

Tips to streamline your artwork process and improve right-first-time

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2009 to current: Vice President Capability Development, Be4ward Ltd, assisting a number of Pharmaceutical clients with packaging management related engagements.

2007 to 2009: headed GlaxoSmithkline's pharmaceutical Global Packaging Strategy.

- Defining GSK's global supply chain strategies for each product dose form, standardising packaging equipment, components and SKUs.

2001 to 2007: global head of pharmaceutical packaging for GlaxoSmithkline, responsible for:

- Structural design, artwork and creative services, packaging legislation, complexity reduction, technical capability development and packaging supplier base development.
- Across portfolio of 25,000 SKUs and 150,000 packaging components.
- Led Global Pack Management Project, a £25m re-engineering of GSK's product change management capability.
 - Implemented Product Lifecycle Management software to 4000 users in 160 markets.
 - Ensuring timely & accurate product changes to meet product launches whilst maintaining product safety information.
 - Reduced information/artwork related recalls by 80%.
 - Rationalised artwork supply from 250 studios to 4 global artwork service centres, one based off-shore in India.
- Established 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.
- Led definition of GSK's strategy for serialisation, authentication, anti-counterfeiting and product coding.

Prior: GSK and specialty chemical industry in various supply chain and operational roles.

- Experiences in merger integration, supply chain process and systems implementation, product acquisition and divestment, lean and six sigma deployment, and operational management.

Masters Degree in Engineering, MBA and Chartered Engineer.

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Accurate artwork design is an essential process in the supply of pharmaceutical product...

Why is artwork important?

- We can only sell our products if they are properly packaged.
- We can only ship our products when the text on the packaging is correct.
- Our patients' lives rely on this text being absolutely correct.
- Our corporate reputation and profit are directly impacted when the text is incorrect.



A minor error in transmission can have catastrophic results.

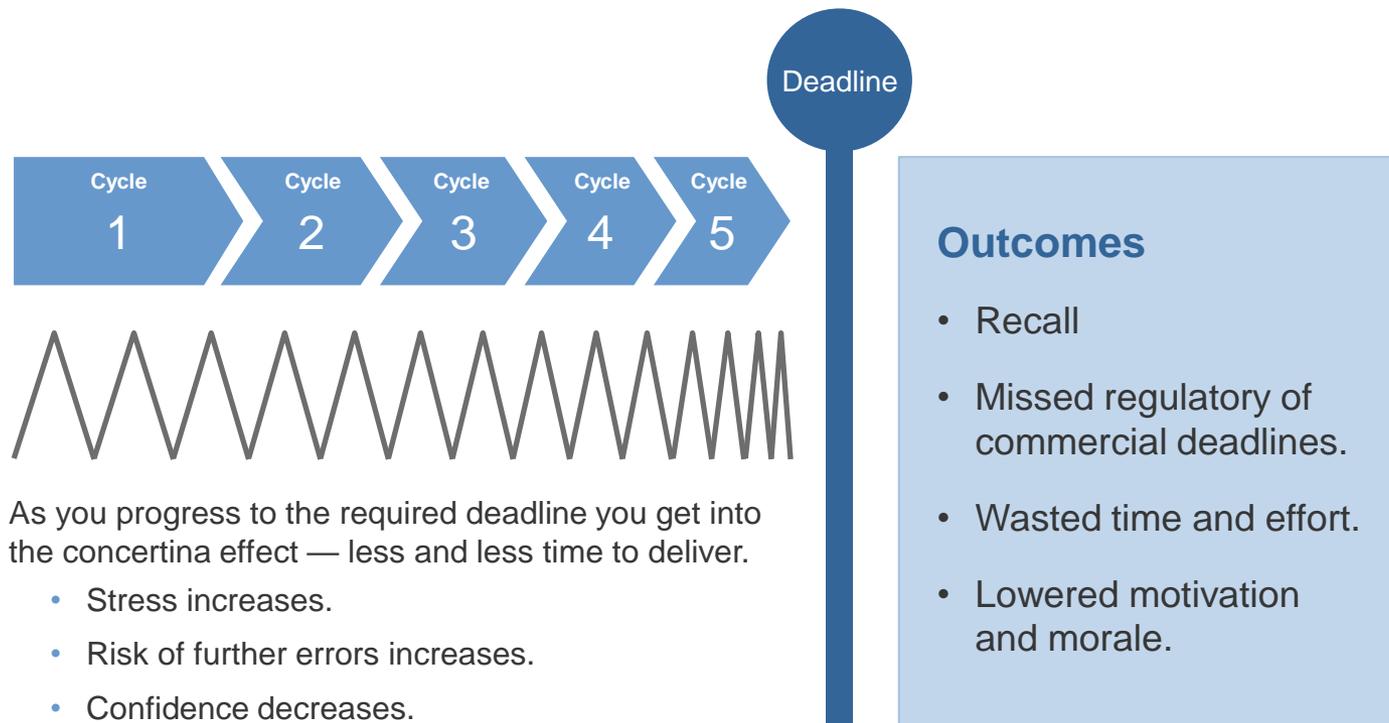


How PharmaCos see artwork

- 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.

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



High right-first-time improves speed and ensures repeatability.

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

TIP **1**

At what points in the 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?

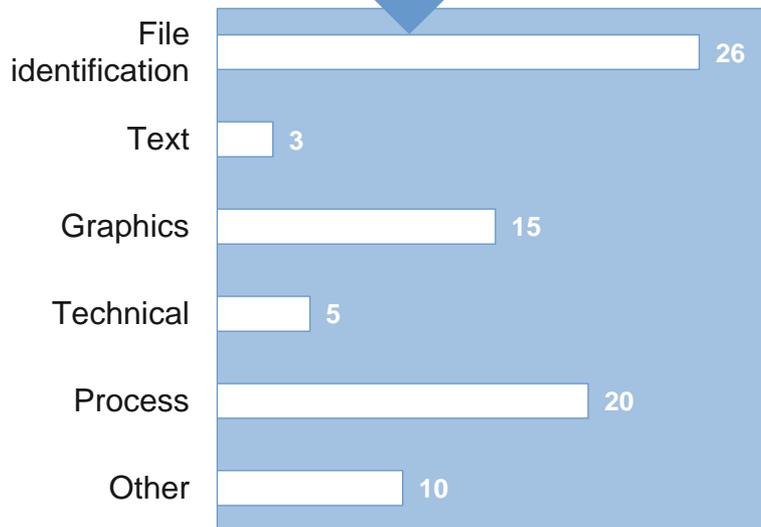
Right-first-time of >95% should be your goal.

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

TIP 2

Types of error codes

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



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 — this is where they channel their energy.

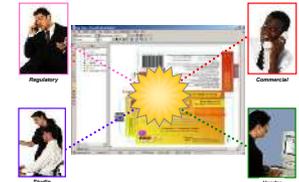
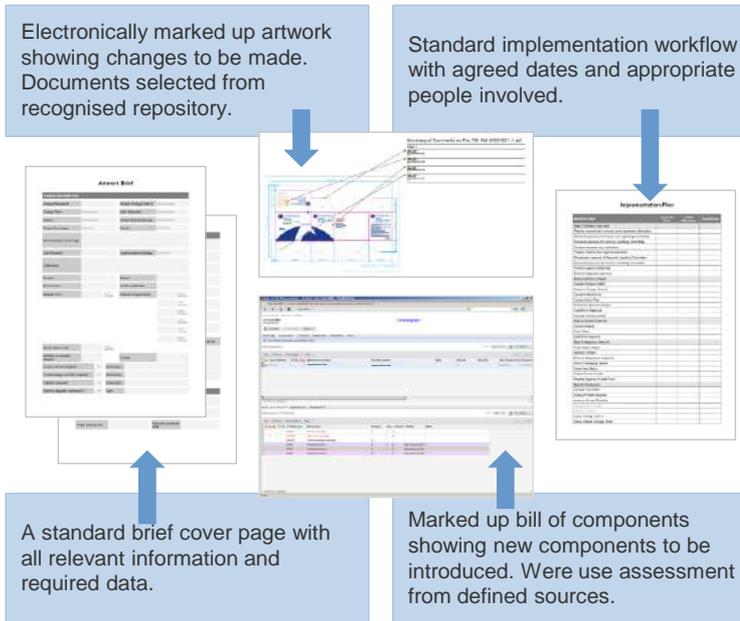
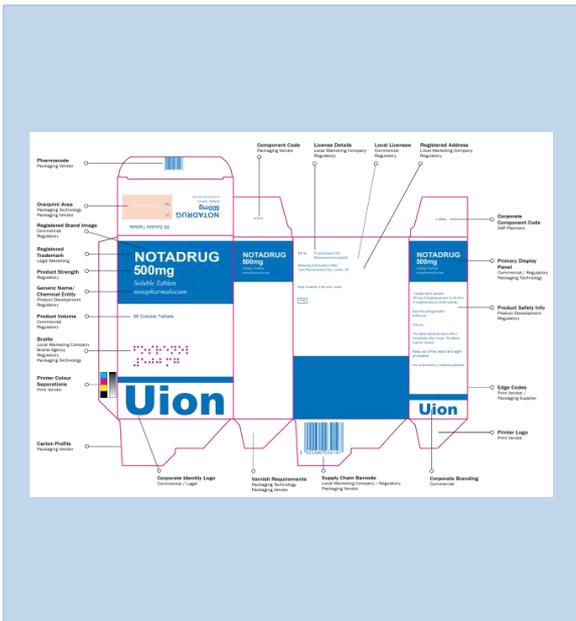
Make sure all of the input information is correct before starting



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.



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

Garbage in = Garbage out.

A full and comprehensive definition of the change required.

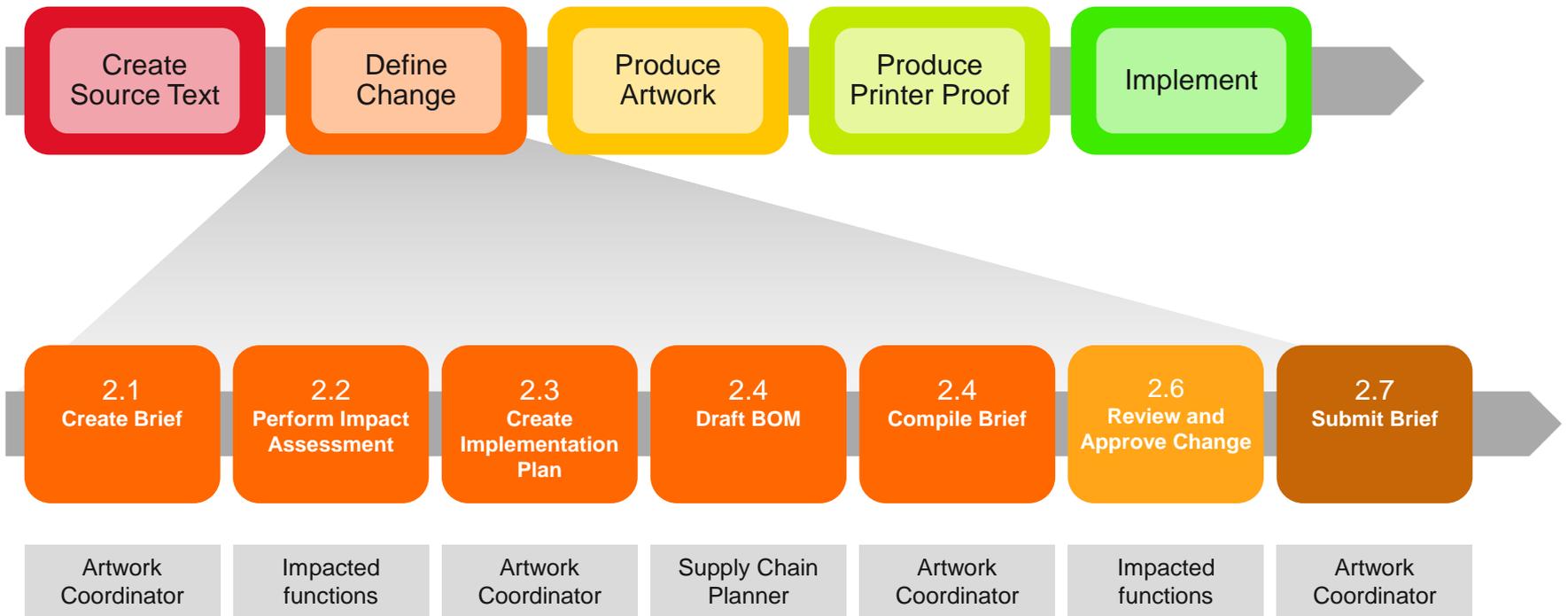
To verify supplied data and endorse the change.

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

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

TIP 4

EXAMPLE PROCESS



Make sure the end-to-end process “joins up” — it is clear who should do each step and the performance expectations for each step is defined and agreed.

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

TIP **5**

There is typically a four step process to assure the quality of the master artwork file

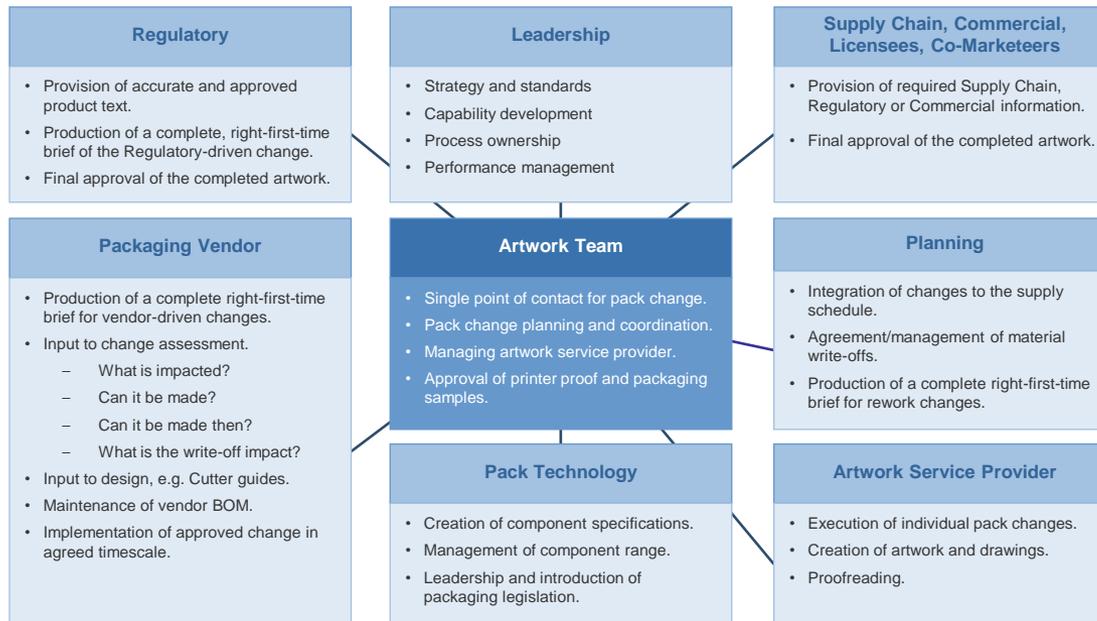


Understand who checks each element and how — back up with detailed checklists.

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

TIP **6**

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



Consider what E&T interventions are required.

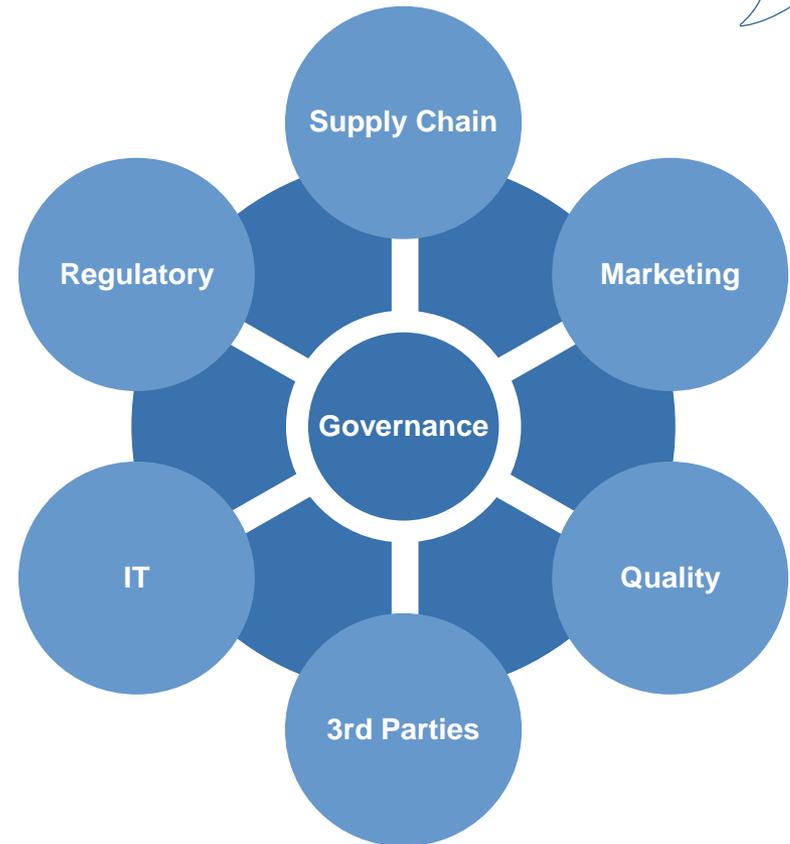
- Initial training when implementing new/revised processes.
- New starter training
- Specialist skill training, e.g. proofreading.
- Face-to-face.
- Web based.
- Online and offline.
- Assessment of competency.
- Ongoing monitoring.

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

- The artwork process impacts many parts of the organisation.
- Each part has a contribution to make in achieving right-first time.
- Leadership needs to take accountability for the performance of their function.
- Leadership needs to sponsor the improvements required in their function.
- 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 and scalable suite of IT tools to support the process and people working with it

TIP **8**

Functionality

Document Management



Translation Management



Submission Management



Forecasting



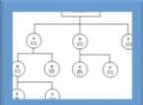
Planning and Workflow



Change Control, Authorisation and eSig



Bill of Material/
Pack Catalogue



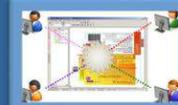
Artwork and Drawing Desktop



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

Providing visibility, information, document control and minimising the risk of human error — available across the extended organisation regardless of geography.

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.

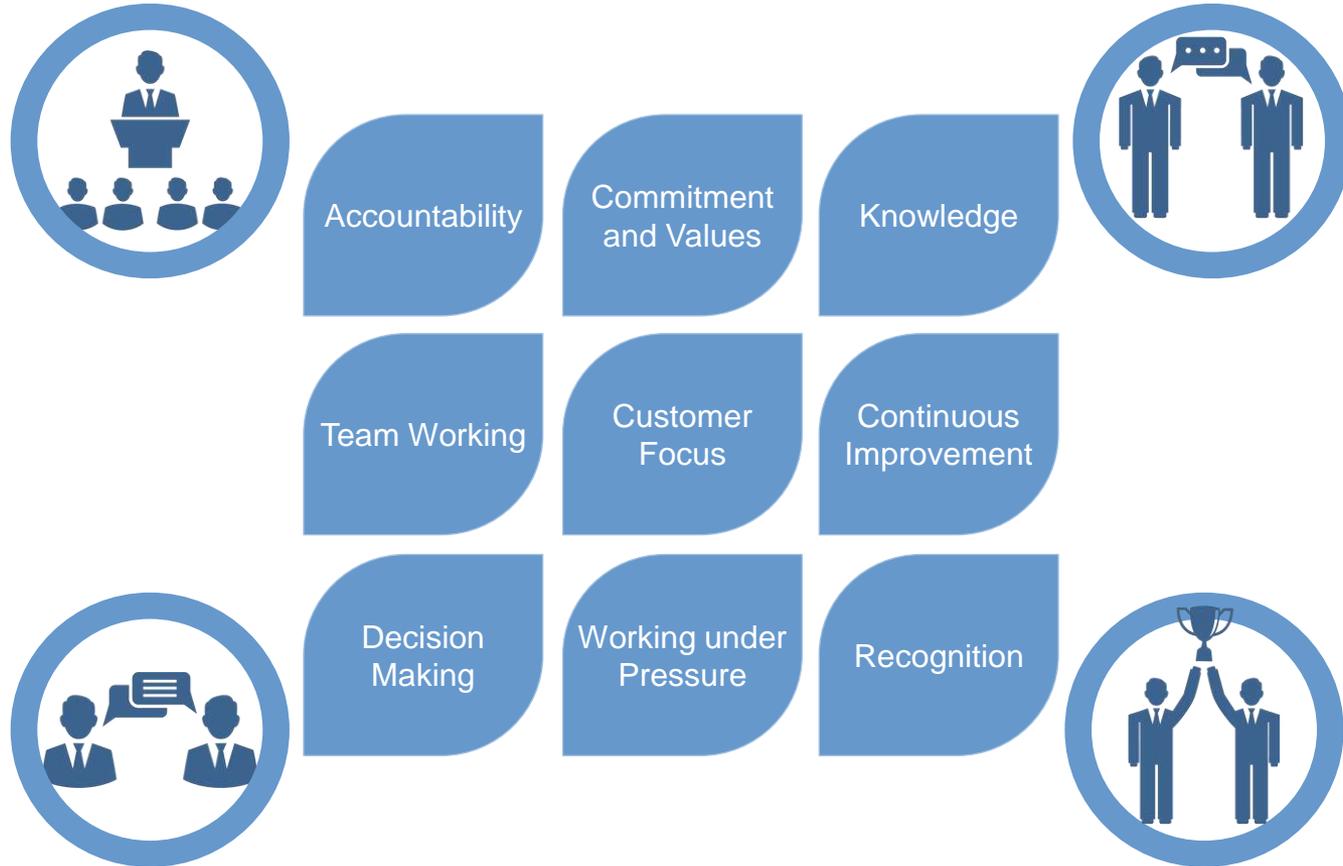


- Space and equipment, e.g. two screens.
- Lighting, temperature, ergonomic factors.
- Clear desk mentality

“I send you an artwork 15 minutes ago — have you approved it yet?”

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

TIP **10**



Having the right culture will lead to the right behaviours
— 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.
- Achieving high right-first-time is achievable, but requires focus and persistence.
- There are many parts to achieving high right-first-time.
- Being right-first-time increases speed, reduces waste and raises confidence.

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

THANK YOU



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Be4ward is a niche management consultancy with award winning success in delivering pack change and artwork capability

Be4ward provides specialist consulting services to the global pharmaceutical 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.

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