Trusted Experts in Serialisation Labeling and Artwork

We have received lots of great customer feedback about our newsletter to include some past articles and more industry news. Therefore, along with our current Be4ward posts, we have also included a Be4ward Executive Briefing, 'Things We Wish We Had Known Before Starting a Serialisation Project or Program' compiled from previous posts. We have also selected some Top News Picks from the industry that we think are worth reading.

Click the links to go to the articles, or scroll down to find them below.

We hope you will find this Be4ward industry newsletter interesting and we would welcome any feedback.

Kind regards,
The team at Be4ward

Featured Artwork Posts

by Andrew Love

Right-first-time tips 4 and 5: Ensuring you have an effective end-to-end process and the right quality checks in place

I believe right-first-time is a key metric and mindset for your artwork process and in this article, I continue my series on top tips to improve it, looking at tip 4, raising the need for a comprehensive and effective end-to-end process with clear roles and responsibilities and tip 5 making sure the right quality checks are undertaken by the right people.

Read it online

Right-first-time tips 6 and 7: Ensuring effective training and cross-functional governance

I believe right-first-time is a key metric and mindset for your artwork process and in this article, I continue my series on top tips to improve it, looking at tip 6, ensuring all the people in the process have the appropriate skills, competencies and capabilities for the role they play and tip 7 making sure there is an effective cross-functional governance.

Read it online

Featured Serialisation Posts

by Stephen McIndoe

New Global Pharma Serialisation Legislation Developments Roundup – Part 1

This is the first of a 3-part update on serialisation legislation developments since my last update in mid-2016.

If you want more detailed information and/or updates, I provide a legislation service which you can subscribe to. Drop me an email for more details.

Read it online

Global Pharma Serialisation Legislation Developments Roundup: Part 2

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Read it online

Global Pharma Serialisation Legislation Developments Roundup: Part 3

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Read it online

Executive Briefing

Things we wish we had known before starting a serialisation program or project

While helping clients implement serialisation programs and projects over the last 10 years, the Be4ward team has recorded many lessons learnt and continues to do so. This series explains some of the key things that we wish we had known before embarking on our early projects. We hope that this information will help you make a success of your serialisation activities and avoid some of the mistakes that were made in the past.

- **Tip 1** Executives need to understand that serialisation will halt sales if implemented poorly
- **Tip 2** The technology is still relatively immature
- **Tip 3** The supply base is overstretched
- **Tip 4** Ensure a robust cross-organisation impact assessment is carried out and maintained
- **Tip 5** Ensure the true complexities of your supply chain are understood early
- **Tip 6** Choose solutions that will be globally capable
- **Tip 7** Develop and leverage standard solutions where possible
- **Tip 8** Do not underestimate the amount of resources required to deliver serialisation

- **Tip 9** Put a capable, dynamic and motivated leader on the problem
- **Tip 10** Ensure you understand the evolution of serialisation legislation and instruct the organisation accordingly
- **Tip 11** Involve local country teams and management early
- **Tip 12** Get an end-to-end solution working early
- **Tip 13** Do not forget the non-legislative benefits of serialisation

Learn more and read the Executive Briefing

Top 3 News Picks

We share some of our latest news picks, on all topics related to Serialisation, Artwork, Proofreading, Packaging and Supply Chain Optimization. Here are three links from the many recently shared articles in the industry that we think are worth your time.

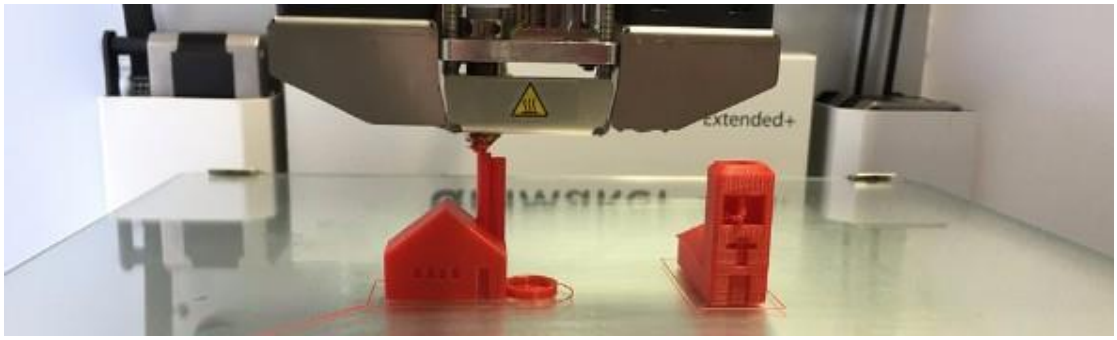
Packaging

Short read

How to Develop Healthcare Packaging Consistency Across Both Physical and Digital Markets

Healthcare Packaging recently published this great article stressing the importance of excellent packaging, labelling and artwork consistency across both physical and digital markets. Did you know that following a diagnosis, 84% of patients turn to an online search to learn more about their treatment options?

Click here to read the article



Medical Devices

Mid read

Implementing 3D Printing

3D printing is coming of age, with global end-user spending on 3D printers set to increase from $1.6bn in 2015 to around $13.4bn in 2018. For many industries, including manufacturing, engineering and architecture, this spells a revolution. 3D printing has the power to accelerate product development and enable faster and more productive design iterations.

Click here to read the article

Pharmaceutical

Long read

Challenge and Opportunity in Medical Marijuana Packaging

With constant changes to regulations, it's an unstable time for the medical marijuana market. But with market estimates in the billions, some packaging suppliers are finding that the risks are worth the rewards.

Click here to read the article

Featured Serialisation Posts

New Global Pharma Serialisation Legislation Developments Roundup – Part 1

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Argentina

- ANIMAT published a new regulation in September 2017 which increases the scope of products covered by the traceability requirements, including all new drugs that are registered in Argentina

Australia

- Serialisation requirements are in place for blood products
- New medicine labelling guidelines have been issued for Rx and OTC products which come in to effect in September 2020
    - This is a batch variable requirement only, with no serialisation

Algeria

- No further update since my last summary in mid-2016

Brazil

- Late in 2016, ANVISA finally officially withdrew their 2016 pilot requirements
- A new track and trace law 13410 was signed by the President in December 2016, which also gave ANVISA the power to define the product scope of the legislation
    - In public presentations in late 2016, ANVISA seemed to be suggesting that they would exclude the likes of OTC, vaccine, parenteral products and Samples when the new RDC is published
    - The effective date of the law is 29 December 2016. This sets the dates for the implementation milestones
- The model will be full track and trace, with a government run central database and extensive reporting requirements for supply chain participants
- ANVISA are currently developing the revised RDC54, which will contain the details of the new system

    - The document is expected to be released for public comment in the late March timeframe
    - Pack marking and the number of data elements contained in barcodes will be defined in the RDC
- As before, a Pilot is required and a cross-stakeholder pilot committee was approved recently
- A service bulletin is expected shortly, which should lay out the scope and participants of the pilot

China

- As I previously reported, in February 2016, the Electronic Drug Monitoring System (EDMS) was suspended pending new regulations which, it is hoped, will align with international standards. In the meantime, GS1 are preparing a position paper on the migration from the current system to international standards
- The CFDA issued new Good Supply Practice for Pharmaceutical Product guidelines in July 2016, that also calls for the building of track and trace systems for pharma product
- In September 2016, the CFDA published opinions that further reinforced their view that manufacturers should uniquely identify individual product packs.
- In January 2017, the CFDA issued a new notice advising that the Chinese National Drug Code, which has been in use since 2009 for the likes of product approvals, is to be used for pack marking and traceability in future
- Ali Health are ceasing support of their EDMS portal in March, although it appears it will still be possible to download serial numbers for use on product. Ali Health appear to be trying to encourage use of a newer system they are providing

- A working group has been set up in China to make recommendations on the replacement track and trace system in China

Egypt

- Requirements for marking of secondary packs in two phases were published in January 2016. The initial phase was for batch variable marking, then for the addition of serialisation
- Final phasing and timing requirements have not yet been published by the local committee tasked with defining this in the law
- There are no clear reporting requirements at this time
- GS1 Egypt is contracting with organizations to manage the master data for the new government system

Ethiopia

- No further update since my last summary in mid-2016

EU FMD

- The deadline of February 2019 to serialise product still stands
- The use of GTIN, NTIN and NHRN codes by the different member states continues to play out. The main issue here is that it is not possible to have an NTIN and a GTIN on the same pack. Therefore, there will be implications on the ability for companies to use multi-market packs for some combinations of countries.
- An updated version of the EU Hub is due to be released imminently
- Member states are continuing to select their National Systems which will connect to the EU Hub and provide local product authentication

GCC Countries

- Apart from those GCC countries I mention specifically, I understand that the likes of Bahrain and Kuwait will follow the lead of the larger countries. Qatar has already done so.

Read it online

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India

- Export Legislation
  - The implementation of the DAVA portal for reporting all export product from India continues to be troubled, as constraints manifest themselves because of the way the system has been configured. The situation does not appear to be being helped by the fact that the DAVA system seems to be being configured for both the export and the separate, yet to be finalised, domestic market requirements.
  - The approach to marking product destined for markets that have serialisation requirements, e.g. the USA, has been causing a lot of confusion, as reporting is still required to the DAVA system, but in Indian law serialisation of product packaging is exempt, as the product will be marked with the destination country serialisation. A process for agreeing these exceptions with the government is being managed by

Pharmaexcil, the India Pharmaceutical Export Promotion Council.
    - The quality of serialised pack marking of US product coming out of India is reported by the wholesalers as having many issues with both what is being printed and the quality of the printing.
- Domestic Legislation
    - There has still not been any publishing of a final domestic legislation.

Japan

- New pack marking recommendations were published in August 2016 for the batch variable marking of prescription drugs with GS1 Databar or Code 128 barcodes by April 2021.
- Discussions are underway to try to move from the Databar to GS1 Data Matrix. This is a batch variable requirement only, with no serialisation.

Jordan

- Requirements were published in early 2016 for a phased implementation of a serialisation model.
    - 1st July 2018 batch variable coding.
    - 1st July 2020 the addition of serialisation.
    - International standards are acceptable.
- Further information is expected from the Jordanian FDA on the scope and reporting requirements. The current concern is that the JFDA seems to be wanting to specify a very broad scope of application, including the likes of named patient supply, samples, tenders.
- It has been confirmed that GTINs issued in any country will be acceptable.

- Only GS1 Data Matrix will be allowed on packs after the end of the transition period on 1st July 2018.

Kazakhstan

- A Kazakhstan Ministry of Health sponsored drug traceability pilot is reported to be ongoing in the country.

Lebanon

- National drug traceability law is being drafted, with a phased implementation of batch-variable coding, then the addition of serialisation.
- The national system could be ready as soon as March 2017.
- The rumoured timelines were very short.
- Final requirements that are overdue have yet to be released. Elections locally appear to be one reason for the delay.

Malaysia

- The current requirement to apply serialised holograms to Malaysian marketed product still stands. However, as there is only one local supplier of the holograms, this causes manufacturers some significant issues.
- The Malaysian Ministry of Health are working with local industry groups on the potential for the introduction of a track and trace system, the adoption of global standards and the phasing out of the hologram.

Nigeria

- No further update since my last summary in mid-2016.

Oman

- Oman Ministry of Health published requirements for a barcoding system in October 2016.
- The scope of the legislation is tender pharmaceutical products.
- Phased implementation, although the exact interpretation of the meaning of the implementation date is unclear.
    - End 2017: Batch variable marking.
    - End 2018: Addition of serialisation.
    - No reporting requirements are stated currently.

Pakistan

- The state of Punjab have just issued serialisation requirements with an implementation date of mid-2017. Clearly this is causing concern and clarifications are being sought.
    - It is understood that, whilst not stated explicitly in the requirements, the GS1 Data Matrix is intended to be used.
    - An unknown Article Identified (27) is also stated as a requirement, which clearly needs some clarification.
    - The requirement, or not, for associated human readable text is also subject to clarification.
- Country-wide legislation is also expected.

Read it online

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Qatar

- Hamad Medical Corporation (HMC) have published requirements for batch variable coding of product moving through their warehouse.
- A barcode label containing the purchase order reference (400) is also required on shipments to HMC.
    - This needs to be done at point of shipment dispatch, which for some manufacturers, may be outside of Qatar
- Requirements not GS1 compliant at present, so work is going on locally to try to bring the requirements in line with other GCC member states.
- Serialisation implementation dates are not yet published, but it is hoped that they will align with other GCC countries.

Russia

- A Decree published in late 2016 lays out the requirements for a complex track and trace system, including aggregation.
- The scope of the legislation includes Rx and OTC products.
- Full serialisation of all products is required by the end of 2018.
- An interview with the Prime Minister emphasised his views that this legislation was key to public safety.
- A decree was published at the end of January laying out the requirements of the pilot, which will run in 2017.

Saudi Arabia

- See my previous update for more details on the requirements.
- Whilst aggregation is not required in the law, it may be necessary for the supply chain to meet the event-reporting requirements throughout the supply chain.

    - A local poll recently indicated that only a few companies are planning initial aggregation.
- It has been confirmed that a list of serial numbers does not need to be included with delivery shipment paperwork.

South Korea

- Reporting of serialisation information started in July 2017, although there was a grace period to the end of 2016 during which non-compliant companies would not be penalised.
    - Reporting is required, at the latest, the day after the transaction occurs.
- Aggregation is voluntary in the law, however, a significant number of manufacturers are aggregating to make the reporting requirements in the supply chain practical.
- The South Korean authorities seem to be stepping back from RFID, which is good news.
- The reporting system requirements are expected imminently.

Turkey

- The comprehensive serialised track and trace system in Turkey continues to operate.
- The Turkish authorities have been visited or invited to key events of a number of other nations developing serialisation, e.g. Saudi Arabia, so we can expect similar requirements emerging elsewhere.

Taiwan / Chinese Taipei

- Draft legislation has been published for comment.
- Complex pack marking and serialisation model affecting primary, secondary and tertiary pack marking and comprehensive reporting.
- Six-stage phased implementation, including:

    - 1st January 2019: Serialisation of a list of high priority products.
    - 1st January 2010: Serialisation of all prescription drugs.
    - 1st January 2021: Serialisation of sales packs of all active pharmaceutical ingredient packs.

Tunisia

- The Tunisia health authority are developing requirements.

UAE

- The Dubai Health Authority have published requirements for a GS1 Datamatrix to be applied to all secondary packs sold to DHA(?) by 1st January 2017 containing batch variable data. They are no longer accepting unmarked product.
- The three other health authorities in the UAE have yet to publish their requirements.
- Companies can meet this requirement, at least in the short term, by having local converters apply appropriately marked stickers, although issues with the quality of these stickers have caused the HDA to require an additional barcode verification report to be sent with each shipment.

US DSCSA

- The November 2017 deadline for serialising all product is approaching fast. Worryingly, there still seems to be a large proportion of smaller Pharma companies and contract manufacturers who have not made significant progress.
- The need to aggregate product continues to be a significant debate.
    - The FDA, in a consultation workshop in October 2016, essentially stated that they will not be legislating on this and it

was up to the supply chain to define what was necessary to meet the requirements.
    - The big wholesalers are calling for aggregation.
    - A significant number of manufacturers are planning to aggregate US product from day one.
    - Other manufacturers, in particular the generic companies, are not planning to aggregate and, in the case of the generic manufacturers, are pushing to never have too aggregate.
- The HMA (wholesalers organisation) ran pilots in 2016, with one of the areas of focus being how they will be able to meet their 2019 requirements to authenticate product returned to them for sale. They concluded that two options are practical and pilots will run in 2017 to investigate them. The two models are:
    - Manufacturers reporting serialisation information to the wholesalers when product is shipped to them. This effectively moves much of the 2023 requirement on manufacturers forward to 2018/9.
    - The establishment of information exchange hub(s) to allow wholesalers to “ask” for real time authentication of packs they are holding. Like the EU hub, this system would have the advantage that each company only needs to connect to one system. However, there is a long way to go before such a system becomes real.
- I wonder what, if any, impact President Trump’s desire for reduced regulation on industry will have on the DSCSA in the long term.

Read it online

Featured Artwork Posts

Right-first-time tips 4 and 5: Ensuring you have an effective end-to-end process and the right quality checks in place

I believe right-first-time is a key metric and mindset for your artwork process and in this article, I continue my series on top tips to improve it, looking at tip 4, raising the need for a comprehensive and effective end-to-end process with clear roles and responsibilities and tip 5 making sure the right quality checks are undertaken by the right people.

Looking first at tip four the need for a comprehensive end-to-end process.

Map the end- to-end process

When you start to measure the right-first-time figures your approach to improve it may be to root cause each incident as it arises. This is a good idea. However, there is a risk, even when you have thoroughly investigated incidents, that you only fix parts of the problem. Issues continue to arise because fundamentally the current process is not ideal.

To really improve your right-first-time metric it is best to review the process as a whole and where possible get external independent expertise. This will enable you to design a process which uses best in class principles and is more likely to include elements which 'future proof' the process.

Map the end-to-end process considering the various different scenarios that arise in your company. The steps for external artwork approval in the EU will differ to that of the US.

Mapping the 'as-is' process and redesigning it will require a number of workshops and support from the senior management team. However the effort will be worth it as you will end up with a process that works, is understood by all and has received full team commitment.

Define the outcome for each step

When mapping each step be clear what should be done, by whom and ensure the performance expectations for each step are defined and agreed. Look at it with fresh eyes where possible. Take the opportunity to achieve your ideal process.

Map the roles and responsibilities for each step

Map the roles and responsibilities for each step. It is useful when mapping the process not to be too bound by the current staffing structures as this can constraint the thinking and prevent a more streamlined process from emerging. This process will almost certainly result in changes in certain roles and you can expect some friction but if this mapping process is done as a group and agreed with the senior team, then it is more likely people will be engaged and go along with the changes.

Make sure there is a clear information flow

Once you have designed the new process, you should ‘trial’ it prior to implementation or configuring any software. Choose a number of scenarios and trial it with the people from each department involved on a day-to-day basis. Then walk through each scenario testing each step and checking they work as expected. Doing this properly will ensure that all the steps are there and in every case, someone is accountable. Only then should you have the confidence to update procedures and configure any systems.

Now let’s turn to my fifth tip which is to make sure the right quality checks are undertaken by the right people. Sounds simple but too often some elements of a piece of artwork are checked by many people and some parts not at all, plus the people reviewing are not necessarily clear how to carry out the check correctly.

The importance of the review and approval steps in the process

There is typically a four-step process to assure the quality of the master artwork file. The initial check carried out by the artwork operator who has created the file, following the brief. The second check is a full and independent proof read, carried out by the proof reader, reviewing all text and graphics against the brief and including a detailed technical check. The third check is done by the regulatory group reviewing the text and content, ensuring any local requirements are met. The final check is done by QA or their representative, checking only that the correct process has been followed and documented. All these people in the chain must be aware of the responsibilities they are undertaking when reviewing and approving at each stage.

The danger of being vague

There is a danger that we are not prescriptive enough when saying what needs to happen when performing a check. If procedures are too vague there is the potential for elements of the artwork to not be correctly reviewed. In particular we often see ‘thick’ SOPs in the central artwork team versus very ‘thin’ SOPs for the regulatory checks done by the affiliates.

Be clear who checks what elements

So its important to spell out in SOPs the responsibilities for each stage and back this up with detailed checklists showing which elements must be checked and by whom. Don’t fall into the trap that everyone checks every element, because actually not everyone is qualified to perform some checks. Only the local language expert can check the context of the language on a leaflet, for example, to confirm how the text will be understood by the local patient or medical professional.

Define the ‘what’ and the ‘how’

It is important to define not only what needs to be checked but how it will be done and with what equipment, if required. State exactly what is involved in each check and what to check against. Regulatory checks will need to be

referenced to listed key documents, for example, as well as the brief. Proof readers will need to be clear what equipment they need, for example, to check bar codes and braille.

In my next article I will look at my next two tips, tip 6 looking at what is required regarding people's competencies/training and tip 7 looking at governance of your process.

Read it online

Right-first-time tips 6 and 7: Ensuring effective training and cross-functional governance

I believe right-first-time is a key metric and mindset for your artwork process and in this article, I continue my series on top tips to improve it, looking at tip 6, ensuring all the people in the process have the appropriate skills, competencies and capabilities for the role they play and tip 7 making sure there is an effective cross-functional governance.

Looking first at tip 6, the need for appropriate skills, competencies and capabilities for each role.

Each role has a different set of requirements – need the right 'fit' for each role

You need a range of skills throughout the end-to-end process. Each step requires a different set of abilities, from creation of the artwork through to the several review and approval stages. People need to show they have the right skills to perform the role but also demonstrate they can use their skills to perform the job successfully. Having the right mind set gives the complete capability for the role.

The artwork coordinator who orchestrates the whole process will require a different skill set to the proof-reader who does the most detailed check of the artwork. The proof reader needs to be highly detail conscious and be

comfortable working alone for most of their working day. The coordinator must be much more people oriented to ensure the artwork is progressed through the business. So, it's important to define what you are looking for in each role, value the differences and select people accordingly.

Recognise some staff are performing tasks daily, some more infrequently

It's important to recognise that, although there are many people involved in this process, many do it only as a small part of their role. In addition, regulatory people in the affiliates who perform the local language review and approval checks, will be doing these tasks quite infrequently. Also, these people tend to change more frequently than those in the central artwork and regulatory teams.

This situation means it is likely there are less experienced people performing tasks in some roles, so it is important to plug this gap with good SOPs and training. Procedures in these areas must give the correct level of detail to enable people to do the job effectively and controls need to be in place so access to systems only happens when the staff have completed the required training modules. Unfortunately, often when we review the SOPs, held centrally and at the affiliates, we discover that the comprehensive SOPs cover the tasks done centrally but SOPs for work done in the affiliates are very high level, lacking essential detail. It should be almost the other way around.

Education and training are key – monitor the effectiveness of the different approaches

SOPs are important but to ensure people have the correct skills and are competent to do the role means effective education and training needs to be provided. Initial training when a process is revised, new starter training, specialist training for certain roles like proof-reading and special focus for those involved in the review and approval steps needs to be considered.

The range of people to reach means a variety of approaches need to be taken. Staff in more remote areas may have web-based training, on and offline training and even recorded videos. There should be a requirement to pass an assessment, following the SOP training.

The effectiveness of the different approaches needs to be monitored, so when issues arise it is useful to identify if inadequate training has been the root cause.

Now let's turn to my seventh tip which is to make sure there is an effective cross-functional governance.

Governance group – required as the process works across many departments

When you 'walk' the complete artwork process from end-to-end you realise it touches many departments and external groups. If the ambition is to achieve an excellent artwork service, then each part has a contribution to make in achieving right-first-time.

I always recommend putting in place a governance group with representatives of the key functions. In most cases this is a new group, as existing groups do not have appropriate cross-functional or geographical representation, or do not have the bandwidth to do the job effectively. If a steering committee was in place for a process redesign the governance group may grow out of this but potentially with more senior members. The members need to be selected with enough authority to carry out their responsibilities and represent their functions/geography effectively.

Leadership needs to take accountability for the performance of their function

Reviewing the right-first-time figures at the governance meeting, with sufficient root-causing activity, should highlight areas where the process just seems to 'get struck'. Each representative then needs to work to resolve

issues that have arisen in their areas of responsibility, in the interests of the whole artwork supply chain.

The leadership team needs to agree to a common vision and sponsor improvements

Good sponsorship means ensuring they agree to a common vision and this vision is communicated out to the organisation, resources provided and any stakeholder conflicts resolved. The team should set out the standard required of the service and agree how its performance will be measured, of which right-first-time will be one of the main measures. The group will also agree priorities for improvement projects identified.

The frequency of meetings will depend on the organisation but I would recommend setting them up on at least a quarterly basis.

In my next article, I will look at my next two tips, tip 8 looking at what is required regarding IT tools and tip 9 factoring in the time and facilities to produce quality work.

Read it online

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