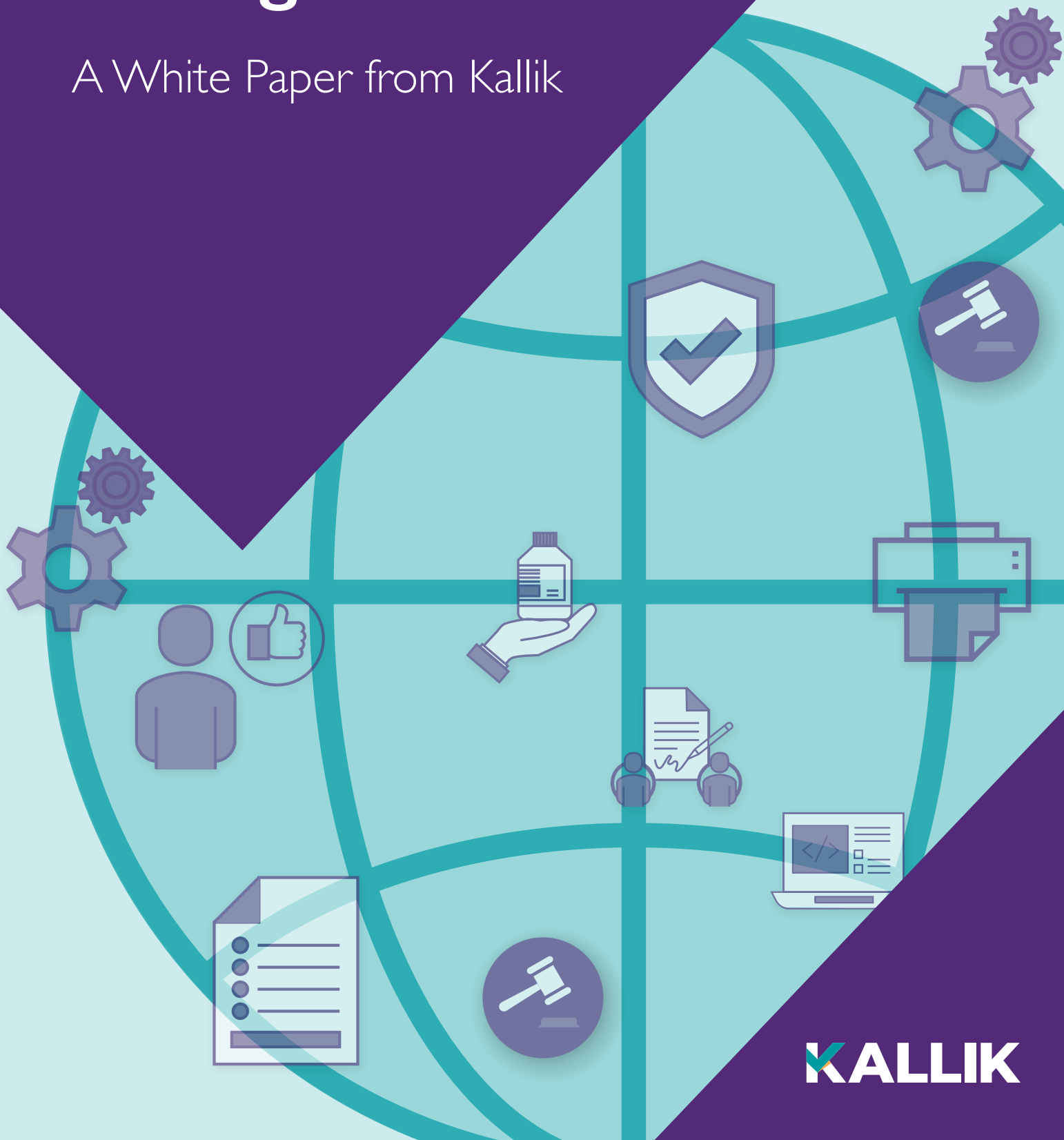


An Intelligent Approach to Labeling and Artwork Management

A White Paper from Kallik



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Introduction

Many organizations today are experiencing unprecedented demands from regulatory authorities and consumers alike for product labeling to be made clearer and more informative. Forthcoming regulations (including the new EU MDR regulations coming into force May 2020) also require that labeling content to be published electronically in addition to print. As companies seek to continuously differentiate themselves in established markets as well as gain entry into new territories, the increase in both volume and complexity of product and market variations will have a direct impact on labeling.

Proliferation of communication channels is another driver, e.g. offering a wider product portfolio across a broader mix of distribution channels will require tailoring of labeling content. For example, the product data sheet shared by manufacturer of chemicals with B2B channels is likely to differ with that shared in a B2B environment.

Many of the processes organizations have in place today, try to manage this problem by documented processes and procedures. These typically define a series of steps to be followed, information to be captured, along with what to do if certain criteria either exists or doesn't exist. Guidelines and instructions are usually captured in procedural manuals, sometimes with amends published via email and hence can quickly become out of date or uncontrolled if not managed carefully. This can be compounded by some of the more experienced users taking on the role of the 'go-to person' for direction and advice and all too quickly, the organization finds itself operating on the basis of 'tribal knowledge.'

Historical Overview

have been focused on automating localised labeling processes as opposed to the more complex needs of primary and secondary packaging. This can be seen in the approaches taken by several of the labeling software vendors offering solutions for downstream print and packaging (typically shipper case and carton labeling). These solutions often rely on fairly low level integration with Product Lifecycle Management (PLM) platforms, applying a simple set of rule criteria to generate the correct output. One example might be that when a 'works order' is generated by PLM to print a set of labels for (e.g.) injectables, a rule that states that a 'sharps' warning statement or symbol must be present, resulting in this content being automatically added to the label.

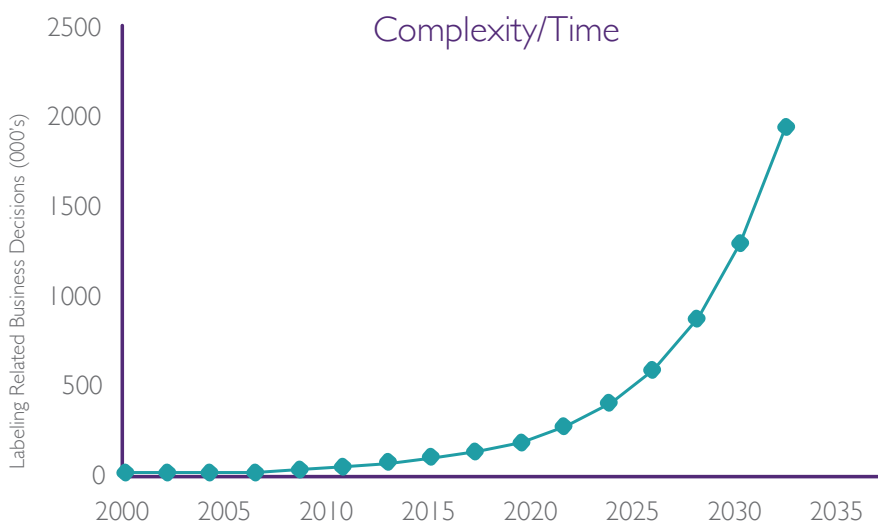
Labeling and artwork processes have tended to be seen more as a cost overhead than a core business activity.

Whilst this type of approach can be effective in satisfying labeling requirements at the point where products are packed for shipping, it fails to address the upstream challenges at the point of primary and secondary packaging. It also omits the need to publish product related information electronically. Quite often these types of software solutions, despite being cloud based, are effectively 'local software instances', meaning that each production facility would have its own set of rules and predetermined User Interface (UI). This can restrict choices when (e.g.) wishing to engage new partners and can increase production costs and other overheads as the business scales. It can also make it difficult to share and trace the use of content across the enterprise, making it harder to prove compliance and maintain alignment with corporate standards.

As outlined above, many of the overheads and risks to non-compliance associated with label print and production are the cause of three main factors:

- 1. Reliance on 'tribal knowledge' or a 'go-to' person for understanding or interpretation of requirements**
- 2. Little of this knowledge and labeling content is captured electronically, creating an increased risk of non-compliance the more decentralised an organization becomes**
- 3. Legacy stovepipe applications with minimal process integration that can obfuscate key elements of data and restrict the flow of information**

With one or more of the above factors present, any organization seeking to increase its global reach and product portfolio is likely to experience unnecessary levels of disruption. This could lead to production downtime or risk product recalls, ultimately impacting profitability and market reputation. A survey of 285 senior executives carried out by Ernst & Young on the effectiveness of decision making within the consumer sector, suggested that employees spent too much time making decisions based on intuition, working on mechanical tasks and focusing on unnecessary detail. A recent study by Forbes also revealed that 98% of managers fail to apply best practices when making decisions.



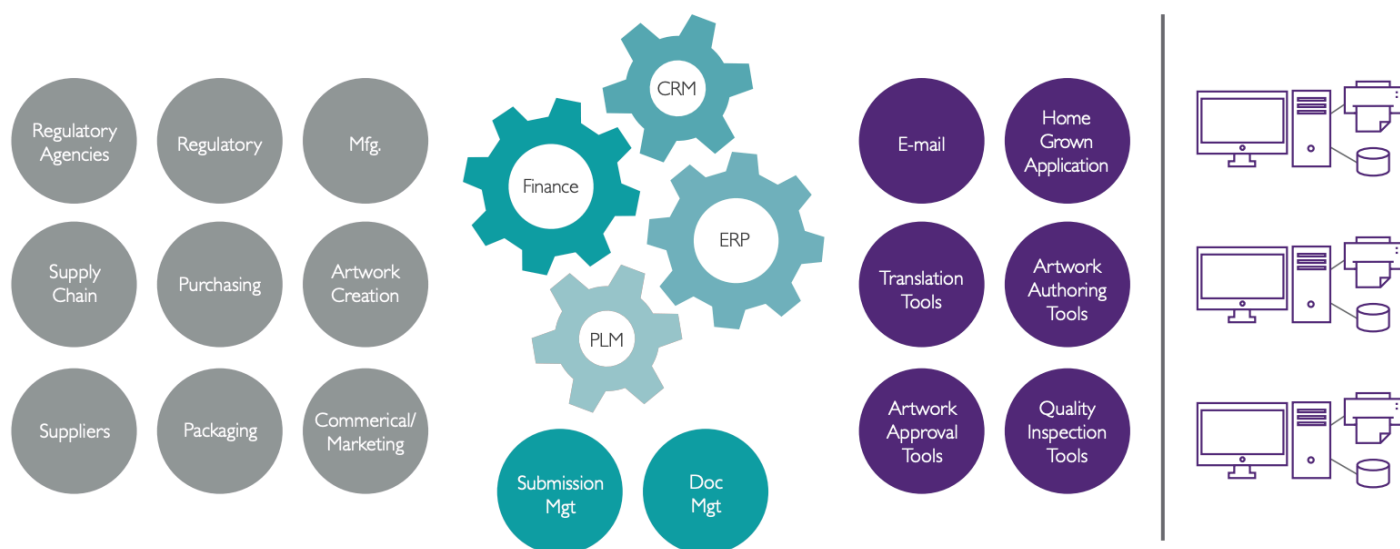
Focusing back on the life sciences industry and with e-Labeling and more patient-centric treatments around the corner, it is likely that organizations will begin to experience an exponential growth in the volume of variable content that needs to be shared with both the prescriber and the patient. This in turn, will impact on the number of business decisions that will need to be made when it comes to labeling. Loosely based on 'Moore's Law', the chart above gives a projection of how the number of decisions related to labeling content is likely to increase over time. This suggests that without some form of decision support system, labeling teams will not be able to respond effectively to increased levels of sophistication and complexity.

This projection is unlikely to come as any great surprise. The combination of a broadening product portfolio, expanding market presence and increasing legislative requirements has already seen the number of decisions needed to ensure appropriate and accurate labeling content increase over time. This trend will continue as recent regulations and directives impacting labeling requirements across medical devices, pharmaceutical, chemicals and cosmetics companies begin to mature.

Adopting a manual based approach is sustainable to a point, but risks labeling and artwork content falling out of compliance with corporate standards and local regulations due to increasing levels of complexity. In effect, there is little corporate governance. There are 'rules' of course, but accurate execution of these rules rely on human awareness and accurate interpretation. Consequently, those responsible for collating and entering labeling content waste time searching for the correct information and instructions contained within emails, PDF files and databases. These also have every possibility of being superseded by more recent regulatory and/or product updates.

As a result, in-country affiliates can become overburdened with unnecessary complexity and can waste time searching for instructions embedded in documents and emails. New staff and supply chain partners responsible for print and packaging need to manually learn each of the rules associated with label creation which can delay time to value. This can lead to frustration, fatigue and in some cases, discrepancies and uncontrolled variations. Furthermore, it becomes almost impossible to identify the source of errors as instructions and guidance notes are often uncontrolled, untraceable and out of date.

The truth is of course, a product doesn't become a product without a label and certainly cannot be sold without one. Further, because the labeling and artwork vendor community has primarily been offering fragmented point solutions rather than a single end to end application, organizations have been falsely conditioned to accept that this is the only available approach.



A Business Rules Approach

Overview

Some might argue that more processes and greater levels of documentation is required to solve this problem, but there is no guarantee that such an approach will increase levels of accuracy and quality. Even if this were the case, the increased overheads of doing so, may further risk productivity and employee motivation. A much better approach is to harness both corporate knowledge and labeling content and embed these into the software tools used by those across all functions of the supply chain; from regulatory right through to final packaging and shipment. This suggests a need for a labeling and artwork centric business rules engine to achieve each of the desired outcomes given below:

- **Minimise the level of human intervention in completing complex tasks**
- **Ensure content alignment across all types of labeling**
- **Automate and simplify the capture and collation of labeling content needed to address specific product and market needs**

Rules Engine Concepts

At its simplest level, a rules engine consists of a set of rules that can act upon a number of 'facts' stored within a 'fact model'. The accuracy and quality of any decision being determined by the data and facts stored within the application. In the context of labeling, a 'fact' may be a statement, symbol, image, phrase, barcode or any other component appearing on a label. The rules engine itself requires that it is pre-populated with a set of 'facts' to which rules can be applied to derive more facts. Once configured, the rules can be executed as part of the core business application.

Most of us will have experienced this scenario when applying for a new bank account, credit card or insurance policy. The presence of certain fields and whether these have been pre-populated or requires that we input data will be depend on how we have answered previous questions, with the rules engine inserting, deleting or updating facts in real-time. Exactly the same concept applies in the context of labeling, although here we are talking about business users interacting with a business application as opposed to consumers completing an online application form.

Why Deploy a Rules Engine?

Business Rules Engines (BRE) and Business Rules Management Systems (BRMS) are acknowledged as being the most effective approaches to developing these kinds of decision-making systems.

Managing the decision-making process as a set of business rules allows for more responsive changes or additions to process as this can be undertaken by business users as opposed to writing code.

This approach also simplifies the ongoing management of decision making logic and also allows for new business logic to be modelled without impacting the existing underlying processes.

Many organizations today use decision making systems to help find the best products to meet customer needs or to protect themselves against the risk of fraud. As discussed earlier, banking and insurance are two common examples of where complex decision making logic has been embedded into business applications to simplify and de-risk the customer engagement process. Just like any other industry however, regulatory and product information may change as will the criteria used to best match customers with products or services.

Moving business logic that is either hard coded in software systems or defined as a set of instructions contained in documents and emails into a business rules engine also simplifies ongoing management and change. Mark Allen of

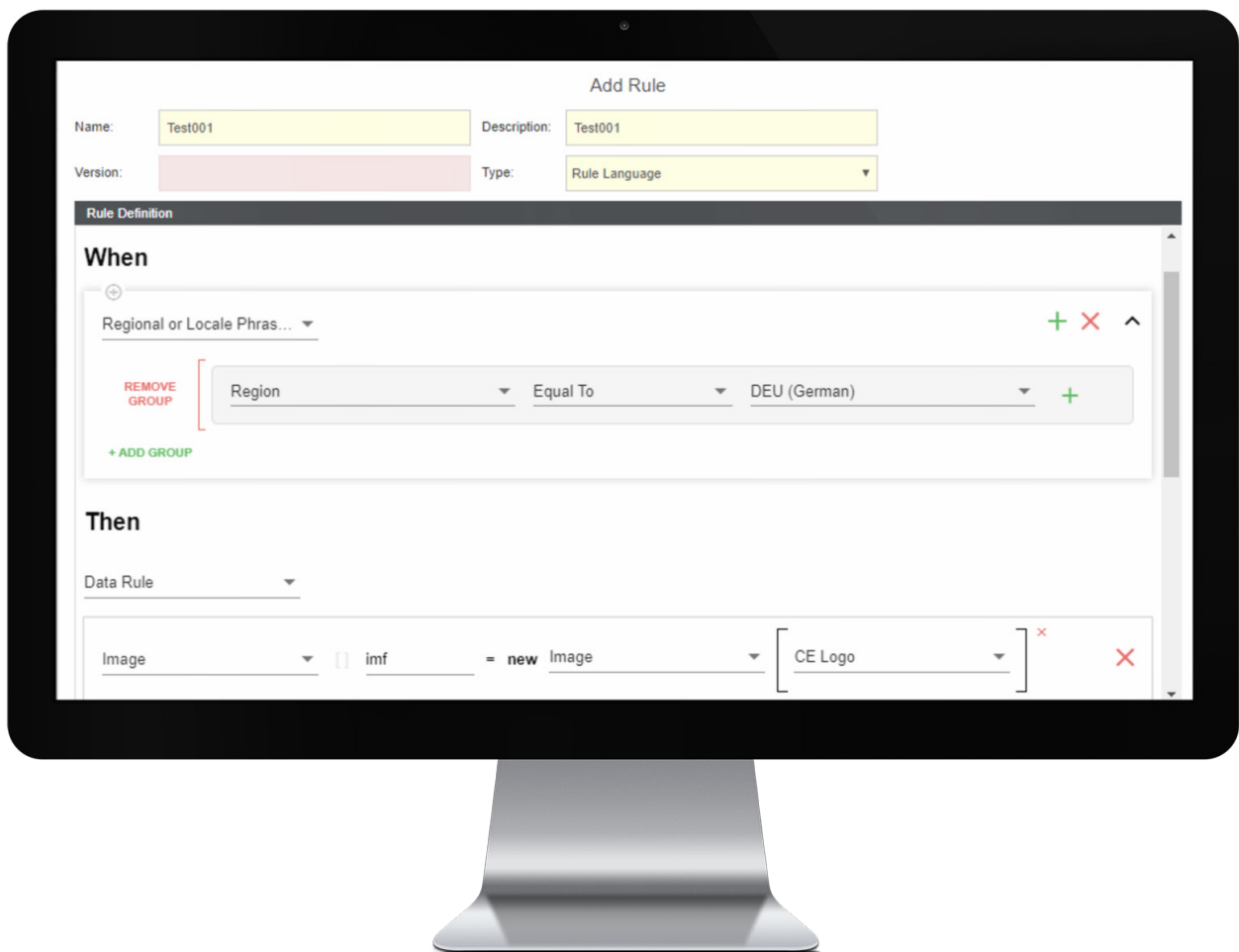
Progress Corticon suggests having the business rules logic separated out from the underlying application can help change business logic by 10 to 25 x faster by removing the backlog of requested changes placed on IT. Allen also states that a BRMS can also significantly reduce the need for manual processing as well as help ensure compliance with regulation and suggests the following benefits are likely to be realised:

- **Being better positioned to keep up with the pace of change**
- **Improvements to productivity and efficiency**
- **Ensure compliance with policy and regulation**
- **Improve customer service**
- **Open new revenue opportunities**

Software systems having automated what were operational and repetitive decisions have shown to improve organizational decision making and corporate knowledge. Instead of being written down in documents and or emails, these elements are continuously enriched and enhanced by new insights. These insights are often gained through knowledge and experience of those engaged with systems and processes engaged in the label creation process.

The problem incurred today with artwork and label creation is that business logic is often hidden in application code across a number of siloed systems. This makes maintenance, analysis and optimisation a time consuming and cost intensive activity. It also inhibits rapid implementation of changes needed to respond to regulatory or market driven changes. With the help of business rule management, organizations can separate their rules based logic from underlying IT logic, making it easier to adapt to changing market dynamics.

Given the complexities of the labeling, we now need to consider whether taking a business rule driven approach to labeling and artwork has the potential to deliver real benefits.

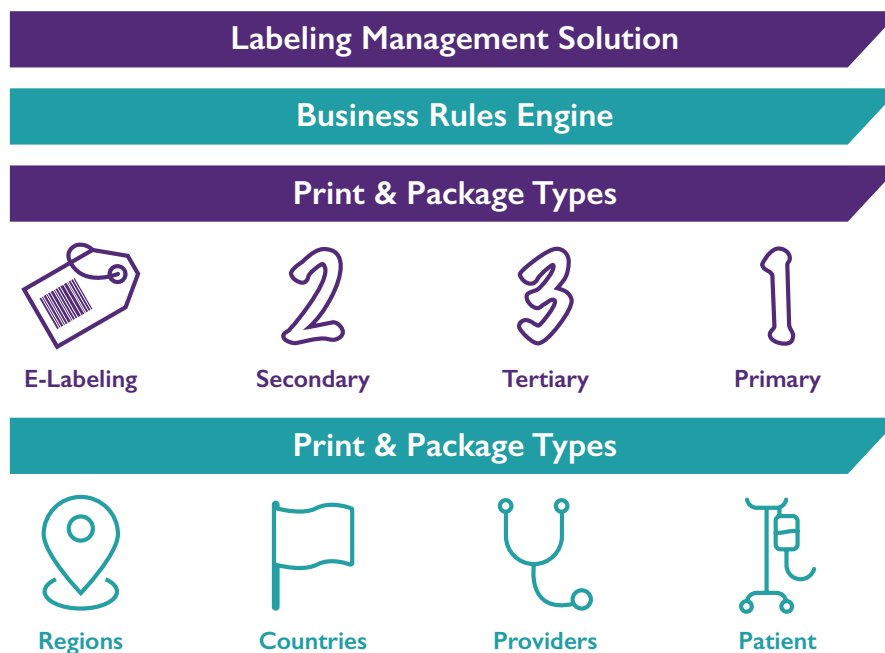


The Role of Business Rules in Labeling & Artwork

Concepts

Correctly applied, a business rules engine brings a level of simplification to what is becoming an increasingly sophisticated activity. Capturing this environment within a two-dimensional view as shown to the right, can help the reader to visualise the application and benefits within the context of labeling. Here, this simplified view shows labeling being applied at several different stages during the manufacturing process and across the supply chain. Typically this would encompass blister packs, cartons, shipper cases, marketing materials and all forms of electronic labeling. In each of these cases, there may be a subset or superset of content printed (or presented) which the business rules engine will either pre-configure or prompt the user to include when populating the label template.

Viewing this from another dimension, each region, country, provider and patient may require content that is unique. Again, with a pre-configured set of rules, the rules engine enables a product destined for a specific group of patients serviced by a particular provider to have certain fields on its associated label automatically populated by the rules engine. Alternatively, or in addition to the above, the rules engine can either add or suppress fields presented to the labeling user to ensure the correct information is captured.



Typical applications

As discussed previously, every element that can appear on a label (whether in printed or electronic format) can be considered a 'fact'. In the context of labeling, such 'facts' could relate to branding, regulatory statements, product information, etc. and can be both text and symbols. The rules engine itself, can then act upon these 'facts' in one of several ways:

- **Auto-population of data**
- **Metadata manipulation**
- **View adaptation**
- **PLM works order manipulation**

A detailed discussion of each of the above operations is beyond the scope of this white paper; however it's worth explaining these in some depth to understand the benefits that a rules engine can deliver to labeling and artwork:



Auto-population of data

Software systems having automated what were operational and repetitive decisions have shown to improve organizational decision making and corporate knowledge.

It is not untypical for labeling and artwork software vendors to provide maximum possible flexibility at each stage of the process, making all fields and options that might be needed for each type label available to the user, irrespective of their role and task to hand. Whilst this provides a large degree of flexibility and accommodates the needs of every potential user and type of label, it has several downsides. Firstly, it may need the user to make a decision which is outside the scope of their role or sphere of knowledge. Secondly, it could lead the user to guess at what is being asked for. Thirdly, the field could simply be left blank. The likely outcome being labeling errors and missing information. This is especially critical where such fields relate to market specific legislative requirements.

A good example of this might be where a product sold into a certain market requires a particular symbol or statement to be included on a 'front label' in a specific position. By specifying the country and product type, the rules engine will determine which 'fact' (i.e. symbol or statement) needs to be included where and subsequently auto populate the label template. In less complex situations, where (e.g.) field values remain constant across multiple instances of labels, auto-population can eradicate many of the mundane repetitive tasks that can otherwise lead to the introduction of errors through fatigue and distraction.

With the chemical sector for instance, a formulation code is populated. The 'auto-populate rules' pull through and populates all the Technical Claims and Safety, Health & Environmental content (SHE data) ensuring consistency and compliance across any product utilizing that product code.

The same applies with the Medical Devices sector, products containing latex are flagged so that whenever that product name is chosen, a Latex warning symbol appears automatically within the labeling content for that product.



Metadata manipulation

Without the labeling and artwork system having in-built intelligence to prompt the user that he/she needs to select and add additional content, the need for this may get overlooked.

An example of metadata manipulation or transformation might be ingesting an abbreviated product name SAP and transforming it to the correct labeling content, potentially specific to a market. Taking numerous pieces of metadata and concatenating them into a single files naming conversion or creating a cohesive technical claim statement from numerous pieces of data.

Similarly to the above example, but in a slightly different context, there may be exceptional cases where some labels may need additional content added that is not otherwise included. Without the labeling and artwork system having in-built intelligence to prompt the user that he/she needs to select and add additional content, the need for this may get overlooked.

An example here might be where a product sold into a certain market requires an additional field added to meet local safety legislation - this may be termed a 'mandatory field'. In this case, given a predetermined rule triggered by a specific product code, the rules engine would automatically present this field to the user for content to be added.

In some cases, it may also be possible to pre-populate such a field by using an 'auto-population rule' as discussed above. This 'metadata manipulation' can also be applied to remove as well as add fields, e.g. in the case where a normally required phrase, or symbol may not be relevant to either the product type or the market into which it will be sold.



View adaptation

One of the most often heard complaints from the labeling and artwork user community is that they find themselves tasked with trawling through screens of prompts without any guidance as to which fields need to be populated in relation to their role and responsibilities.

Again, this is often a symptom of software vendors wishing to build maximum flexibility into their products, but this fails to help the users who are tasked with only needing to provide a subset of the required content.

Here, a rules engine can also modify the interface presented to the user based on their role such that he/she only sees relevant fields and not the full scope of options that may or may not be relevant. Furthermore, not all fields will be relevant to all regions or locales. In some cases a subset or superset of fields may be required depending on local regulatory requirements. For example, local in-country affiliates may only see the fields that need to be populated with local regulatory statements or symbology, whereas those in marketing and regulatory may be given a broader (and possibly different) selection of fields to populate. This vastly simplifies the role of each stakeholder called upon to input content and reduces the risk of omissions and errors.

View adaptation also equates to solution only presenting the labeling data or fields related to the specific product or packaging type. For example, the I3-labeling attributes that appear on the product label will also be needed for the carton or pouch. If configuring labeling data for the IFU (Information for use) leaflets, then additional data will be needed over and above that which is required for product labeling.

Another example is 'multi-language' labels. Here, the technical claims may only be required in 3-languages whereas the SHE statements are required in all 6-languages. Manufacturing addresses are another example. In most countries this is only required to be in one language, but for Turkey it must be in 2-languages. In this case, the screen presented to the user would show the additional language field to be populated ensuring exceptional cases such as this are not overlooked.



PLM works order manipulation

Insertion of a rules engine at this point, can automatically translate from what could be termed 'unstructured data' to content that is 'labeling ready', saving significant effort and potential re-work.

Many large organizations have implemented Product Lifecycle Management (PLM) software to underpin their product design and manufacturing processes. Therefore, much of the 'standard' content (product name, ingredients, instructions, etc.) can reside in these systems. In which case, it may be stored in a truncated form or possibly codified to support machine-to-machine communication with other business applications. Whilst a selection of this data will be needed for product and package labeling (including electronic labeling), it is not necessarily in the structure and format required for printing directly onto each type of label.

Working through this example, the PLM system may have truncated one or more attributes associated with the product that may need to appear on the label - a typical example being product name. Alternatively, PLM system may generate a product code that may need to be transformed into a product name. Insertion of a rules engine at this point, can automatically translate from what could be termed 'unstructured data' to content that is 'labeling ready', saving significant effort and potential re-work.

Which Rules Engine?

Having analysed the above use cases, it seems clear that adopting a rules based approach to labeling and artwork management can make a positive impact on existing operational processes. If we accept that this is the direction we wish to take, we need to consider which rules engine we need to adopt and how best to integrate this into existing labeling and artwork processes.

Organizations wishing to deploy a rules engine can choose from a number of different options, including both open source and commercial offerings. Rather than describe the pros and cons of various types of rules engines and attempt a comparison between adopting an open source or commercial option, here we will look at some of the criteria to consider when making such a decision in the context of labeling and artwork.

It may be that organizations have previously evaluated and selected a rules engine as their corporate standard and wish to extend use of this across labeling and artwork processes. It may be seeking a more closely coupled solution that enables a more contextual approach. This often yields better outcomes when working across a very domain specific process such as labeling and artwork as much of the 'fact' data will be held within the labeling and artwork application.

Rules engine selection criteria

Listed below are a number of factors that may be worth considering when evaluating a suitable rules engine to simplify your labeling and artwork processes:

- **Domain specialism** - whilst there are a number of both open source and commercial off the shelf rules engine products available, it's worth considering the extent to which these will satisfy some of the unique requirements that labeling and artwork tasks often present
- **Configurable rules** - to what extent are the rules configurable to satisfy the needs of your organization, users, markets and products?
- **Dynamic rule application** - will the rules engine allow you to dynamically create and update a range of label types (e.g. primary, secondary and factory printed labels) from a single request?
- **Rules admin** - how easy is it to create the rules and collate these to create 'rule sets' and then apply certain rule sets across different operating regions (e.g. Europe, North America, Asia, etc.) - some rules engines provide a 'business user interface' to enable more competent users (e.g. super users) to configure and apply the rules themselves
- **Rules execution** - does the rules engine perform validation of any transformations where data entered within the system generates a match to a symbol or phrase that doesn't exist in the system and therefore requires an entry into the audit log
- **Batch upload** - as much of the data populated within labeling and artwork systems is derived from external sources, having a rules engine that can execute rules during any 'batch upload' process can save time, cost and improve quality
- **Flexible configuration** - whilst the rules engine should offer sufficient flexibility to address the wide scope of conditions and exceptions discussed in this paper, it should also allow for a 'base view; to be created (i.e. for the fields that will always be present across all labels) with a set of standard fields
- **Trigger points** - flexibility to enable rules to be triggered and re-triggered at multiple points during the data capture process, e.g. if and when data changes during data collation process

Kallik's view

Having chosen an enterprise-wide labeling solution, our customers have benefitted from gaining much greater awareness and understanding of the internal roadblocks and pain-points that can frustrate their labeling and artwork processes. As one customer put it; "We are now managing by reality as opposed to perception." This is often the first step in the customer journey towards complete transformation of their labeling and artwork business processes. With greater levels of transparency giving a better understanding of how and where organizational productivity is suffering, the next step usually taken is to start to automate some of the manual repetitive tasks that will free up resources to attend to higher value activities.

The modular structure of our AMS360 product has enabled us to implement a business rules engine that is fully integrated with existing processes used for label creation. This enables a stepwise approach to be taken, enabling our customers to specify and apply business rules to high priority tasks first. At Kallik, we acknowledge that our customers understand their business processes far better than most software vendors are likely to. We also believe the real benefit of adopting a rules based approach to labeling and artwork is that it allows organizations to tailor the system around their business processes rather than needing to adapt their processes to meet the requirements of the system. Furthermore, having enterprise-wide data consistency enables the same number of users to process many more projects, delivering a critical productivity benefit.

"We believe the real benefit of adopting a rules based approach to labeling and artwork is that it allows organizations to tailor the system around their business processes"



Summary

In considering the application of a business rules led approach across artwork and labeling processes we have seen how industries such as banking and insurance have already taken this initiative with high levels of success. We've also considered a number of scenarios specific to the capture and collation of artwork content where a business rules engine could both simplify and de-risk the overall process making organizations leaner and more agile. We concluded with an overview of Kallik's approach and the benefits this can deliver, in particular the reduction of errors and increased levels of productivity.

The feasibility of adopting a rules based approach to labeling and artwork and demonstrating how this can be applied to a number of scenarios shows clear benefits. As organizations continue to grow, many acknowledge that satisfying increasingly stringent regulatory requirements plus meeting increased levels of user sophistication will be challenging if continuing to using manually driven processes. The alternative of deploying rules into a stand-alone BRMS has also been considered, and whilst this is possible, we feel that the semantic nature of artwork and labeling content is better served by an integrated onboard rules engine.

Finally, if you would like more information on how we can help you to both de-risk and eliminate cost from your labeling and artwork processes, please get in touch with us and we will be delighted to talk with you. In the meantime, please feel free to visit our website where you can find out more about Kallik and our products. You can also keep abreast of latest industry trends in labeling and artwork by subscribing to our blog.

For more information, visit: www.kallik.com

About Kallik

Kallik, the enterprise labeling company, provides regulated industries with a responsive, end-to-end label management platform they can trust.

Its cloud-based labeling platform, Veraciti™, delivers definitive compliance and supply chain efficiency for all the content assets that make up product packaging, labeling and customer information documents. From barcodes to safety symbols and text, Veraciti manages any format, in any territory, on any material and via any channel - with complete reliability and traceability

Medical device manufacturers, pharmaceutical firms, chemical and cosmetics companies use Kallik to deliver trust in their labeling, confidence in their brand and integrity in their process.

To find out how we can support label and artwork management transformation in your business, please get in touch by emailing us at info@kallik.com.