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

Beware of the concertina effect with other underlying issues

In this article I discuss what I believe are the two other significant underlying reasons, the rework they cause and what can be the impact, often not appreciated, on the commercial timelines.

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Ensuring you have an effective Artwork Capability

In my recent blogs I have focused on the problems and what can go wrong in your company's artwork provision, but in this blog I would like to talk the key elements I believe you will find when your company has in place an excellent artwork capability.

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Developing an Artwork Service - Part 1

In this blog I am going to focus on the initial steps required when you start to develop an excellent Artwork Service capability for your company.

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Developing an Artwork Service - Part 2

In this blog I am going to continue to talk about the key aspects to think about when you start to develop the Artwork Service capability for your company. In particular I would like to talk about ways of establishing the service culture and the need to define a set of guiding principles before you look at your process. >>Read it offline

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The Core Artwork process - on the surface it seems so simple to achieve

In this blog I am going to look at the core artwork process itself. I will be highlighting the key parts of each step and aiming to show what is the difference between a good process and an excellence one.

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The Artwork process link to the company's interfacing processes

In this blog I am going to look at the importance of getting a good fit with other processes in your company that need to operate in conjunction with your artwork process. Getting effective links to these other (interfacing) processes is an important element...

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The importance of the supporting processes

In a previous blog I gave a description of the core artwork process. Having a well-designed artwork process is of course critical to your success, however it is not sufficient enough to provide a complete capability.

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Featured Serialisation posts from Stephen McIndoes's blog

10 tips for developing a serialisation Strategy - Tip 4

Serialisation legislation is relatively new to the pharmaceutical industry and therefore the solutions available from the supply base are correspondingly immature and in many cases evolving.

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10 tips for developing a serialisation Strategy - Tip 5

Resource implementation projects with sufficient serialisation specific knowledge to minimise the risk of wasted resources, delays and implementation failure.

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10 tips for developing a serialisation Strategy - Tip 6

Understand global versus local The question of global versus local needs to be considered on several different dimensions.

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10 tips for developing a serialisation Strategy - Tip 7

The need for flexibility Serialisation legislation and responses are emerging across the globe from multiple different parties. Whilst often based of standard building blocks, the detail of the requirements shows significant variation.

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10 tips for developing a serialisation Strategy - Tip 8

The next tip addresses developing and agreeing the key principles required to govern the life cycle of the serialisation capability.

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10 tips for developing a serialisation Strategy - Tip 9

Given the cross-functional and cross-organisational nature of the serialisation capabilities, establishing the right inclusive leadership and governance is key to the long-term success of the activity.

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10 tips for developing a serialisation Strategy - Tip 10

As a place to start, we would recommend a small focussed piece of work with the following objectives.

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Recent serialisation legislation movements - Part 1

It’s been a long time since I did an update on serialisation legislation activity, so over the next two weeks I will give you a summary of some of the main things that are happening.

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Recent serialisation legislation movements - Part 2

Last week I did part one and this week is part two of a summary of some of the main things that are happening.

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Serialisation posts

Tip 4: Understand the immature and evolving solution supply base and select appropriate implementation partners

Serialisation legislation is relatively new to the pharmaceutical industry and therefore the solutions available from the supply base are correspondingly immature and in many cases evolving. Supplier selection will often be the start of a very long relationship, as solutions that are initially implemented will need to be supported and adapted to new requirements over time. There have already been several examples of suppliers that have come and gone as legislation has evolved or been delayed. Understanding the supply base and choosing the most appropriate suppliers will be critical to long term success.

Defining complete requirements covering all aspects of the solution's lifecycle and then realistically judging the supplier's ability to meet these requirements also presents challenges.

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Tip 5: Resource implementation projects with sufficient serialisation specific knowledge to minimise the risk of wasted resources, delays and implementation failure

The specific challenge during the design, build, test and implementation phases of solution projects is to resource them with sufficient serialisation subject matter skills and knowledge to avoid common pitfalls, reduce wasted effort and the risks of delay and solution failure.

Organisations need to plan for these resource requirements, build sufficient capabilities internally and secure access to sufficient external resources where appropriate.

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Tip 6: Understand global versus local

The question of global versus local needs to be considered on several different dimensions.

Firstly there is a need to consider what is being standardised. There are some elements of the strategy and resultant solutions that need to defined, built and operated at a global level so that all supply chain nodes can be supported. Other capabilities may need to have globally defined standards, but the build and implementation can be addressed locally. In other cases, it may be appropriate to direct all of the activity to local teams if there is no network-wide impact from locally generated solutions. Typical topics where the degree of standardisation needs to be considered include:

- Policy
- Requirements
- Solution Selection
- Design
- Build
- Test/Validate
- Implement
- Operate
- Support

The second consideration is where serialisation activities are to be undertaken. Again there will be a mix of global, regional or functional or local answers to where you are doing things. So for example it may not be appropriate for all supply chain nodes to be individually tracking emerging legislation, but also packing operations are likely to stay at local supply chain nodes.

The final consideration is to what degree is the resultant capability global or local. Maintaining the number management systems is likely a global capability

whereas maintaining the on-line printing and verification systems is more likely to be local.

In order to ensure that the capabilities required are appropriately specified and managed through their lifecycle understanding and agreeing what is done globally, regionally or functionally and locally is a key success factor in a serialisation strategy.

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Tip 7: The need for flexibility

Serialisation legislation and responses are emerging across the globe from multiple different parties. Whilst often based of standard building blocks, the detail of the requirements shows significant variation. Whilst this is frustrating and a global set of common standards and solutions may be more cost effective, it is the reality of the situation and companies need to develop solutions to cope with it. This is why many companies have held back from progressing their serialisation projects for fear of developing the wrong solutions or backing the wrong technologies.

Furthermore, capabilities required to deliver additional benefits from serialisation capabilities installed initially to meet legislative requirements also need to be considered.

Therefore when developing your serialisation strategy, you need to be thinking of not just known, but also emerging and likely requirements. Solutions designed need to have a sufficient degree of flexibility to be able to cope with these requirements. This is not easy, but is a key challenge that must be made aware to solution design teams.

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Tip 8: Define and agree some governing principles

The next tip addresses developing and agreeing the key principles required to govern the life cycle of the serialisation capability. These principles should provide guidance for teams on what is permissible or not and would be approved and managed via the governance team.

Examples of principles could include:

- A single serialisation enterprise management system will be implemented and used by all supply chain nodes for transmission and receipt of serialisation numbers.
- A single serialisation issue investigation capability will be established with a physical presence in each geographic region.
- Supply nodes must ensure they have competent local capability to support installed on-line printing and verification equipment.

The benefit of such principles is that they clearly define the ‘rules of the game’ to all parties, thus providing a boundary and a decision making framework for the development of solutions. If anyone would wish to go outside of or change a principle, they would have to gain permission from the governance team.

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Tip 9: Implement effective cross-functional governance

Given the cross-functional and cross-organisational nature of the serialisation capabilities, establishing the right inclusive leadership and governance is key to the long-term success of the activity. All stakeholder groups involved in the delivery of the serialisation capability need to contribute effectively or the whole process is at risk of failure. Therefore, all parties must buy into their roles in the processes and actively contribute to them. This will rarely happen if they are

simply passive bystanders in the design of the capabilities or the delivery of the resulting activities.

A cross-function governance team should therefore be established to steer the definition, establishment, ongoing delivery and development of the overall serialisation service across the multiple stakeholder groups involved. This governance body should include membership from all of these stakeholder groups involved in the processes, including, where appropriate, external service providers. Typical activities that would be included in the role of such a Serialisation Governance Team include ensuring:

- A clear vision and strategy is defined and communicated.
- Decision making is taken with all impacted parties, at the right levels in each of the organisations involved.
- A Target Response' is defined that specifies what the organisation must achieve and by when, given the current state of legislation and the organisation's considered view of how and when capabilities are required.
- Changes to the target response are carefully managed and cascaded to all impacted groups.
- Appropriate approval serialisation capability designs.
- The performance of the serialisation service is meeting business needs.
- The programme of legislative responses and improvement activities are prioritised and approved
- Resources are in place for the serialisation service and improvement activity.
- Stakeholder group conflicts are effectively resolved.

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Tip 10: Understand where to start

As a place to start, we would recommend a small focussed piece of work which has the following objectives:

- Understand the issue as it relates to your business.
- Understand the likely impact across your organisation.
- Identify, educate and mobilise an effective cross-functional governance team.
- Establish an effective legislative monitoring capability.
- Define an initial ‘Target Response’.
- Define a plan of action.
- Identify any initiatives that are currently underway and define how they should proceed.
- Understand the high level budgetary implications.

From here, a programme of activity can be implemented to effectively manage the legislative risk and oversee subsequent capability deployment.

Read it online

Recent serialisation legislation movements - Part 1

It’s been a long time since I did an update on serialisation legislation activity, so over the next two weeks I will give you a summary of some of the main things that are happening. If you want to know more details then just drop me an email.

Algeria

- Draft regulations under development.
- Decree expected imminently.

- Thought to be considering serialised sticker model with price on it, which is clearly causing concern.

Brazil

- The existing serialisation law RDC54 still stands, so there is a risk that come the end of 2016, all product will need to be serialised.
    - Many companies have reported that they have stopped activity at present.
- However, a new draft law PLS 276/2015 has been approved by the Senate and is due to go to public consultation from ANVISA shortly with an expected publishing in September. This should nullify RDC54.
    - Scope of products up to ANVISA, so hope that can remove samples and OTC products which were in RDC54.
- Proposed timelines: Pilot for 3 batches in 1 year, then approximately a year's consideration and publishing final requirements, then 3 years to enforcement.
- The new draft law is still under evolution, but appears to have a number of positive points over the existing law, e.g.
    - Manufacturers will not be responsible for data collection down the supply chain.
    - Serial numbers will be unique to GTIN, not MAH.
    - Serial numbers will up to 20 digit alphanumeric.

China

- Issued a suspension letter for the current requirements, stating they wish to change the drug tracing system.
- Responses have been fed back to the new China proposals.
- Scope of new proposals includes Medical Devices and Food Safety.

Egypt

- The Egypt MoH have signed an implementation plan for serialisation that will be published soon.
- Timelines appear to be:
    - 1st July 2016: 17 master data fields for all products need to be provided to GS1 Egypt, who are coordinating the maintenance of that data in the national product master database for a small annual fee.
        - GS1 Egypt are also managing the taking of photographs of product secondary packs, which is also a master data requirement.
    - 1st September: GLNs required.
    - 1st July 2018: GTIN, Lot & Expiry.
    - 1st July 2019: Serialisation.

Ethiopia

- Considering serialisation and holding a workshop in July.

EU

- FMD Delegate Act published, setting deadline at February 2019.
- National system moving forward as soon as possible.

India

- Exemptions for export products are coming through from the Indian authorities, but as per the law are only for secondary packs, one tertiary level must have an SSCC.
- Product images required for master data.
- Single database being used/developed for the Export and emerging domestic market legislation which is causing issues.

    - An Industry / Ministry working group is being established to handle issues.

Japan

A draft serialisation legislation is currently out for public review until the 24th June.

- Non-biologics deadline proposed of 2021 for serialisation.

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Recent serialisation legislation movements - Part 2

It's been a long time since I did an update on serialisation legislation activity, so last week I did part one and this week is part two of a summary of some of the main things that are happening. If you want to know more details then just drop me an email.

Jordan

- Requirements published which are fully aligned with global standards
    - 1st July 2018: 2d with GTIN, Lot and Expiry
    - 1st July 2020: addition of serial number
- JFDA want everything in scope, i.e. samples, tenders, named patients - this is clearly causing concern
- No news on data exchange requirements

Malaysia

- The local manufacturers appear to be working to get rid of the holographic label and move to more global serialisation standards

Nigeria

- Work is under way to define a global standards based serialisation requirement to follow up on the current SMS messaging system used in the country.

Oman

- New legislation drafted for Tenders
    - 1st January 2017 serialisation deadline
    - Pharma and medical devices at present
    - Based on the Saudi Arabia legislation, but originating from the central purchasing organisation rather than the MoH, and is aimed at helping product flow
    - A circular was sent to many companies, but the MoH only got two responses stating they would have issues complying

Pakistan

- No dates set yet for their new requirements being published, but expected soon

Philippines

- New serialisation regulation in draft with very short timelines, e.g. Jan 2017

Russia

- Regulation still being finalised, no recent new Concept Paper has been published
    - Microchip (RFID?) being rumoured
    - QR codes rumoured to be being considered
    - Pilots being discussed for the first half of 2017 - an email has been issued naming a number of companies that are apparently

    - going to be involved, although without clear understanding of the objectives and scope of the pilot, there is some concern
    - January 2017 still believed to be the date for the first group of products
- The MoH was leading this initiative, but it has switched to the Ministry of Finance and Taxes, who are already implementing some very strict rules on other products

Saudi Arabia

- New Decree was circulated which ratified older requirements
    - Packaging size/quantity dropped
    - New Saudi drug code requirement dropped
- Scope clarified
    - All marketed product including tenders in scope
    - Samples and named patient products out of scope
- Stakeholder group formed to work on reporting standards
- No news on reporting requirements yet, except for verbal assurances from government representatives that it will be easy
    - The Saudi authorities have visited Turkey several times, so it is not unlikely that their solution will be similar
- Track and trace with aggregation is on the way in a 3rd wave
    - SFDA reported at a recent conference that they were building the database
- There are some apparently conflicting requirements between the serialisation legislation requirements and the Saudi customs and import regulations:
    - SFDA are not specific about where product is serialised
    - Customs authority seem to require product to come directly from the manufacturing origination source

Taiwan

- Requirements being drafted, some publication expected imminently
- 1st July 2017 to 1st Jan 2018 have been stated as deadlines in various conflicting communications

UAE

- Intend to move from recommendations to regulation
    - 2d for traceability
    - QR code for traceability - concern that this will cause confusion
- GS1 attempt to start a pilot to demonstrate requirements could be met with global standards did not get off the ground unfortunately

USA

- FDA pilot scoping workshop held, but pilot scope not yet clear
- Growing support for EPCIS 1.1 standards to be used, as supported by the likes of McKesson
- Big wholesalers published requirements which effectively bring deadlines forward

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Artwork posts

Beware of the concertina effect with other underlying issues

In my last post I talked about the importance of having provenance for each artwork element and how gaps here can be a significant underlying cause of artwork error. In this article I discuss what I believe are the two other significant underlying reasons, the rework they cause and what can be the impact, often not appreciated, on the commercial timelines.

The risk of the data being entered incorrectly needs to be managed

Sometimes an operator makes a mistake and a good piece of data is corrupted when added to the component artwork, perhaps typed incorrectly. An example might be the item code is put in with the wrong numbers, or much more significantly, the wrong dosage is added. Attention to detail is important with this operation and so it is vital to design your processes to make such errors as unlikely to happen as possible, select and recruit the people with the right aptitude for this role and measure their levels of accuracy on an ongoing basis.

It is also important to recognise that these types of errors will be made occasionally and to manage that risk. I always recommend to our clients that an artwork process includes a full and independent proofreading step and we have always seen a reduction in errors when this investment is made. I will return to the subject of proof reading in a future blog.

Be aware of the ‘Concertina’ effect

The other significant cause of errors is when the operator produces the artwork correctly but the people involved in approving the artwork change their minds and ask for changes. It is not uncommon for people to request multiple changes and what happens is the artwork goes through many rework stages. However, in most cases, the deadline has not changed and this might be for a launch or to meet a regulatory requirement.

The timelines to complete the change and have it approved and the component ordered have been compressed and it is often in this slightly ‘panicky’ environment that a mistake is introduced, perhaps the wrong change is made as the instructions are no longer clear on what is required.

So to avoid the concertina effect happening and make the likelihood of introducing an error much less likely you need to introduce discipline into your process. I always recommend the introduction of an artwork brief. Here all parties must agree and sign for the changes required. The artwork operator will

then follow the brief and it is understood no changes can be made without going to the start of the whole process.

It is likely some groups will resist this discipline at the beginning, as they believe you need a ‘responsive’ process, but once the procedure is understood and operating correctly people see the benefits as the lead times for changes reduce.

In my next blog I talk about introducing a controlled process and explain how this does not happen by accident but occurs when a company sets out to develop their artwork capabilities with the right supporting infrastructure.

Read it online

Ensuring you have an effective Artwork Capability

In my recent blogs I have focused on the problems and what can go wrong in your company’s artwork provision, but in this blog I would like to talk the key elements I believe you will find when your company has in place an excellent artwork capability.

Developing an excellent Artwork Capability requires looking beyond the core process

When we are brought in in to assist a new client with their Artwork operation it is common that all the focus is on the core artwork generation process and perhaps what technology is required to assist the operation. It is, of course, very important to get the core process working efficiently and effectively, and having a trained team to carry it out. However, in my experience this is by no means the complete story. You cannot have an excellent artwork capability without considering other aspects.

One aspect of importance is defining what the service will provide (and what it won’t), what you would like the culture in the organisation to be, and importantly what will be the standards of service. In this aspect the standards should be

driven by the requirements of the customers themselves and perhaps captured in a Service Level Agreement (SLA).

Groups external to the artwork team, involved in delivering the capability, but which are not part of the core team, need to be brought on-board as the process is being developed. This includes groups perhaps external to the company, who may provide a key element for the core process, an example might be Translation agency or perhaps an external Artwork studio.

When the core artwork process is being redesigned it will also be necessary to look at the Interfacing processes. These are the other processes in the organisation that the artwork process has to work with examples being the item code creation and the change control processes. It is important to clarify the touch points between the artwork and the interfacing processes and ensure the steps, timelines, data flows and data content are all aligned.

What is often forgotten is the importance of good Governance

In my experience the aspect of putting in Good Governance with the right supporting processes is the area often overlooked.

You should of course define the roles and where they fit in the whole organisation and the competencies requirements for all those involved. This should follow the definition of the business process. However I also recommend the establishment of a cross function governance team to steer the establishment, ongoing delivery and the development of the overall artwork capability. The benefits of the governance team are that they not only provide a decision making capability but that they also provide leadership in particular to the overall strategy and vision for the service.

I will look in future posts, at some of the key elements of developing an artwork capability, starting with the need to define what service is required and how this should fit with customer needs.

Read it online

Developing an Artwork Service - Part 1

In this blog I am going to focus on the initial steps required when you start to develop an excellent Artwork Service capability for your company. In particular I would like to talk about establishing the dimensions of the provision and the importance of involving your customers.

Recognise the Artwork Operation is providing a service to the business

It is very important, in the first instance, to talk to the artwork operation's customers and establish what they think of the current provision. It is vital to understand from their point of view what is going well and needs to continue, what needs to stop happening and what is currently not done but is something that needs to be put in place. Examples might be that communication is going well and needs to continue, that there are too many late surprises and this needs to stop and that currently the service doesn't cover commercial samples and it needs to do so. It is useful to understand what the customers see as the ranked priorities, as this will drive the changes you are going to make.

One of the other key things you need to establish are what are the dimensions of the service? By this I mean what does the Supply Chain team think should be the beginning and the end of the service? So where in the process does the Artwork team pick up from the Regulatory group and at what point does their responsibility end - is it when the artwork is signed off or is it when the cartons, with the new regulatory change, have been received in the market? Often the customer's expectations are different, so it is important to get as much alignment as possible and make sure the final vision is agreed on by all parties.

Another important aspect is what is needed in terms of the standard of service. This should be driven by the requirements of the customers themselves and perhaps captured in a Service Level Agreement (SLA). This will also mean new or adjusted metrics so if your customers are fed up with too many changes causing delays you will need metrics to control the amount of rework.

Are there any hidden customers?

All the groups who receive information from the artwork team and those who send data to the team are the customers. However there could be some vital groups that need to have a say so make sure you spread your net wide when you are having these discussions.

Finally it is useful to understand what the organisation's appetite for change is. If you find out that the majority of your customers 'want change and want it now' you will know you there will be plenty of momentum but if you find out that there are initiatives which need to take priority over this one or the organisation see this as a low priority then you may need to adjust your timings and budget.

I will explore this topic further in the next post, looking at establishing the principles of the service and if there are any changes in the culture required.

Read it online

Developing an Artwork Service - Part 2

In this blog I am going to continue to talk about the key aspects to think about when you start to develop the Artwork Service capability for your company. In particular I would like to talk about ways of establishing the service culture and the need to define a set of guiding principles before you look at your process.

Establishing the service culture with the internal and external partners

In the last blog I talked about the importance of speaking to your customers to establish what they require from the artwork service, the dimensions and standards expected. The customers are of course not just the commercial group but the many groups involved in the supply chain who come into play during the artwork and labeling process. These groups are both internal and external to the company and as I have said before, to achieve a high standard of artwork, produced in a timely fashion, requires the careful orchestration of these different parties. Each person involved in the process must perform their

task in the process in the correct sequence, using the right information and tools in order to achieve a quality result.

So to achieve this I would recommend the requirements are communicated across all groups in the form of a clear mission statement, with performance measures and underpinned by a set of guiding principles for the service. Communication of these expectations must happen inside the company and be reinforced by managers and sponsors. Often parties need to cooperate across different locations and countries so these common principles really help.

External groups must also be brought on board, whether they are regulatory groups in the markets or providing a direct service for example translation providers. It is important to take a the long view in this as the way of working needs to be embedded, and for the relationship to be successful, effort needs to be put into it from all parties.

Guiding principles will help to shape the development of the common process

One of the really helpful aspects that is useful to put in place, even before you look at the process, is agreeing a set of principles for the service. I would recommend you agree this with your set of sponsors who hopefully you have gathered to represent all the key interested groups. This steering committee establishes the direction and resources the project implementation and will later oversee the operation of the artwork operation in a governance role.

The principles will cover aspects like roles and organisation, documentation management, process principles, the role of IT, performance and improvement management, education and controls, work management and managing your service providers.

In my next article I will talk about the development of the core process. People often think there is common process which all companies can use but, as you will see, trying to force fit such a process into your company is unlikely to result

in excellence. Although there are common steps in the process, each company's end-to-end process will require subtle differences.

Read it online

The Core Artwork process - on the surface it seems so simple to achieve

In this blog I am going to look at the core artwork process itself. I will be highlighting the key parts of each step and aiming to show what is the difference between a good process and an excellence one.

Define your process before structuring your organisation

One comment to make before talking about the core process is about roles and organisation structure. Many organisations will try to force-fit a new process into the existing roles and organisation structure, but that will also result in a sub-optimal outcome. It is much more effective to define your process then look at the structure and roles required to support.

It is important to define the start and end points of the process. You need to consider how far back in the creation of the product text you want to go. Does the process commence with the creation of the company core datasheet, or the request for local translation or the provision of an approved local text? What triggers are there to request an artwork change and who is authorised to activate those triggers?

Does the process end when the artwork is approved, the artwork file is with the printed component supplier, the component is at the factory or the new components are received in a finished product batch in country? All are valid options but present different implications to the design of your core process.

What are the common steps of a process?

Assuming that the process starts with the request for local country text and finishes with the component entering production, there are, broadly speaking, five main steps - 'Create local language text', 'Define change', 'Produce

artwork', 'Produce Printer proof' and 'Implement'. Each of these delivers an approved outcome - an approved local language text, an approved change definition, an approved artwork, an approved printer proof and an approved component. These can be considered as key 'gates' controlling your process.

When creating the local language text for a new component the company core data sheet is the input document. The text produced in this process step will have the medically critical information so it is vital the meaning is not changed. Controlling this step is key when working across several languages and fonts.

'Define the change' having a clear set of instructions of what is required avoids the common trap of overlapping requests for further changes and mistakes being made in the confusion. We recommend the creation of an artwork brief which is agreed by all parties.

'Produce artwork' this step of the process consists of creating the artwork, checking that is meets the requirements of the brief, proof-reading, approving it and archiving it. Operators who are using well defined layout templates with rules of where logos and text are placed, combined with a well-structured brief are in a good position to produced artwork which will be approved first time.

'Produce Printer Proof' covers, in most cases, the production of an electronic printer proof, produced by the printer's pre-press processes which allows the customer to verify that the proof is graphically the same as the printer proof. Many companies are moving to providing print ready artwork, where the file is prepared so that the print supplier can use without modification. This is encouraged as it removes a potential source of error.

'Implement' in this process step the components, having been put into a bill of materials, are ordered, produced at the suppliers and then go through a quality check before release to production.

The importance of critical control points

It is worth remembering this whole process produces information to be read and acted on and, if incorrect, can have a significant impact on patients. So it is

vital that at each stage in the process there are defined control points to ensure the quality of the output. Each stage must have a check for accuracy and a formal approval by key individuals to proceed.

These individuals will vary and what they are approving will be tailored to their area of expertise.

In the next post, I will look at the implications of ensuring your artwork process operates effectively with other interfacing processes in your organisation.

Read it online

The Artwork process link to the company's interfacing processes

In this blog I am going to look at the importance of getting a good fit with other processes in your company that need to operate in conjunction with your artwork process. Getting effective links to these other (interfacing) processes is an important element of success of the Artwork process.

Artwork should be like a piece of jigsaw that fits seamlessly into the overall company process picture

The artwork process does not operate in isolation. It is a process which relies on information and activity in many other processes in order to operate successfully. Sometimes these processes may be underpinned by systems (which you may want your artwork system to interface with) and sometimes they may be entirely manual. An added complication is that some of these processes may be operated by external groups where you have much less control so it's important to identify the touch points, what the triggers are, what information is exchanged and when, and in what format the information is required. If these are not understood then it is likely delays will occur - not good if a launch is involved.

The processes I am talking about here are either where the artwork process is requesting information to be included in the artwork, for example requesting

component codes from the management process which controls the codes in the Company Enterprise system, or those processes which guide the production of the artwork, so the brand management processes.

In the design you will need to think, ‘Can I work with the process that exists at the moment or will an adjustment be required?’ Adjustments to other people’s processes may be possible and may be your ideal, but equally you may need to relook at your process to see if it can be modified to give a better fit. Companywide processes like the change control process will also be involved and it may not always be possible to modify, particularly if they are hard wired into systems, so a compromise may be required.

Getting even the language right is key

What is noticeable when I visit companies is that people use different terms to describe the same things. What is an item code in one company may be a product code in another. Some companies may talk about master qualification plans but in others it will be a validation master plan. It is perhaps not a surprise, therefore, that when you are dealing across departments, regions and external bodies that you must try to get as consistent language as possible, or at least understand the differences and make sure this is embedded in the training material you provide with the newly designed process.

All companies will have similar sets of processes but what will be unique for your company will be how your company systems mesh with each other and the language that is used. It is for this reason the idea that you can take an off the shelf artwork process and slot it into your company systems, will not work or certainly not work optimally. We believe your artwork process needs to be designed to fit your company’s own ‘jigsaw’.

In the next post, I will look at the importance of the supporting processes when designing your artwork system.

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The importance of the supporting processes

In a previous blog I gave a description of the core artwork process. Having a well-designed artwork process is of course critical to your success, however it is not sufficient enough to provide a complete capability. A number of support processes need to be in place to achieve this.

Defining the process is not sufficient on its own - supporting processes are needed

There are a number of managerial processes which support the artwork service and when these are in place it is my belief that an effective and sustainable artwork capability is more likely. So let's go through the key ones.

Governance process: The Artwork process is, at its core, a cross-functional, international and in many companies a cross-organisational process. So it is important to have the key functions, regions and organisations represented in the governance of this new artwork capability. In my experience this is a new group to the company and in the early days this can be the steering group for the project and later transitions to the ongoing governance group.

Educational and training material development and maintenance: You have defined your process and created the process documentation (SOPs, work instructions) so now you need to prepare all the education and training material to ensure competency.

You manage what you measure

Performance Management: Once you have established your new process, it is important to actively manage it to ensure it is meeting your business needs, using appropriate measures. If you can do so, before you introduce the new process, it will be helpful to get some baseline measures on key aspects like the 'right first time measure' or 'lead time'.

Forecasting and budgeting: The artwork process is similar to a production line in that instead of producing tablet packs it produces a piece of artwork. Capacity is required to be available for the forecasted workload and if this is not

sufficient, more capacity e.g. more people and potentially more equipment, will be need to be brought in. So you need to establish a forecasting process for artwork demand.

Service provider management: Most organisations will use some external service providers for some aspect of the artwork process, perhaps a translations provider or artwork provider. It is important a process is established which manages the selection of the providers and the ongoing relationship.

Issue management and corrective actions: In any new process there are bound to be some issues that arise in the early days but with good corrective actions, you should find the number of incidents reduce. I always recommend putting in a process for issue management, where issues are logged, categorised and the actions tracked through to completion.

Process lifecycle management: It is likely the process you introduce at the beginning will not be the same one a few years down the road. However it is important that changes to the artwork process are assessed and managed through a formal process. This is particularly important as you are dealing with a process that works across functions, regions and potentially also outside the company. Risk assessments are a useful element in this process.

In the next post, I will look at the roles within the artwork capability and what needs to be considered when putting together this team.

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