

Successfully Managing Your Clinical and Commercial Artwork in a Complimentary Process

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BSMA Online Webinar

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2009 to current

Vice President Capability Development, Be4ward Ltd: Assisting pharmaceutical clients with packaging management related engagements

2007 to 2009

Headed the GlaxoSmithkline Pharmaceutical Global Packaging Strategy: Defining global supply chain strategies, standardising packaging equipment, components and SKUs



2001 to 2007

Global Head of Pharmaceutical Packaging at GlaxoSmithkline: Responsible for Structural Design, Artwork & Creative Services, Packaging Legislation, Complexity Reduction, Technical Capability Development, Packaging Supplier Base Development

Prior to 2001

Various supply chain and operation roles within GlaxoSmithkline and specialty chemical industry:
Merger Integration, Supply Chain Process & Systems Implementation, Product Acquisition & Divestment, Lean & Six Sigma Deployment & Operational Management

Qualifications

Masters Degree in Engineering, MBA and Chartered Engineer

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First, some definitions:

CLINICAL TRIALS ARTWORK

Artwork prepared for printing on packaging components that are used in support of clinical trials.

COMMERCIAL ARTWORK

Artwork prepared for printing on packaging components that may be used for the regulatory submission or commercial supply of commercial products.

In both cases, we are considering the packaging artwork

An artwork capability is required for both clinical supply and commercial product

Creation of timely and accurate packaging component artwork is a key requirement of a clinical trial...

...and the clinical trial artwork process is an underpinning process for your clinical trials.

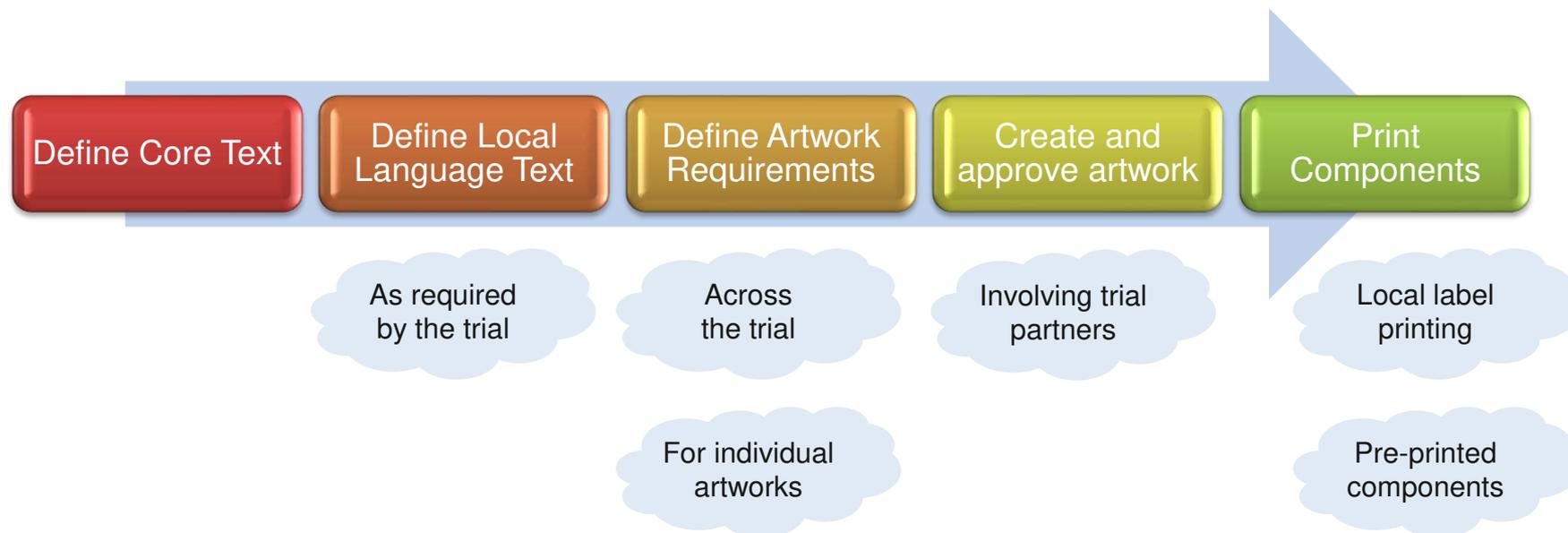
Similarly, provision of artwork for packaging components for commercial products is a key requirement for commercial supply...

...and the commercial artwork process is an underpinning process for your commercial supply process.

Is there opportunity to leverage and share capabilities?

A typical clinical trials artwork process comprises a series of standard steps...

Typical Clinical Trials Artwork Process



...and the structure of your process may vary depending upon company process architecture and the needs of external partners

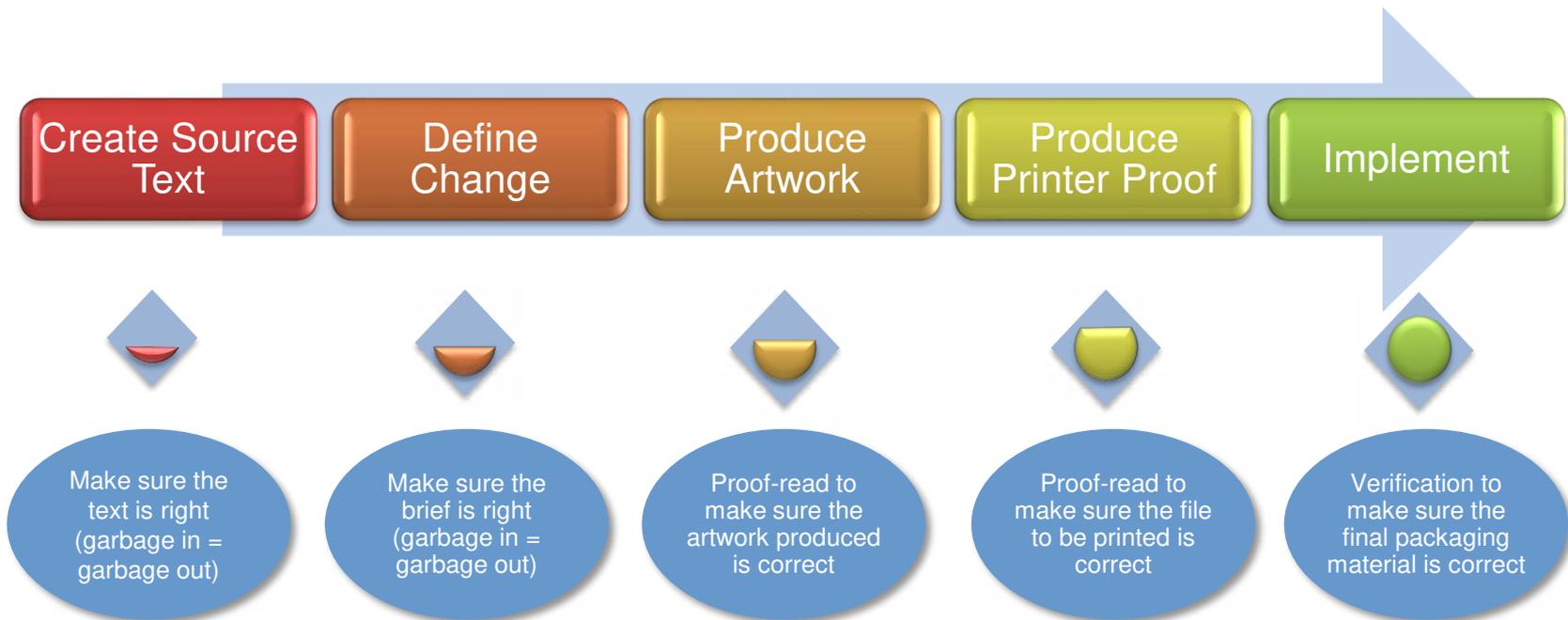
The nature of clinical trials means there are some specific factors a clinical trials artwork process must meet

Flexibility	Information is evolving as trial progresses. The process needs to be flexible and accurate to cope with this volume of change.	Multiple packaging formats	Often using other products for comparative studies requiring repackaging or over-labelling and driving multiple artwork profiles.
Timely	Timescales in trials are usually under pressure so lead-times for artwork change are constrained.	Networked	Complex network of service providers undertaking different parts of the trial (and not always the same tasks).
Dynamic	Trials are usually a project type environment — highly matrixed with many dependencies.	Accurate	Critical product information being determined so suitable decision making and data accuracy essential.
Multiple file output formats	Often using online label printing so file formats need to meet printer requirements.	Repeatable	Can be many iterations of artwork through whole trial. Processes need to assure repeatable outcomes.

In larger companies the clinical artwork process is often delivered through dedicated teams supported by bespoke IT tools

At a high level, a commercial artwork process looks very similar to the clinical trials process

Typical Commercial Artwork Process



There are some synergies but also some differences

There are **synergy** opportunities between clinical trials and commercial artwork capabilities....

ORGANISATION

- Artwork organisation, project management and tracking
- Artwork creation - depending upon external partner RACI and artwork tools used

PROCESS

- High level process design and stage gates
- Rigour and accuracy delivery from process design
- Version control

IT

- Document Management
 - Centralised, controlled electronic repositories for the storage of artwork files.
- Workflow
 - Tools that allow the routing of tasks to stakeholders and facilitate the execution of the process.
- Electronic Approval
 - Controlled and validated electronic signatures.
- External Communication
 - Communication of files to external parties and involvement of external parties in the artwork system.

... but also a number of **differences**

ORGANISATION

- The stakeholder teams (both internal and external) involved in process, particularly approval
- Artwork competency - level of graphic content
- Accuracy of workload forecasts / prioritisation

PROCESS

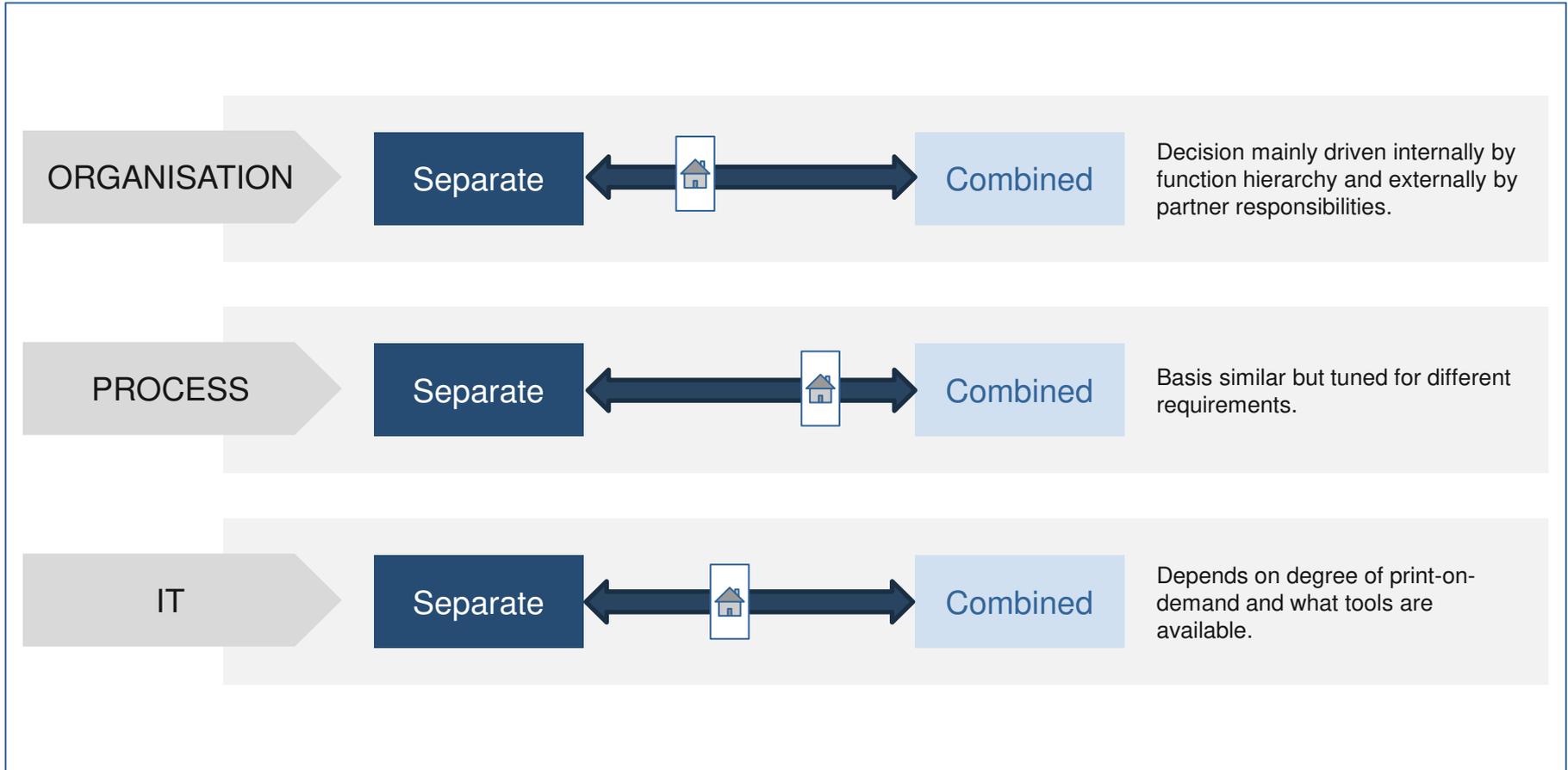
- Text requirements and formats
- Application of company change control processes (sometimes applied for commercial product)
- Company file and component numbering methods
- Components inspection and verification
- Performance metrics

IT

- Data field definitions
- Online printing requirements
- Artwork creation tools in clinical trials are often integrated with a print-on-demand capability whereas in commercial supply are more focused on generating an output PDF
- Detailed workflow configuration

How you deal with these synergies and differences will determine how much integration there is between your clinical and commercial artwork operations

Multiple configurations of your clinical supply vs commercial artwork capabilities are possible



There are many different scenarios adopted by Pharma / Biotech companies

Some trends suggest the overlap could become greater...

CLINICAL

COMMERCIAL

- Everything is moving to be more project-based; launches, safety changes, transfers, legislative responses.
- Sales-per-SKU is falling - outside of the US volumes becoming closer to clinical volumes - drive to print-on-demand for commercial product.
- More complex networks of external partners needing systems access.
- Both scenarios need rigour and flexibility.

Where services are managed disparately, this could bring them closer together

In summary...

- There are synergies between your clinical trials and commercial artwork capabilities.
- However each scenario has some specific requirements that must be provided to ensure the success of each process.
 - These requirements are sufficiently acute to necessitate customised instances for either scenario.
 - But trends suggest they may become less unique over time.
- Therefore there are opportunities to leverage aspects of either your clinical trials or commercial artwork capability when building the other.
 - But care should be taken to ensure what you build is optimised for its purpose.



Claim your complimentary copy of Andrew Love's book...

Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities



The essential resource for implementing sustainable packaging labelling and artwork capabilities. Foreword by Steve Richmond, Head of Global Packaging, AstraZeneca. The knowledge and expertise contained in this book will help you to understand and deliver the right mix of packaging artwork capabilities for your organisation, in a shorter period of time, at lower cost and with significantly less risk. Inside you will find in-depth discussion on the following topics: The importance of artwork capabilities in delivering today's business strategy, the causes of artwork errors, detailed discussion on each of the elements which go to make up the overall artwork capability, including: business processes; education, training and competence assessment; organisation design; technology and outsourcing, making sustainable improvements happen and future developments.

To claim your complimentary copy of Andrew Love's book, please email your postal address to:

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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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