Workflow Systems for Pharmacetical Artwork Development

WHO WE ARE

Vakils Premedia provides specialist artwork and labeling outsource services to Pharmaceuticals Industries globally.

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THE CHALLENGES

Label and Artwork Management (LAM) is an extremely complex business operation that involves several stakeholders working together to deliver compliant artwork.
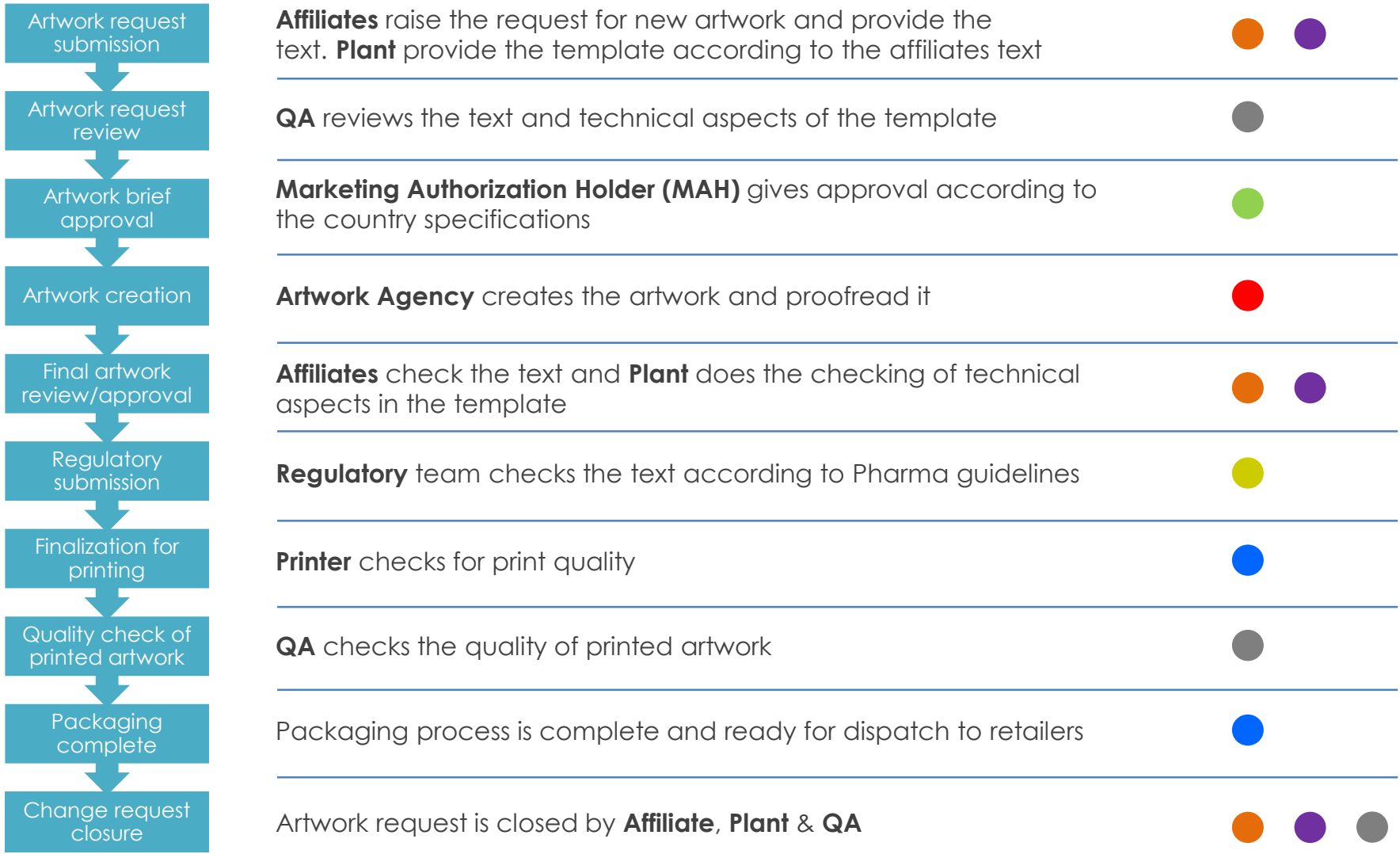
THE CHALLENGES (continued)

Pharma companies annually deliver a few hundred to several thousand artworks based on their product portfolios.

While the timely delivery of packaging artwork is crucial to business, its quality is paramount to a successful program.

The implications of a low quality product can be catastrophic. A single mistake in labeling can cause recalls, lawsuits and millions of dollars in compensation and regulatory fines

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THE SUPPLY CHAIN PROCESS

Process Step	Description	Responsible
Artwork request submission	**Affiliates** raise the request for new artwork and provide the text. **Plant** provide the template according to the affiliates text	🟠 🟣
Artwork request review	**QA** reviews the text and technical aspects of the template	⚫
Artwork brief approval	**Marketing Authorization Holder (MAH)** gives approval according to the country specifications	🟢
Artwork creation	**Artwork Agency** creates the artwork and proofread it	🔴
Final artwork review/approval	**Affiliates** check the text and **Plant** does the checking of technical aspects in the template	🟠 🟣
Regulatory submission	**Regulatory** team checks the text according to Pharma guidelines	🟡
Finalization for printing	**Printer** checks for print quality	🔵
Quality check of printed artwork	**QA** checks the quality of printed artwork	⚫
Packaging complete	Packaging process is complete and ready for dispatch to retailers	🔵
Change request closure	Artwork request is closed by **Affiliate**, **Plant** & **QA**	🟠 🟣 ⚫

Legend:
🟠 Affiliate   🟣 Plant   ⚫ QA   🟢 MAH   🔴 Artwork Agency   🟡 Regulatory   🔵 Printer

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WHY ARTWORK MANAGEMENT SYSTEM?

An Artwork Management System improves:

- Productivity and costs

- Collaborative review and approval

- Compliance and validation

WHY ARTWORK MANAGEMENT SYSTEM? (continued)

As Pharma goes evermore global, the importance of meeting parameters such as:

- **Quality**
- **Productivity**
- **Turn-around-time (TAT)**
- **Compliance**
- **Traceability**
- **Transparency**

continues to be an ongoing challenge.

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ERRORS

Technical Errors

- Incorrect barcode and braille

- Incorrect logos and colors

- Design and strength errors

Content Errors

- Ambiguous presentation of information

- Omission of data

- Incorrect symbols

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BENEFITS OF ARTWORK SYSTEM

- Cost reduction through improved efficiencies

  - Faster approval process and reduction in artwork lead times

- Reduced asset misuse (wrong versions, errors, reprints and recalls)

  - Increased speed to market and timely product launches ensured

- Better asset reusability - common database

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PHARMA ART WORK WORKFLOW SOLUTIONS

- GLAMS PH – global artwork management system

- Indegene

- Twona Artwork Management System

- Perigord GLAMS Solution

- Esko Web Centre

- Manage Artworks

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HOW ARE WE USING THE ARTWORK MANAGEMENT SYSTEM

- Receiving project instructions

- General communication

- Internal and external approval cycles

- Track timelines

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COMMON PITFALLS
TO A SUCCESSFUL ARTWORK
WORKFLOW IMPLEMENTATION

- Artwork process not clearly defined.

- Standards not in place or not detailed enough

- Artwork Management System incorrectly used

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IMPLEMENTATION CASE STUDY

CUSTOMIZED DASHBOARDS

▼ My Projects

Project Name:

Search

Found: 668 items.   Page 1 of 34 | Next | Last>>

	Name	Actions ▾	Status
☐	ProStrakan / vakils PREMEDIA	CTN-PAB-IE-003	**Project Live**
☐	ProStrakan / vakils PREMEDIA	LFT-PAB-IE-003	**Project Live**
☐	Strakan / vakils PREMEDIA	LFT-SYT-GB-004	**Project Live**

- Each project has a status indication of position in the lifecycle.

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IMPLEMENTATION
CASE STUDY (continued)

- List of active projects along with the start date, due date and individuals with key roles.

IMPLEMENTATION
CASE STUDY (continued)

JOB HISTORY

Folders (8)

Documents (3)

Project Documents (0)
- 01_RAW (3)
- 02_Review Documents (3)
- 03_Report (0)
- 04_3D (0)
- 05_QRD (0)
- 06_Dispatch (0)
- 07 Proof (0)

CTN-ABS-KR-105_P1_10Oct2016.pdf (283.9KB)
Low Res PDF for your review

...ct2016.pdf (1.2MB)

...ct2016-signed.pdf (1.3MB)

Total Documents 6

Hide Thumb

CTN-ABS-KR-105_P2_20Oct2016.pdf

WebCenter by Esko - Version 14.1.1 - Build r14

- All revisions, client annotations and versions/comparisons.

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IMPLEMENTATION
CASE STUDY (continued)

Artwork Dev & Proof Check	Workflow	ADMIN (ADMIN)			
Preflight/Validate inputs		Gupta, Vikas (VIKAS) as VAKILS PM	✓	Sep 29, 2016	Sep 29, 2016
Prepare Artwork according to Brief		Sharma, Mukesh (MUKESH) as VAKILS PM	✓	Oct 10, 2016	Oct 10, 2016
Review of Artwork		Biggar, Catriona (CATRIONA) as PS SC APP, PS SC REV	✓	Oct 10, 2016	Oct 10, 2016
Corrections by Reviewer		Sharma, Mukesh (MUKESH) as VAKILS PM	✓	Oct 19, 2016	Oct 19, 2016
Review of Artwork_1		Biggar, Catriona (CATRIONA) as PS SC APP, PS SC REV	✓	Oct 20, 2016	Oct 20, 2016
Decision on Project Progress		Biggar, Catriona (CATRIONA) as PS SC APP, PS SC REV	✓	Nov 2, 2016	Nov 2, 2016
Artwork Approval		Biggar, Catriona (CATRIONA) as PS SC APP, PS SC REV	✓	Nov 2, 2016	Nov 2, 2016

- Shows the job tracking an workflow process for a particular job.

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IMPLEMENTATION
CASE STUDY (continued)

PROOF APPROVAL
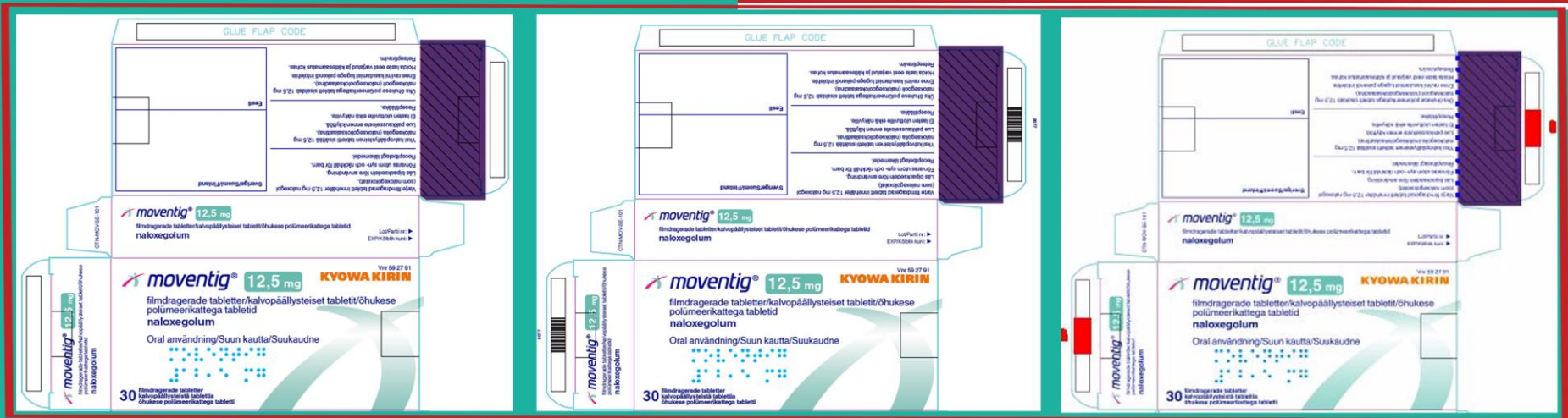
Previous Version

Current Version

Comparison between 2 versions are highlighted in **Red**

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IMPLEMENTATION CASE STUDY (continued)

Project	Actions ▾	Description	Archival
	Droperidol Italy Label LBL-DRO-IT-201	Create new Label with enclosed QRD using existing carton as template ProStrakan Code - LBL-DRO-IT-201	**Project Archived** Project Archived — PROJECT MANAGAR - PS
	Droperidol Italy Carton CTN-DRO-IT-201	Create new Carton with enclosed QRD using existing carton as template ProStrakan Code - CTN-DRO-IT-201	**Project Archived** Project Archived — PROJECT MANAGAR - PS
	Pabrinex IV Ireland Carton Mock Up (Current template new design)	Create new carton using current Ireland carton as template (attached) kept the text the same but change the layout and design to match the final proof of Pabrinex IV Carton CTN-PAB-GB-002	**Project Archived** Project Archived — PROJECT MANAGAR - PS
	Pabrinex IV Ireland Carton Mock Up	Create new carton in new template with new design (to look like final proof in Pabrinex IV Carton CTN-PAB-GB-002) using the text as per current Ireland carton, attached in the raw folder	**Project Archived** Project Archived — PROJECT MANAGAR - PS
	Desuric Spain PIL LFT-DES-ES-001	Create new PIL using the existing PIL as template Changes marked on the existing PIL New ProStrakan Code LFT-DEC-ES-001 Reason for Change - Change of Spanish name	**Project Archived** Project Archived — PROJECT MANAGAR - PS
	Desuric Spain Foil FOI-DES-ES-001	Create new foil using existing foil as template Changes marked on current artwork New ProStrakan Number - FOI-DEC-ES-001 Reason for Change: Change of Spanish name	**Project Archived** Project Archived — PROJECT MANAGAR - PS

- Retrieval of historical work is a click away.

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IMPLEMENTATION
CASE STUDY (continued)

Quality Check Reports

category	OK	NOT OK	NA
Check corresponding AWRef guidelines (NA for Condensed flow)	○	○	○
AW creation OK + save (NA for Condensed flow)	○	○	○
for Illustrator/Indesign : close document + re-open native file (NA for Condensed flow)	○	○	○
for ESKO: close document + re-open native file (Business Partners not having Backstage) (NA for Condensed flow)	○	○	○
for Illustrator/Indesign/ESKO: create certified artwork PDF+check (NA for Condensed flow)	○	○	○
Attach Certified artwork PDF in e-Packmat	○	○	○
Print sep. PDF+Print comp. PDF (not for inline printed materials)	○	○	○
Text control (NA for Condensed flow)	○	○	○
Text control: Tradename (NA for Condensed flow)	○	○	○
Text control: Trademark (NA for Condensed flow)	○	○	○
Text control: concentration (NA for Condensed flow)	○	○	○
Text control: presentation (NA for Condensed flow)	○	○	○
Text control: customer logo (NA for Condensed flow)	○	○	○
Layout type (NA for Condensed flow)	○	○	○
Control PCC (in legend and artwork)	○	○	○
Check legend (NA for Condensed flow)	○	○	○
Technical drawing/template control	○	○	○
Control colours in separation (NA for Condensed flow)	○	○	○

Category	OK	NOK	NA
Compare versions Certified PDF vs hardcopy proof (*Page Info.*)	○	○	○
Check legend	○	○	○
Text control: 1st run	○	○	○
Text control: Rerun	○	○	○
Text control: Tradename	○	○	○
Text control: Concentration	○	○	○
Text control: Presentation	○	○	○
Text control: Customer logo	○	○	○
TVT Check	○	○	○
Template/Technical Drawing Check	○	○	○
Control PCC (in legend and artwork)	○	○	○
Colour OK	○	○	○

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IMPLEMENTATION
CASE STUDY (continued)

IMPLEMENTATION
CASE STUDY (continued)

TVT Report

Project: CTN-ACP-GB-001_Changes for Vakils_27A

TVT 7.0.4 Project Report

Project Information

Originals:	CTN-ACP-GB-001_Changes for Vakils_27April15.pdf
	29.04.2015 11:26:10 C:\Users\Mukesh.Sharma\Desktop\Mukesh\Adcal Caplet Carton
	SHA1:b315c0a968a0521ca08b3f1dbab987880a87039
Words in Originals:	477
Copies:	CTN-ACP-GB-001_P7_29Apr15.pdf
	29.04.2015 14:41:10 C:\Users\Mukesh.Sharma\Desktop\Mukesh\Adcal Caplet Carton
	SHA1:5715d328dc2ae6as2cbc5515924580f3bb384581
Words in Copies:	503
Settings used:	Leaflets (with ligature expansion)
Hidden Map Warnings:	0
Importers used:	PDFIN 1.70

Project History

Date	User	Machine
29.04.2015 11:54:55	Mukesh.Sharma	WSHAPAPP03
29.04.2015 12:00:33	Mukesh.Sharma	WSHAPAPP03
29.04.2015 12:02:24	Mukesh.Sharma	WSHAPAPP03
29.04.2015 12:03:17	Mukesh.Sharma	WSHAPAPP03

		1886 - - 67 x 67 x 96 mm UK English		1886 - - 67 x 67 x 96 mm UK English			
DEV4	Deviation	6 06-Jan	1	7 29-Apr	1	Mukesh.Sharma, 29.04.2015 12:00:48	accepted
DEV8	Insertion		1	Font Type: Verdana, Helvetica Font Size: 9pt/10pt/11pt/15pt Reason for Change: To add calender to the pack	1	Mukesh.Sharma, 29.04.2015 12:01:21	accepted
DEV12	Deviation	ADC	1	ACP	1	Mukesh.Sharma, 29.04.2015 12:03:02	accepted

Order Breaks

GID	Type	Original Text	Page	Copy Text	Page	User / Time	Comment
OB1	Order Break After	.	1	.	1		
OB2	Order Break Before	This	1	This	1		
OB5	Order Break Before	Date	1	Date	1		
OB6	Order Break Before	EXP	1	EXP	1		
OB7	Order Break After	Sun	1	Sun	1		
OB9	Order Break Before	Swallow	1	Swallow	1		
OB10	Order Break After	.	1	.	1		
OB11	Order Break Before	Calcium	1	Calcium	1		
OB13	Order Break After	001	1	001	1		

Project State

Type	Sum	Accepted	Marked
Deviations	4	4	0
Order Breaks	9	0	0
Hyphenations	0	0	0

IMPLEMENTATION
CASE STUDY (continued)

Compliance Validation

- Developed to GAMP5 guidelines

- Validation Services

- FDA 21 CFR Part 11 compliance controls built in

- Developed to GMP guideline standards

- Full audit trail and version control

- Traceability

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IMPLEMENTATION
CASE STUDY (continued)

Meeting the Challenges

- Managing job instructions

- Issues related to reviewing and approval process

- Tracking all the jobs

- Managing different versions

- Managing and Searching assets

- Communication issues between different departments and global suppliers

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Thank You

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