GLAMS™
IMPACT
ANALYSIS

Integrate. Automate. Control.

GLAMS Impact Analysis solution provides a smart way to integrate, assess and automate regulatory driven changes, creating a single connected view across regulatory and artwork processes.

x10 Faster delivery of Production Information change impact identification to artwork brief creation

50% Efficiency gain over current regulatory artwork change planning activities

20% Reduced manufacturing costs

GLAMS™
Powered by Perigord

Learn more,
Scan the Code

DESIGNED FOR LIFE SCIENCES

The Challenges and Solution

The Challenge of Managing Changes on Drug Labeling

With more and more products being brought to market and an increase in local regulatory change requests, maintaining the balance between patient safety, compliance and business efficiency is ever more complex. Frequent and unexpected updates and revisions to drug product labeling place significant pressure at all points in the labeling change processes where automation is low.

Manual Methods for Managing these Regulatory Safety Changes:

- are labour intensive
- are error-prone
- can cause significant delays due to rework
- represent an increase in compliance risk
- add to the environmental and monetary costs of your packaging

The Solution – GLAMS Impact Analysis

We are delighted to introduce our GLAMS Impact Analysis solution, designed specifically to address the rigorous challenges of change management in drug product labeling. This comprehensive, advanced software streamlines the entire workflow of Regulatory Labeling Change Assessments, seamlessly integrating with your existing Regulatory Labeling Management Applications and Artwork Management Systems (AMS).

With our solution, organizations gain the power to track and understand their data's journey, ensuring compliance, data integrity, and informed decision-making. Our advanced features enable seamless data origin tracing, monitoring of data movement and transformations, comprehensive data quality analysis, and impactful change assessment. This results in improved visibility, accuracy, efficiency and compliance throughout the lifecycle of core, regional or local Regulatory product information (PI) safety change implementations.

GLAMS Impact Analysis will standardize and automate the activities related to labeling-driven artwork changes in order to minimize risk including:

• **Change Trigger**
Automatic creation of a Regulatory Change Impact Assessment Project

• **Automated Impact Assessment**
System generates list of impacted components with intelligent insight

• **Automated Artwork Brief Markup**
System transfers approved impacted updates from source PI documents to artwork PDFs

• **Automated Workflow Initiation**
System initiates mock-up and production artwork workflows from Regulatory Assessment

The Journey of **a GLAMS™ User**

Current Process

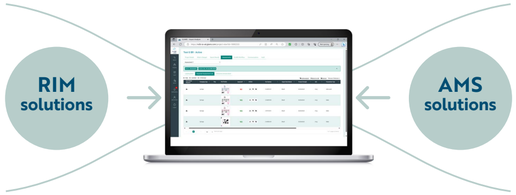
1. Currently the artwork impact assessment relies on a manual spreadsheet-based process, resulting in inconsistencies.
2. Updating the source documents is a manual, free-form process.
3. And the initiation of AMS workflows requires manual metadata entry and file uploading.

Future Process

1. With GLAMS Impact Analysis, the artwork Impact assessment will be automated.
2. Updating the source documents will also be automated.
3. And the initiation of AMS workflows will be automated too. GLAMS Impact Analysis is truly transformative.

How it Works

A single unified view of Regulatory and Artwork files and metadata



1 Discover

GLAMS Impact Analysis streamlines change management by using advanced algorithms and Natural Language Processing (NLP) to extract and analyze modifications in drug product labeling documents. It efficiently identifies tracked changes from the provided labeling document to be used in the assessment, greatly reducing time and effort in locating affected assets.

2 Define

Once changes are identified, GLAMS Impact Analysis provides comprehensive tools for evaluating their effect on artwork files. You can easily review labeling document modifications and their impact on artwork elements like text, format, and visuals. The solution's thorough documentation features help articulate specific potential impacts, ensuring full understanding of the scope of the impact on the artwork content.

3 Implement

GLAMS Impact Analysis optimizes the change management process, integrating seamlessly with your AMS. It automates the transfer of marked-up changes from labeling documents to related artwork, reducing errors and ensuring precise synchronization. Moreover, it triggers workflows within your AMS, sending notifications and facilitating the artwork update process.

4 Auto-Initiate Workflow in AMS

Integrated with your AMS, our GLAMS Impact Analysis Solution auto-initiates workflows post-impact analysis, promptly notifying relevant stakeholders. This automated process enhances collaboration, accelerates task execution, and ensures regulatory visibility of the artwork update process.

Features

Focused on addressing the current pain points and manual ways of working within the E2E labeling, artwork, and marketing & communications creation process.

Automated Change Detection

- System provides What's Changed functionality to highlight file status and manage version changes.
- Comprehensive Regulatory Labeling Change Impact Assessment.
- Enables detailed assessment with visual comparisons and precise identification of impacted areas.
- Provides critical insights into downstream system influence.

Regulatory Content Version Tracking

- Tracks data flow, transformations and changes for regulatory transparency and accuracy.
- Offers comprehensive tracking of content and metadata, including versions and dependencies.
- Auto-initiates workflows for prompt notification and efficient execution of actions.

Insight and Compliance Audit

- Ensures comprehensive understanding of change implications and user decisions.
- Supports regulatory compliance through meticulous record-keeping and data governance.

Repurposing and Compatibility

- Facilitates repurposing of tracked changes from Microsoft Word PI document to Artwork PDF file.

Batch and Multi-stage Assessments

- Facilitates assessing a single source of change against multiple artworks.
- Supports multi-stage assessments to facilitate internal SME and external Health Authority rejections and updates to the original assessments scope of change.

Benefits

Compliance

Reduce the number of errors, rework cycles and improve right first time creation of labels and promotional materials.

Patient

Faster execution reduces time to market of updated product information.

Company

Tightly integrates regulatory and artwork teams, reduction in manual effort frees up teams to focus on strategic and proactive decisions.

Health Authority

Increase credibility with agencies via timely and thorough response to inspections and labeling related questions.

Supporting ePI and Artwork Automation

Impact Analysis integrates with metadata and content, such as regulatory word documents, and can be reused and extended to support Electronic Product Information (ePI) and artwork automation initiatives.

Faster Delivery

x10 faster delivery of PI change impact identification to artwork brief creation.

Efficiency

50% efficiency gain over current regulatory artwork change planning activities.

Cost-Savings

Up to 20% reduced manufacturing costs.

Summary

GLAMS Impact Analysis solution revolutionizes the change management process in drug product labeling. By automating the discovery, definition, and implementation phases of a required global, regional or local safety change procedure, our solution enhances efficiency, accuracy and compliance throughout the entire Regulatory labeling change assessment lifecycle. Providing transparency and insights into data movement and transformations via our RPA-driven data lineage capabilities enhances data quality, governance, and overall efficiency. With advanced features, including NLP-driven discovery, comprehensive impact assessment, seamless integration with your AMS and Regulatory Applications and workflows, our solution empowers your organization to navigate Regulatory change management challenges with ease and deliver positive outcomes for the manufacturing supply chain in terms of cost, time, and risk reductions.

GLAMS – An Adaptable Platform to Streamline and Enhance the Efficiency of Your Artwork, Labeling, Content, and Marketing Management Processes

Built specifically for the Life Science industry, the GLAMS Auotmation Management System revolutionizes the way Pharmaceutical, Biotech and Medical Device companies organize, track, curate, change, and distribute packaging and marketing assets across the globe.

Dedicated Solutions for Large, SME and Emerging Life Science Companies:

Contact Us

For more information about **GLAMS Impact Analysis** email **info@perigord-as.com** to arrange a call with a Perigord Data subject matter expert and schedule a personalised demonstration or visit **www.glams.com** to learn more about our full **GLAMS** range of solutions.

Mark Ennis
Global Business Development Director
mark.ennis@perigord-as.com

Why Choose Perigord

Experience you can trust

At Perigord we know the pharmaceutical industry inside out. We work closely with 15 of the top 20 pharma companies worldwide so we understand the unique challenges they face and know how to overcome them.

Five solutions, one team and a digitized supply chain

We provide best-in-class supply chain solutions to the Life Science industry. We offer experience and expertise across creative, marketing, packaging artwork and labeling and software and our deep knowledge shapes our approach.

Tried and tested by the world's leading pharma companies

GLAMS was developed in conjunction with some of the world's leading pharma companies and is used and validated by them, so you know that it will deliver for your organization.

Quality assured

At Perigord quality is at the heart of everything we do and patient safety is our top priority. All of our processes are fully GMP/GAMP-compliant and we're committed to ensuring that our clients meet their quality standards.

Fully audited and ISO certified

With a fully audited quality system certified to ISO 9001:2015, ISO 27001:2013 and PS 9000:2016 standards for both software and artwork services, Perigord was the first company in the world to receive PS 9000 certification for software development. (ISO 27001, ISO 9001 and PS 9000 certification available on request.) The GLAMS system facilitates compliance with the electronic records and electronic signatures rules of 21 CFR Part 11 and Annex 11, which may be managed through a risk and gap analysis process.

PHARMACEUTICAL QUALITY GROUP
PS 9000 CERTIFIED SUPPLIER No. 000

bsi. ISO 9001 Quality Management

bsi. ISO/IEC 27001 Information Security Management

Our Global Footprint

Six Centres of Creative & Packaging Excellence.

GLAMS™ Powered by Perigord

DESIGNED FOR LIFE SCIENCES