Pharmaceutical Packaging and Labelling Summit

# 2016 Trend Report

Perigord
life science artwork solutions

Pharma iQ
a division of IQPC

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# FOREWORD

According to recent research, the global pharmaceutical packaging market is forecasted to reach more than US$80 billion in revenue by 2020.

This expanding market is advancing towards optimization in regards to effectiveness. However, as noted in recent research, this wasn't always the case: "Packaging was considered as an afterthought which was required merely in the final stages of manufacturing for many pharmaceutical companies about a decade ago. But of late, pharmaceutical packaging has quickly become an essential part of the drug delivery system.." (1)

Off-patenting drugs, the growing generics industry and the progression seen within manufacturing are all expected to fuel the advancement of the packaging market.

The pharmaceutical packaging and labelling market is predicted to feel a boost from the maturation of the biologics market and its new therapies with pre-filled syringes and parenteral vials forecasted to experience the fastest growth.

Asia and Europe follow North America - the biggest market for packaging and labelling equipment. This is due to strong awareness and healthcare investment within the US. (2) Rising contract manufacturing activities' are due to fuel the rapid growth that is ahead for the Asian market.

Upped demands for primary pharmaceutical containers and for flexible and integrated packaging are due to propel the market's activity also. (2) Although, these surging demands can only be catered for if the relevant pharmaceutical packaging and labelling compliance requirements are met.

With this in mind, the packaging, labelling and artwork divisions of the pharmaceutical market face pressures from a range of directions. These include:

- **Producing efficient packaging streams that are compliant and implemented swiftly at a low cost**
- **Varying country requirements**
- **Effectively adhering to new serialisation guidelines**
- **Refreshed regulations**
- **Controlling demanding overheads**

One challenge is presented by the recently revealed Falsified Medicines Directive (FMD) requirements. After waiting for these regulations to be confirmed, market players are now left with the task of achieving requirements by the allocated deadline. Cross-industry insight is of prime value in this instance, as many are keen to learn from other companies' implementation strategies.

In regards to labelling, one key challenge is navigating around country specific guidelines – especially with the amount of information that is required on a package in ratio to the amount of space available.
In this research report, Pharma IQ explores the trends, both those currently prominent and those which are emerging, within the pharmaceutical packaging and labelling market. Also, Suzanne Ivory, Head of Quality at Perigord provides insight into overcoming artwork obstacles on the route to market.

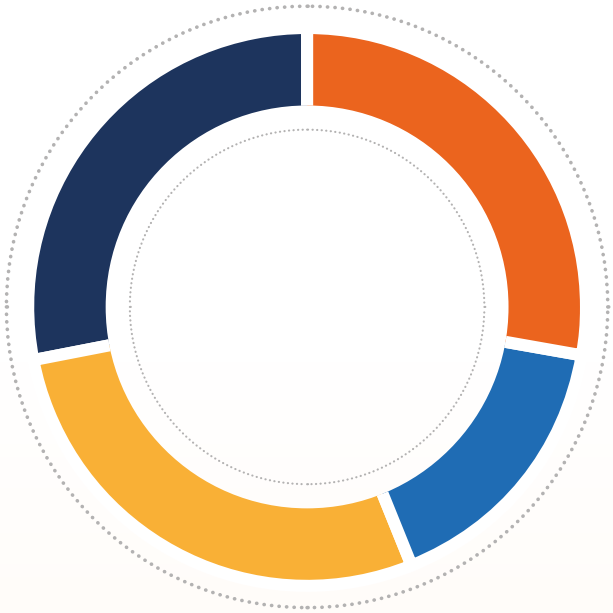
I hope you enjoy

**Chanice Henry**
**Editor of Pharma IQ**

# ABOUT THIS RESEARCH

Pharma IQ invited its community of pharma and biotech professionals to partake in an online questionnaire in Q1 of 2016 to assess current industry trends in Pharmaceutical Packaging and Labelling industry.

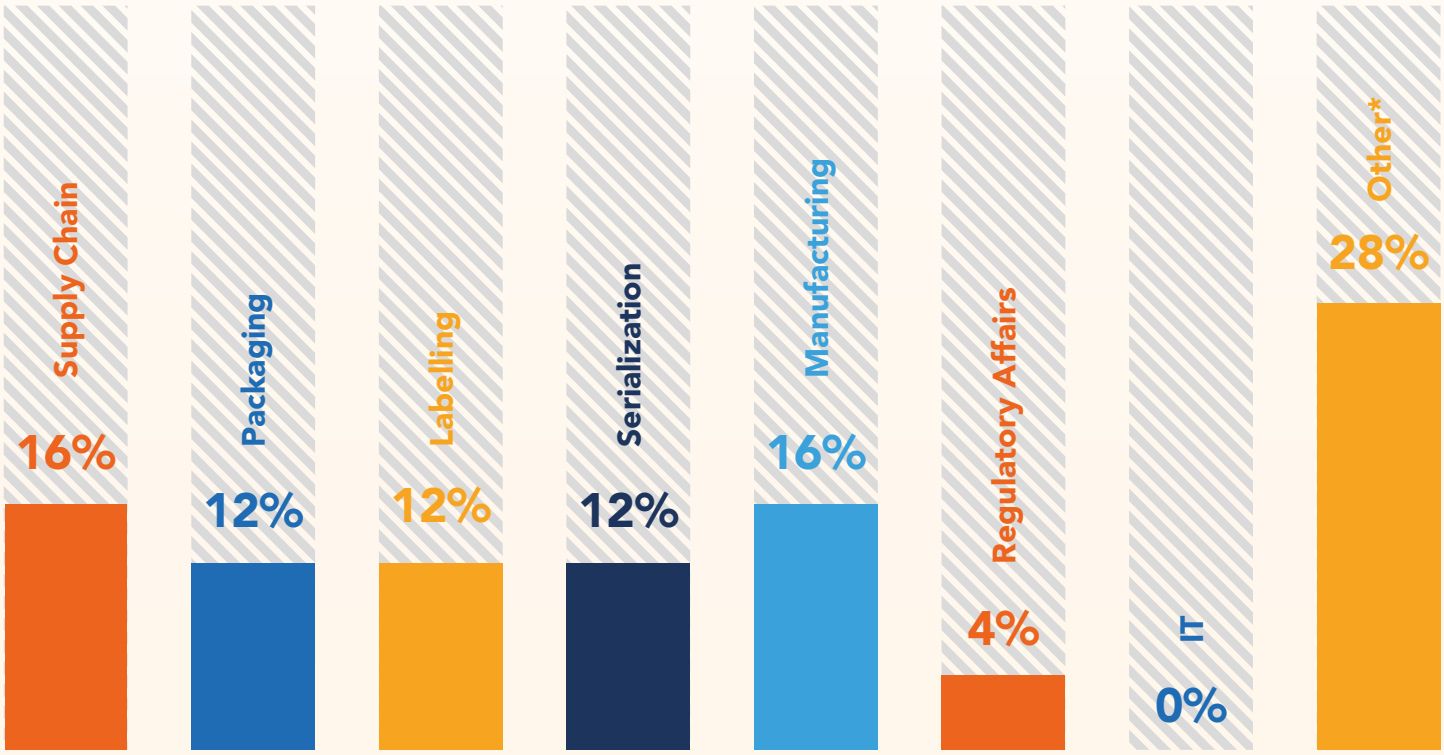
## WHAT PROFILE COMPANY ARE YOU FROM?



- Large pharma/bio manufacturer ..... 28%
- Small-to-mid-sized pharma/bio manufacturer ..... 16%
- Medical device manufacturer ..... 0%
- Government ..... 0%
- Solution Provider ..... 28%
- Other* ..... 28%

*Other: Secondary pharma packaging manufacturer, Label manufacturer, Pharmaceutical/MedTech Manufacturer, Wholesaler, OTC manufacturer, small

## WHICH FUNCTION DO YOU SIT IN?

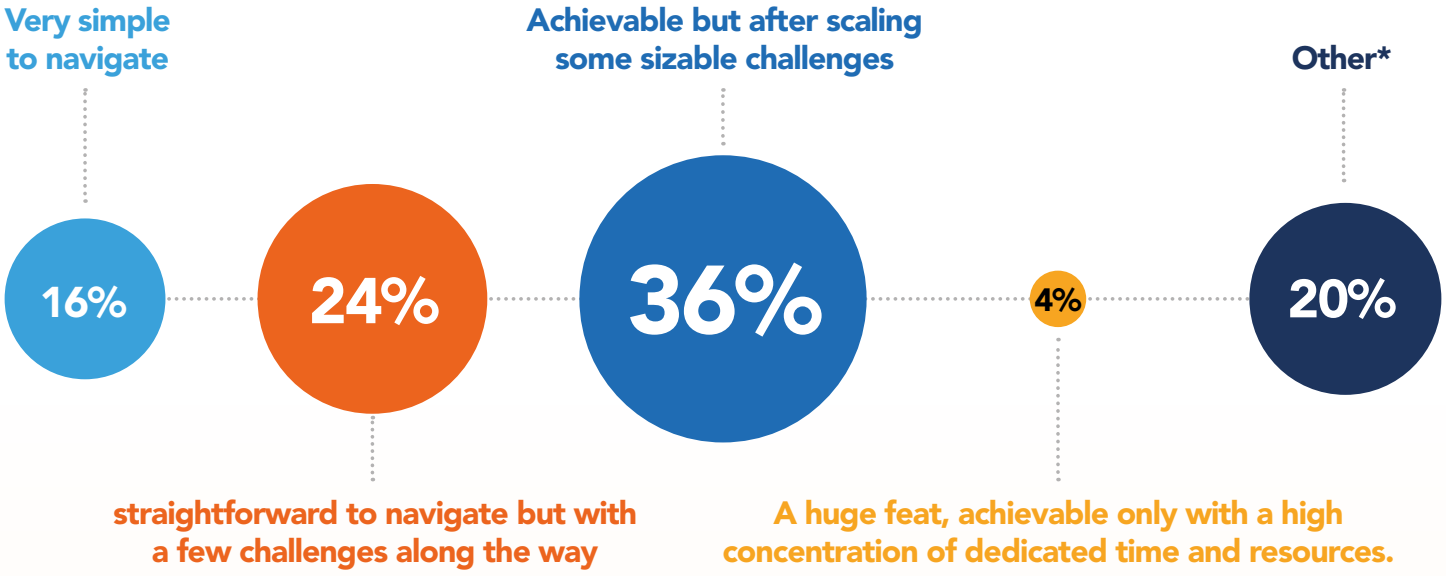



* Consulting Manufacturing and Supply Chain, QA, Product management, Business Development, Implementation Partner

# DATA ANALYSIS

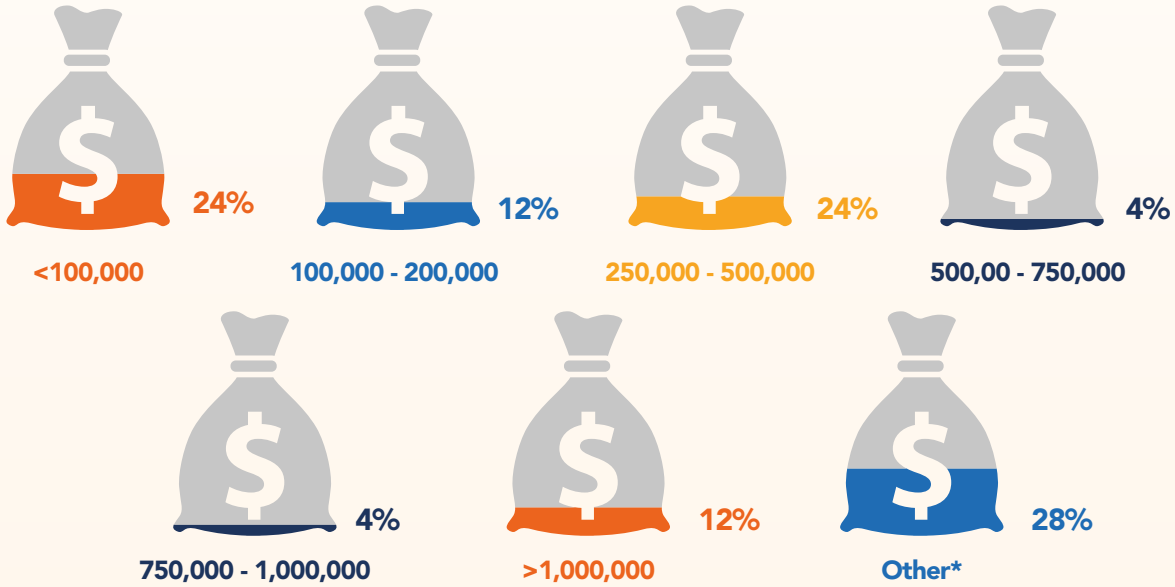
## PACKAGING

### IN LINE WITH MEETING THE NEEDED FMD DEADLINES – DO YOU THINK YOUR FIRM'S ROUTE TO AIRTIGHT COMPLIANCE IN TERMS OF PACKAGING IS GOING TO BE?




*Other: Clients will underestimate the complexity and effort, Not applicable

### HOW MUCH ARE YOU DUE TO INVEST INTO STREAMLINED & EFFICIENT PACKAGING COMPLIANCE OVER THE NEXT 12 MONTHS?

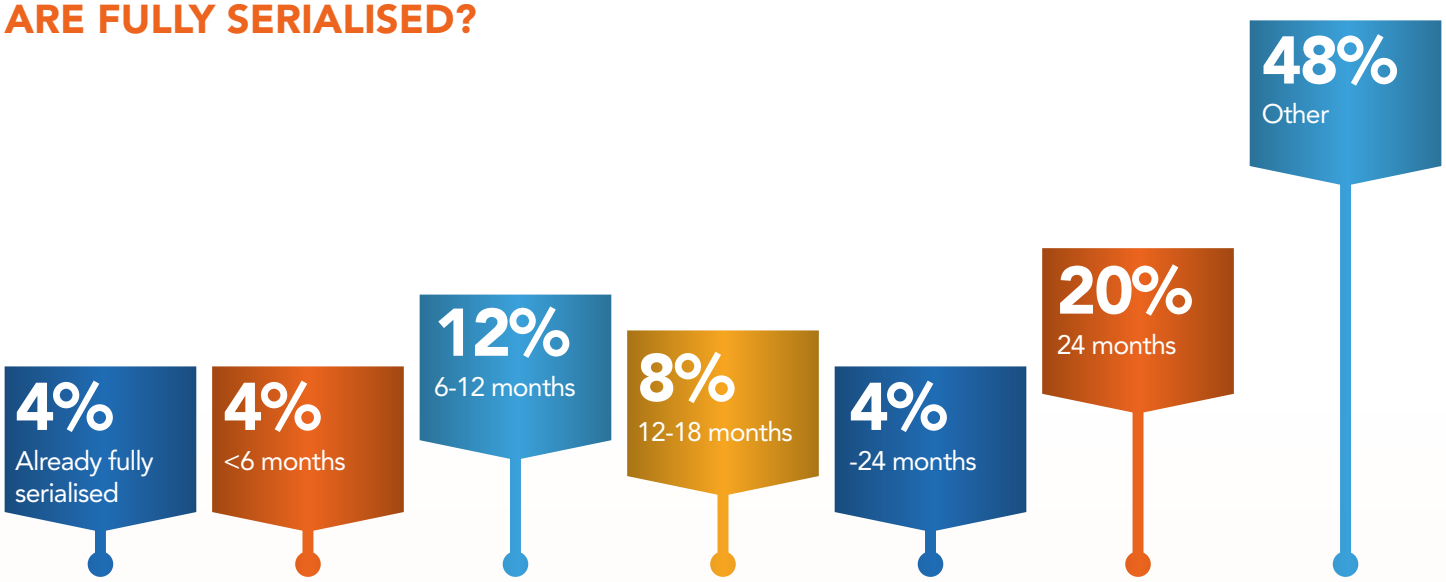



*Other: Not applicable, Not sure dependant upon approvals

After reviewing these results, Dieter Mößner, Project Engineer Pharma, Edelmann GmbH notes a charted confidence in achieving full FMD packaging compliance. In response to the projected investments towards packaging compliance, he perceives that the costs may have been underestimated and participants may have only regarded the direct and external costs and didn't consider not internal costs like project people and training which can be substantial.

# SERIALISATION

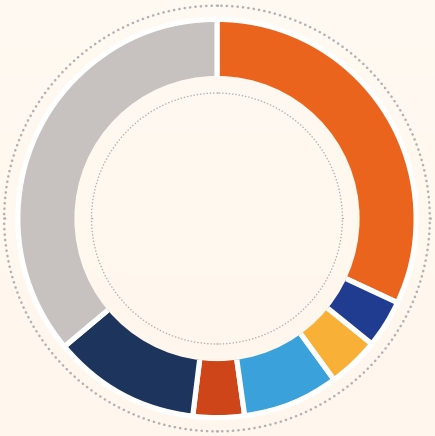
## HOW LONG DO YOU ANTICIPATE IT WILL BE UNTIL YOU ARE FULLY SERIALISED?




*Other: Depends on manufacturers, More than 2 years, Time line has not been set yet, Not even started

Only 4 per cent of our participants labelled themselves as fully serialized. Whereas following the 'other category', most people said that they foresaw it would take them around 24 months to reach full serialisation. In Pharma IQ's 2015 research most people said it would take just over 24 months to reach complete their serialisation projects. Surprisingly, some participants noted that a timeline hadn't even been started yet in their organization.

## IF APPLICABLE, HOW MANY PACKAGING LINES WILL YOU NEED TO UPGRADE IN RESPONSE TO SERIALISATION?

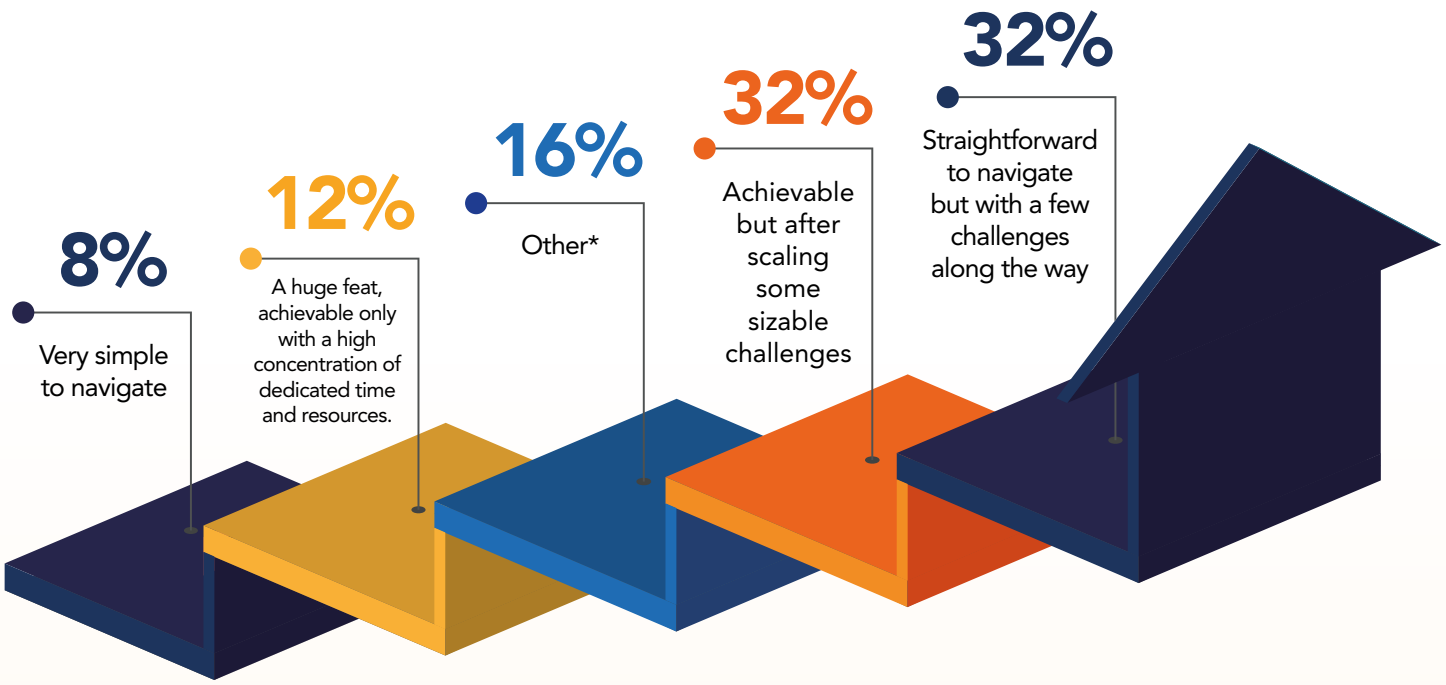


| | |
|---|---|
| Less than 10 | 32% |
| 10 – 19 | 4% |
| 20 – 49 | 4% |
| 50 – 99 | 8% |
| More than 100 | 4% |
| Don't know | 12% |
| Other* | 36% |

*Other: Only need to do pack lines in Serilaisation market scope, Need to design that into the process.

In terms of the amount of packaging lines that need to be upgraded in line with serialisation, a large amount of participants noted that less than 10 lines required attention.

# IN LINE WITH MEETING THE REQUIRED FMD DEADLINES – DO YOU THINK YOUR FIRM'S ROUTE TO AIRTIGHT COMPLIANCE IN TERMS OF SERIALISATION IS GOING TO BE?

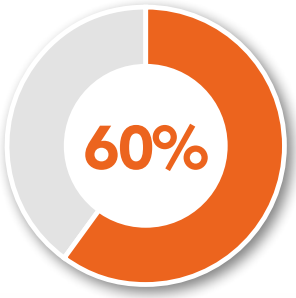



*Other: N/A

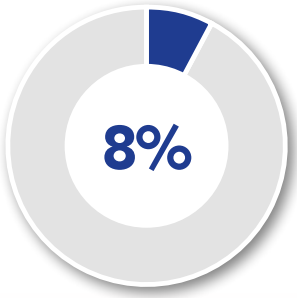
The majority of participants agree that the adherence to FMD deadlines is going to present challenge in someway. With 32% expressing confidence that the route to airtight compliance will be straightforward, another 32% of the research base stated that it will be achievable once some substantial challenges have been navigated. This could be perhaps have a correlation to the size of firms within the research.

# LABELLING & ARTWORK

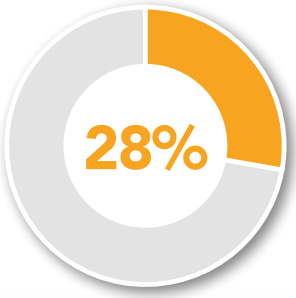
## WHAT AREA OF THE COUNTRY SPECIFIC GUIDELINES IN TERMS OF LABELLING USUALLY PRESENTS THE MOST CHALLENGES?



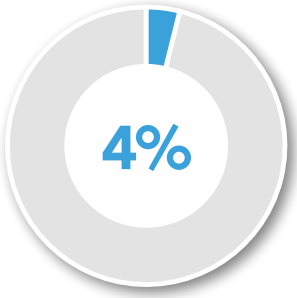

Space for the details required




Anti-Tampering requirements




Translation




Other*

"No particular surprise here about space being the predominant issue. Because it's become an increasing challenge to fit more and more and more content on a small packaging, You don't want to make the carton 2 feet by 3 feet to fit everything on, as it has to be convenient for people to carry.

"If you look at serialisation and tamper evidence that's driving a requirement for even more space because you have to allow space for the serialization code and you need somewhere to put tamper evidence seals, if you choose to use them. So, the regulators are demanding more. The commercial people want more content and you have technical requirements coming through as well now. It's always been a challenge and I think it will always remain to be a challenge.

"The solution to it is to be thinking very carefully early on when deciding the size of the components, what the space requirements are going to be. My view is that ultimately we will be driven away from the huge paper leaflets into booklets before we eventually manage to achieve paperless leaflets, where leaflets are delivered electronically."

Andrew Love, VP Capability Development, Pharma IQ columnist

## IN REGARDS TO EFFICIENTLY HANDLING COUNTRY SPECIFIC GUIDELINES, WHICH COUNTRY PRESENTS THE MOST CHALLENGES?

1. Brazil
2. China
3. EU
4. US
5. Asian, Middle and Far East countries
6. Great Britain
7. Canada
8. Latin America
9. Commonly clustered markets e.g. DE/AT/FR/NL/BE/LU
10. Russia

"Those 4 top countries are a large percentage of company sales as they are a big sales market. They have very different requirements across them. And certainly looking at Brazil and China there is quite a lot of change in their regulations, they are evolving quite rapidly.

"From the EU perspective you have got the complication of different types of filing depending on which regulatory approach you are taking, that can drive some complexity. With the FDA there are ongoing changes which come through there – so it doesn't surprise me that those countriescame in as the top four.

"Looking at the Asia Middle East and Far east – what is interesting there is that lots of companies are growing [within these regions].The regulatory environment is again evolving but there is very little commonality between different countries so they are all coming up with their own specific county requirements so it is very difficult to share product between those markets. What you have to do is put in more market specific product which then increases the complexity in the supply chain which people are trying to avoid.

"I could have expected to see Russia higher up the list but that is dependent on how many respondents are really selling product into Russia. But again it is a very fluid country at the moment the regulations are evolving, requirements are changing all the time so it can be a difficult market to deal with."

Andrew Love, VP Capability Development, Pharma IQ columnist

# WHY ARE SIMPLE AUTOMATED TRANSLATION SYSTEMS NOT SUFFICIENT TO OVERCOME THE MULTI-LINGUAL CHALLENGES PRESENTED BY A GLOBAL MARKETPLACE?

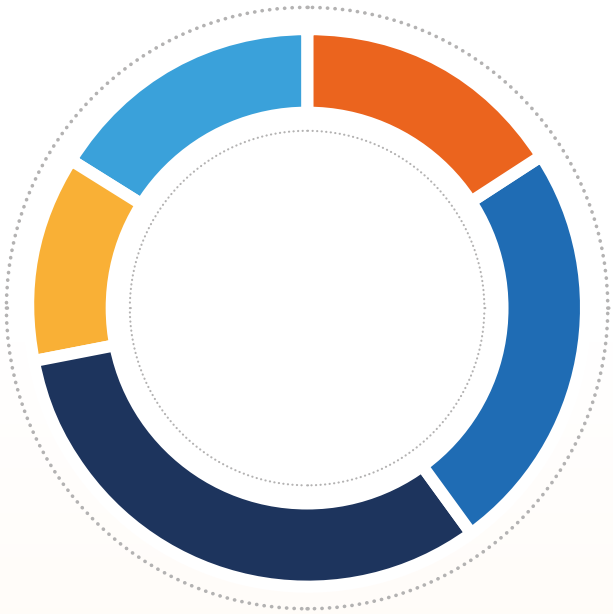

"The points here cover very well the issues using automated translation. The nuances about language can have a big impact on how people read it. And an electronic translation doesn't necessarily have that sensitivity.

Companies that have looked into this a lot have found that a lot of language is product specific. We all dream of a world where the regulatory person can put in the English language and then automatically the artwork is updated in all the different languages through a translation engine and automatic artwork creation. The translation side of that is very challenging to make happen. If you used an automatic translation generator, I think you would still want to have a native speaker to review that translation to ensure that it flowed and made sense.

People are generally starting to see translations as a bigger risk area. I think this is an area that will get an increasing amount of focus over the next few years."

Andrew Love, VP Capability Development, Pharma IQ columnist

## IN LINE WITH MEETING THE REQUIRED FMD DEADLINES – DO YOU THINK YOUR FIRM'S ROUTE TO AIRTIGHT COMPLIANCE IN TERMS OF ARTWORK IS GOING TO BE?



- Very simple to navigate ..... 16%
- Straightforward to navigate but with a few challenges along the way ..... 24%
- Achievable but after scaling some sizable challenges ..... 32%
- A huge feat, achievable only with a high concentration of dedicated time and resources. ..... 12%
- Other* ..... 16%

*Other: N/A

> "If you compare this to the answers given to a similar question earlier in the report in regards to serialisation. There is a marked difference seen in those who chose to select the first answer – very simple to navigate. There are less people saying that Serialization is simple to navigate in comparison to artwork compliance"
>
> Andrew Love, VP Capability Development, Pharma IQ columnist

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# OVERCOMING ARTWORK OBSTACLES ON THE ROUTE TO MARKET

**Suzanne Ivory,** Head of Quality at **Perigord**

With pharmaceutical regulatory demands advancing at a rapid pace, the task of getting a drug to market quickly is becoming littered with added obstacles.

Pharma IQ speaks to Suzanne Ivory, Global Head of Quality, at Perigord for her insight into the biggest struggles faced by artwork professionals in today's pharmaceutical packaging industry. In addition to this, she provides her strategies for how these hurdles can be beaten.

**Please provide some insight into the struggles for the pharmaceutical packaging industry between the focus on commercial success and the need to be compliant?**

In order to ensure commercial success, the main focus of our pharmaceutical clients' lies in getting their products to market on time, with the need to remain compliant being present throughout the process. However, the reality of a speedy route to market can be complicated by a number of factors.

From an artwork perspective, some pharmaceutical companies underestimate the amount of effort and complexity that can be involved in getting compliant accurate artwork market-ready, on time. While content and regulatory aspects are accounted for, the process needed to create and approve artwork and the interaction of the many stakeholders often isn't.

The effect of issues such as delays in the approval processes and engineering or regulatory changes are not foreseen and because the process to create artwork is not clearly defined the impact on the cost and timing of having a product ready for market can be significant.

Not having clear brand guidelines depicting the positioning of information can result in incorrect artwork or a delay in the approval. For example, the ability to update a leaflet or a carton is greatly complicated if the additional details, be them compliance-led or content-led, cannot fit on the packaging for each market and language.

Therefore, it is critical that this section of the supply chain is managed properly and documented. By ensuring that the artwork process is clearly defined, the integration and communication lines of each stakeholder is clear and that there is complete ownership on the development of the artwork and obtaining swift approval, pharma companies can have a substantial influence on their own commercial success.

**What are the costs of not getting packaging and artwork right first time on both a commercial and a compliance level?**

When pharma product artwork is not executed correctly the first time, we certainly see the commercial impacts it has on clients. Each time an artwork is processed risk is introduced, and the number of approval cycles subsequently created can have major cost and time implication, but more importantly from a compliance and quality perspective – incorrect artwork can pose a threat to patient safety and so the influence of incorrect packaging stretches far beyond the costly financial implications.

It's crucial that the artwork process is managed with patient safety in mind and not just as a minor part of a packaging chain. The artwork, in the form of patient information leaflets, labels and cartons, indicates how a drug is used. The packaging instructs health practitioners and patients on how to use the product correctly and this is where the strength of the product is displayed. The accuracy of these aspects can be jeopardized if companies don't understand the artwork processes applied when creating products of varying strengths, for example, is one carton used as the basis to create the rest? If so what are the risk factors and how are they mitigated? In a lot of cases content can be correct but a lack of understanding on how versions are managed can still lead to the use of incorrect artwork and in turn a product recall.

In line with being fully focused on patient safety, artwork has to be thoroughly evaluated and pharma companies have to know the hotspots where errors can happen. We see big gaps in the industry when it comes to artwork departments having robust and efficient end-to-end quality management systems.

**How big of an issue is this end-to-end awareness for the industry?**

It's a huge issue for the industry. I regularly attend and speak at pharma packaging conferences in the USA and EU and get a lot of feedback on this issue from the conference participants and also our clients. When we ask conference audiences: 'How many companies understand and have analysed the artwork process from end to end?' we don't get a huge amount of people confirming that this has been done. Regardless of whether artwork is managed and created in-house or by an external supplier they should clearly define and understand the process from the content stage through to the delivery of printed product. This visibility is so important to a pharma company. They need to understand where the process is managed, by whom, where the approvals take place and where improvements can be made. In obtaining this visibility, it often becomes apparent that old processes are in place that need drastic review.

Regulatory professionals need to understand why they're approving at certain stages so they are able to pinpoint any mistakes. For instance, several different people could be conducting approvals at varying stages between engineering, marketing, quality, regulatory, technical and printing personnel. However, these individuals will not always know the reasons why the approval is being done at that stage or what happens after their stage. The more times an artwork is touched, the higher level of risk associated with the process. In this regard, a system should be deployed that limits the amount of cycles from an internal approval and an external approval process.

The market influences and impacts seen from product proliferation, serialization and safety changes required on packaging have compounded the need for industry players to have the highly efficient artwork processes and quality systems in place.

**What are the key things to keep in mind when looking to solve this visibility complication?**

It's important to fully understand who the stakeholders are and what their exact objectives are. Aspects to consider when optimizing an artwork process include:

- Is the present process kept in-house or is it outsourced? In the case of the latter, who has ownership and control on the artwork?
- In terms of technologies being used, which ones are impacting the artwork process and what other technologies are available?
- Are there defined procedures in place for managing the artwork workflow including version control.
- Are all the approval stage objectives understood? E.g. when a final approved file is issued to the printer can any changes be made – if so, why?
- Are there specific work instructions in place detailing how artwork is completed?
- Does the Artwork studio have a comprehensive quality management system?
- Which parts of the process can be automated?
- What KPI metrics are being recorded? Is there a detailed analysis completed on internal and external Right First Time?
- What inspection technologies and process are in place and from a metrics perspective how effective are they? When was the process last reviewed in line with changing complexities of artwork?

The creation of detailed and transparent metrics from considerations similar to the above can greatly assist with implementing a continuous improvement program.

**Industry analysts have noted that the regulatory realm is likely to remain ever evolving, how can pharma company's stay on top of the task of remaining compliant? – is there ever a way of future proofing a strategy?**

In comparison to previous years, there is indeed a higher level of market changes impacting product artwork. Product proliferation has caused the industry to oversee a much higher volume of products. Serialisation requires amends to be applied to a large amount of cartons so codes can be applied. Also, a lot of rebranding is occurring in the market due to various mergers and acquisitions. So, if pharma companies do not have an efficient way of adhering to these advancements, like using an artwork management system for example, they are likely to find the current market climate difficult.

A few years ago, artwork management systems were seen as merely very beneficial. Now, they are an absolute necessity. It's very difficult to have a manual process that allows pharma companies to accurately manage artwork. Adequate folder structures are advantageous, but without a robust artwork management system that ensures only the right version is available to the right people at the right time, pharma companies will discover it's very difficult to grow or to even handle the demands of today's market changes.

The chosen artwork management system must be highly configurable in nature. In theory, having a system that's configurable allows pharma companies, not only to work within their current markets, but also in those which they plan to operate within. The key to being future proofed is to adopt systems that can be integrated and are not purchased on a standalone basis to solve one problem. An artwork management system needs to allow integration into software comparison systems and ERP systems for example. There has to be a direct link across processes so each stage does not stand as an individual event.

The rising popularity of this holistic workflow approach is evidenced by the main buzzword we hear in the market as of late, which is 'end-to-end labelling'. This entails the management of labelling from the creation of Core Data Sheets through each market label. So, in obtaining this approach, if operating software is configurable, the pharma company will be able to sidestep complexity and validation costs associated with changes needed to update the systems.

**Finally, any predictions for the future of the packaging and labelling industry?**

The artwork side of packaging is ever-evolving, it's probably one of the most technically advanced areas within the packaging supply chain. There are constantly new ways to approach artwork with new automations emerging and it takes the pharmaceutical companies a while to see how beneficial these new methods actually are. It's important for industry stakeholders to stay informed of the available technologies and ensure that the selected software matches their processes as this will help them counter the challenges that lie ahead.

Perigord will be present at June's Pharmaceutical Packaging and Labelling Conference in Geneva. On site you will have the opportunity to visit their stand and attend to their session focused on The Need for Quality Management and Process Control in a Pharma Artwork Studio.

## Closing Remarks

The most popular response to meeting FMD regulations in terms of packaging requirements, was that even though the task is achievable, a few large hurdles will obstruct the route to full compliance. Some investment is planned for the area of packaging compliance, with most individuals noting that up to £100,000 would be dedicated to this purpose.

A majority of our participants have initiated their serialisation programmes, with some even stating that they are fully compliant. However, other individuals noted that a timescale hadn't even been set for this implementation.

As expected, space for required materials came out as the top challenge for labelling. In regards to country specific guidelines, Brazil and China were noted as the countries which present the most challenges – which may be related to the recent delay of the finalization of their pharmaceutical packaging requirements.

Despite the challenges that lie on the road ahead, the research results here note a lot of activity scheduled for pharmaceutical and packaging industries.


## ACKNOWLEDGEMENTS

Pharma IQ would like to express thanks to all those who participated in this research report and helped in its analysis. A special thanks to Perigord who assisted in the creation of this report.


## RESOURCES


1. http://www.marketsandmarkets.com/Market-Reports/pharmaceutical-packaging-market-890.html
2. http://www.medgadget.com/2016/03/global-industry-analysis-on-pharmaceutical-packaging-equipment-market-2014-2020.html