Trusted Healthcare Experts
Transforming Supply Chains

Be4ward®

Welcome to our Be4ward newsletter, our opportunity to share with you our most recent articles, along with our company and wider industry news.

In this issue we share our company news, including the latest article in our series looking at the benefits of applying traceability to the global rollout of the Covid-19 vaccines; a look at our Be4ward website refresh complete with new content and in our industry news section you can review the agenda for the Making Pharmaceuticals Conference at which a selection of Be4ward Associate Consultants will be speaking this autumn.

The online webinar section includes the recent Pharma Supply Chain Virtual Conference, at which Be4ward presented, and as always, we share our consultants' thoughts and knowledge via our monthly blogs, including our new Covid-19 vaccine article and our expert advice on how to drive value out of EPCIS compliance. You can find these in our Featured Blog Post section below, available for you to read on or off-line.

We're pleased to share with you our Executive Briefing for this issue: **Top 10 Right-First-Time Tips to Streamline and Improve Your Artwork Process** outlining our top tips for avoiding costly delays, by getting your artwork right first time, every time.

In our Top News Picks we share with you a few articles from the industry that we think are worth a read.

We appreciate you taking the time to enjoy sharing our news and updates. As always we welcome your thoughts and comment. If you and your business require advice or assistance in any of these areas, please do not hesitate to get in touch.

Kind regards,
The team at Be4ward

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Go to Executive Briefing

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Company News

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ARTICLE
Covid-19 as a Catalyst for Traceability
Grant Courtney | Principal Consultant Be4ward

The global rollout of the Covid-19 vaccines has presented significant and unique challenges, testing supply chain security. Grant Courtney examines the current state of play with vaccine security and the effect of unsecured supply chains on vaccine hesitancy. With serialisation as a recognised method of enhancing supply chain security, why have the benefits not been leveraged for the current vaccine rollout? And looking to the future, how can the adoption of even a partial traceability model to the vaccine distribution, leave a lasting legacy for the future of healthcare serialisation?

Read the article

Covid-19 vaccines: applying healthcare traceability learnings to ensure safe global distribution

Countering Covid-19 criminality: battling pharmaceutical cybercrime

www.be4ward.com

Visit our website to see our refresh

We've retained much of the original valuable content, built over 10 years of Be4ward, and applied a fresh new look along with new sections to reflect our growing team of experts, our expanded areas of expertise and our ever-evolving publishing, news and events.

Visit the new site

Industry News
_____Be4ward

Making Pharmaceuticals 2021 has new dates

Review the agenda

Webinars and Online
_____Be4ward

Pharma Supply Chain Virtual Conference
Connecting Leaders to Create Agile and Resilient Supply Chains

Watch-back now available

An interactive, one-day digital event, where VPs, Directors and Heads of Supply Chain and Logistics came together to share their experiences, brainstorm challenges and take advantage of new opportunities in the global pharma supply chain industry. Helping you transform, redefine and innovate your supply chain strategy during these unprecedented times and beyond.

Day 2: 11:00 am

Benefits Beyond the EU Falsified Medicines Directive – The Hospital Setting
Grant Courtney, Be4ward

The EU Falsified Medicines Directive (EU FMD) introduced new requirements for hospitals to verify the authenticity of prescription medicines. Two years on and hospitals are working to reduce the cost impacts and starting to leverage significant additional benefits. A new report published by Be4ward, the supply chain transformation consultancy, looks beyond the prevention of falsified

medicines to understand what other benefits can be gained in the hospital setting.

Company Blogs
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COVID-19 AS A CATALYST FOR TRACEABILITY

By Grant Courtney | Principal Consultant

The global roll out of the Covid-19 vaccines has presented significant and unique challenges, testing supply chain security. Grant Courtney examines the current state of play with vaccine security and the effect of unsecured supply chains on vaccine hesitancy. With serialisation as a recognised method of enhancing supply chain security, why have the benefits not been leveraged for the current vaccine rollout? And looking to the future, how can the adoption of even a partial traceability model to the vaccine distribution, leave a lasting legacy for the future of healthcare serialisation?

Read it offline

Read it online

DRIVING VALUE OUT OF EPCIS COMPLIANCE

Electronic Product Code Information Services (EPCIS) is a global GS1 Standard for creating and sharing supply chain information, both within and across enterprises, which enables companies to gain shared, often real time visibility of

their end-to-end supply chains. Anyone who has been involved with trying to make business processes and information flow across multiple organisations and IT systems will understand the value of such standards to govern data format and transfer methods. This is the reason for the existence of organisations like GS1 and why it's member organisations pay it's fees, and often contribute significant employee time to helping develop these standards. This is also why those same member organisations implore regulators to adopt and mandate those standards in their legislation.
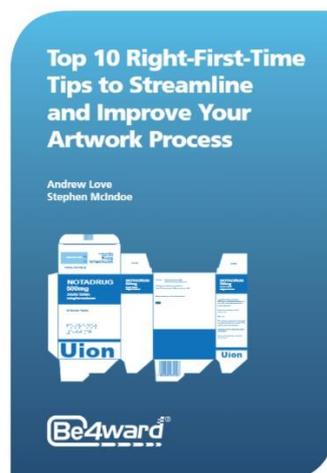
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Executive Briefing

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Executive Briefing: Top 10 Right-First-Time Tips

to Streamline and Improve your Artwork Process

Stephen McIndoe

Andrew Love

Introduction

We all understand that packaging and artwork still present a significant compliance risk and delivering right-first-time artwork is a complex endeavour involving many moving parts. Furthermore, being right-first-time increases speed, reduces waste and raises confidence.From this booklet, we can see that achieving high right-first-time is doable, but there are many parts to be addressed, requiring focus and persistence. As such, right-first-time is as much a mindset as an outcome.

An Overview

The importance of accurate artwork for your company

Is the importance of having accurate artwork stressed in your company? Do people assume that artwork needs several versions before it is approved? What happens when your affiliates spot errors that, thankfully, have not reached the customer and what is the reaction when unfortunately, there is a recall when one gets through? It is essential to remember, a company can only sell its product when they are correctly packaged, can only ship its product when the text on the packaging is correct and at the end of the day, patient lives rely on the text being absolutely correct. If this is forgotten and management live with a lacklustre right-first-time record then the company's reputation and profits will be directly impacted when errors do occur.

So why is getting artwork right-first-time so important?

Accepting that the first version is unlikely to be correct is a risky business. The closer you get to the launch or the implementation deadline you see what I refer to as the concertina effect — less and less time to deliver. In this environment

when chasing for the final version through multiple iterations, the stress increases, confidence drops and the potential for mistakes increases. Alternatively, when you focus on getting artwork right-first-time, things that are not correct are eliminated early in the process and potential sources of errors are designed out. When lead times are squeezed, as they often are in these types of situations, your risk of an error has hopefully passed and the likelihood of a recall reduced. Focusing in this area will have the additional outcome of more consistent lead-times, capacity will increase and everyone will have more confidence in schedule adherence.

Read the **Executive Briefing** to learn more

Read it offline

Read it online

Top News Picks
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Fake Pfizer Vaccines Found in Mexico and Poland

By Tim Hayes Contributing Editor, Healthcare Packaging

A recent *BBC* article discussed two different investigations into counterfeit Pfizer vaccines. Doses were seized in both Mexico and Poland and tests confirmed the doses were fake.

Click here to read the article

£3m worth of illegally sold meds and devices seized in UK

By Selina McKee - Pharma Times online

UK officers have seized more than 3 million medicines and medical devices valued at over £9 million as part of a global operation tackling the illegal online sale of medicines and medical devices.

GETTY IMAGES

Thousands of fake online pharmacies shut down

By BBC News

A record number of fake online pharmacies were shut down in May as part of a global crackdown.

Anti-counterfeiting technologies set for post-COVID boom, according to new report

By Packaging Europe

According to a new report from Smithers, brand protection, track and trace, and other anti-counterfeiting technologies in packaging are increasing in use, as economies across the globe adjust to a post-COVID world.

Click here to read the article

FDA details plans for DSCSA implementation in four guidances

By [Joanne S. Eglovitch](#) - Regulatory Affairs Professionals Society

The US Food and Drug Administration (FDA) on 3 June released four guidances on its plans for implementing the *Drug Supply Chain Security Act* (DSCSA), setting the agency's expectations for how pharmaceutical manufacturers should comply with new product tracing requirements.

[Click here to read the article](#)

Executive Briefing:
_____Read offline

Executive Briefing: Top 10 Right-First-Time Tips to Streamline and Improve your Artwork Process

Introduction

We all understand that packaging and artwork still present a significant compliance risk and delivering right-first-time artwork is a complex endeavour involving many moving parts. Furthermore, being right-first-time increases speed, reduces waste and raises confidence.From this booklet, we can see that achieving high right-first-time is doable, but there are many parts to be addressed, requiring focus and persistence. As such, right-first-time is as much a mindset as an outcome.

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It is essential to remember, a company can only sell its product when they are correctly packaged, can only ship its product when the text on the packaging is correct and at the end of the day, patient lives rely on the text being absolutely correct. If this is forgotten and management live with a lacklustre right-first-time record then the company's reputation and profits will be directly impacted when errors do occur.

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reduced. Focusing in this area will have the additional outcome of more consistent lead-times, capacity will increase and everyone will have more confidence in schedule adherence.

Achieving a high standard in right-first-time requires focus and attention to detail

Best-in-class organisations achieve a right-first-time figure in excess of 95%. However, to achieve this requires continual focus and likely enhancement or redesign of your artwork process, combined with a degree of focus on what is required at each stage. It will also require regular support from a senior management team, made up from the groups involved. Technology will have a part to play to enable a high quality process, both for the production and checking of the artwork itself but also in the tracking and approval process. Finally, the right culture will be required, displayed across all the teams, to ensure success.

In this briefing we will explore this topic further and outline 10 Top Tips, based on the experience we have gained working with many companies, to help deliver an excellent right-first time measure.

How Be4ward can help

Understand where to improve your labelling and artwork capabilities with our Capability Effectiveness Assessments

Delivering right-first-time labelling and artwork involves the coordination of a complex set of interrelated business processes, organisational groups and suppliers, IT systems and facilities. Understanding how all these moving parts should fit together to deliver an efficient and effective result is not trivial.

Be4ward have developed two capability effectiveness assessments to help you understand your current situation and where improvements may need to be targeted. The tools vary in scope and depth of analysis, to allow you to select the most appropriate assessment for your situation.

Labelling and Artwork Capability Effectiveness Assessment

The Labelling and Artwork Capability Effectiveness Assessment will give you a complete and thorough analysis of your end-to-end labelling and artwork capability, identifying issues and potential areas for improvement. Be4ward use their comprehensive Labelling and Artwork capability model as the basis for this study, which has been developed over many years of working with companies to improve their labelling and artwork operations.

Whilst always tailored to a company's particular situation, the comprehensive labelling and artwork capability assessment will typically include:

- Multiple on-site visits to assess current operations and capabilities.
- Interviews with internal staff and key supplier personnel involved in all aspects of the processes.
- Interviews with senior management who are responsible for the processes, or are key customers of it.
- Examination of key documentation and performance metrics.
- Governance team feedback.

These in-depth studies are led by one of our executive level labelling and artwork consultants.

The result

- An in-depth understanding of your company's current end-to-end labelling and artwork capabilities ranked against Be4ward's capability model.
- Identification of issues and specific suggestions for areas of improvement that are appropriate to your situation.
- Education and feedback to your governance team.

Artwork Capability Effectiveness Assessment Express

Be4ward also offer an express artwork capability assessment targeted at companies who wish to get an overview of where their current artwork process

is and some direction for areas of improvement. Whereas the Labelling and Artwork Capability Effectiveness Assessment provides in-depth analysis of the labelling text creation and artwork processes, the express assessment limits scope to artwork creation and approval steps.

The express assessment typically involves remote interviews with a small number of key individuals and a single on-site visit of a key location.

Central to Be4ward's Labelling and Artwork Capability Effectiveness Assessments is the Be4ward labelling and artwork methodology

Tip 1
Measure your right-first-time — if you don't measure, you don't manage
Right-first-time, I believe, is a key metric and goal for your artwork process and in Tip 1, I will discuss my suggested Top Tip for improving this measure. I will talk through the need for measuring, who looks at the figures, where in the process to measure and what types of changes to include.

How to measure right-first-time and where are the figures reported
There are many ways you could measure right-first-time, but in our view it is a simple pass or fail metric — did the artwork pass through the process once or was any change required? The calculation should be straightforward — the number of artworks completed right-first-time divided by the total number of new artworks created (note: would not include non-right-first-time revisions in this total). This gives a percentage right-first-time. This can be used to give a baseline performance and set targets for the process. As you remove sources of error this will enable the team to track the improvements.

You manage what you measure
It is important the team own this measure and use it to drive improvement and there are a few points to consider here. Trending the measure will show all if performance is improving or declining. Setting clear targets to be achieved shows the performance gap to be closed. A process for the team to analyse the

reasons why the artwork requires reworking will help understand what is going wrong (and I will talk about this later in a further tip).In addition, the figures need to be reviewed regularly by the cross-functional governance group. Errors can arise from many sources and the support of the governance team will be required to help resolve these across the many impacted departments.

So where in the process do you measure and what do you include? Many companies already measure right-first-time, but there are many differences in the scope of what is measured. There are numerous points through the end-to-end process where right-first-time should be checked: at the approval of the artwork brief, after creation of the artwork, after proof reading, after artwork approval, after receipt of packaging materials, to name a few. You need to consider the milestone and rework points in your process and measure right-first-time at those points. To avoid the risk of an error being released to the public, you need to drive your right-first-time performance as early in the process as possible.

There are numerous types of artwork change — new products, safety updates, technical changes, line trial components. Some are easier than others, but even though it may be difficult to achieve right-first-time for some, it doesn't mean you shouldn't manage. However, you may wish to report different types of change separately with different initial targets for each.

Artwork quality standards should be as high as expected for a production document GMP drives your manufacturing and packaging operation to produce a high quality process so the products produced are safe for the patient. Producing artwork should be considered in the same way. Errors need to be driven out so you end up with a safe, repeatable right-first-time process.

Tip 2
Use codes to categorise errors, then ensure a thorough root cause analysis to eliminate source of errors

Right-first-time, I believe, is a key metric and goal for your artwork process and in Tip 2, I will explain the need for a detailed understanding of why the errors are happening. I will discuss the categorisation of the types of errors found so you can eliminate them one by one.

Categorise the types of errors

Measuring your right-first-time will tell you what your performance is but not why. You will need to delve deeper into the data. I suggest you set up a system for collecting and categorising the errors found, reporting them monthly. You need to determine the broad categories, and recognise this list may change, as you understand the issues more clearly. A typical set of error categories may include errors attributable to file identification/properties, text content, graphical content, supplied data, process failures and the technical aspects of the artwork. You may even need to break these broad categories into more specific error types.

Recording the reasons for a non-right-first-time artwork will then let you track the frequency and volume of different types of error, to identify the ones that are most significant. This is where you then need to target your energy for improvement.

A clear differentiator of companies that have excellent right-first-time performance is that they are obsessive about eliminating sources of errors by designing them out of the process. They have managed to minimise the effort they expend on cleaning up after an incident and instead channel that resource and energy into eliminating the potential for errors to occur.

Develop a good root cause process — consider the 5 Why's approach

Once you have decided which category you need to focus on, you need to make sure you root cause the sources of the failures. This will ensure you are applying the right corrective actions.

Every company has their preferred method to root cause but I will suggest you consider the 5 Why's method as it is easy to train and very effective. Simply, you

ask "why" for as many times as you need to, until you get to the ultimate root cause.

Looking at an example: an error has been discovered where the braille on a launch pack is obscuring some key information and there have been complaints. Why has this happened?

Answer: The job was rushed and the team say they were not clear braille was needed until the last minute.

Why did they not know it was needed and where it was to be positioned?
Answer: This information was not clear at the point prior to when the artwork was being generated and had to be added later.

Why was this information not available at this point in the process?
Answer: There is no discipline for providing all the information prior to starting the art-work and people put the braille where it normally fits.

Why is there not the discipline at this point for both of these points?
Answer: There is no process for gathering all the information and signing it off prior to starting. People don't know where to put the braille in general.

Why don't people know where to put the braille?
Answer: The line drawing doesn't show where braille should be.

The actions from this process would be to update the drawings to show the braille location and put into your process the discipline of having all the information available, using an artwork brief, prior to the artwork generation process starting.

Having implemented solutions, continue to measure to ensure sustainability
Once improvements have been made you should continue to measure the error categories to ensure the frequency of occurrence for the ones you have targeted

for improvement have reduced. This will tell you if your improvements have been effective and also sustainable. The last thing you want is the same errors occurring again, especially if you think they have been addressed.

Make sure all of the input information is correct before starting
Right-first-time, I believe, is a key metric and goal for your artwork process and in Tip 3, I will explore the artwork brief to make sure you have all the information before starting. Unfortunately, many companies start with incomplete information, so in this tip I talk through why this happens, why having the information upfront is so important and how to manage the process.

People mistakenly think starting early will make it faster
Why is it that there are so many issues with pharmaceutical artwork? Well getting artwork right is tricky. It requires gathering all the correct different elements, from different departments in the company, often from different countries, and making sure they are placed onto a piece of artwork in exactly the right position, accurately.

Companies often jump straight into designing the artwork, thinking that getting ahead of the game will speed up the overall process but they are mistaken. Consistently, I have seen that proceeding this way not only makes it more likely for mistakes to happen but often the overall timescales are longer.

One analogy is to think of the situation where you are arranging for your house to be painted. You test to get the colours you want and then agree that up front with your painters. You don't get them to try different colours until you see one you like and you don't want to have to pay them again if they use a colour you don't like!

A good artwork brief defines 'the change' completely, with no ambiguity
Events either inside or outside a company will result in the need to introduce new

artwork or change existing artwork. So a 'change' is required. I always recommend to clients, to have all the information before starting and make sure it is correct. The 'change' is captured in an artwork brief, signed off as approved by key parties before starting. A perennial source of artwork not being right-first-time is incorrect input information or a key stakeholder not agreeing the change during artwork approval.

A good brief is a clear and concise record of the change required with no room for any misinterpretation and contains the following information:

- The standard cover page with all the relevant information on the change and the data required.
- A standard implementation workflow with the people who will be involved in the change and their agreed dates.
- A draft bill of materials with the component numbers required, both new and existing.
- The electronically marked up artwork amended and presented with suitable software.
- The source documents selected from a recognised repository.

All this information is collated and presented as one brief.
It is important the same groups who approve the artwork, sign off the brief

A powerful use of the brief comes from the key stakeholders agreeing this is the change required. The signatories will need to be defined for each part of your company and their approval forms a critical control point in your process.

The final artwork review and approval would be made against the artwork brief, by the same signatory departments and ideally the same people who approved the brief, making sure all the changes required have been implemented and that no other changes have been made inadvertently.

Tip 4

Ensure there is a comprehensive and effective end-to-end process with clear roles and responsibilities

Right-first-time, I believe, is a key metric and goal for your artwork process and in Tip 4, I will focus on making sure you have a clear process. I will be raising the need for a comprehensive and effective end-to-end process with clear roles and responsibilities.

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.

Tip 5

Make sure the right quality of checks are undertaken by the right people

Right-first-time, I believe, is a key metric and goal for your artwork process and in Tip 5, I will explain why it is important that the right quality checks are undertaken by the right people. This 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 it is 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.

Tip 6

Ensure all people in the process have the appropriate skills, competencies and capabilities through effective training

Right-first-time, I believe, is a key metric and goal for your artwork process and in Tip 6, I will focus on ensuring all the people in the process have the appropriate skills, competencies and capabilities for the role they play.

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 mindset 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 progressing 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.

Tip 7

Ensure there is effective cross-functional governance

Right-first-time, I believe, is a key metric and goal for your artwork process and in Tip 7, I will focus on making 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 stuck'. 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.

Tip 8
There needs to be an appropriate and scalable suite of IT tools to support the process and people working with it
Right-first-time, I believe, is a key metric and goal for your artwork process and in Tip 8, I will focus on looking at what is required regarding IT tools. Ensuring there

is an appropriate and scalable suite of IT tools to support the process and the people working with it.

There is a range of tools available to support artwork operations

I am not going to go through every tool in this blog but instead highlight some of the key types.

Document management and workflow tools allow you to manage your documents in a controlled electronic environment and route them to key users to perform the process tasks necessary. These tools sometimes also permit planning of artwork projects. Document review and approval tools allow users to view, comment and approve documents electronically (usually with an electronic signature). These above tools are the typical functionality of Artwork Management Systems.

Electronic proof reading tools allow you to electronically check text, graphics, barcodes, braille and, depending on the package, other artwork elements. Artwork and drawing tools are typically used by artwork operators to generate artwork and engineers to create the profiles and templates for components.

Technology helps right-first-time

Two of the ways technology can assist with right-first-time is to automate activities and reduce opportunity for human error. A frequent source of error in a manual process is mistakes with document versions. An electronic document management system can avoid this as they typically provide closed loop version management, automatically version-numbering iterations of a document and ensuring it is obvious which is the most recent version.

Human error is always a challenge when proof reading large documents which require long periods of focused attention. Electronic proof reading tools can assist here by providing an electronic means of proofing that is consistent and accurate.

Technology presents some downsides that need to be considered

We often hear the same thing when we engage with a client that has undertaken a major technology project: "We have implemented a new system but our right-first-time performance has not improved — why?". The answer to this is pretty simple — application of technology is part of the solution, not the whole solution. If you look back through this set of Top Tips, there are many things that need to be done to raise performance beyond technology: addressing process, people and organisational issues. Missing these means that you are unlikely to achieve an holistic outcome.

Another downside is that technology costs money, both in the initial cost of the tool and in implementation, maintenance and support requirements. We often find that people trying to implement systems look only at the initial license costs, which once you have considered project resource and validation costs and ongoing running costs, are a small part of the total lifecycle cost of a system. This total cost is often a surprise.

Finally, technology is used by people, and in the case of artwork systems, many of those people may use the system only occasionally (think of the regulatory staff in your different countries). So even a technology project is really about people, as you have to give them the motivation and capability to change and the education and training to be able to use the tools correctly.

Choose a strategy that fits with your needs

Therefore, in defining how to move forward with technology you need to consider the needs of your individual company. As a broad generalisation, the technology needs become greater the larger the size of your company. We typically measure this in the number of artworks required. If you have 360,000 artworks to manage you need some sophisticated capabilities. If you only have three, your approach can be much simpler. But remember that technology takes time to implement, so if you are growing fast you need to be thinking ahead.

Tip 9

Ensure there is quality time and quality facilities to do quality work

Right-first-time, I believe, is a key metric and goal for your artwork process and in Tip 9, I will discuss ensuring there is quality time and quality facilities to do quality work.

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 stuck'. 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.

Quality time for quality work

We talked early in these Top Tips about the 'concertina' effect in artwork projects, where numerous rounds of rework occur but the deadline is fixed so work gets continually squeezed into faster and faster rework cycles. This is a downward spiral as the increasing pressure likely results in either shortcuts being taken or more errors being made. How often have you seen the situation where an artwork has to be sent out at 5pm on a Friday followed by a phone call asking if you have approved it yet?

One of the greatest benefits of achieving a high right-first-time is to get out of this whirlwind of rework and chasing. Schedules become more stable and outcomes become more predictable. People get the quality time to do the quality work required because they don't have to do it again and again.

We often hear, "Let's get the artwork started now because is takes forever". Invariably this means starting without knowing all of the information — this is just a guaranteed way of generating rework. Surely the better way is "Let's get all of the information together and correct and then do the artwork really quickly — ONCE!"

Quality facilities — a tidy desk is a tidy mind

Line clearance procedures in pharmaceutical packaging facilities are a critical quality process. Why? To avoid the risk of cross contamination of products or components from one batch to another.

The principle also applies to artwork. A routine source of error is when source information gets mixed up and the wrong documents are compared. This can be a particular risk when there are a number of strengths of a product being compared against a number of reference documents — it can be easy to be looking at a wrong combination. A clean-down of the workspace between each artwork should be undertaken.

Think about workplace design

Most artwork activity is desk-based in offices, but there are some specific facility requirements that should be considered. Proof reading and artwork review needs good lighting, space to lay out large documents and quiet areas. Many of the roles need two screens so they can be looking at an artwork and a set of instructions, or comparing two artworks.Think about the facility and equipment needs of the people who undertake the tasks in your processes. If they don't have what they need, they will be unlikely to be able to do quality work.

Tip 10

You need to have the right culture, displayed across all teams involved in the end-to-end process to ensure success

Right-first-time, I believe, is a key metric and goal for your artwork process and in Tip 10, I will discuss the importance of culture and the need to ensure you have the right culture displayed across all teams involved in the end-to-end process, to ensure success.

Why think about culture?

So what do we mean when we talk about culture in the context of the workplace? Culture is a facet of the way people engage and behave towards each other. It is prevalent in the way people respond to instructions and rules. It affects the way people respond to different types of recognition and reward. Workplace culture is influenced by the different national and geographic cultures present in the workplace.

Culture could be considered as the informal rules in the workplace or "the way things get done around here". Therefore, if you want certain behaviours from your team, you need to make sure you have a culture that promotes those behaviours.

What would define a winning culture?
There are lots of ways you could define your target culture. We typically use nine parameters as a starting point:

- Accountability
- Commitment and values
- Sharing of knowledge
- Team working
- Customer focus
- Continuous improvement
- Decision making
- Working under pressure
- Recognition

This list is not exhaustive but covers the key elements we consider most important. However, this isn't necessarily a list you can just lift and use. Many companies have culture and value statements at a corporate, if not also functional, level and so your target culture needs to align with these. This may impact the parameters you chose or the language you use.

Once you have agreed your parameters, you need to decide what good would look like for each. If you were displaying a successful outcome for each parameter, how would that manifest itself? How would it look and feel? Could

you measure it? It is best doing this as a team exercise to build buy-in to the desired outcomes.

How do I get the right culture?

Once you have defined your target culture you can look at how you can achieve it. What is different from today and what will need to change to make that happen? Changing mindset and behaviours is difficult and takes time and perseverance. Do you need to change any management processes? Do you need to do team working training? Do you need to change the way people are measured? How do you reward for people who are doing what you want and what do you do about people who are not?

Your culture will not change automatically — you need to define the actionable steps that you will take to make it happen. Again, work with your team on this transition plan to build their buy-in.

The role of leaders in attaining the right culture

Leadership is key in realising and sustaining cultural change. Leaders need to express, model and reinforce the new culture you want to achieve. They need to role model the new behaviours — if they don't, people will not believe it is real. They need to be seen to actively promote the culture you want, recognising teams and individuals who are displaying your new culture and behaviours. Therefore, your target culture needs to align with the expectations of your governance, so you need buy-in from leadership as well as the teams involved.

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Covid-19 as a catalyst for traceability

By Grant Courtney | Principal Consultant

The global roll out of the Covid-19 vaccines has presented significant and unique challenges, testing supply chain security. Grant Courtney examines the current state of play with vaccine security and the effect of unsecured supply chains on vaccine hesitancy. With serialisation as a recognised method of enhancing supply chain security, why have the benefits not been leveraged for the current vaccine rollout? And looking to the future, how can the adoption of even a partial traceability model to the vaccine distribution, leave a lasting legacy for the future of healthcare serialisation?

The perfect storm

Where demand for a highly desirable product outstrips supply, it creates the perfect conditions for opportunist profiteers to move in. The falsified product activity we have seen blighting the bottlenecked PPE and Covid-19 test kit supply chains since the start of the pandemic has now, as predicted, started to impact vaccines with instances of falsified vaccine activity reported in Mexico, US, China, Ecuador, Italy, and South Africa so far.

In December 2020 falsified vaccine activity prompted Interpol to issue an orange warning (1) regarding the threat that fake vaccines pose to public safety. An individual was arrested in Washington in January for vaccinating as many as 30

people with fake coronavirus vaccines, charging up to $1,000 per dose (2). Six were arrested in Mexico for trafficking fraudulent vaccines at a profit of around $2,000 per dose (3) After publicly criticising the lack of supply, an Italian official was dubiously offered 27 million doses of Pfizer shots for purchase outside of the European Union procurement system (4). Chinese authorities seized over 3,000 fake vaccines from a criminal ring involving up to 80 individuals believed to have been operating and distributing saline-filled vials since September 2019 and in the first cross-continental incident reported, over 2,400 doses of fake vaccine were found to have travelled from China to South Africa, before being intercepted by Interpol (5). As more variations of the vaccine appear, the falsification opportunities increase. Echoing Interpol's concerns, in February the EU's anti-fraud agency OLAF issued a statement (6) urging members to be vigilant against scammers attempting to defraud the purchasing European authorities. Such is the desire to join the 'vaccinated' population, and enjoy the anticipated freedoms therein, we have seen instances of theft and falsification of ID for vaccination, proof of vaccination as well as falsification of the vaccines themselves.

There are many reasons why people will look outside of the legitimate supply chain to procure a vaccine. It could be born of a fear that due to a lack of supply the vaccine will not reach them or reach them too late. It could be due to a reluctance to engage with the authorities and healthcare systems, or a simple case of queue jumping. In a previous article I examined some of the measures adopted to help tackle Covid-19 vaccine related cybercrime, one of which is the education of the general public regarding the safe acquisition of the vaccine and the avoidance of illegitimate supply. The high profile of the Covid-19 vaccines has certainly helped the cause here. It has been highly publicised that global supplies are limited. The resounding message from global authorities is that, unless a vaccine is administered by an authorised body, it is not legitimate. There are no legitimate vaccines for sale, there is also no 'spare' vaccine, and all illegitimately sourced vaccines will likely be fake. Yet equally it is these headlines that can fuel the fear and drive consumers to seek the vaccine illegitimately. With instances of theft, diversion and hijack of the genuine vaccine being reported, it is still considered plausible that real vaccines can be sourced illegitimately,

despite the very real chance these vaccines have been spoiled or rendered ineffective through improper handling or administration.

It is possible that falsified or stolen product may enter both the illegitimate and legitimate open vaccine supply chains. This has many dangerous consequences including patients and consumers falsely believing they are vaccinated, and therefore not taking the necessary preventative measures of the consciously unvaccinated. Another damaging consequence of an unsecured vaccine supply chain is the erosion of consumer trust and confidence, a contributory factor in vaccine hesitancy. A deterioration in levels of trust in the safety and efficacy of various vaccines has dominated the headlines recently. It is imperative that people trust the vaccines they are offered both in terms of legitimacy as well as safety and efficacy and therefore anything that erodes trust, including discussions around falsification of vaccines, can further contribute to hesitancy and further hamper the efforts of the global roll out.

Falsification is by no means a new issue for the healthcare industry and there are many bodies, businesses, and processes in place to reduce the impact of these crimes. The Covid-19 vaccines however present us with a rather unique situation, one that in some way helps us in the falsification battle over and above other therapeutics. The fact that there are so few variations of the vaccine, an unusually low number of SKUs and that those that do exist are rolling out through highly visible and scrutinised supply chains, are all factors that help us keep tighter control over the supply chain.

Traceability as a solution

A proven technique for reducing the opportunity for falsification is serialisation of product, mandated by the likes of the DSCSA in US and EU FMD in Europe. Serialisation offers high level visibility and traceability to primary pack level, 360-degree supply chain transparency providing the ability to trace a product back to its source, ensuring authenticity. It requires common identification of an item, standard barcodes, accurate product master data and supply chain partners who are able to share data and transact through common processes. The benefits are far reaching, going beyond just efficiency and security of the supply chain, to providing valuable data for example, for the management of product recalls. A

significant enabler in this space is GS1, who has developed common standards for serialisation with a view to enhance patient safety and drive supply chain efficiency within healthcare.

Huge steps have been taken in recent years by countries such as Turkey, South Korea, and Argentina to leverage the many benefits of traceability. However, such is the uniqueness of the Covid-19 vaccine global distribution effort, that even where existing traceability systems were in place, they were initially given dispensation from serialisation in favour of speed of delivery to market, an understandable compromise due to the urgency of distribution. In some cases, partial track and trace has been applied to the vaccines with, for example, barcoding to secondary packaging. In the US, the Center for Disease Control (CDC) has retrospectively implemented a tracking tool to help people locate suppliers and stock of the vaccine in their local area ([7](#)). This is a rudimentary solution, far surpassed by full traceability and as recent falsification incidents have demonstrated, the lack of full serialisation of this most precious of commodities has effectively left the vaccines more open and vulnerable than a readily available and cheap, serialised pack of paracetamol.

There is a tendency for serialisation to be undertaken only under the pressure of approaching legislative deadlines and only a few countries in the world have currently implemented traceability systems across their end-to-end supply chain. Turkey was the first and perhaps remains the most comprehensive system currently in operation. Their system tracks the product from the point of manufacture through to the point of dispense and is used to prevent falsified products, reimbursement fraud, product diversion and promote the safer use of drugs. UNICEF has requested serialisation as a preferred requirement for Covid-19 vaccines ([8](#)), but it is not yet mandated. This has been the situation for the launch of the vaccines, we could yet see a level of serialisation applied to future rollouts, once the pressure on the supply chain has eased.

Again, the uniqueness of the Covid-19 vaccine supply chain has seen new manufacture and distribution parties coming together and having to devise new

working systems. A serialisation system requires considerable investment both in terms of finance and time and therefore where a system was not already in place, in the case of these vaccines there was no time to implement one. Visibility in the Turkish system was achieved through the implementation of a central traceability system financed by the Turkish Medicines and Medical Devices Agency (TİTCK), which is affiliated to the Turkish Ministry of Health. This project took four years to achieve, starting in 2008 and completed in 2012, costing significant time as well as money.

The steppingstone to full traceability

There exists a spectrum of serialisation models from, for example, point of dispense in Europe, to full track and trace in Turkey, Argentina, and others. The gold standard is full traceability across the supply chain, in a closed environment. This is where every product is identifiable to the individual pack and all product is checked into a closed environment, tracked through that supply chain, and checked out of the environment at the point of administration. This type of system is seen where serialisation is mandated and legislated and is currently in play in places such as Turkey, Argentina, South Korea, and the EU. These stand as beacon examples of closed and controlled supply chains.

Some traceability models can exist within an open environment. This is where partial serialisation is utilised in an optional or voluntary capacity, offering some level of supply chain visibility and the associated benefits. A successful example of this was implemented by Danone for its baby milk powder ([9](#)), whereby manufacturers applied mobile phone scannable QR codes to the packaging, enabling the consumer to verify the quality and authenticity of the product. Two codes exist on the inner and outer packaging providing data on place of manufacture and product legitimacy but also supplementary health and nutrition information and parenting guides and support. In the healthcare industry GSK made strides in the partial serialisation space as far back as 2014, when they applied SMS technology to their antibiotic in the Nigerian market ([10](#)), allowing pharmacists and consumers to verify the authenticity of Ampiclox by texting a unique code on the blister pack to a central number, which in turn confirmed product legitimacy via a return text. This pilot led to the Nigerian medicines

regulatory authorities mandating the verification process for all antimalarial and antibiotic drugs ([11]).

These flexible and fast models of verification have also been seen is FMCG and apparel markets. They do not offer the myriad of benefits of a full track and trace system, but without the significant investment required for such systems, they do offer significant benefits beyond the enhanced consumer experience such as being able to detect missing batches and illegal product diversion whilst allowing the sharing of data with customs and other authorities.

A closed environment with full traceability is undoubtedly more secure than an open environment with partial traceability, yet there are significant benefits to these models, since some level of supply chain visibility is better than no visibility. These partial models also stand as foundations and steppingstones to full traceability. They start the process, introducing the necessary systems, equipment and methods and enable the realisation of the benefits of full track and trace, potentially paving the way to a closed environment model. Applying such models to the many supply chain issues surrounding the Covid-19 vaccines could potentially see the pandemic leaving a legacy of significant new developments in the traceability space, as yet unseen in the healthcare industry and of huge benefit to societies and economies worldwide. This complex and ground-breaking global vaccine roll out could act as an enabler to the development of traceability, as a catalyst for discussion to build upon the foundations which already exist. It could prompt governments and stakeholders to consider and implement traceability solutions faster, making a significant acceleration in the global serialisation journey.

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Driving value out of EPCIS compliance

Electronic Product Code Information Services (EPCIS) is a global GS1 Standard for creating and sharing supply chain information, both within and across enterprises, which enables companies to gain shared, often real time visibility of their end-to-end supply chains. Anyone who has been involved with trying to make business processes and information flow across multiple organisations and IT systems will understand the value of such standards to govern data format and transfer methods. This is the reason for the existence of organisations like GS1 and why it's member organisations pay it's fees, and often contribute significant employee time to helping develop these standards. This is also why those same member organisations implore regulators to adopt and mandate those standards in their legislation.

Today, compliance to these standards brings benefits such as a reduction in the cost of maintenance or upgrade of interconnected system and increased agility to change supply chains. In future, adherence to these standards will be the key enabler that allows companies to take advantage of supply chain big data, artificial intelligence and end-to-end visibility technologies that will bring benefits simply not possible today.

During the global deployment of Pharma serialisation/traceability over the last 15 years, much time and effort has been put into the development of the EPCIS standards to enable the frictionless flow of supply chain visibility information, but what exactly does it mean to be 'compliant' with EPCIS?

Does it mean ensuring the EPCIS messages you generate and receive conform to the EPCIS Schema and Core Business Vocabulary and conform to published guidelines from GS1 Member organisations?

Or does it mean that systems just work for getting data from point A to point B and hopefully loosely follow EPCIS?

And how do we measure and monitor this compliance?

Within your own organisation, are your system suppliers claiming their compliance is sufficient? Are the various EPCIS compliance/testing services adequate?

And what importance is the industry placing on being 'compliant' in any form?

In response to a global manufacturer wanting to evaluate their overall EPCIS compliance, Be4ward, supported by tools from their partner Jenneson, developed a four-level methodology focusing on:

- Technical adherence to the EPCIS standards
- Measuring risk associated with the proper/improper use of EPCIS for market regulatory compliance
- Best practice EPCIS design to enable future value opportunities from serialisation/traceability data

Our in depth compliance review allows you to take control of your own EPCIS compliance.

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