Trusted Experts in Serialisation Labeling and Artwork

Interesting serialisation, labelling and artwork articles from the Be4ward team

We have had a number of requests from people asking to be sent the articles we publish in email form so that they are more readily accessible to them. Therefore, we have created this email newsletter that allows you to read our most recent articles on-line or off-line, whichever is more convenient for you.

We hope you will find these interesting and we would welcome any feedback.

Kind regards,

The team at Be4ward

Featured Artwork Posts from Andrew Love's Blog

Packaging Artwork and Labelling: a hidden nerve centre of your operations

Pharma and healthcare companies are currently facing many challenges from operating in the global market. Organisations are launching new products and expanding into many new markets resulting in a more complex product

portfolio. Added to this, they need to interact with many different stakeholders...

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Artwork errors: Detecting them and minimising their impact

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Working with your external partners to ensure an effective response to an artwork related drug call

Pharmaceutical supply chains are becoming ever more complex, involving an increasing number of external partners. This week, I want to speak about the external partners that might be involved in an artwork related drug recall and how pharma organisations can work effectively with them...

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Technical errors vs human errors with labelling and artwork - important you treat them differently

In this blog I discuss the importance of recognising you need to respond to the type of errors differently and how you might future proof your process to make such errors much less likely. When performing an audit of your current process it is important to root cause the type of mistakes made and determine if they are caused by human error or caused by technical problems.

Read it online

Why design and controls are important for your Artwork Program?

We discussed in my previous blog the main differences in dealing with errors created by humans and technology. Another source of error can be attributed to the lack of robustness or effective control points in your artwork process.

Read it online

[2nd Anti-Counterfeiting Pharma 2016 Conference, 9 and 10 March, London]

I had the opportunity to attend and chair the first day of the 2nd Anti-Counterfeiting Pharma 2016 Conference in London last week. Many thanks to Pranita Nangia, Jasneet Gulshan and the team at Reconnect for organising the event...

Read it online

[Why do Artwork Errors Happen?]

In this article I talk about what I believe is a significant underlying cause, explaining why mistakes are made, and why the risk is, if not tackled, will continue to happen.

Read it online

Featured Serialisation posts from Stephen McIndoes's blog

[Tip 5 - Ensure the true complexities of your supply chain are understood early]

To implement effective solutions to address serialisation, it is important to understand the true complexities of the product / supply chain mix. Many day-to-day realities of a modern pharmaceutical supply chain can present significant issues to serialisation implementation activities if not understood early.

Read it online

[Tip 6 - Choose solutions that will be globally capable]

With the drive to implement initial solutions quickly, it is often tempting to keep things simple by selecting and implementing solutions that are only capable of meeting the immediate or limited requirements.

Read it online

Tip 7 - Develop and leverage standard solutions where possible

For larger organisations, where there will be a number of sites, packaging lines and possibly distribution operations to enable for serialisation, developing standard solutions has proved very useful in enabling roll-out in a timely and resource efficient way.

Read it online

Tip 8 - Do not underestimate the amount of resources required to deliver serialisation

Given the broad reaching impacts of serialisation across an organisation, a great deal of time and effort is required to deliver effective solutions. As with all projects, deliverables cannot be achieved to acceptable time, cost and quality without sufficient resources with the right skills and knowledge being applied to the problem at the right time.

Read it online

Tip 9 - Put a capable, dynamic and motivated leader on the problem

Serialisation is clearly a complex and evolving topic that touches many parts of an organisation. With the challenges facing the leadership that is charged with implementing such capabilities, they need to have a broad range of skills, the drive and motivation to anticipate risks and issues, as well as ensure they are effectively managed proactively.

Read it online

Tip 10 - Ensure you understand the evolution of serialisation legislation and instruct the organisation accordingly

Serialisation legislation can be somewhat vague, incomplete and sometimes contradictory, with individual pieces of legislation often evolving over a long period of time. Interpreting the legislation as it evolves and predicting its impacts can present significant challenges.

Read it online

Tip 11 - Involve local country teams and management early

In many cases, particularly in track and trace serialisation models, local country teams will have to work with the local supply chain and local suppliers to ensure that robust local elements of the overall serialisation solution are implemented. This is in addition to the local responsibilities with respect to interpreting the legislation that we have described elsewhere.

Read it online

Tip 12 - Get an end-to-end solution working early

The end-to-end serialisation solution in any organisation is complex and holds a myriad of opportunities for individual solution elements to not work as planned, interfaces to fail and other things to go wrong.

Read it online

Tip 13 - Do not forget the non-legislative benefits of serialisation

Our experience suggests that serialisation programs often set out from one of two places. On the one hand, there is the first group of programs that are very pragmatic and strive to deliver solutions which are focused on meeting hard legislative requirements and nothing more.

Read it online

Serialisation posts

Tip 5: Ensure the true complexities of your supply chain are understood early

To implement effective solutions to address serialisation, it is important to understand the true complexities of the product / supply chain mix. Many day-to-day realities of a modern pharmaceutical supply chain can present significant issues to serialisation implementation activities if not understood early.

Situations such as: local re-labelling and kitting activities; sale of product packs into one market which are designed and manufactured for another; locally

driven cross-market supply; and multi-market presentations can all present significant challenges.

Also look for situations where your organisation is acting as a contract manufacturer for another company. In this type of situation, you will be faced with integrating your solutions into the serialisation model of your customer. This is an area where standards and solutions are not well developed in many instances.

Furthermore, the high cost of implementing serialisation capabilities means that it is sometimes appropriate to change the supply chain to reduce cost. This type of change often requires significant time to achieve and, in the case of such things as regulatory approvals, is not always within the control of the pharmaceutical company.

Read it online

Tip 6: Choose solutions that will be globally capable

With the drive to implement initial solutions quickly, it is often tempting to keep things simple by selecting and implementing solutions that are only capable of meeting the immediate or limited requirements.

Clearly tactical solutions of limited scope and or capability have their place. If nothing else, they may be the only practical way to meet short term legislative deadlines in some cases.

We have experienced several instances where initially selected tactical solutions become the company standard by default over time, despite the fact that these solutions were not originally selected for a broader capability and or geographical scope. This often creates significant issues to subsequent implementations which could have been avoided.

We therefore recommend resisting the temptation to rush into implementing short term tactical solutions wherever possible. Where this is necessary, some

mechanism should be put in place to review their suitability in the face of expanding requirements and allow switches to more appropriate solutions if necessary in a timely manner.

Read it online

Tip 7: Develop and leverage standard solutions where possible

For larger organisations, where there will be a number of sites, packaging lines and possibly distribution operations to enable for serialisation, developing standard solutions has proved very useful in enabling roll-out in a timely and resource efficient way.

Serialisation systems are complex and therefore not trivial to design and implement. The various solutions also need to interface effectively with each other. Selecting and developing standard solutions therefore provides an opportunity to design and prove capabilities once and significantly reduce the overall timeline, cost and risk of subsequent implementations.

In complex organisations, it is unlikely that it will be practical to develop single solutions for capabilities such as the packing lines. However, it should be possible to achieve significant simplification by adopting this approach and selecting a small number of standard solutions and or methodologies.

A knock-on impact of this approach is that there needs to be time built into the project plans to enable this approach to be successful. The initial implementations need to be given the time and resources to develop well thought through and comprehensive solutions. Furthermore, ideally these solutions need to be implemented and optimized before rolling out subsequent solutions so that learning can be built into these later implementations. Unfortunately, given the long lead times of developing and implementing initial solutions, time is rapidly running out for companies wanting to fully benefit from this approach.

Read it online

Tip 8: Do not underestimate the amount of resources required to deliver serialisation

Given the broad reaching impacts of serialisation across an organisation, a great deal of time and effort is required to deliver effective solutions.

It is all too easy for projects to focus on aspects such as line solutions and the enterprise IT and miss some of the other impacted areas.

As with all projects, deliverables cannot be achieved to acceptable time, cost and quality without sufficient resources with the right skills and knowledge being applied to the problem at the right time.

Many of us have a tendency to underestimate the amount of resources required to achieve any given set of tasks. This can often be compounded by the new nature of serialisation; meaning, that organisations have little or no analogous experience to be able to adequately assess the resources needed.

Therefore, in order to ensure the correct level of available resources throughout the project, we would recommend starting conservatively in defining the resource levels required and tracking the achievement of resourcing plans and resource utilization.

Read it online

Tip 9: Put a capable, dynamic and motivated leader on the problem

Serialisation is clearly a complex and evolving topic that touches many parts of an organisation. With the challenges facing the leadership that is charged with implementing such capabilities, they need to have a broad range of skills, the

drive and motivation to anticipate risks and issues, as well as ensure they are effectively managed proactively.

Serialisation is a complex technical problem involving engineering systems at the line and distribution operation levels, as well as enterprise IT systems at the site and global levels. It should also be remembered that many of the solutions lack maturity, therefore, there will be many practical issues to deal with during implementation. Consequently, the leadership of a program needs to have the technical strength and breadth to succeed in managing this technical challenge.

Furthermore, serialisation touches many parts of any organisation, often crossing the traditional organisational lines of supply chain, commercial and research and development. More often than not, company boundaries also need to be negotiated as contract manufacturing, third party logistics providers and commercialisation partners need to come together to provide effective end-to-end solutions. Therefore, the leadership of a program often needs to have the cross-functional and cross- organisational skills and experience to effectively navigate this complex change management environment as well as the technical skills and knowledge described above.

Read it online

Tip 10: Ensure you understand the evolution of serialisation legislation and instruct the organisation accordingly

Serialisation legislation can be somewhat vague, incomplete and sometimes contradictory, with individual pieces of legislation often evolving over a long period of time. Interpreting the legislation as it evolves and predicting its impacts can present significant challenges. We have found that there are several key pieces of expertise required to successfully interpret evolving requirements. Local regulatory and legal representatives will be required to obtain the legislation, manage dialogue with the regulatory agencies, and interpret its application to a companys products and the consequences of non-

compliance. Serialisation expertise is clearly a necessity, both in the technical aspects of the topic, but also in the ways that serialisation legislation typically evolves. Local and central management also need to be involved to ensure that the requirements are interpreted appropriately in the context of the local environment and company situation. Also, an important and practical point to remember is that the legislation will more likely than not, need accurate translation into English.

When considering the timelines allowed in the legislation, history has shown that timelines are often vague and subject to change. However, when implementation dates are finally set, they often do not allow enough time for robust implementation. Therefore, waiting until the legislation is clear can result in missing deadlines.

Given the uncertainties in requirements and timing, organisations need to ensure there is a clear way of communicating their considered view of the legislative requirements at any particular moment to the various project teams who are responsible for designing and implementing solutions. Failing to do this will potentially result in individual functions or groups creating their own interpretations of legislation and timelines, which at minimum is wasteful of resources, but at worst, results in capabilities being implemented which do not meet the eventual requirements of the legislation.

Read it online

Tip 11: Involve local country teams and management early

In many cases, particularly in track and trace serialisation models, local country teams will have to work with the local supply chain and local suppliers to ensure that robust local elements of the overall serialisation solution are implemented. This is in addition to the local responsibilities with respect to interpreting the legislation that we have described elsewhere.

A few things need to be considered for this to be successful. Firstly, local country management is typically sales and marketing focused which often means that supply chain and technology issues are not high on their agenda. Secondly, the lead-times required to deliver complex serialisation solutions are often far longer than typical local project timelines in sales and marketing organisations. Thirdly, local IT and engineering resources are either non-existent, or very thinly spread across many issues.

Local teams are often most appropriate to deliver local solutions. However, it is often neither efficient nor effective for such teams to operate in isolation of central or other resources who have established experience of designing and implementing serialisation solutions. This is particularly important where the implementation of standard solutions is required and will always be the case when interfacing local solutions with central capabilities. We recommend that central teams and their governance consider carefully how to ensure this happens effectively.

As difficult as the technical challenges are to overcome, the cultural and geographical challenges of distance can often be greater. Good change management practice is essential to ensure that effective relationships are formed, collaborative design activity is carried out and implementation is managed in a coordinated way. We have found that there is no effective substitute for some degree of face-to- face activity throughout a project, with its implications on travel budgets and resource time. Furthermore, constant focus needs to be given to establishing effective day-to-day ways of working between remote teams. Simple issues such as establishing effective video/teleconference facilities can often be surprisingly challenging.

Another aspect which needs to be considered is that of culture. Central teams need to understand the local culture, particularly with respect to local decision making, day-to-day working styles and risk and issue management. Once understood, mechanisms need to be put in place to ensure a culturally effective management and governance approach is established.

Therefore, we would recommend engaging with local country management and resources early to ensure that robust and timely local plans are in place, supported by the right level of competent resources and ways of working.

Read it online

Tip 12: Get an end-to-end solution working early

The end-to-end serialisation solution in any organisation is complex and holds a myriad of opportunities for individual solution elements to not work as planned, interfaces to fail and other things to go wrong. In our experience, organisations benefit a great deal from learning first-hand how to deal with these practical complexities and put the appropriate support capabilities to deal with them through the implementation of early end-to-end solutions.

It is also the case that certain aspects of serialisation present significantly more difficult challenges, complexity and knock-on impact than others. An obvious example of this is implementing track and trace capability and the requirement to aggregate product to shippers and shipments that it drives.

Whilst an organisation may not have the legislative drive to implement complex capabilities early, there are likely to be many learning benefits in implementing such a complex end-to-end solution early. This can test and prove solutions as well as creating lessons learnt from these early and complex implementations at a time of lower business risk.

Buy-in by senior management to such an approach is essential, as investment decisions will need to be supported earlier than they otherwise would.

Read it online

Tip 13: Do not forget the non-legislative benefits of serialisation

Our experience suggests that serialisation programs often set out from one of two places. On the one hand, there is the first group of programs that are very pragmatic and strive to deliver solutions which are focused on meeting hard legislative requirements and nothing more.

On the other hand, there is the second group that strives to deliver a broader capability and benefit to the organisation at the outset. For example, capabilities that can be leveraged to enhance product security, improve customer relationships and provide product movement information and supply chain visibility. Often, senior management is rightly concerned in getting the maximum return for the organizations significant investment in this area.

Regardless of the starting point, many programs quickly iterate towards the first category as the practical reality of the size of the legislative task alone hits home.

Whilst it is often appropriate for a program to focus in the shorter term on delivering to the hard legislative deadlines, it is unfortunate if this is also done by limiting scope and capability designed into solutions to merely meet these short term needs. If this is allowed to happen, then reaping the broader future benefits from the solutions may prove to be significantly more difficult than it otherwise might have been.

Therefore, we would recommend putting mechanisms in place to monitor the ability of solutions to properly support the broader solution requirements, even when these are not immediate priorities.

I hope you enjoyed this instalment on *Things we wish we had known before starting a serialisation program or project*

Read it online

Artwork posts

Packaging Artwork and Labelling: a hidden nerve centre of your operations

Pharma and healthcare companies are currently facing many challenges from operating in the global market. Organisations are launching new products and expanding into many new markets resulting in a more complex product portfolio. Added to this, they need to interact with many different stakeholders such as governments, purchasing groups and regulatory organizations from all around the world. Companies need to recognise the growing complexity on their organisation and the impact on their resources.

Maintaining a high focus on patient safety and strong corporate reputation is essential to keep and win new business. Companies need to maintain trust with authorities and customers to enable them to be in the position to offer and further develop innovative pharmaceutical treatments.

Artwork errors represent one of the largest sources of pharma recalls. Therefore, the organisation has to give special attention to the packaging artwork and labeling process. They need to ensure they have the right capabilities in place to enable the effective creation and adaptation of texts and graphics, meeting the regulatory requirements of dozens of countries with different languages.

And this is where the biggest challenge lies, being able to orchestrate all the related activities with the right process design, good technological systems in multiple facilities and with different suppliers. Oddly enough, there is a risk this complexity is not fully recognised in some companies, so assessing and redesigning the process to be compliant, efficient and effective is missed despite its critical role in the supply of product. This challenge exists whether you are a large pharma group or a smaller company, it is just then a matter of scale.

Well see in the next posts, the many risks the packaging, artwork and labeling process can represent to the smooth running of the business operations of a pharma company.

Read it online

Artwork Errors: Detecting them and minimising their impact

Artwork errors are an ongoing risk in a Pharma organization. I already listed the different types of errors you can have in my blog post Excellent Packaging Artwork Capabilities 2 Consequences of errors, and whilst a number of errors present minimal risk to the safety of the patient, for example non-consistent spacing between paragraphs, others can have a major impact such as putting a wrong dosage on the packaging. In this blog we discuss the different approaches required depending on where in the supply chain the error is spotted.

The artwork errors can be detected two ways. They can be spotted internally at the various verifications through the supply chain or they can be identified externally, for example by a healthcare provider. Each case leads to specific actions to correct the issue to minimise the impact and to prevent the issue happening again. Here some of the priority actions that should be integrated very quickly after the incident.

When the error is spotted internally

- Key Quality and Operational personnel have to be informed to decide on corrective actions that need to be taken to address the quality issues with products.
- The affected product and all associated components held in inventory must be quarantined
- The Quality function has to make appropriate decisions about the severity of the error, whether the incorrect components can be used or not, and if the product can be released or will require rework with revised packaging components.

- Once the immediate supply issue has been resolved, a more thorough investigation should be conducted to determine the root cause and learn from the incident to stop it happening again.

When the error is spotted externally

Recall from the external marketplace is obviously a complex activity requiring significant communication to ensure the safety of the patient is protected:

- The organisation should have robust communication mechanisms as the error could be conveyed through local country operations, customer service help-lines or even through local county Regulators.
- As the product is already out in the supply chain, the first steps of the company communication would include the impacted local Regulatory authorities and an assessment of the error to determine what level of recall is appropriate.

The scope of the recall can vary from a wholesaler level right through to patient level. This has an obvious impact on the patient and healthcare professionals trust in the product and the company. An immediate comprehensive response is key to address the error and minimise its impact on the patient. As described with internally discovered errors, there then follows a series of corrective actions to resupply the marketplace and preventative actions to ensure the root causes of the incident are identified and addressed to prevent reoccurrence.

In my next post I will discuss on how to work effectively with your external partners to minimize the impact of a drug recall.

Read it online

Working with your external partners to ensure an effective response to an artwork related drug recall

Pharmaceutical supply chains are becoming ever more complex, involving an increasing number of external partners. This week, I want to speak about the external partners that might be involved in an artwork related drug recall and how pharma organisations can work effectively with them to minimise the risks involved. We saw in the last Artwork 101 post the main actions to do when the error has been spotted externally to the company. The implications of an artwork error can be as far-reaching and serious as any other error with the supplied product. In a recall situation you will likely have to work with a range of external partners to carry out the corrective actions required to recall the product and resupply the market and the preventative actions required to address the root causes of the failure.

There are a number of external partners involved who have unique roles to play

Joint ventures, local external marketing companies and local distributors: Many pharmaceutical companies work with local partners in different countries around the world to market their product in that local country. In a recall situation, these local companies may be the main point of contact to the impacted customers in that local market and also to the local Health Authority. Therefore they have a key role in maintaining relationships with customers and regulators. Your company is likely to have well defined recall processes that would be invoked for an artwork related error and these local partners will have communication roles to play within these processes.

Artworks will need to be updated to resupply the market and these local partners will likely have to be involved in definition and approval of these new artworks.

When assessing the root causes of the incident and the preventative actions required, the end-to-end process for artwork definition and approval through these external parties must be considered. How robust are these processes and how well have you trained your partners?

Wholesalers and Distribution partners: These are the operations that move product through your supply chains. They will be involved in the corrective actions, quarantining and returning product and supplying new product to the market. Again this should be through your company's standard recall and resupply processes.

Contract Packaging Operations and Printed Packaging Suppliers: Most pharmaceutical companies use external partners to manufacture packaging materials and to pack product. Like the above, these partners will be involved in recalling and resupplying the market, quarantining incorrect packaging materials and packed product in their inventories, manufacturing new packaging materials and repacking impacted product where feasible. They will also be involved in the approval and quality control of the artwork on the resupplied packaging materials.

The end-to-end process again needs to be reviewed when assessing root causes to ensure the effectiveness of the artwork process steps undertaken by these partners.

External Graphics/Artwork providers: You may use external agencies for artwork creation. Revised artworks will be required and likely with some urgency. You need to ensure that rigor is maintained to avoid errors occurring when people are in a rush situation. As with the previous partners, assess the end-to-end process through these artwork partners to ensure that the root causes of the error are identified.

Clear processes that are well understood by your partners

A recall is an event that any pharma company wants to avoid. It risks the well-being of the patient, places a burden on healthcare providers and causes unnecessary disruption to customers. However mistakes do happen and therefore it is essential to ensure that there are clear effective processes across the extended supply chain to manage the recall, revise the artwork, resupply the market and ensure that the root cause of the error is eliminated so it is

prevented from happening again. Working closely with your external partners is key in ensuring a controlled outcome.

Read it online

Technical errors versus human errors with labelling and artwork- important you treat them differently

In my previous blog post, Working with your external partners to ensure an effective response to an artwork related drug recall, I talked about the significance and impact of labeling and artwork errors in your company. In this blog I discuss the importance of recognising you need to respond to the type of errors differently and how you might future proof your process to make such errors much less likely.

When performing an audit of your current process it is important to root cause the type of mistakes made and determine if they are caused by human error or caused by technical problems.

Artwork errors caused by humans versus technical €˜machine issues

Root causing errors in your process will almost certainly give you some common failings. A classic human error example is misinterpretation of the requirements of an artwork change where the end result is not what the person had intended when they gave their input. Another example would be where the leaflet artwork has been checked but not proof read correctly or perhaps a proof reading step has not been included and the text is incorrect.

A technical error example would be where a work flow software package has been utilised but a system error has caused the wrong version of the file to be used. Another technical issue could be where proof reading software has caused an error by lacking the functionality to read text embedded in illustrations, but users not being aware of that limitation.

When future proofing your process or responding to existing issues how you might respond?

With technical issues it is important to recognise that software packages come with limitations, so its critical to understand these from your vendor and put in extra checks as required. Software validation is key to verify the system works as intended and should pick up configuration and functionality errors before implementation.

Regarding human issues there are three things to consider:

1. **Remove the ambiguity factor** by introducing standard processes with checklists to remove the potential for interpretation and ensure you comprehensively train everyone in those processes. Key when designing the process is identifying the high risk areas and putting in robust steps.
2. **Address the lack of discipline factor** consider that some errors are caused by people not following the process for various reasons and embed controls to ensure the process is followed with rigour.
3. **Recognise the limitations of the human brain** which has a tendency to €˜fill in the gaps when reviewing text and support them with effective proof reading processes, training, checklists and tools.

In the next blog we will be considering this topic further with some more insights into the designs and controls in your artwork process.

Read it online

Why design and controls are important for your Artwork Program?

We discussed in my previous blog the main differences in dealing with errors created by humans and technology. Another source of error can be attributed to the lack of robustness or effective control points in your artwork process.

The categories of errors that can result from poor process definition and controls include:

Gaps and inconsistencies in the process

As its name suggests, these errors occur when the design of the business process is incomplete or conflicting. A common problem is where the provision of a particular piece of information is not well defined. An error of conflict is where there is a shared market pack and a change proposed by one market is made but the other market approver is missed off approving the change. An example of an incomplete process is where the safety compliance team have not been included in the €˜loop for an existing product and the text does not include the latest safety data.

Insufficient competence

The same way, if the definition of the process is not well established, it can lead operators not to have the right set of skills and knowledge to perform the tasks required. An area of particular concern is where people are trained in a task but are required to do it infrequently. An example is where personnel in the affiliates are asked to approve artwork in a workflow package which they only use every few months. In these circumstances, it is key is for them to be able to refer to a procedure with easy to follow instructions.

Not enough of quality time

On a similar note, if time allowed to do the task in the process is constricted, this can lead to errors. An example would be when the time agreed for the proof reading step is squeezed. Proof reading, when done properly, must be performed in a quiet well lit room, free from interruptions and the time allotted must be allowed if you want a quality result.

Ambiguity

Previously we have talked about the role of ambiguity in causing errors. An example would be where the markets requirements for a change have not been well specified, resulting in the artwork operator misinterpreting the information

and the artwork has to be redone, causing delays. It is important the markets instructions are not sent via imprecise methods like emails or voicemails but captured in a formal process with no room for confusion.

Process definition and control are, among others, key components in building up artwork capabilities and reduce, as much as possible, the level of errors. The care and consideration given to this step in creating the artwork processes will help you maintain a certain quality level.

After reviewing the main causes of errors, we will focus our next topic on the consequences of errors on company operations.

Read it online

2nd Anti-Counterfeiting Pharma 2016 Conference, 9 and 10 March, London

I had the opportunity to attend and chair the first day of the 2nd Anti-Counterfeiting Pharma 2016 Conference in London last week. Many thanks to Pranita Nangia, Jasneet Gulshan and the team at Reconnect for organising the event.

Presentations from Day 1 of the event were:

Comparing European, US and Middle East counterfeit markets

Bawan Ahmed, Senior Pharmaceutical Assessor, Kurdistan Medical Control Agency

Bawan presented on the counterfeit market in Iraq in comparison to the rest of Middle East, Europe and the US. The Kurdistan region is an autonomous part of Iraq and has its own Medical Control Agency. There are 500 registered pharmacies and 6000 unregistered pharmacies which is an outcome of the many years of sanctions against Iraq. This informal supply base is uncontrolled, with pharmaceutical product being sold in market stalls, shops

and even butchers! Product may be manufactured locally or imported and is shipped around the region in taxis.

Bawan and his team are seeing around 1000 cases of counterfeit medicines a year but with only 5 staff in a dangerous and fluid environment, its difficult to police. The situation is improving through greater collaboration between enforcement parties and the pharmaceutical companies and improved training of staff.

GS1 Standards a tool to combat counterfeiting?

Glen Hodgson, Head of Healthcare, GS1 UK

Glen discussed the GS1 standards and how they can help combat counterfeiting. GS1 standards underpin most serialisation and authentication solutions. He explained the requirements of authentication and traceability, gave an overview of the overall responses from Interpol, WHO and WCO and outlined GS1s involvement in the Joint Initiatives Council which is shaping solutions to the counterfeit drug challenge.

Tamper Evidence Implementation in Packaging Lines

Andreas Brandt, Business Development Manager, Baumer HHS GmbH

Andreas presented on the other main aspect of FMD tamper evidence. He explained the solutions that are available and issues to consider when selecting tamper evidence solutions. He showed the various examples of tamper evident solutions and focussed on the types of glue solutions. Using a combination of hot melt and cold glue gives the benefit of quick adhesion but without the risk of re-opening that you get with hot melt only.

Andreas highlighted that all products must have tamper evident features applied by 2019. The lead-time to get new tamper evidence equipment installed and products produced is short so it is an issue that needs to be addressed soon.

2D Barcodes: Implications on Branding, Patients and Anti-counterfeiting

Aaron Barzey, CEO, ADB Medical

Aaron discussed some of the recent counterfeit issues that have happened around the world. He explained some of the different coding solutions and in particular the use of QR codes in Europe and the US. He also discussed some other types of covert and overt brand protection solutions, for example micro-taggants applied to the drug product.

Challenges of Serialisation and Track and Trace applications on a company level

Michael Urso, Product Manager Pharma & Packaging Solutions, Atlantic Zeiser GmbH

Michael presented on the concerns about serialisation that they have seen at various clients in the projects they have been involved in. He gave an overview of different options for incorporating the equipment necessary for serialisation into packing lines. He also discussed the architecture options for the level 3 and 4 systems that can be required and the impacts of managing number allocation to multiple locations and packing lines.

Anti-counterfeiting Technology An investment not a cost

John McKeon, Technical Director, Portalis Ltd

John outlined the capabilities that Portalis have developed to help companies implement serialisation solutions. He discussed the various components of a packing line that are impacted by serialisation and how to ensure these requirements were built-in in a cost effective way. Understanding the overall architecture is critical to ensure that data flows between Level 1 and Level 4 as necessary. There are many variations possible, but the cheapest solution is not necessarily the most appropriate.

Strategies to mitigate risk in the supply chain

Elizabeth Haveman, Director, Anti-counterfeiting, Global Product Protection, Abbott

Elizabeths presentation covered the activities Abbott undertake globally to address the threat of counterfeit products. Presented as a list of 20 tips she covered topics including what to do to monitor activities in markets and across the supply chain, management of external partners, laboratory capabilities required, influencing and engagement with authorities, and use of anti-counterfeiting technologies. She gave examples of some of these activities in use and the benefits delivered to Abbott.

Towards the digitisation of pharmaceuticals

Prof. Lee Cronin, Regius Chair of Chemistry, School of Chemistry, University of Glasgow

The subject of Lees presentation was the vision of being able to create chemical entities automatically from code rather than through traditional chemical processing. Drawing parallels to digital printing where objects can be created from a digital instruction using standard machinery and building blocks, he discussed a future where standard chemical processing machines could take base materials and through a standardised digitised methodology or recipe, could create chemical and pharmaceutical entities.

Whilst this technology is some way in the future he explained some of the development work being executed under his stewardship to develop conceptual and prototype machines.

Understanding Global Regulatory Laws

Ewan Townsend, Associate, Arnold & Porter (UK) LLP

Ewan discussed the development of the legal framework for pharmaceutical regulation, as legislation evolved from numerous significant patient safety events, and leading to the Directives seen in the EU today. From this, he showed how this has resulted in numerous and sometimes inconsistent laws regarding counterfeit medicines around the world that have had to incorporate the views of many different stakeholders. This slows progress and requires much cooperation between partners.

He also discussed some potential future trends:

- Porous borders where there is a difference in price
- Targets will diversify to where enforcement is low if organised crime still manages to make high margins
- Increased global cooperation and a harmonisation to global responses and solutions
- Increased involvement of charities and philanthropists in driving for solutions

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Why do Artwork Errors Happen?

In my previous blogs I have talked about some of the different types of errors and the impact on your organisation. In this article I talk about what I believe is a significant underlying cause, explaining why mistakes are made, and why the risk is, if not tackled, will continue to happen.

Artwork generation requires the coordination of information from many people

In many artwork operations the standard output produced is high. However mistakes do occur. Pick up a standard pharmaceutical carton and look at all the pieces of information which appear. Item codes, logos, safety statements, overprint areas, Braille, licence details and the registered address are just some of the detail and lets not forget the corporate brand image, the fact the carton drawing must be correct for that product and the production machine. All the information which appears is provided and approved for use by many departments and external agencies: Regulatory; Packaging Technology; Commercial; Safety; Legal and Government Agencies are the main ones but there are others.

A key requirement is good provenance for each piece of information

In my experience a lack of robustness with the multiple processes involved in providing each piece of information and approving its use, is one of the significant underlying causes of errors.

Lets compare two examples the item code and the price. The raising of the Item Code is generally covered by a standard operating procedure and is raised in a highly controlled validated environment, usually the company Material Resource Planning (MRP) system. All the item codes are held in Bills of material (BOM) associated with that product. The planning department will usually be the one to check and release the information, and the artwork department can easily refer to it on the system, ensuring it is correct before it is inserted in an artwork brief. The planning department when agreeing the artwork brief can recheck the item code provided by themselves by looking within their validated MRP system.

The Price unfortunately has a less assured path. It will usually come from the local market commercial teams and will be provided via non- validated systems like email or in a letter. The exact source of the information may be unclear and because of this its accuracy cannot be guaranteed. The artwork coordinator putting together the artwork brief will probably only have a letter or email to refer back to and when the commercial person goes to sign off the brief may have no further information to check against.

So the key to reducing the risks with artwork is to look at the process for each text/ design element, agree on each origination process, how it will be checked and released and by which trained personnel.

Well discuss in the next post what I believe are two other significant underlying reasons for error, the rework they cause and what can be the impact on the commercial timelines.

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