Perigord
LIFE SCIENCE SOLUTIONS
A TECH MAHINDRA COMPANY

GLAMS
POWERED BY PERIGORD

White Paper | May 2022

Advanced **Artwork and Labelling Production Analytics**

Pharmaceutical Artwork Departments can accelerate business impact with AALPA

Brought to you by Perigord and GLAMS

Contents

01 Introduction

As global healthcare markets become more cost constrained, pharmaceutical companies are leveraging the data generated across all aspects of the supply chain to drive decision making and gain competitive advantage over their rivals.

It has been estimated that operating efficiencies achieved by enhancing processes or eliminating inefficiencies identified using Advanced Artwork and Labelling Production Analytics (AALPA) can range from between 50% to 70%. This presents a concrete opportunity for pharmaceutical companies to increase productivity, reinforce compliance, accelerate time-to-market and remove unwanted waste from the supply chain.

While many pharmaceutical companies are well on their way to mastering big data at a macro level, most organisations still struggle to collect and deliver real-time data at a micro level. It is harnessing this process-specific data that is key to extracting true business intelligence and providing critical departments with the right data at the right time so they can deliver the savings needed.

Using AALPA, companies can deploy more sophisticated techniques to uncover more and better insights into their artwork and labelling processes. The challenge lies in mastering all the capabilities afforded by AALPA. Once this has been achieved business owners can then use the analytic-generated insights to drive their commercial strategy and deliver a stronger bottom line.

To build these sustainable commercial strategies that will maximise an artwork department's potential, pharma companies must fully embrace coal face data and the advanced analytical tools that will help their organisations take the steps necessary to improve their processes. This is what AALPA affords; it helps an artwork manager identify and solve problems quickly and efficiently by providing end-to-end process visibility across all work streams in real-time.

Benefiting from upstream and downstream data feeds and pulling from designated data lakes, AALPA dashboards provide early warnings and identifications of potential roadblocks before they occur and, additionally, signpost the root cause of current bottlenecks and inefficiencies which are causing breaks in compliance and the missed deadlines.

This paper explores the role of artwork management in the production/product life cycle, examining how issues caused in the creation and production of regulated artwork and labelling can be identified using AALPA on a standalone basis or in conjunction with existing BI tools. The ways AALPA can help business unit managers and owners develop future-proofed solutions will also be identified, driving efficiency and compliance across the packaging supply chain, whether they are applied to one team in one location or across a global network.

As more and more companies are digitising their packaging and labelling supply chain, they continue to seek ways to improve efficiencies and maintain supply chain agility. To achieve these goals it is critical that they can, at the touch of a button, have available a set of reports which measure all critical outputs and the KPIs of both internal and external teams in real-time, this is where AALPA comes into its own.

Sam Cole,
Director of Client Services,
Perigord Data

02

Managing Artwork and Labelling Production Complexity

In today's world of regulatory complexity, the artwork and labelling that is used to produce patient information is an essential, valuable and critical element in the communication of product efficacy and usage of the product by the patient. As such, the production of packaging artwork and labelling requires a well-managed and controlled process, that minimises the opportunity for error and enables artworks to be produced efficiently and Right First Time (RFT).

Unfortunately, many processes that organisations use to manage the production of artwork and labelling can break down under pressure, causing long delays in getting a product to market and failures in compliance.

It is forecasted that the cost of getting pharmaceutical products to market is set to increase over the coming years, driven by many factors including:

- The shortage of properly trained and qualified staff
- The need to reduce the cost of getting product to market
- Healthcare/pharma economics
- A rise in the number of generics coming onto the market
- The cost of packaging materials increasing (sustainability and cost)

These drivers, combined with the inevitable increase in regulatory scrutiny, is forcing organisations to reassess their process, and how they manage their artwork workflows and coordinate with manufacturing sites. This market trajectory was identified in research by Siemens in 2018, which shows that a productivity gap exists between most manufacturing and artwork processes, leading directly to packaging write-offs, which account for between 0.25% and 3% of corporate revenue.

While this research dealt mainly with the FMCG sector, applying this analysis to other sectors suggests the impact of these disconnects could deliver similar results, with Life Science being no exception. Life Science organisations need to rapidly evolve new ways for their artwork studios to keep up with the pace of change in manufacturing processes and the increasing need for supply chain agility or they will see costs increase.

Advanced Artwork and Labelling Production Analytics are central to maintaining control, managing complexity and driving efficiencies across complex contemporary supply chains and future-proofing them against the expected increase in complexity of the supply chains of tomorrow.

> ***The disconnect between Manufacturing and Artwork production can result in a loss of up to 3% of corporate revenue.[1]***
>
> ***– Siemens***

[1]Siemens PLM Software (2015). Packaging and Artwork Management for Consumer Products. Available at: https://www.plm.automation.siemens.com/en_us/Images/13792_tcm1023-61321.pdf

03

Mitigating the Drivers of Artwork and Labelling Inefficiencies and Errors

Patient safety is a strategic priority for Pharmaceutical and Life Science Companies. At a time where the pharmaceutical supply chain is gravitating ever more towards outsourcing even as increasing numbers of companies enter the market, regulatory bodies are raising the level of inspection across all areas of the supply network to ensure complete compliance with the standards and regulations, as can be witnessed in the analysis of FDA warning letters and inspections for 2020[2].

But where does artwork and labelling sit in the supply chain?

Pharmaceutical artwork and labelling creation, production and management across the supply chain involves project management, label regulatory control and resource management. Not having the right processes, team and, most importantly, reporting and analysis, undercuts a manager's ability to deliver the efficiencies and control necessary to ensure their organisation's packaging needs are met and all the tasks undertaken in the production of artworks are completed with fully traceable approvals and in adherence with global regulations. Any mistake, even a minor one, can lead to recalls.

Pharmaceutical artwork and labelling production is difficult and fraught with challenges. The key to overcoming these challenges is the ability to see them before they happen, identify the root cause of a problem in real-time, and have the correct information available to allow you to avoid errors and production bottlenecks. Having the right tools for pharmaceutical artwork management can help you maximise productivity and minimise a product's time-to-market.

Artwork management of pharmaceutical packaging is a difficult process. Due to the changing nature of the market and regulatory scrutiny, the artwork manager of tomorrow has many challenges they must overcome:

> ***Research indicates that approximately 40% of all FDA product recalls are due to labelling-related errors.[3]***
>
> ***– FDA Recall Data***

[2] *The FDA Group, LLC (2022). FDA Warning Letter & Inspection Observation Trends. Available at: https://www.thefdagroup.com/blog/2019-fda-warning-letter-inspection-observation-trends*

[3] *FDA U.S. Food & Drug Administration (2022). Recalls, Market Withdrawals, & Safety Alerts Data. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts*

Challenge 1:

Identifying and eliminating bottlenecks in the process

AALPA reports at your fingertips:

- Campaign Tracker Report
- Project Overview Report
- Artwork Cycle Time Report
- Packaging BOM Report
- Artworks WIP Report
- Task Overdue Report

Outcomes:

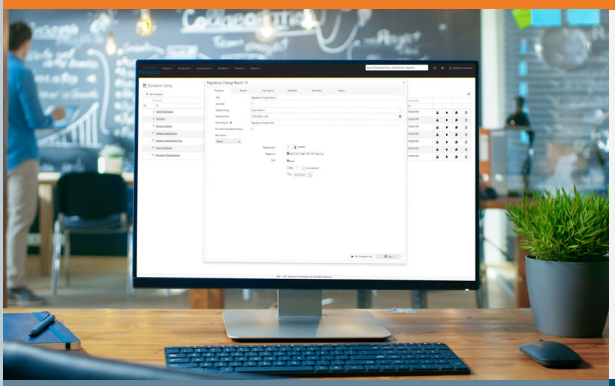
These reports identify the processes and tasks causing the blockage and address the issue with training, process reengineering and resource redeployment.

Benefits:

Ability to reduce time to market, generate increased revenue, reduce costs by removing over and underutilisation of resources and reduce product recalls.

Challenge 2:

Lack of visibility on pending regulatory changes



AALPA reports at your fingertips:

- Regulatory Change Tracking Reports

Outcomes:

These alert style reports can be generated automatically by the underlying system's ability to securely connect to and access sources of upcoming regulatory changes. Team members will be able to plan and act accordingly in a timely manner to pending changes.

Benefits:

By having Early Warning Alerts built into your AALPA dashboard, you can avoid lengthy process changes, enhance compliance monitoring and assist in regulatory reporting.

Challenge 3:

No real-time work-in-progress visibility

AALPA reports at your fingertips:

RFT Report
Task Overdue Report
Acceptance Task Report
Project Overview
Active Task Report
Where Used Report

Outcomes:

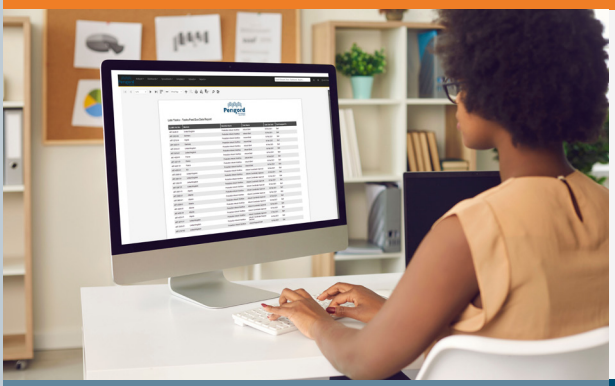
These reports provide up-to-date progress information on all tasks in the Artwork Management System being tracked. This allows for the ability to adapt and change existing processes so that, for example, one piece of artwork doesn't slow down an entire project or SKU getting to market. This also allows you to recognise if you need to provide extra attention and resources to address an issue to speed up a process.

Benefits:

Faster decision making based on immediate information provided/ processed directly by the subject matter experts.

Challenge 4:

Internal stakeholders receiving outdated information



AALPA reports at your fingertips:

RFT Report
Task Overdue Report
Acceptance Task Report
Project Overview
Active Task Report
Where Used Report

Outcomes:

These reports can be integrated into all ERP and data tools, providing the subject matter expert with the ability to access that data in the most efficient and timely manner. This allows all levels of a company hierarchy, including team lead, department lead, etc., to access fresh data and query it in real-time.

Benefits:

Faster decision making based on immediate information provided and processed directly by subject matter experts.

Challenge 5:

Difficulty tracking and troubleshooting at-risk artwork

AALPA reports at your fingertips:

- Artworks WIP
- Task Overdue Report
- Acceptance Task Report

Outcomes:

These reports provide up-to-date progress on all tasks in the Artwork Management Systems tracked, with the ability to adapt and change existing processes so that, for example, one piece of artwork doesn't slow down an entire project or SKU getting to market. This also allows you to provide extra attention and resources to address issues with the process.

Benefits:

Faster decision making based on immediate information provided and processed directly by subject matter experts.

Challenge 6:

Inability to track variance in end-to-end process cycle times

AALPA reports at your fingertips:

- Artwork Cycle Time Report
- RFT Report
- Task Overdue Report

Outcomes:

These reports help identify and compare proof cycle vs pass cycle reports across the relevant life cycle, including issues relating to artwork and labelling creation or brief creation and other sources of consistent delay.

Benefits:

Identifies process inefficiencies, skills and knowledge gaps and resource deficits.

Challenge 7:

Skills gaps go unidentified

AALPA reports at your fingertips:

Rejection Reason Report
Comments Report
Active Task Report
Artworks WIP
Task Overdue Report

Outcomes:

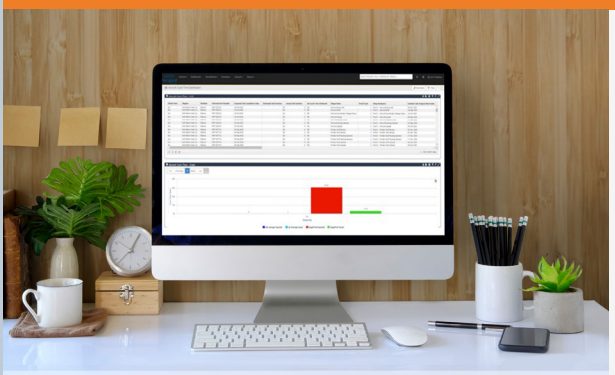
Reports like the Rejection Reason Report allow you to identify skills gaps with your internal stakeholders and determine which areas of training are needed to eliminate mistakes.

Benefits:

Identifies gaps and areas for training which, once completed, will drive improved RFT, direct input into HR decisions and planning and reward successes.

Challenge 8:

Overly complex, labour intensive cost allocation process



AALPA reports at your fingertips:

Artwork Cycle Time Report
RFT Report
Task Overdue Report
Integrations

Outcomes:

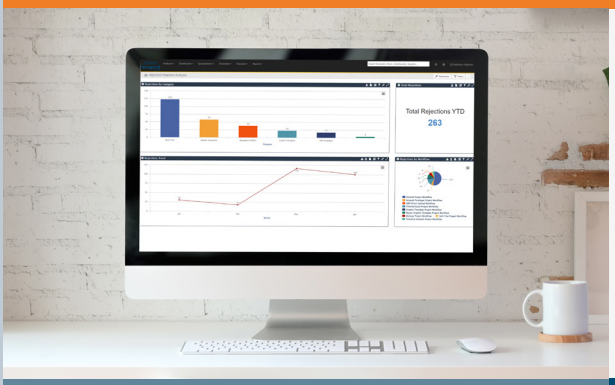
These reports can be entered into the Transaction Process System's (TPS) process allocation, which will help simplify auditing and classify costing types – such as metadata classified change type (work type = new, major, minor) and other change-related information (proof count, RFT, on-time).

Benefits:

Allows for streamlined, simplified and automated cost recognition.

Challenge 9:

Sub-optimal quality and artworks requiring multiple resubmissions are at a greater risk of recall and delays in getting to market



AALPA reports at your fingertips:

- Right First Time Report
- Rejection Reasons Analysis

Outcomes:

These reports identify the level of work that is delivered correctly the first time by artworkers and identify the reasons artworks are rejected. This can help to identify areas where there may be a need for additional training to reduce the cycle time, improve the quality of outputs and increase the Right-First-Time metrics.

Benefits:

Efficient and maximised artwork teams, reduction in project delays, removal of waste across the supply chain.

Challenge 10:

Overdependence on spreadsheets creating data inaccuracies

AALPA reports at your fingertips:

- All Report types

Outcomes:

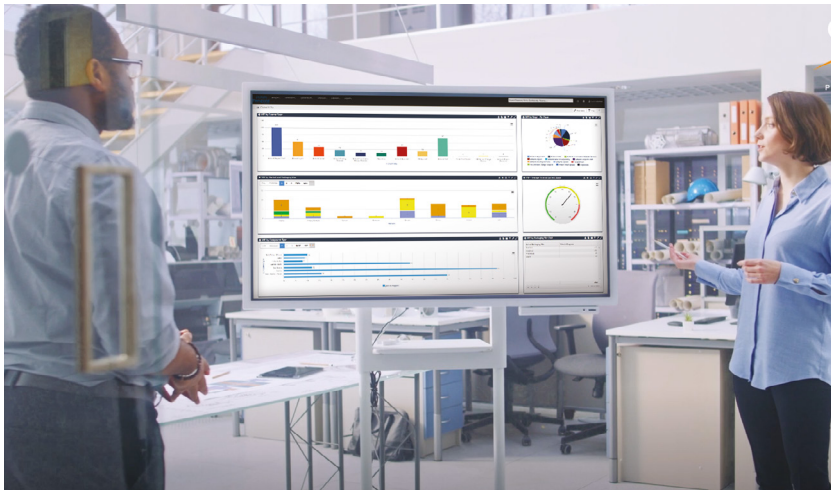
Centralised reporting control with governed data access to high quality reliable and timely information. Existing spreadsheets can be imported and converted to managed secure data tables.

Benefits:

Continuity, quality and consistency of data through multiple systems. Elimination of error-prone spreadsheets and the ability to highlight data quality issues in the Artwork Management Systems.

Self-Service Reporting & High Impact Visualisations

Once the underlying datasets have been prepared and made ready for use, artwork managers are enabled to personalise and create reports configured to their own specifications. These dashboard visualisations of key metrics provide focus and draw attention to the key drivers for improvement within the business.



This type of direct, real-time access to data without the need to go through a technical resource like a database analyst is vital in ensuring the uptake and trust in both the AALPA system itself and the information that is being presented. Ultimately, the purpose of visualisation is to provide insight into any anomalies, issues or opportunities the data reveals, and to investigate, address or act on the information as soon and as effectively as possible. This improved agility in turn leads to less risk, greater efficiency and more productive use of process-relevant data.

One way to ensure the system is in meaningful use is by making sure the AALPA is capable of publishing information in a wide variety of formats to suit different audiences with different needs. Being able to schedule reports to be automatically sent at any time will increase the dependency on the system. Rather than having people search out information, having a system that pushes information to stakeholders is far more effective.

People need information to make decisions and sharing of information based on trusted data is essential. Once AALPA has been adopted, the true test of usage is whether users could work effectively if it was suddenly taken away?

Peter Madden,
Information Technology
Business Analyst, Perigord Data

04

How to Become AALPA Ready

Advanced Artwork and Labelling Production Analytics provides the user with the ability to maintain the highest level of agility and be proactive as artworks move through the development life cycle, while at the same time maintaining the flexibility to react to ongoing regulatory changes without affecting the quality, security and the timing of the outputs from artwork studios.

To take advantage of AALPA, a studio manager/business owner needs to put in place and ensure the following:

1. They have a fully validated artwork management system specific to the Life Science industry.
2. They create a catalogue of sources that should be available within the system and automatically generated.
3. That system can be fully integrated into other existing business information platforms used by the business, for example ERP, DIM, RIM etc.
4. The AMS application programming interfaces (API) conform to your business' API protocols
5. Existing artwork studio operating procedures are fully understood and documented (workflows and processes).
6. A detailed list of reporting criteria is generated to identify the appropriate data sources for the supply of the required information to generate reports in real-time.
7. That key stakeholders are included in the project team, which should include: IT, cybersecurity, regulatory affairs, quality, business unit owner, studio managers, supervisors, team leads and HR.

05

Understanding the Data Requirements

Data Science and the use of machine learning algorithms is increasing in prominence across all industries. The promise of revealing hidden insights in data through AI is receiving much attention. However, the path to success in AI relies fundamentally on the quality, quantity and variety of the underlying data. With AALPA capable of being a data source for algorithms, as well as providing the ability to use third party machine learning technologies such as natural language processing, predictive analytics and robotic process automation, is an exciting prospect in the world of artwork management.

When building an AALPA solution that creates and supplies real-time, actionable information into the hands of your team, it is important to understand that securing access from the right and trusted data sources is key. As with all critical business information, AALPA requires data to be cleansed and prepared to ensure its veracity and quality before being used to create reports.

Within any large organisation there will be a multitude of disparate, heterogenous data sources. These sources may be stored in a variety of silo types such as data warehouses, datalakes, datamarts, relational databases, ERP data, unstructured data, cloud data (via APIs), flat files and so on. Each of these repositories may support the individual needs of one or many business units across an organisation.

For instance, a data warehouse can serve as the overarching source for balanced scorecards (KPIs) or detailed sales performance information and take feeds from business units globally. In addition, local business owners and line managers often use locally developed databases for their immediate and pressing ad-hoc needs. The primary source of data at the centre of AALPA will be from the Artwork Management System, which can be linked to the other sources to enrich the information being presented to the artwork team. AALPA will facilitate and manage a continuous and secure data flow upstream and down.

Companies are awash with information but getting real-time, coal-face data is what makes a difference and empowers individuals to make quick and decisive decisions.

Maurice Lynch,
CEO, Nathean Technologies, Principle Consultant and Advisor to Perigord Data

Solution Capabilities

When looking at an AALPA solution here are some data considerations:

1 Data Governance & Auditing

Good data governance ensures an organisation's data is properly manged in terms of availability, usability, consistency, integrity, and security. When choosing AALPA it is essential that data governance technologies are built into the platform. This will help you:

- Decrease the risk of regulatory and compliance fines
- Improve Right First-Time metrics
- Enable better planning by supervisory employees
- Eliminate or minimise re-work
- Provide better information quality
- Increase confidence in decision making
- Improve data security
- Establish process performance baselines to enable improvement efforts

2 Linking to any Data Source & Type

At the core of AALPA is the workflow and asset data capture in the Artwork Management System. The business value of the AMS increases when data is merged from other systems, augmenting the insights produced from the AMS.

For example:

- linking in data from the finance or ERP system can enrich the AMS data with additional cost measures.
- linking to supplier fed data or data from a stock management system.

The AALPA should be capable of connecting and extracting from the widest possible data source types and have a scheduler to enable automatic importing of data or publishing of data and reports, as required.

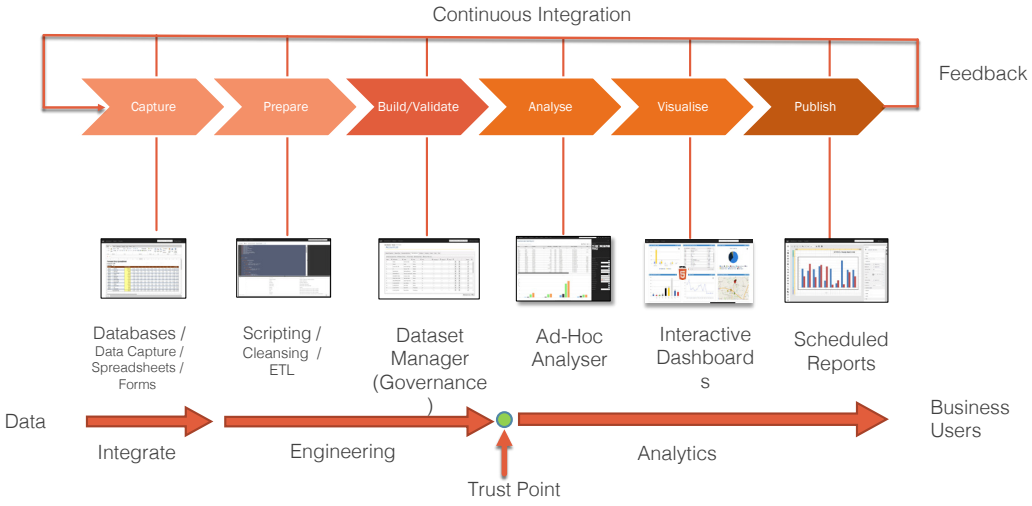
3 Data Preparation & Data Blending

With the ability to connect to any data source, the AALPA should be capable of cleansing and preparing data for further use in reporting from the Artwork Management System. With data preparation the system should be able to blend (or merge) datasets to form new first class data sources within the system for further consumption and information generation.

4 Data Management Strategy

With the right platform in place for AALPA, which has the fundamental capability of accessing, linking and blending any number of data sources, then the process of creating the foundational data management strategy will be quicker to implement and maintain.

The Information Pipeline



Phase 1 – Connect, Prepare and Blend

Because it is imperative that the artwork team trust the information derived from AALPA to make everyday business decisions, the first phase involves determining the trusted sources which will feed the information workflow. Again, the sources can involve multiple sources such as corporate datalakes or warehouses.

The feeding of information into the AALPA can be scheduled at whatever intervals are required, depending on how up-to-date the data needs to be. Further cleansing may be required from the original source, as well as being merged with other sources to best suit the artwork's needs and KPIs.

The nature of an agile AALPA means any future changes are relatively easy to implement and roll out. A catalogue of sources should be available within the system and automatically generated to enable periodic auditing and tracking of usage and performance statistics. Such a capability ensures that the number of sources is kept under control and that only relevant sources are being accessed and reviewed.

Phase 2 – Develop KPIs

A primary functional requirement of the AALPA is being able to rapidly create and update KPIs to match the pace of the business rather than the pace of IT turnaround. Being able to respond to business or regulatory changes is important to staying on top of information.

06

Final Thoughts

Knowledge is Power

In a world of AI, BI and analytics, organisations are awash with data. The challenge is getting the right information to the right people at the right time, empowering them to make business-critical decisions that drive efficiency and increase the value of their outputs. This is where Advanced Artwork and Labelling Production Analytics comes into its own.

Positioning AALPA at the centre of your information and analytical process provides the user with top down and bottom up KPI reporting which, in real-time, allows them to act and drive change across the artwork production supply chain. Taking direct feeds from other ERP systems and amalgamating this data with coal-face information, AALPA can be configured to provide real-time reports which can deliver insights, allowing organisations to, for example:

- Improve Right-First-Time metrics
- Process work faster
- Shorten time to market
- Identify regulatory changes early
- Identify skills gaps

Incorporating fully configured and aligned AALPA into your artwork lifecycle process will allow you to access, align, analyse and present KPI dashboards which can report on your organisation's performance in areas such as:

- Project Overview
- Artwork Cycle Time
- Tasks Overdue
- Active Tasks
- Artworks WIP
- Cancelled/Phased Out
- Project Acceptance Tasks
- Project Rejection Reasons
- Project Comments
- Campaign Tracker
- Packaging BOM
- Scorecard Information

In closing, having Artwork and Labelling Production Analytics is essential for any Pharmaceutical and/or Life Science organisation to accurately identify and maximise efficiency opportunities across the artwork production supply chain.

07

About the Contributors

Sam Cole

Director of Client Services, Perigord Data

Sam has responsibility for all client engagement across Perigord's software division. Sam has oversight of all implementation projects, having developed processes that ensure efficient, yet compliant, delivery of validated systems into Perigord's customer base. He also heads up the Customer Success team, ensuring Perigord develop strong and lasting partnerships with all of their customers, who are then able to realise the maximum potential and benefits of Perigord's suite of products. Sam has spent 15 years in Artwork Management Systems and started his early career in a packaging studio, so brings a wealth of experience in implementing and delivering artwork and labelling solutions into the Life Science sector.

Peter Madden

Information Technology Business Analyst, Perigord Data

An IT Business Analyst since 2017, Peter Madden is responsible for helping Perigord's clients implement GLAMS by analysing their requirements; documenting, defining and refining their workflows and configuring the system for them. Having previously worked as an artworker and artwork coordinator for Perigord Premedia, Peter combines the experience garnered from multiple successful implementations for global pharma companies, with insights borne from being a day-to-day GLAMS user.

Maurice Lynch

CEO, Nathean Technologies, Principle Consultant and Advisor to Perigord Data

Maurice Lynch is CEO of Nathean, a company which specialises in the development of analytics software with a focus on solutions for the Life Science and Healthcare sectors. An experienced CEO, board member and technical leader, Maurice drives the strategic direction of the company and oversees its business operations while playing an active role in the company's product direction. Nathean is a founding industry member of CeADAR – Ireland's Centre for Applied AI, on whose board Maurice has served for 5 years. Maurice holds a B.Sc. in Computer Science from Dublin City University and has completed the Leadership4Growth program at Stanford University.

Authored by Robert Saunders, Global Commercial Director.

Perigord
LIFE SCIENCE SOLUTIONS
A TECH MAHINDRA COMPANY

We are here to help.

At Perigord Data, we provide solutions to over 50 Life Science companies. These organisations rely on data and KPI reports to manage and increase the efficiency and quality of the outputs from their internal and external artwork studios.

GLAMS (Global Artwork Management System), Perigord's innovative proprietary software, is a web-based Life Science artwork management solution, developed and designed to control and manage artwork within the Life Science industry. GLAMS' modular system connects all the stakeholders in a customer's artwork production process, including new products.

To find out more about AALPA and GLAMS, visit www.perigord-as.com/software-solutions or contact us at:

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

Sam Cole
Director of Client Services
sam.cole@perigord-as.com

You can also contact one of our Global Centres of Creative and Packaging Excellence:

Europe – Dublin, Ireland
Perigord Life Science Solutions
Unit 1, Lyncon Court
IDA Business and Technology Park
Snugborough Road,
Blanchardstown
Dublin 15, D15 N283
+353 1 440 3222

Central Europe – Waldkirch, Germany
Perigord Life Science Solutions
Fabrik Sonntag 4b
79183, Waldkirch
+49 7681 49393-10

North America – Branford, CT, USA
Perigord Life Science Solutions
4 Pin Oak Drive
Branford, CT, 06405
+1 203 433 4054

Asia – Hyderabad, India
Perigord Life Science Solutions
10 A, B, C & D 10th Floor, Vaishnavi Cynosure
2-48/5/6, Telecom Nagar Extension
Gachibowli, Hyderabad
Telangana, 500 032
+91 40 29801699