Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities

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24 April 2013



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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

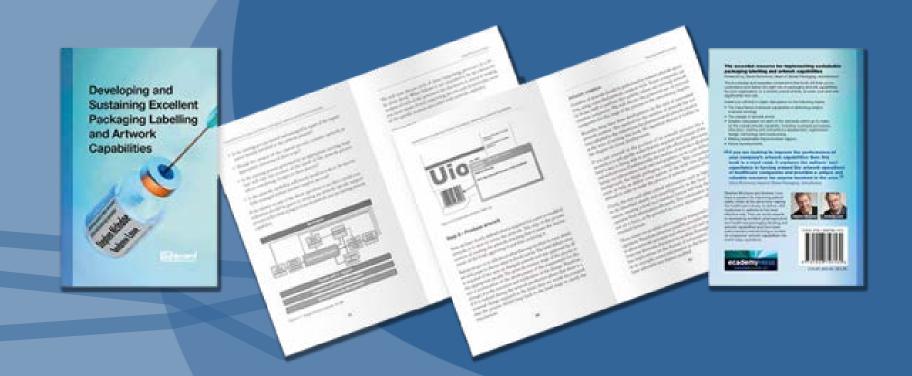
• Experiences in merger integration, supply chain process and systems implementation, product acquisition and divestment, lean and six sigma deployment, and operational management.

Masters Degree in Engineering, MBA and Chartered Engineer

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Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities

- Ensuring patient safety
- Reducing recall risk



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

This is what was printed

A minor error in transmission can have catastrophic results.



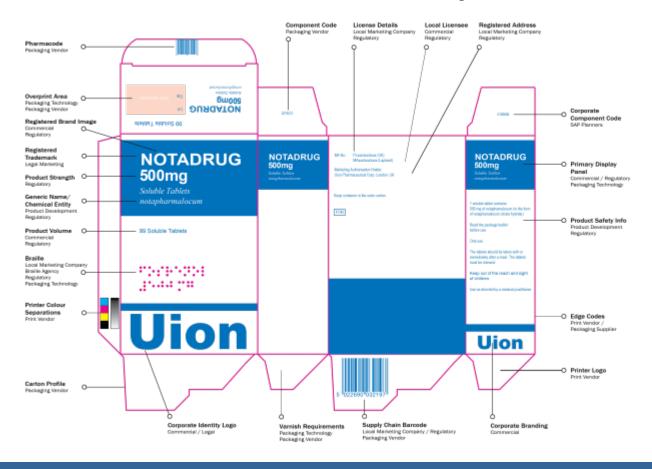
How PharmaCo's see artwork

- 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

Artwork design involves coordinating information from many different sources

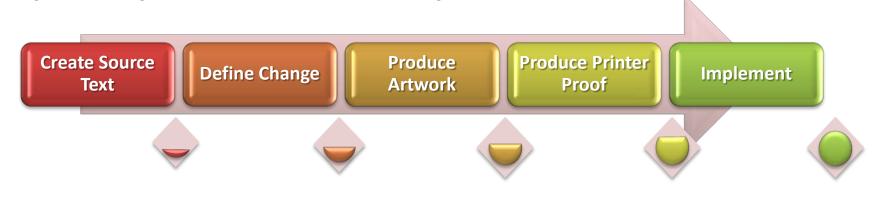
Typical sources of artwork information for a product carton picture



There are many opportunities for error.

Clearly defining the process control points is critical to ensuring error free artworks

Example model process with defined control points:



Make sure the text is right (garbage in = garbage out) Make sure the brief is right (garbage in = garbage out) Proof-read to make sure the artwork produced is correct

Proof-read to make sure the file to be printed is correct Verification to make sure the final packaging material is correct

Ensuring accuracy at each control point assures right first time artwork

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In order to be successful, a number of elements need to be in place to have an effective artwork change capability

Elements Required for a Successful Artwork Capability

End-to-End Process

Document Management

Work Management

Service Provider Selection & Management

Organisation & People Management

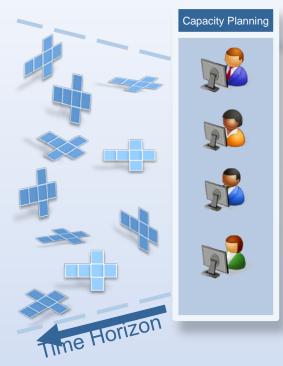
Governance, Leadership & Culture

LT.

Performance & Improvement Management

We will have a look at some of these areas in more detail.

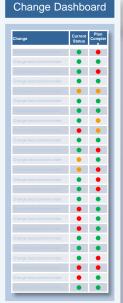
Work Management - processes and tools providing an integrated forecasting, planning and execution capability





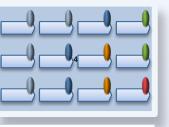
- Comprehensive method for identifying future changes across the entire portfolio
- Clear visibility for timelines/expectations
- · Capacity contingency & business continuity in place
- Planning algorithms to ensure sufficient capacity is planned
- Based on standard and achievable lead times





PLANNING

- Clear communication of timelines & expectations
- Alignment of committed dates, production schedule and stock management
- Standard change plan: forward or backward scheduling; known step lead times
- Supported by project & programme reports to allow management by exception
- Ability to group/manage program of changes
- Permits project mgmt and schedule adherence







EXECUTION

- Visibility to all of status and location of a change
- A Portal entry page that lets all see what they need to do and what is coming
- Work in progress monitoring to help flow / identify & resolve bottlenecks
- Lets people plan their own work
- Ensures effective delegation & escalation
- Ensuring visibility of priorities, issues and workload to all

People and Organisation - making sure all parties understand and effectively perform their role in the process

Example roles and responsibilities

Regulatory

- Provision of accurate and approved product text
- Production of a complete, rightfirst-time brief of the Regulatorydriven change
- Final approval of the completed artwork

Packaging Vendor

- Production of a complete rightfirst-time brief for vendor-driven changes
- Input to change assessment
 - What is impacted?
 - Can it be made?
 - Can it be made then?
 - What is the write-off impact?
- Input to design, e.g. Cutter guides
- Maintenance of vendor BOM
- Implementation of approved change in agreed timescale

Leadership - Global Logistics

- · Strategy and standards
- · Capability development
- · Process ownership
- Performance management

Artwork Team

- Single point of contact for pack change
- Pack change planning and coordination
- Managing artwork service provider
- Approval of printer proof and packaging samples

Pack Tech

- Creation of component specifications
- Management of component range
- Leadership & introduction of packaging legislation

Supply chain, Commercial, Licensees, Co-Marketeers

- Provision of required Supply Chain, Regulatory or Commercial information
- Final approval of the completed artwork

Planning

- Integration of changes to the supply schedule
- Agreement / management of material write-offs
- Production of a complete right-firsttime brief for rework changes

Artwork Service Provider

- Execution of individual pack changes
- Creation of artwork and drawings
- Proofreading

Typically, this involves coordinating the activity of people from a number of organisations.

IT - an appropriate and integrated suite of IT tools to facilitate and apply the process,

























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FUNCTIONALITY

Disaster Recovery User Permissions
Management

Information Security

Error-Free WYSIWYG & Printing

Resource Management Defined Artwork Related Data Sources

Informing & Alerting

Global Multi-Organisation Information Access

CAPABILITIES

Providing real-time information and a self-service approach for all impacted parties, regardless of geographic location

Companies typically make improvements to their artwork capabilities in a phased manner

Step 3 World Class

Step 2 Efficient & Effective

Step 1 In Control

- Compliant GxP process
- Formal approvals at key control points
- Meeting critical artwork change milestones
- Meeting performance requirements of business
- Optimal use of resources
- Processes tuned to ensure effective execution
- Appropriate use of best practices
- Benchmarked with external capability
- Agile adaptation to changing business models

Not everybody needs to be world class in all capabilities

Making it happen

In Summary

- Packaging and artwork presents a significant compliance risk
- Packaging artwork management capabilities are critical to delivering business strategy
- Delivering quality artwork is a complex endeavour involving many moving parts
- Excellence is achievable

How might you start

- Current situation assessment
 - Understand the current situation for each element of your capabilities
 - Base against a comprehensive assessment model
- Gap Analysis
 - Against 'fit for purpose' requirements
- Improvement recommendation development
 - What are the key improvements you want to make
 - What engagement do you need to make across your organisation

Example: Major PharmaCo - 80% reduction in artwork related recalls

Key learnings to consider

Kotter's Steps for Implementing Successful Change	Some thoughts on how this relates to artwork capability improvement
Create a sense of urgency	 Identify and communicate the compelling reasons for action. Develop To-Be design that directly resolves key issues and supports delivery of overall business strategy. Phase capability improvement activity - focus on delivering shorter term, critical improvements first.
Develop a guiding coalition	Identify a senior business sponsor.Establish cross-functional governance group to steer project and make key decisions.
Develop a vision for change	 Collaboratively develop To-Be vision, involving key impacted stakeholder groups.
Communicate the vision	 Develop materials and messages to explain To-Be vision that is understandable by all impacted parties. Use materials and messages to communicate in many ways to broader population.
Empower broad-based action	 Deliver overall change though a number of individual initiatives. Ensure projects involve appropriately cross functional teams. Engage broader group of stakeholders in key solution design activities.
Generate short term wins	 Phase improvements activity to deliver shorter term, critical improvements first. Deliver some "low hanging fruit" type benefits and publicise wins. Publicise key progress milestones.
Don't let up	 Ensure sponsor and steering team hold projects and organisation accountable to deliver to promise Address the inevitable issues that occur.
Make it stick in the organisation culture	 Ensure initiatives focus on developing and supporting culture and behaviours that help ensure sustainable solutions. Maintain cross functional governance after project(s) have finished with accountability to maintain and develop the capability and culture.

Be4ward



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
- Contact details:
 - PO Box 4151, Maidenhead, SL60 1DP
 - London, UK: 0800 098 8795, 0203 318 0395, fax 0203 318 0396
 - Montreal, Canada: 888 308 8657

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.