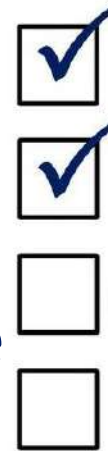


LABELING AND ARTWORK WEBINAR

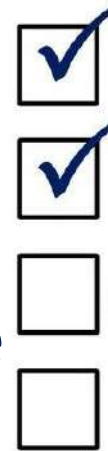
Do It Right The First Time:
Reduce Compliance Risk and Streamline
your Labeling and Artwork Processes
into World-Class Capabilities



Presentation starting @ 10am PDT

LABELING AND ARTWORK WEBINAR

Do It Right The First Time:
Reduce Compliance Risk and Streamline
your Labeling and Artwork Processes
into World-Class Capabilities



Presentation starting in 2 minutes

LABELING AND ARTWORK WEBINAR

Do It Right The First Time: Reduce Compliance Risk and Streamline your Labeling and Artwork Processes into World-Class Capabilities



Speakers



Dave Malenfant

Executive VP Industry Liaison and
Talent Development

BSMA

Davem@biosupplyalliance.com



Andrew Love

VP Capability Development

Be4ward

Andrew.love@be4ward.com



Do It Right The First Time:

Reduce Compliance Risk and Streamline your Labeling and Artwork Processes into World-Class Capabilities

ANDREW LOVE

Be4ward Ltd

April 2018



Profile: Andrew Love

Andrew is VP Capability Development for Be4ward. He is currently leading a number of engagements with life-sciences clients including a global pack change and artwork capability transformation , rationalising the artwork supply base and implementing a global IT system

Between 2007 and 2009 Andrew headed GlaxoSmithkline's (GSK) pharmaceutical Global Packaging Strategy. This project defined GSK's global supply chain strategies for each product dose form, achieving best practice KPIs for customer service, compliance and product launch, whilst standardising packaging equipment (50% reduction), components (75% reduction) and SKUs (40% reduction)

Prior to this Andrew spent six years as GSK's functional head for pharmaceutical packaging with global responsibility for structural design, artwork and creative services, packaging legislation, complexity reduction, technical capability development, and packaging supplier base development across a portfolio of 25,000 SKUs and 150,000 packaging components. In this role, Andrew led:

- the Global Pack Management Project, a £25m business re-engineering of GSK's product change management capability. This implemented Product Lifecycle Management software to 4000 users in 160 markets to ensure timely and accurate product changes to meet product launches whilst maintaining product safety information. This reduced information/artwork related recalls by 80% and rationalised artwork supply from 250 studios to four global artwork service centres, one based off-shore in India
- The establishment of GSK's global packing design capability to drive product standardisation, legislative compliance, effective packaging support to product launch and the company's capabilities to manage SKU portfolios
- The definition of GSK's strategy for serialisation, authentication, anti-counterfeiting and product coding.

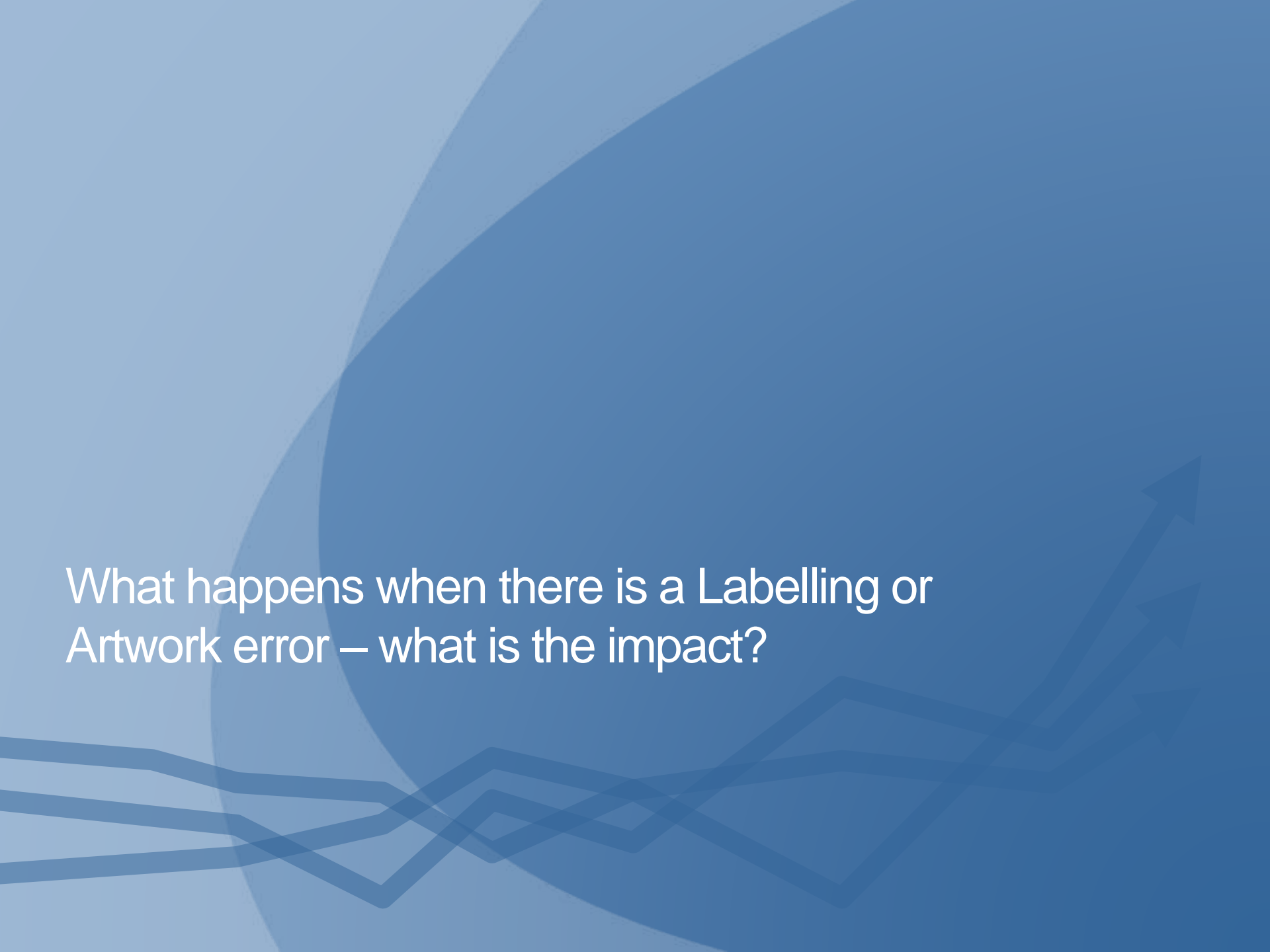
Prior to the above, Andrew spent nine years with GSK in various supply chain and operational roles with experiences in merger integration, supply chain process and systems implementation, product acquisition and divestment, lean and six sigma deployment, and operational management.

Andrew has a Masters Degree in Engineering and an MBA. He is a Chartered Engineer and Member of the Institute of Mechanical Engineers.

Be4ward is a niche management consultancy with award winning success in delivering serialisation and packaging management change

- Be4ward provides specialist consulting services to the global pharmaceutical, biotech and medical devices industry
- Our team combines operational management experience, subject matter expertise and excellent consulting skills to help our clients deliver successful change
- Whilst we have in depth knowledge of the supply base in our areas of focus, we provide independent advice to our clients
- Our current areas of focus include:
 - **Packaging and artwork management**
 - Product coding, serialisation and anti-counterfeiting
 - Product complexity management, late customisation and postponement
 - Secondary packaging supply chain design
 - Post merger legal entity and brand integration

Our team have won many awards for their work, including the establishment of a world class global artwork capability for a Top 3 Pharma Co.

The background is a solid blue color with several overlapping, semi-transparent circles of varying shades. In the lower half, there are several thick, dark blue lines that resemble a line graph or data series, with some lines ending in arrowheads pointing upwards and to the right.

What happens when there is a Labelling or
Artwork error – what is the impact?

Accurate artwork design is an essential process in the supply of healthcare products

WHY IS ARTWORK IMPORTANT?

- Companies can only sell products if they are properly packaged
- Companies can only ship products when the text on the packaging is correct
- Patients' lives rely on this text being absolutely correct
- Corporate reputation and profit are directly impacted when the text is incorrect

THIS IS WHAT WAS INTENDED...



A minor error in transmission...

...can have catastrophic results



...THIS IS WHAT WAS PRINTED

HOW PHARMA COMPANIES SEE ARTWORK

- Critical enabling process supporting product launch and patient safety
- Same level of GxP attention as the efficacy of an active, packing line clearance and change control
- Not a strategic competitive advantage

...and still one of the highest causes of recall in the industry.

There are clear benefits to providing error-free artwork

Increased patient safety

Improved regulatory compliance

Increased sales

Increased profit margins

Improved reputation

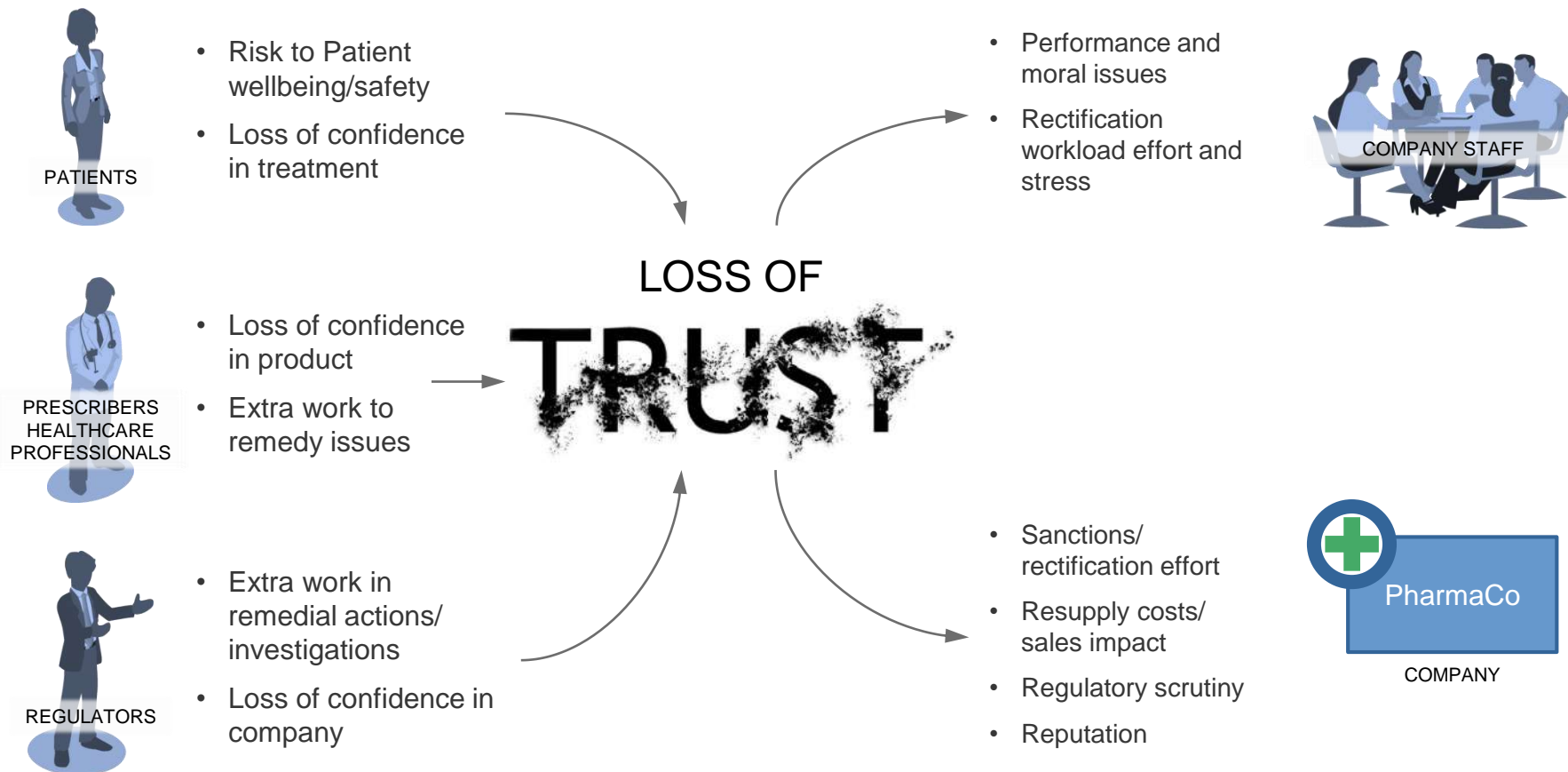
Reduced cost and valuable resource absorption

As portfolios and subsequent numbers of changes increase, typically so does the number of artwork errors they witness

TYPES OF ERROR

Gross errors	Significant information is omitted e.g. completely missing the need to change a piece of artwork for a new regulatory requirement
Context or meaning errors	Information is presented in an ambiguous or incorrect way on artwork e.g. inappropriate use of hyphenation causing incorrect meaning
Content errors	Errors or omissions in detailed content of artwork e.g. incorrect symbol being used
Technical errors	Errors and omissions in technical aspects e.g. wrong specification of barcode

The implications of an error are far reaching and serious



As artwork explains how the product is used, errors can be as serious as any other error with the supplied product.

A well-designed and effective artwork process should ensure artwork errors are controlled and rectified

HOWEVER, WHEN THE PROCESS FAILS,
THE SOURCE OF DETECTION WILL BE EXTERNAL

By chance	Seeing a discrepancy that wasn't noticed
Through diligence	Medical professionals checking product before use
Through use	Identifying an issue when trying to use the product
Through incorrect use	By witnessing an adverse reaction from using either the wrong product or in the wrong way

Actions that need to be taken when an error is discovered

AN EXTERNALLY
IDENTIFIED ERROR WILL
NORMALLY RESULT IN...

- A customer complaint
- A report of an adverse regulatory action
- A complaint to the local regulator



Immediate correction actions required
(Often in parallel)

- Assess severity of risk
- Investigate recall procedures
- Inform external regulator/s
- Quarantine product in supply chain
- Prepare revised artwork/obtain replacement components
- Rectify/repack or destroy recalled product
- Provide replenishment stock

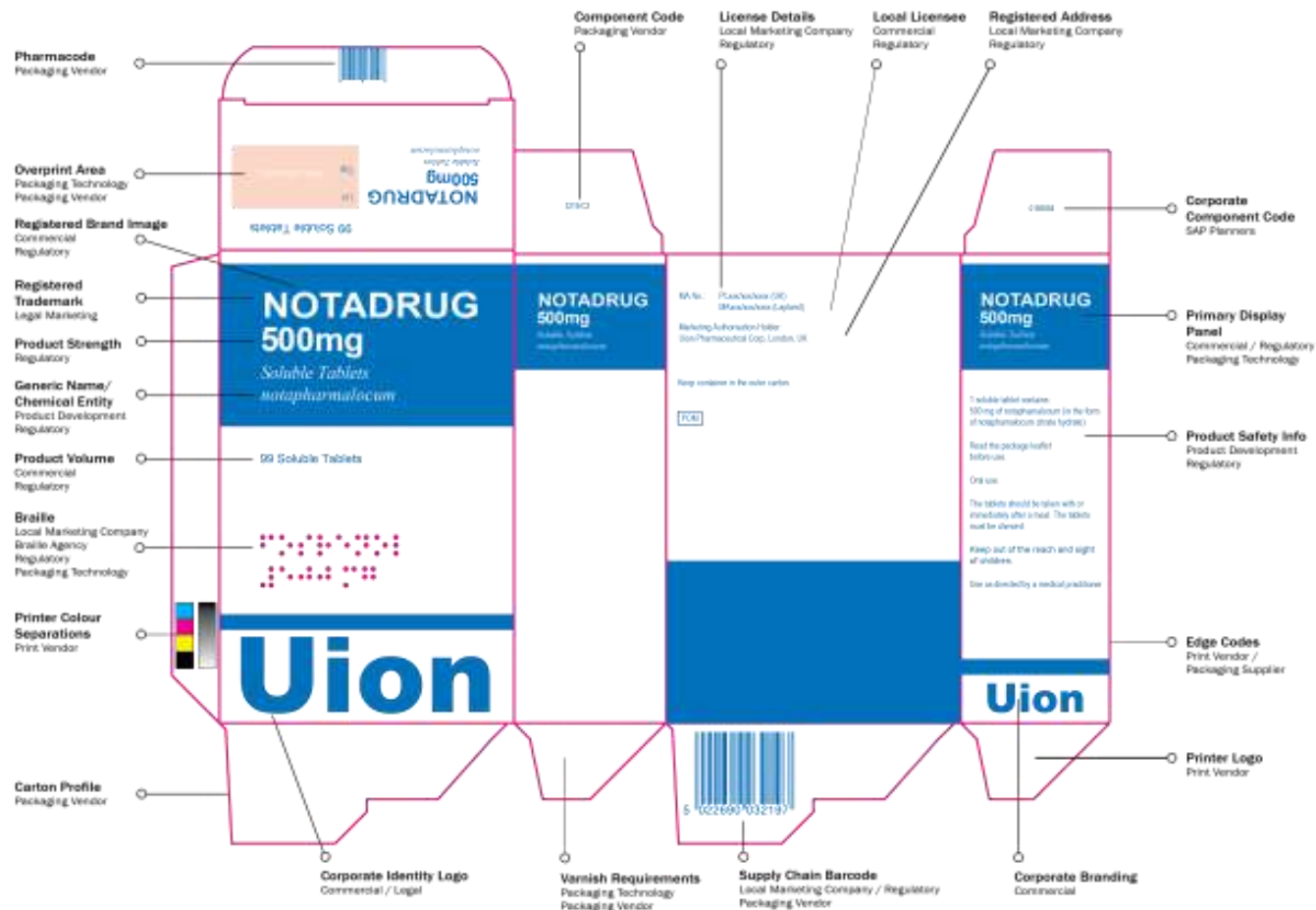


Preventative actions

- Identify root causes of incident
- Design and implement necessary improvements
 - Process
 - Training
 - Tools
- Track completion of improvements across whole organisation
- Address any further regulatory requirements
- Rebuild moral

Artwork design involves coordinating information from many different sources...

- Text
- Data
- Graphics
- Technical Requirements



...which indicates there are many opportunities for error.

An artwork error can arise for a number of different reasons

PROCESS GAPS/INCONSISTENCIES

e.g. incomplete processes, lack of required process steps

LACK OF COMPETENCE

e.g. insufficient skills, knowledge or experience to undertake required tasks

INAPPROPRIATE DECISION MAKING

e.g. choosing to miss critical steps to expedite a priority projects

AMBIGUITY

e.g. unclear instruction that can be interpreted in many ways

ERRORS IN SOURCE INFORMATION

e.g. text and content incorrect when supplied

HUMAN ERROR

e.g. our natural ability to see things how we want to see them/filter out wrong information

TECHNOLOGY ERRORS

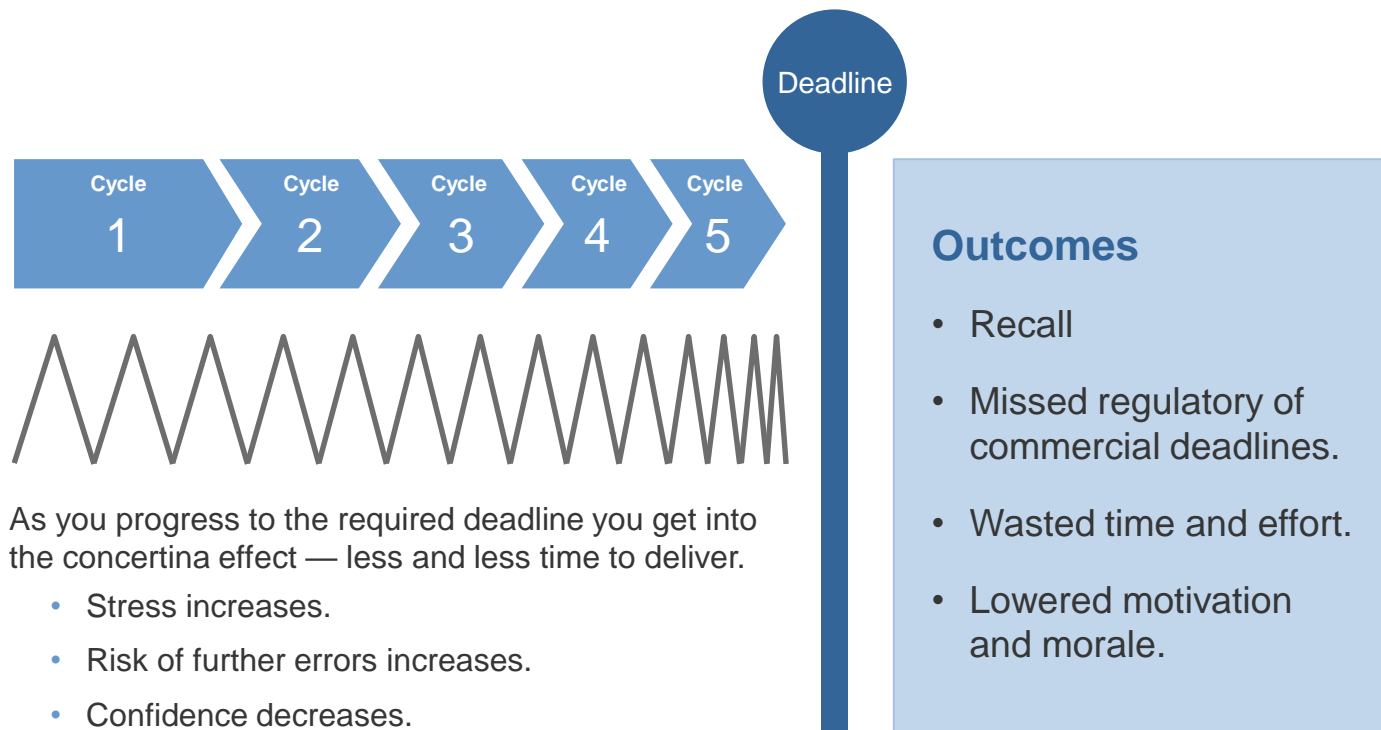
e.g. software operating incorrectly not providing a true image, font transcription errors

The three top ones are typically an artwork operator error, an error in the source material or someone changing their mind at approval

The background is a solid blue color with several overlapping, semi-transparent circles of varying shades of blue. In the lower-left and bottom-center areas, there are several thick, dark blue lines that resemble a line graph or data series, with some lines ending in arrowheads pointing towards the upper right.

Steps to take to improve Labelling and Artwork accuracy

Right-first-time artwork is a critical outcome, impacting achievement of your company's goals



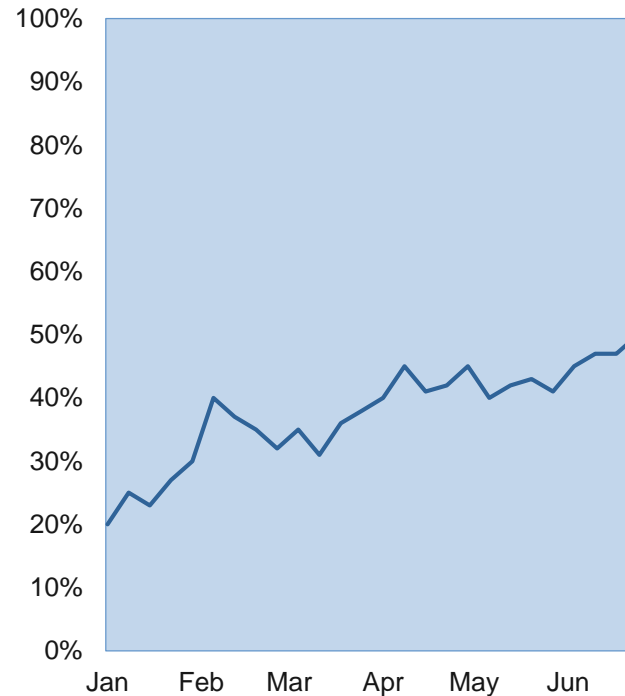
This impact is the same when producing any of the source materials

Measure your right-first-time — if you don't measure, you don't manage

TIP **1**

At what points in the artwork process do you measure:

- Artwork creation?
- Proof reading?
- Artwork approval?
- Receipt of components?



What scope of changes do you measure?

- Non-product introductions?
- Safety changes?
- Technical changes?
- Text/routine updates?

But you also need to measure the RFT of your inputs

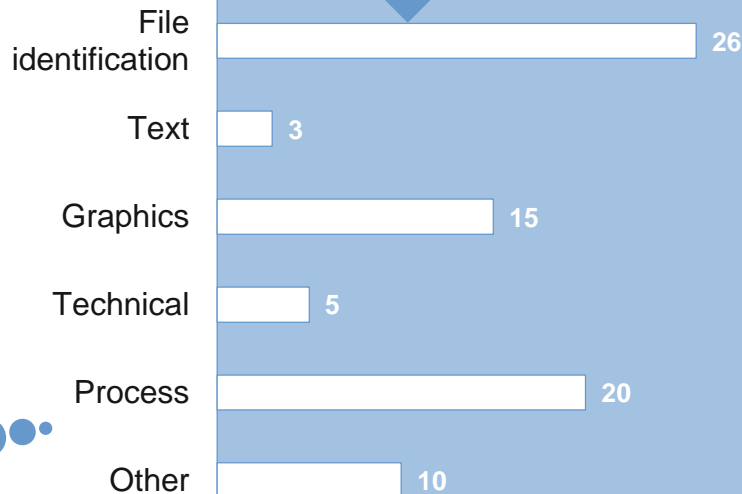
Use codes to categorise errors, then ensure a thorough root cause analysis to eliminate source of errors

'How can I be expected to get it right when no-one else does?'

TIP 2

Types of error codes

- File identification
- Text
- Graphics
- Technical
- Process
- Other



Include source materials as types of error codes

This gives you the highest sources of error

Target major error types and thoroughly root cause.

- | | |
|--------|---|
| Step 1 | Define the problem |
| Step 2 | Collect data |
| Step 3 | 5 Whys |
| Step 4 | Identify root causes. |
| Step 5 | Recommend and implement solutions. |
| Step 6 | Keep measuring to ensure solution is sustained. |

Companies with high RFT are obsessive about eliminating source of errors particularly in source materials — this is where they channel their energy.

Make sure all of the input information is correct before starting

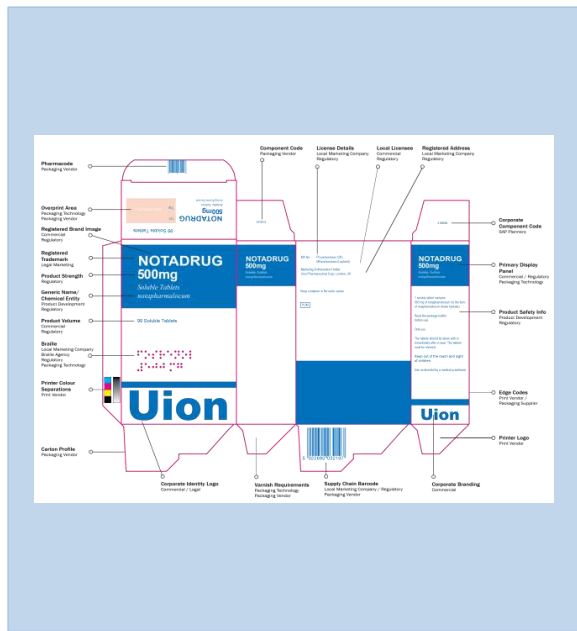
TIP 3

A formal sign-off that source material is correct

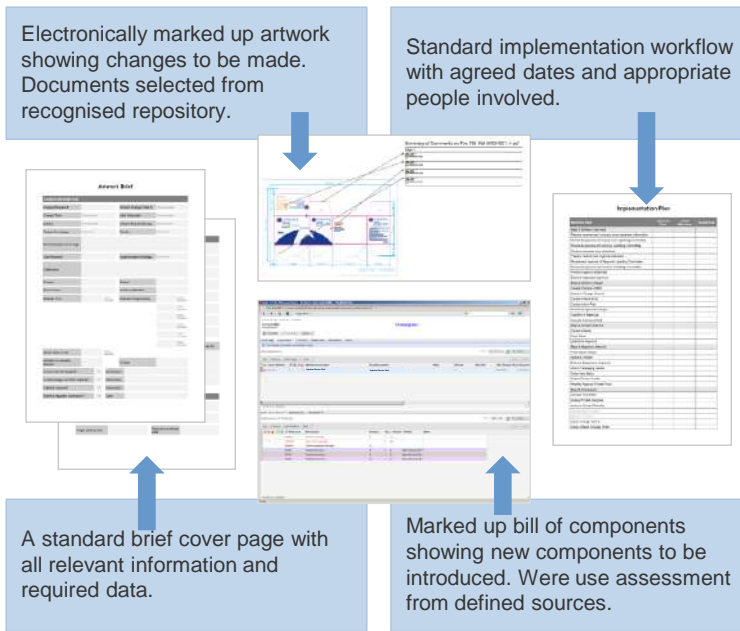
The information required for an artwork comes from many sources — existing and new.

This needs to be collated into a requirements document — The Brief.

This needs to be approved by the relevant stakeholders.



Garbage in = Garbage out.



A standard brief cover page with all relevant information and required data.

Marked up bill of components showing new components to be introduced. Were use assessment from defined sources.

A full and comprehensive definition of the change required.



- Collaborative Review**
- Mandatory**
- Artwork
 - Regulatory
 - QA
 - Planning
 - Packaging Vendor
- Optional**
- Commercial
 - Co-licensee
 - Distributor/Local Agent
 - Print Supplier
 - Legal

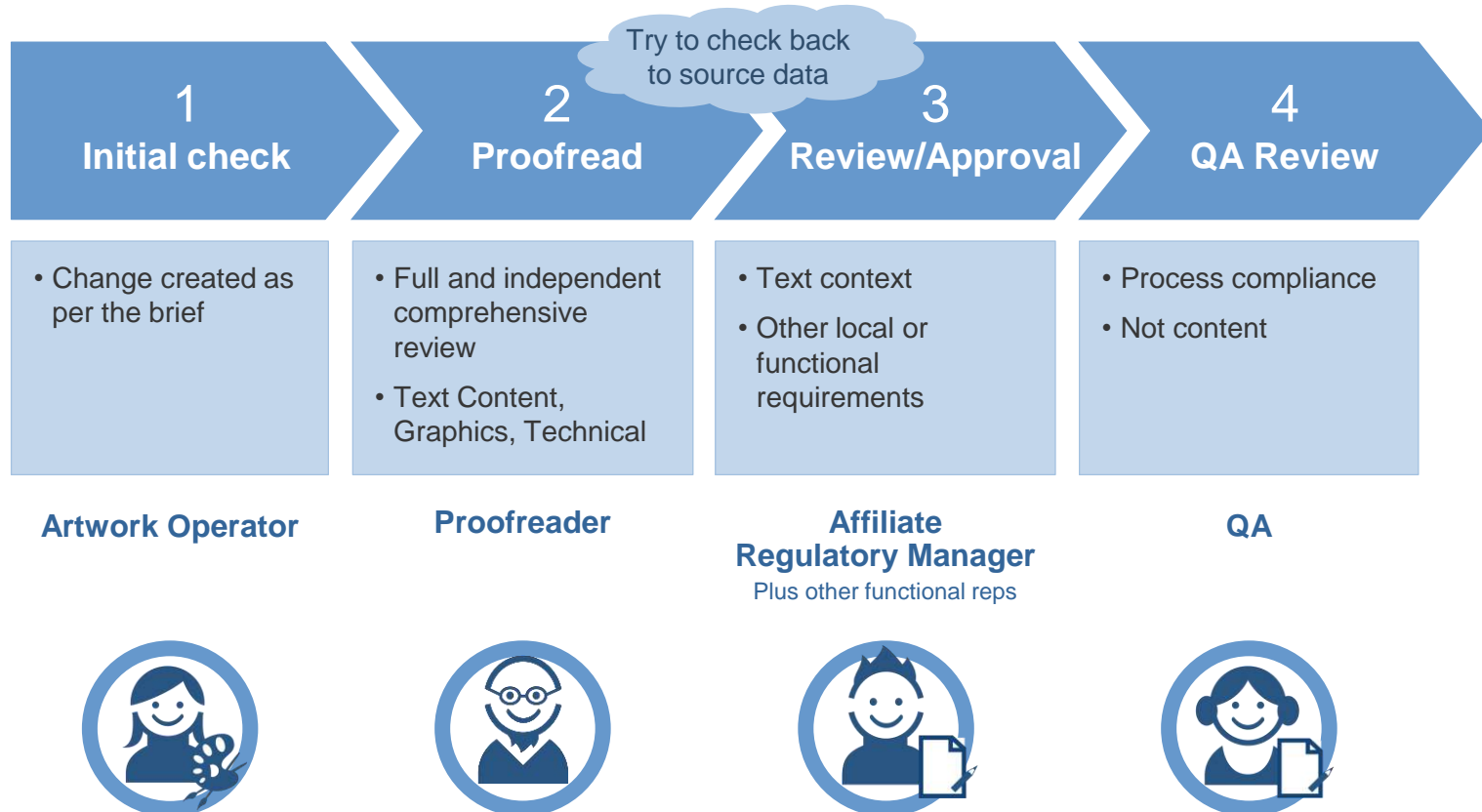
To verify supplied data and endorse the change.

It is tempting to start an artwork before all information is available and approved but that will just result in rework loops — losing time and wasting effort.

Make sure the right quality of checks are undertaken by the right people – this applies to artwork and source materials

TIP **5**

There is typically a four step process to assure the quality of the master artwork file and source data inputs



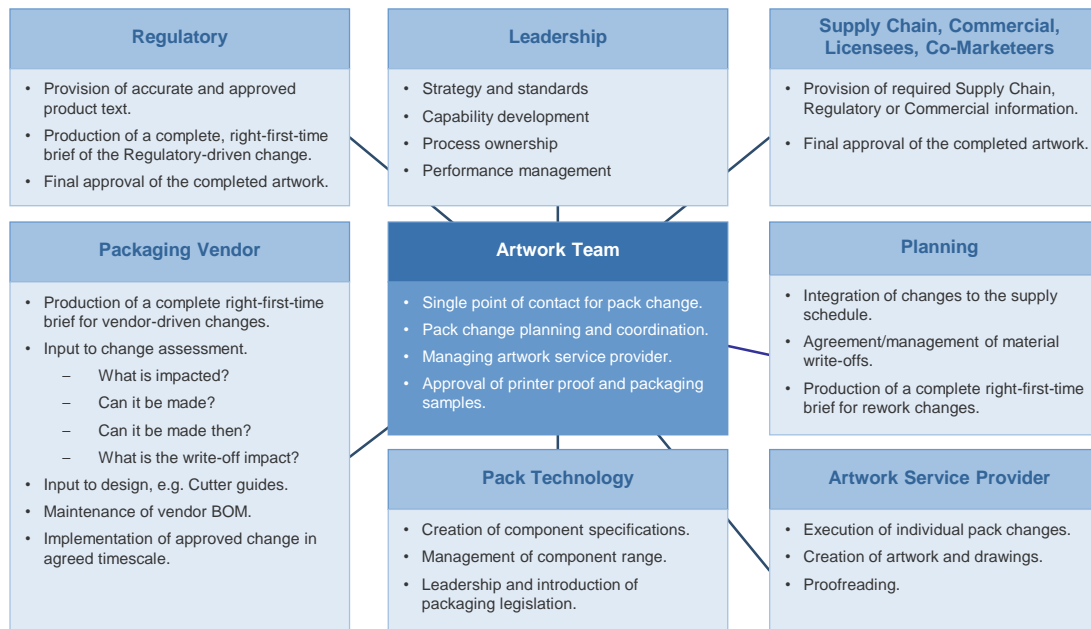
Understand who checks each element and how — back up with detailed checklists.

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

TIP **6**

Different functions have different views on process rigour

Many people are involved in the artwork process but do it only as a small part of their role.



Consider what E&T interventions are required.

- Initial training when implementing new/revised processes.
- New starter training
- Specialist skill training, e.g. proofreading.
- Face-to-face.
- Web based.
- Online and offline.
- Assessment of competency.
- Ongoing monitoring.

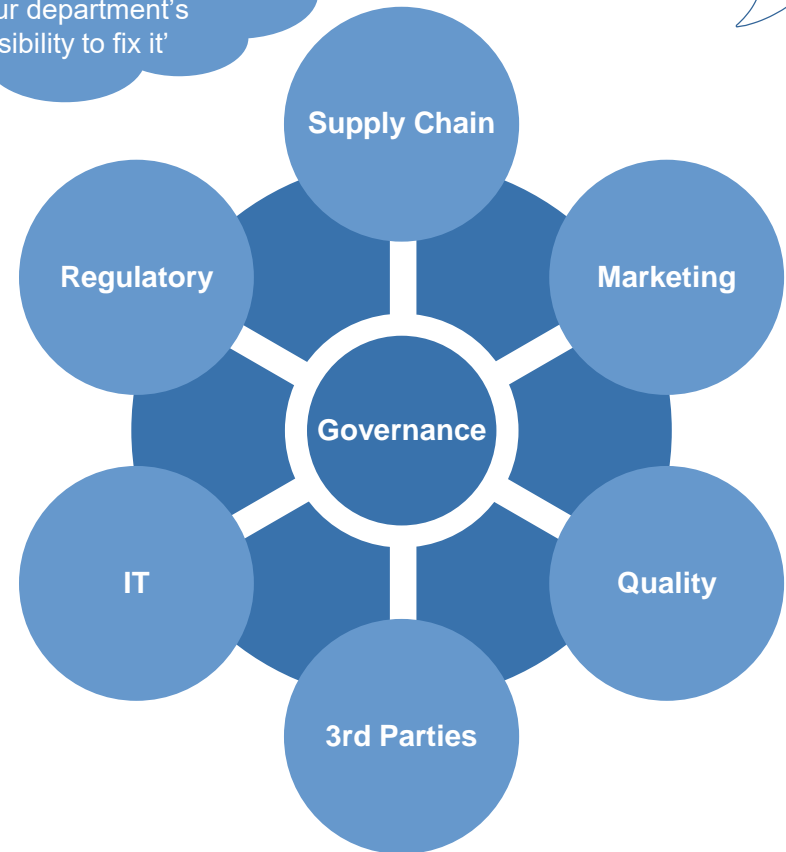
You are expecting people to do quality critical tasks right-first-time — you need to give them the skills and capabilities to be able to and you need to monitor they remain effective.

Ensure there is effective cross-functional governance

TIP 7

'It is not my department's responsibility to get it right – it is your department's responsibility to fix it'

- The artwork process and the input processes impact many parts of the organisation.
- Each part has a contribution to make in achieving right-first time of artwork and inputs.
- Leadership needs to take accountability for the performance of their function.
- Leadership needs to sponsor the improvements required in their function.
- The governance team must review performance and drive appropriate action
- The governance team needs to define targets and agree priorities.



All impacted parts of the organisation(s) need to be appropriately represented in the governance forum — change has to be driven down through each function.

There needs to be an appropriate suite of IT tools to support the processes and people working with them

TIP **8**

Functionality

Document Management



Translation Management



Submission Management



Forecasting



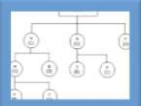
Planning and Workflow



Change Control, Authorisation and eSig



Bill of Material/
Pack Catalogue



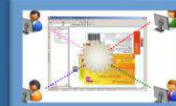
Artwork and Drawing Desktop



Proof Reading



Collaborative Review and Approval



cPDF/Print Ready Artwork



Performance Management



Capabilities

Disaster Recovery

User Permissions Management

Information Security

Error-free WYSIWYG and Printing

Resource Management

Defined Artwork Related Data Sources

Informing and Alerting

Global Multi-Organisation Information Access

Provide visibility, information, document control and minimize the risk of human error. Pay particular attention to where information is manually transmitted between system boundaries – high risk area

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

TIP 9

We expect people to do quality critical tasks right-first-time

We need to give them sufficient quality time...



- Clear plans and agreed step leadtimes.
- Visibility of deadlines and pipeline of work.
- Allow parties to plan their time.

...and appropriate facilities to operate in.



- Space and equipment, e.g. two screens.
- Lighting, temperature, ergonomic factors.
- Clear desk mentality

“I need the source text now – where is it?”

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

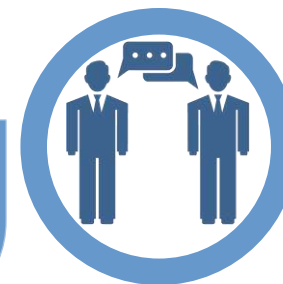
TIP **10**



Accountability

Commitment and Values

Knowledge



Team Working

Customer Focus

Continuous Improvement

'We want rigour, but not rigor mortis!'



Decision Making

Working under Pressure

Recognition



Having the right culture will lead to the right behaviors
— leaders need to model and reinforce.

In summary

- Packaging and artwork still present a significant compliance risk.
- Delivering right-first-time artwork is a complex endeavour involving many moving parts.
- If the input is wrong, the artwork will be wrong
- Achieving high right-first-time across inputs is achievable, but requires focus and persistence.
- There are many parts to achieving high right-first-time across each process.
- Being right-first-time increases speed, reduces waste and raises confidence.

Right-first-time is a mindset not an outcome.

Thank you for your attention

Questions?

We will answer any questions you have.

THANK YOU



Contact details

Andrew.love@be4ward.com

48 Warwick Street, London, W1B 5AW, UK

London, UK: 0800 098 8795, 0203 318 0939

Montreal, Canada: 888 308 8657

www.andrewrlove.com