

e-Labeling A Practical Guide

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ENDOLOGIX

How.....

- ▶ We just heard about the:
- ▶ What?
- ▶ Which?
- ▶ Why?
- ▶ When?
- ▶ Where?
- ▶ Really?
- ▶ Here's the How.....

How.....

- ▶ Sometimes labeling projects are like herding cats.....
- ▶ https://www.youtube.com/watch?v=m_MaJDK3VNE

eLabeling – Benefits Review



- ▶ Environmental impact by reducing:
 - Printing
 - Shipping
 - Disposal
- ▶ Patient safety improvement thru more efficient method for managing product information.
- ▶ Reduces product launch timelines for both new and sustaining product changes.
- ▶ And of course – reducing cost \$\$\$\$\$

➤ Strategy



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Start with an eLabeling Strategy



- ▶ Considerations:
 - Cost/benefit (ROI) analysis:
 - Sustaining products & NPD strategies
 - Paper savings
 - Revision notification
 - Targeted introductions
 - Software display changes
 - Safety /Back-up mechanisms
 - Risk Assessment
 - Initial
 - Scheduled updates

Strategy Continued...



- Website change control
- Technology requirements
 - Data Protection
 - Tampering
 - Hacking
 - Data Security
 - Available only to the right users
 - Data Retention
 - Previous revision access (2–15 years)
- Customer Privacy
 - Personal data protections

Strategy Continued...



- Customer Service Access
 - “Free of Charge” contact number – EU does not support a common Toll-Free number
- Accessibility of web data
 - Must be available at all times
- Web site – design – ease of use/understanding
- Paper Requirements
 - How does customer gain access if web is down?
- Plan for customers that do not like the change.
 - Paper cost

Strategy Continued...



- Product Label Notification for customers on how to access information
 - Additional Leaflet?
 - Label – change current label, additional label?
- In-house or Outsourced/Hosted Solution?
 - Large company – good infrastructure to support in-house systems
 - Medium to small company – minimum support available – outsourcing option

» Planning



Project Planning



➤ Project Steps

- Identify Team Members
- Develop implementation plan
- Identify website source: in-house vs outsourced
- Develop risk assessment
- Submit to notified body for approval
- Develop inventory reduction plan
- Develop cost review/reporting schedule
- Communicate/train Customer Service/Sales
- Develop change control process/procedures for web

Project Planning



➤ Project Steps

- Scope out plan for Customer Service support for “Free of Charge” service and paper requests
- Develop labeling plan for customer label notification on/in product
- Develop IT plan for web design, customer web access, potential web downtime, data protection, security, retention and customer privacy
- Develop web design, processes & procedures

Project Planning



➤ Implementation Project Team

- Project Management
- Engineering – NPD & Sustaining
- Label Development
- Regulatory Affairs
- IT Customer Service
 - Communication to sales force, customers
- Supply Chain/Demand Planning
 - Reduction in future purchasing, inventory reduction
- Distribution
 - IFUs for non-eLabeling countries
- Quality
- Marketing
- Finance

Planning – Customers

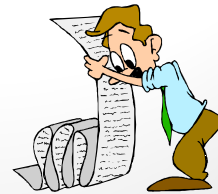


➤ Communicate early with customers about expectations of e-labeling

➤ Review & Consider:

- Comfort level working with eLabeling
- Technical capabilities?
- Concerns
- Follow-up with customers for feedback on ease of use

Implementation



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Implementation



➤ Execute to Plan

- Consistently review & update schedules
- Adjust deliverable dates when required
- Manage and adjust inventory reduction plan
- Maintain regular cost, timeline reviews & reporting schedules

➤ Communication

- Deliver regular communication to team & leadership

» Examples

Endologix Solution

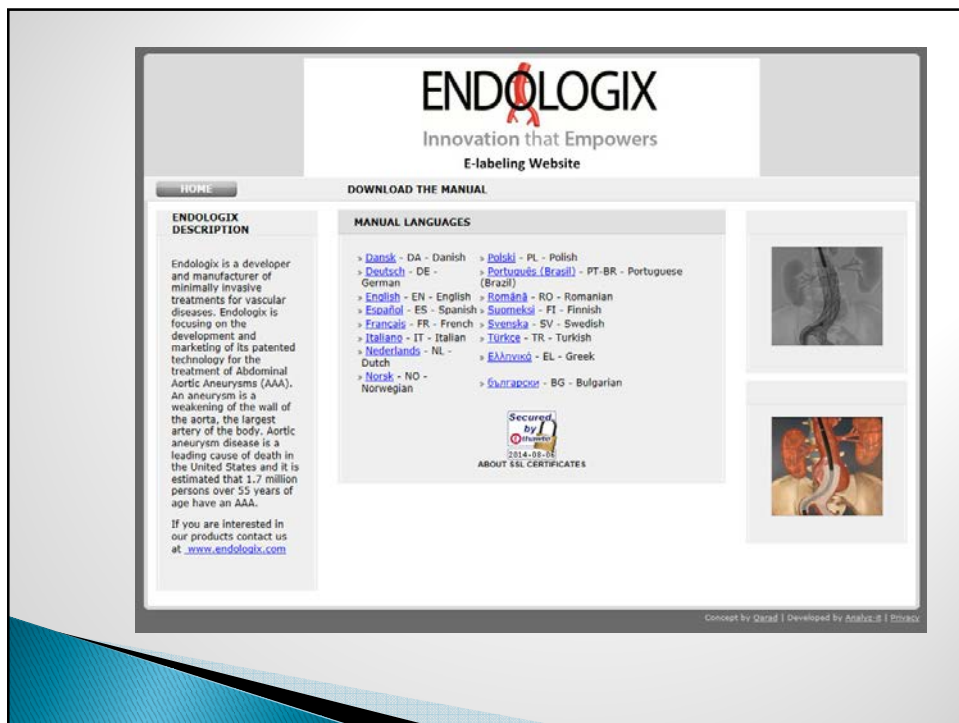
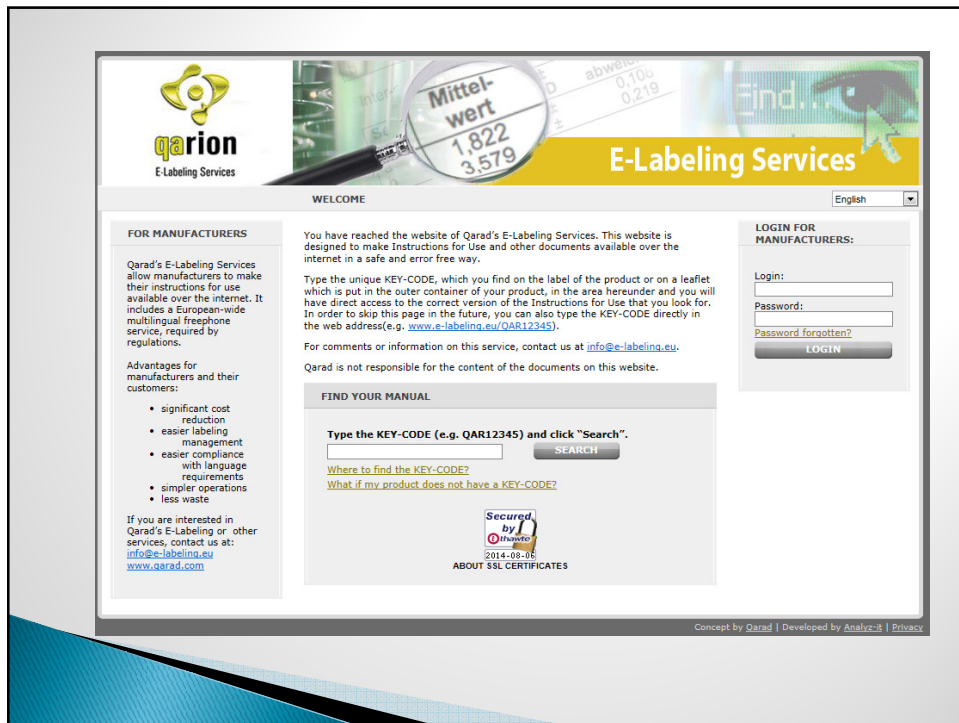
- Mid-size company
- IT requirements are significant
 - Data protection, security and retention
- Limited IT support (5 people – which 3 are Help Desk)
 - Project execution at risk – 3rd party desirable
- Customer Service constraints for call support
 - Limited resources to address web issues, paper fulfillment

Endologix Solution

- Contracted with 3rd party – Emergo/Qarad (eLabeling in IVD for over 10 years)
- Hosted website
- Ease of use
 - Website – set up in 30 minutes
 - IT requirements – data protection, security & retention managed by Qarad
 - IT support 24/7
 - Customer Service support 24/7
 - Specific global numbers to call for support/paper copies
 - Paper copy turnaround – compliance with regulation
 - Reasonable pricing structure
 - Supplied easy to use manuals, label design samples, & Risk Analysis templates
 - Website link to Adobe Reader

Sample Label

ENDOLOGIX			
EU Clinicians Only:	www.e-labeling.eu/ELX10000		
US Clinicians Only:	www.e-labeling.eu/ELX10001		
	EU: +800 135 79 135		
eIFU indicator	GR 00800 161 220 577 99		
	IS 800 8996		
	LT 880 030 728		
	RO 0800 895 084		
	SK 0800 606 287		
	TR 00800 142 064 866		
	LI +31 20 796 5692		
	MT +31 20 796 5693		
	non-EU: +31 20 794 7071		
	US +1 855 236 0910		
 ENDOLOGIX 11 Studebaker Irvine, CA USA 92618-2013 Tel: +1 (949) 595-7200 (800) 983-2284	<table border="1"><tr><td>EC</td><td>REP</td></tr></table> EMERGO EUROPE Molenstraat 15 2513 BH, The Hague The Netherlands C01218-01 Rev A	EC	REP
EC	REP		



Important!

- Do not underestimate the complexity of implementing an eLabeling project..
- Note that most issues encountered are technical issues..

Questions?



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