market leading products, and domain specific concepts. We offer cost effective solutions and services. For a closer look at Artwork Management System and its capabilities, and for more information on our Content Compare, please visit us at <http://www.informait.com>.

For more information please contact us at

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