Digital Transformation through Content Management & Artwork Automation

Reduce Risk & Gain Efficiencies in Packaging, Artwork & Labeling

Samantha Thompson September 2023



Agenda

- Introduction
- Business Challenge
- Typical Current State
- What is Automated Artwork?
- The Esko Solution
- How to Get There
- Next Steps



Introduction



Meet Your Presenter



Playing a Pivotal Role in the Fight Against COVID-19

DIAGNOSTIC TESTING

VACCINES & THERAPEUTICS



Point-of-care (POC) rapid molecular tests



BECKMA

OUITER

RADIOMETER

IDT	Primer & probe kits provide detection
	component in diagnostic tests

POC blood gas analyzers & tests in ER, ICU

Antibody serology tests and high-throughput antigen test

PALL therapies Cytiva

Supporting research, development and production of COVID-19 vaccines and



REVENUE BY END-MARKET:

Living Our Shared Purpose: *Helping Realize Life's Potential*

Life Sciences

Danaher Today





Pie chart is a % of total revenue and includes Cytiva 2020 total annual revenu

Purpose-driven science & technology leader

Danaher R The Life Science Industry

8 of the Top 10 Global Pharma Companies manage files and content with Esko's Workflow Solutions

16 of the Top 25 Global Pharma Companies manage files and content with Esko's Workflow Solutions



Business Challenge



Emerging & Evolving Regulatory Framework



Source: Deloitte – A bold future for life sciences regulation | Predictions 2025

ESKO

Regulatory Labeling Challenges



Need for Speed & Consistency

- Faster pace of change
- Teams are being asked to deliver faster
- Risk of inconsistencies can have high consequences

Demand from Patients

- Real time, accurate information
- ePIL/ePI
- Mobile-friendly







Current State



It should be simple, right?

Labeling Content

Perioperative Management The dose level and dosing intervals for surgery depend on the procedure and local practice. A guide for dosing with ESPEROCT during surgery (perioperative management) is provided in Table 2 below

Table 2: Dosing for Perioperative Management with ESPEROCT

Type of surgery	Adolescents/Adults ≥12 years Pre-operative Dose (IU/kg)	Children <12 years Pre-operative Dose (IU/kg)	Additional Doses
Minor Including tooth extraction	50	65	Additional dose(s) can be administered after 24 hours if necessary
Major Intracranial, intra-abdominal, intrathoracic, or joint real accurate surgery	50	65	Additional doses can be administered approximately every 24 hours for the first week and then approximately every 48 hour until wound healing has occurred

Routine Prophylaxis

Adults and adolescents (≥ 12 years): The recommended starting dose is 50 IU of ESPEROCT per kg body weight every 4 days. This regimen may be individually adjusted to less or more frequent dosing based on bleeding episodes

Children (< 12 years): A dose of 65 IU of ESPEROCT per kg body weight twice weekly. This regimen may be individually adjusted to less or more frequent dosing based on bleeding episode

ESPEROCT also may be dosed to achieve a specific target Factor VIII activity level, depending on the severity of hemophilia, for on-demand treatment/control of bleeding episodes or perioperative management. To achieve a specific target Factor VIII activity level, use the following formula:

Dosage (IU) = Body Weight (kg) × Desired Factor VIII Increase (IU/dL or % normal) × 0.5

- · Base the dose and frequency of ESPEROCT on the individual clinical response. Patients may vary in their pharmacokinetic and clinical responses. If monitoring of Factor VIII activity is performed, use a chromogenic or one-stage clotting assay appropriate for use with .
- ESPEROCT [see Warnings and Precautions (5.3)].

Preparation and Reconstitution

- . Always wash hands and ensure that the area is clean before performing the reconstitution procedures
- Use a septic technique during the reconstitution procedures.
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 If the dose requires more than one vial of ESPEROCT per infusion, reconstitute each vial according to the following instructions

Overview of ESPEROCT Package







HA Submission Package

HHA A





Cut & Paste Presents Risk





Digital Transformation with Automated Artwork



What is Artwork Automation?

The ability to automatically apply labeling content changes to an artwork

Labeling Content

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Automated flow of content into artwork





Key Benefits



Consistency, Quality & Reduced Risk

Speed & Productivity



Artwork Types



Labeling Artwork

Leaflet Artwork



Automation Types



Semi Automated Automation Lights Out Automation Online Editing



What's Needed to Get There?



Separating Content from How it's Presented





The Esko Solution



WebCenter Content Management

Streamline the content process, re-use content and reduce risk

- Update content once & apply to all impacted outputs
- Easy to use MS Word-like interface for content writers
- Manage the content lifecycle in a consistent and traceable way
- Flexible workflow capability to manage your processes
- Repository for approved content and relationship management







Systematically Manage Content Relationships

DEFINITIONS

Topics

Text content that can contain one or many paragraphs

Map

A map is a container for topics used to transform a collection of content into a publication. It gives the topics' sequence and structure

Publication

The output of the map; An artwork in InDesign, an MS Word file, an XML document etc.

EXAMPLE





Our Offering for Life Science

Core Platform with **Enterprise Content Management & Automation** including standard configurable **iPaaS** connectors for integration





How to Get There



Next Steps





Labeling Content & Automation Maturity Model



UNSTRUCTURED

- Reactive
- Source of Truth in Word, Excel, or Artwork
- Manual Management

ORGANIZED

- Partially Structured and Aligned
- Relationship between
 Base and Translation
 Languages
- Lack of Relationship between Product and Variants/Strengths

OPTIMIZED

- Database-Driven
- Instant Impact Assessment / "Where Used"
- Content Reuse



AUTOMATED

- Task Automation
- Rules-Based Application of Content
- Automated Artwork Updates

INTELLIGENT

- Al
- Advanced Automation
- Assisted Authoring



Planning Needed





Benefits Summary



Speed

- 5 x faster -75% reduction of Process Lead Time
- Reduction of waiting time & involved parties
- Overall faster to market
- Changes from health authorities can be implemented quicker



Flexibility

- Preparation to be ready for the future
- Add-Ons and future needs & innovations can be implemented by one system partner
 (to be state of the art)
- (to be state of the art)
- No strict dependency of managed volumes and costs



Efficiency

- Much leaner, harmonized and automated processes
- Less handovers & coordination needed
- Single changes can be easily scaled up into mass changes (volumes)
- Enables Artificial Intelligence



Security

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- Increase patient safety
- Reducing risk of not being compliant
- Bringing back and keep data within customer
- Not dependent on external suppliers anymore



Accuracy & Quality

- Higher accuracy based on predefined rules
- Increase predictability
- Enables analytics & reporting
- Real time visual control function & error detection



Cost Saving

- Operational cost saving (no external vendor, less coordination and reduced FTE effort)
- Less rework, recalls
- Cost reduction per PM





Thank you!