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USE CASE

GCI PowerTools for Life Sciences

BACKGROUND

OpenText Content Server is used by many organizations within the Life Sciences (Pharmaceutical, Biotech, Diagnostic, Medical Devices) industry for managing the documents and processes related to clinical trials, new drug development / discovery and manufacturing. Many of these processes are highly regulated by governmental guidelines such as the FDA's 21 CFR Part 11 and the EU's Annex 11. As such, the processes and tools used need to be validated and businesses are subject to regular audits from the various regional authorities.

Using a combination of GCI PowerTools and Content Server, Life Sciences companies have found a solution that is able to meet these complex business challenges through configuration alone. By eliminating the need for proprietary development, new business processes can be efficiently designed and rolled out company-wide with **significant time and cost savings.**

Managing Regulated Documents

Many Life Sciences companies use Content Server to manage their *controlled documents.* Central to effective management of these documents is the editing, approval and release process. Unlike regular business documents, controlled documents need to be developed, signed-off and published using defined and approved processes. These processes need to be followed to the letter and a full audit history showing all events and decisions must be kept. With many people involved, these processes can be long and complex, with significant time often being lost waiting for users to review documents that have been sent to them.

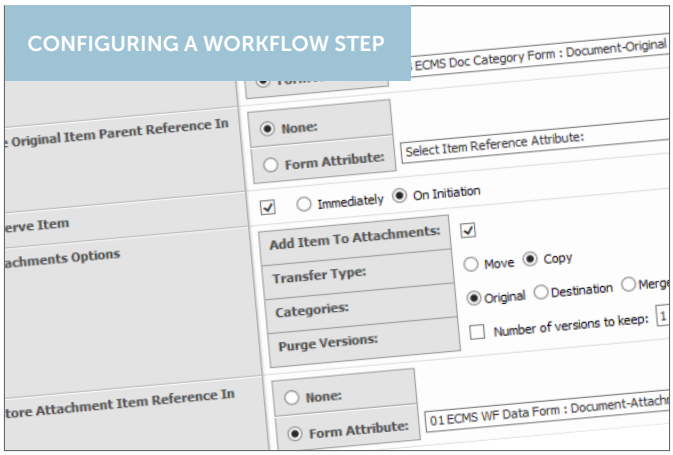
Many large Life Sciences companies have found that, through the use of PowerTools, workflows can be configured to automate large parts of this management process. Using GCI PowerTools for Workflow they have been able to optimize their business processes and remove redundancy within existing workflows. PowerTools for Workflow has enhanced their workflow designs, introducing time-saving elements such as *escalations, auto-completion, enhanced delegation, and informational notification emails.*

Controlling the Signing Process

When it comes to signing documents, there is often a dossier of items relating to a specific clinical trial or product registration that needs to be reviewed and approved as part of a single package. Many times these documents also need to be merged into a single file ready for a final signature.

By choosing PowerTools, leading Life Sciences companies are able to present multiple documents and forms for approval *within the same Content Server workflow.* Using GCI PowerTools for OpenText Electronic Signatures these companies extend the standard Content Server signature capabilities and enable approvers to approve some documents and reject others. Additionally, all approval and rejection reasons are captured and stored into audit logs for future reference.

During the signing process PowerTools also enables these companies to add and remove document watermarks and stamps within which they can choose to include extended metadata, workflow or form data. In addition their workflow designers are able to specify whether native documents are automatically converted into PDF and/or merged into a single document during the signing process. Auto-creation of a table of contents and the creation of front and back pages are additional configuration options.



Within most Life Sciences companies the signing process itself is often carried out by a combination of scientists and business executives. These people usually do not work within Content Server on a daily basis. As such, when it comes to using standard workflows, they can require more training than regular users and can be easily confused by complex user interfaces.

By simplifying the Content Server workflow interface and presenting only relevant data at the appropriate time these companies have seen significant improvements in user adoption, as well as a reduction in errors caused through incorrect data entry. Additionally, by providing detailed alerts to users when their participation is required, through PowerTools for Workflow's configurable email notifications, they have also seen reductions in response times and an increase in overall participation.

Once approved and signed, the final publishing of documents is also something that many regulated organizations choose to automate. Reducing the number of manual procedures can save on process-related documentation and also ensures that the signed documents are distributed to the correct people in a timely manner.

Optimizing Regulatory and Management Reporting

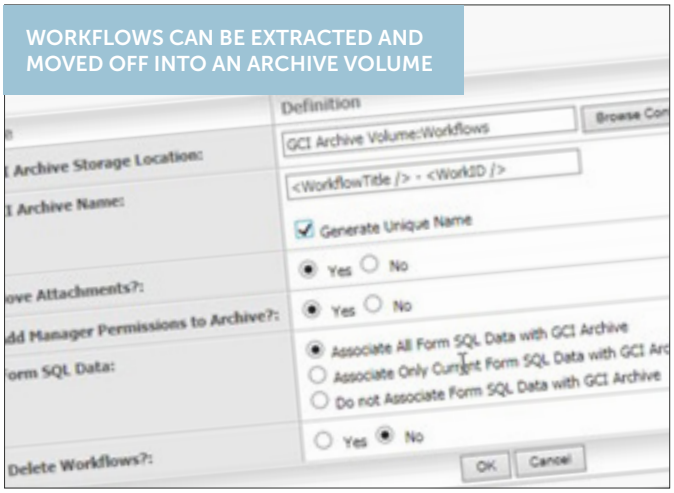
The constant oversight from governing authorities is something that all regulated organizations operate under. While an essential part of business, regulatory reporting can be a significant cost overhead that provides no direct financial returns. By ensuring that regulated processes are as optimized as possible companies can save significant amounts of time and money.

Of the Life Sciences companies that use GCI PowerTools for Reports & Views, many of them use it to create reporting dashboards to support such management functions. These provide staff, management, and regulatory authorities with visibility into the status and history of regulated processes. Links within the dashboards provide their users with direct access to workflows, their attachments and audit history. Using PowerTools for Reports & Views users have also been able to incorporate multiple data sources; providing insights into processes right across their business.

Migrating from Development, to UAT, to Production

Another often-seen regulatory requirement is that updated processes and technologies need to be developed and tested in isolation from current operational areas. Once tested and signed-off on, those changes need to be migrated from a development system into a user acceptance testing (UAT) platform, and then finally on to a production system. Typically this is a highly manual process requiring large amounts of time and a significant quantity of documentation.

With the introduction of GCI PowerTools for Deployments organizations have been able to establish simple and highly automated methods for moving Content Server content and applications from Development, to UAT, and then to their Production environments. The migration processes typically include objects such as workflow maps and reports, as well as content like documents and forms. By using a reliable, automated process powered by PowerTools, these companies have been able to substantially reduce the time taken to implement changes from days to a matter of hours.



WORKFLOWS CAN BE EXTRACTED AND MOVED OFF INTO AN ARCHIVE VOLUME

Archiving Information out of the System

As a best practice within Content Server, workflows need to be regularly archived or deleted from the system to ensure that the environment remains responsive to end-users. This regular maintenance practice also ensures that legal liabilities from old data are eliminated. Within regulated environments, however, this information cannot just be deleted and must be controlled and managed like any other business record.

GCI PowerTools for Archiving has provided these companies with a way to safely archive completed workflows and audit events. Using PowerTools, historical information is safely extracted, optimized and placed back into the repository in an unmodifiable format. Once archived, Content Server's records management tools are used to apply corporate disposition policies that ensure potential legal liabilities are eliminated while remaining in compliance.

The Essential Combination

Used as part of certified Content Server environments worldwide, the GCI PowerTools Suite is a proven and tested solution within Life Sciences and other heavily regulated environments worldwide. As our many clients have found, the benefits of PowerTools deliver time and cost savings from day one. Whether improving business processes, simplifying user experience, or reducing exposure to legal liabilities, the PowerTools Suite is the only out-of-the-box solution purpose-built for the Life Sciences industry.

About GCI PowerTools Suite

GCI PTW — GCI POWERTOOLS WORKFLOW

GCI PowerTools for Workflow (PTW) provides a robust collection of extensions and enhancements to extend the capabilities of the Content Server Workflow, enhance the user experience, and make workflow data available for views and reporting.

GCI PTES — GCI POWERTOOLS ELECTRONIC SIGNATURES

PowerTools for OpenText Electronic Signatures (PTES) is the essential companion to OpenText Electronic Signatures (eSign) for Content Server. Its powerful workflow enhancements enable the development of electronic signing processes that allow the simultaneous signing of multiple documents and the creation of workflows that more closely align to existing business procedures.

GCI PTRV — GCI POWERTOOLS REPORTS &VIEWS

PowerTools for Reports & Views (PTRV) allows for the creation of Display Views and reports via XML, XSL, JavaScript and HTML. The data sources can incorporate multiple data like SQL results, search results, other Content Server reporting tools and transmittals.

GCI PTfD — GCI POWERTOOLS DOCUMENTS

PowerTools for Documents (PTfD) allows for the automation and creation of PDFs from multiple documents and formats. PowerTools for Documents can easily merge documents; create tables of contents, headers, footers, and watermarks. It also provides the ability to create digitally signed PDFs and associate them with business processes.

GCI PTD — GCI POWERTOOLS DEPLOYMENTS

GCI PowerTools for Deployments (PTD) can export all Content Server users, groups, content, objects, and metadata; like documents, categories, attributes, workflow maps, form templates, forms, reports, etc. into a set of XML files. PTD then supports the import of the XML files into a different environment. PTD will recreate the entire structure, content, objects, and metadata in the new environment. The references between all the imported objects, and the references to the users, including permissions, are all maintained after the import. Circular category dependencies and links between objects are also maintained.

GCI PTA — GCI POWERTOOLS ARCHIVING

GCI PowerTools for Archiving (PTxA) enables the safe extraction, archival and records management of critical workflow and audit data. It improves the user experiences and reduces the legal liability associated with data that is otherwise trapped within the Content Server repository.

For further information and demonstrations of the GCI PowerTools for Content Server suite please visit our website at **www.globalcents.com.** ›

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