



Building a GIM Solution in a Regulated Industry

Successes, Challenges and Lessons Learned

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Agenda

- Company and department overview
- Identifying the problems and drivers
- Establishing documentation life-cycle
- Building a business case and implementing the supporting tools
- Utilizing standards
- Working with regulatory constraints – risk and change management
- Time and resources
- Benefits, Challenges, Lessons Learned, Best Practices

About CaridianBCT, Inc.

- Medical device manufacturing company
- Specializes in the design and production of blood component technology
- Four business areas:
 - Therapeutic Apheresis/Cell Therapy
 - Automated Collections/Blood Bank Technology
 - Pathogen Reduction Technology
 - Whole Blood Processes
- Global Headquarters – Lakewood, Colorado, USA
- European Headquarters – Brussels, Belgium
- APAC Headquarters – Hong Kong, China
- Employees in 30+ countries



Technical Communications Responsibilities

- Authoring and translation of
 - All labeling for CaridianBCT equipment: Operator's Manuals, Instructions for Use (IFUs), kit, case, and bag labels, Tyvek disposable kit covers
 - Service materials: service manuals, preventive maintenance procedures, schematics, installation procedures, spare parts instructions
 - Other technical documents as requested: training materials, protocols, Standard Operating Procedures (SOPs)
 - Quality assurance and regulatory compliance for all deliverables
 - Localize into 20+ languages



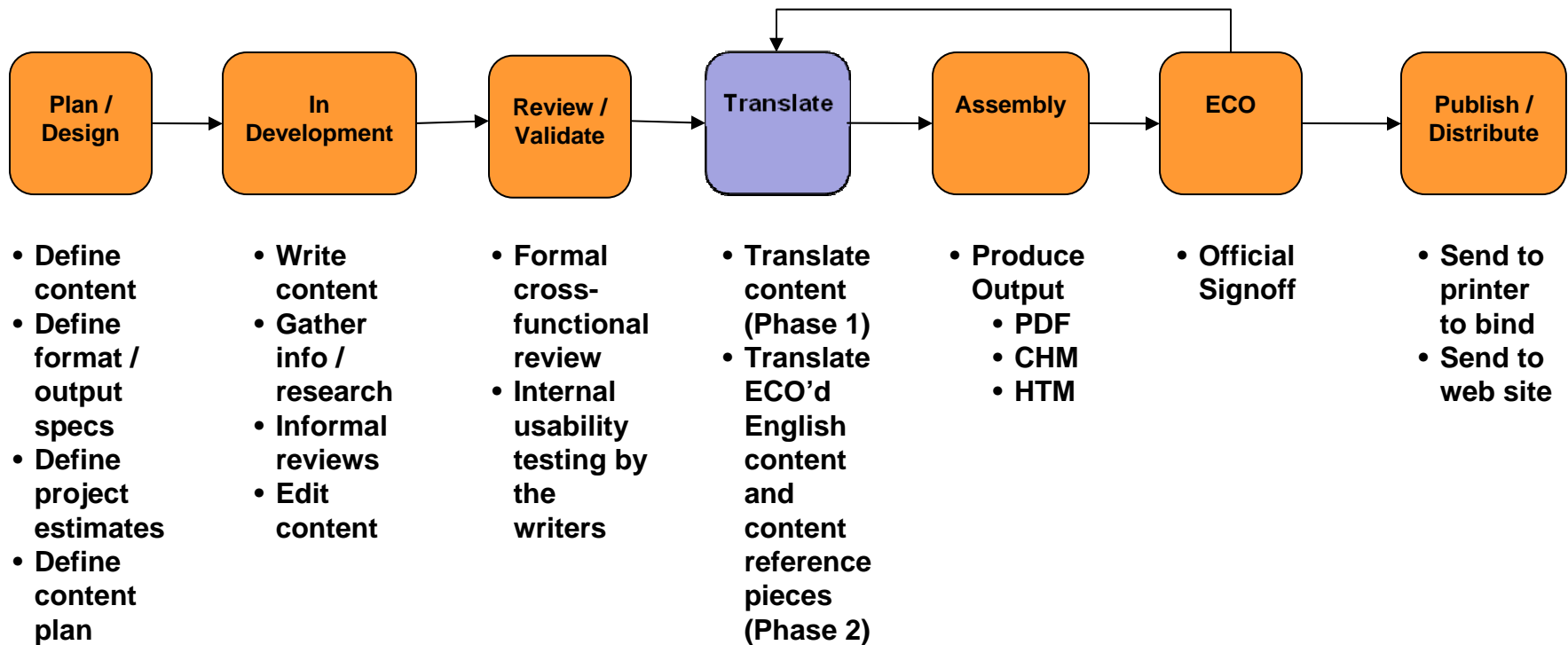
Identifying the problems and drivers

- Authored content in FrameMaker, InDesign, Word, Illustrator
- Each author had their own development approach and authoring style
- Localization process was manual – each PM used their own workflow
- No terminology management process whatsoever
- Love/hate relationship with LSPs:
 - Loved us because they benefited from our lack of control
 - Hated us because our lack of control made it nearly impossible to manage
- Model was reactive and not scalable

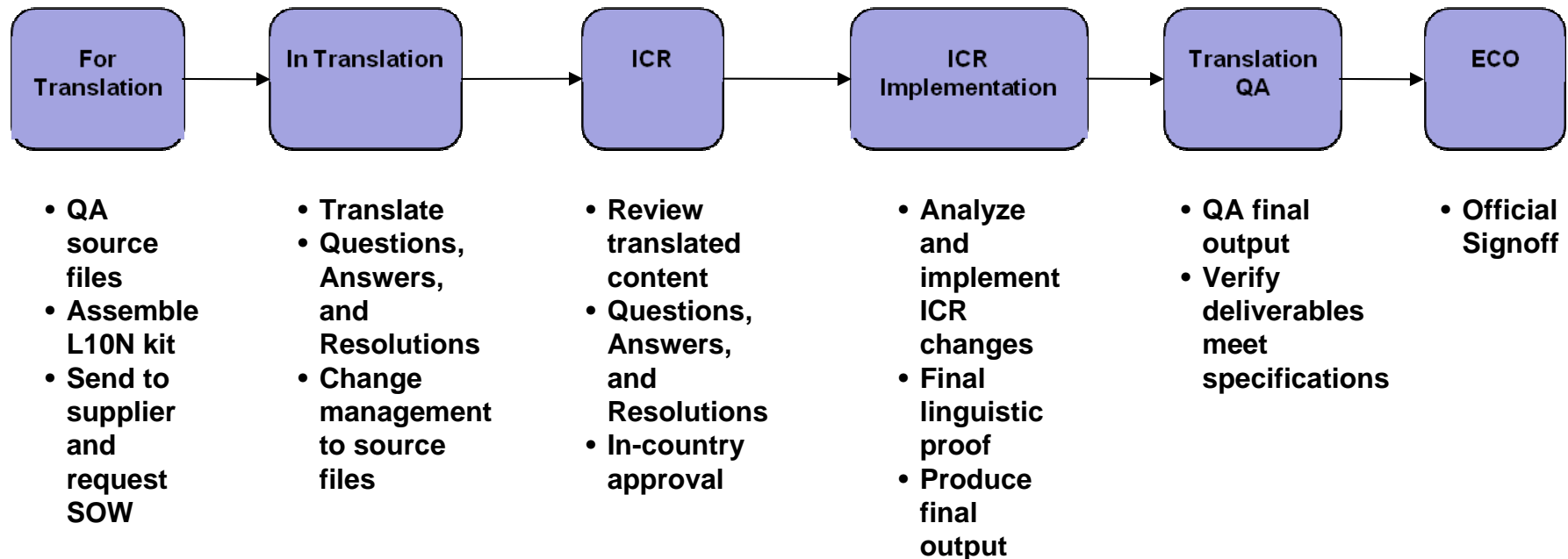
Establishing the documentation life-cycle

- Performed in-depth process analysis
 - Retained value-added process steps and threw out the rest
- Built a baseline manual process
 - Still used traditional authoring tools, email, FTP, very few standards
- Worked through multiple iterations to develop the future process
 - analyze, modify, implement, execute, repeat
- Finally found some scalable and realistic efficiency

CaridianBCT Documentation Life-cycle



CaridianBCT Localization Life-cycle



CaridianBCT's Tech Comm Current Process

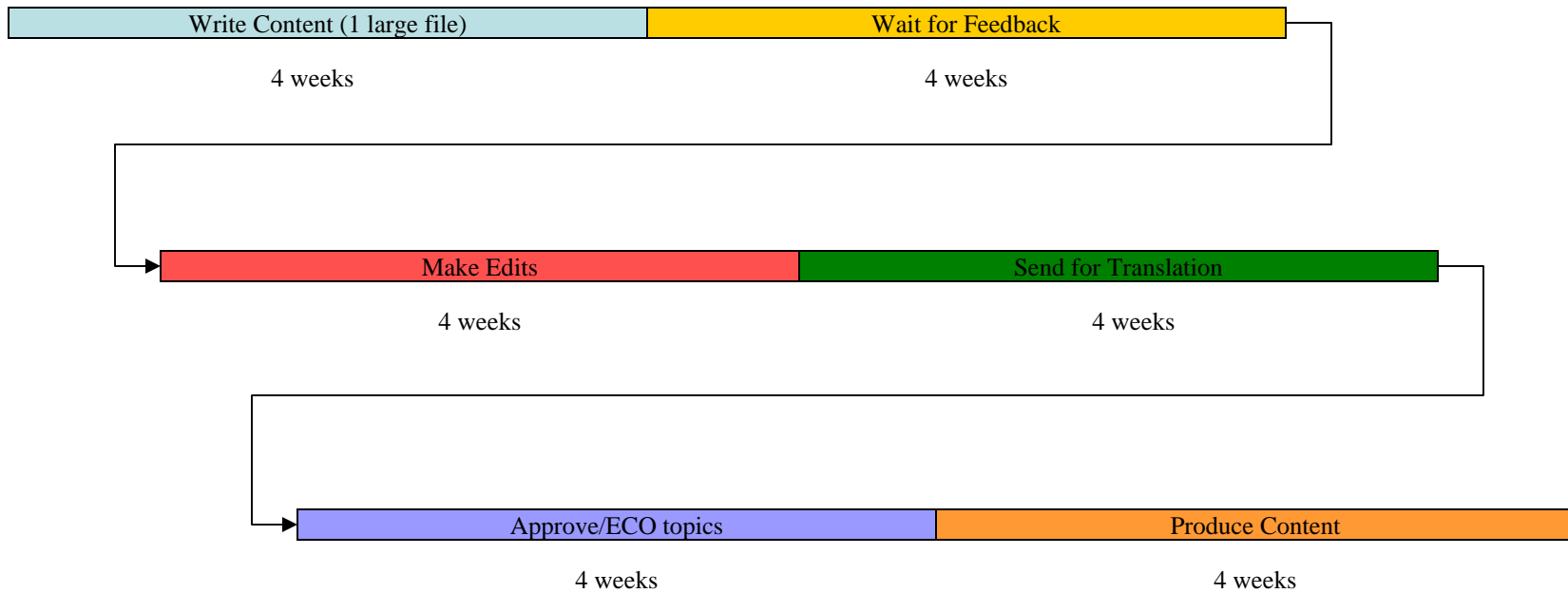
- Plan/Design
 - Authors create project plan specification, master topic list, and initial shell DITA Map (TOC) for review
- In Development
 - Authors create topics of content (tasks, concepts, references)
 - Authors initiate a workflow to send groups of topics for review
- Review/Validate
 - Reviewers open the task in the CMS Reviewer tool and add comments
 - Clinical, Regulatory, Legal, Marketing, R&D
- Approve
 - Content approvers review and approve the content at the topic level to freeze the topics before sending them for translation
 - The CMS records the comments and sends the information through the rest of the workflow to be produced as a deliverable

CaridianBCT's Tech Comm Current Process (cont.)

- Translate
 - Send groups of topics that have changed source content to translation rather than sending the entire deliverable to translation again
- Assemble/Produce
 - Apply style sheets to publish output (PDF, HTML, RTF, PDA/Mobile device)
- ECO (Engineering Change Order)
 - Content approvers review the document as a whole to approve the final output. Much of the content approval is complete at this stage due to the previous approve stage. This is a regulatory step to approve the final output.
- Publish/Deliver
 - Send final output to the printer or web publishers group



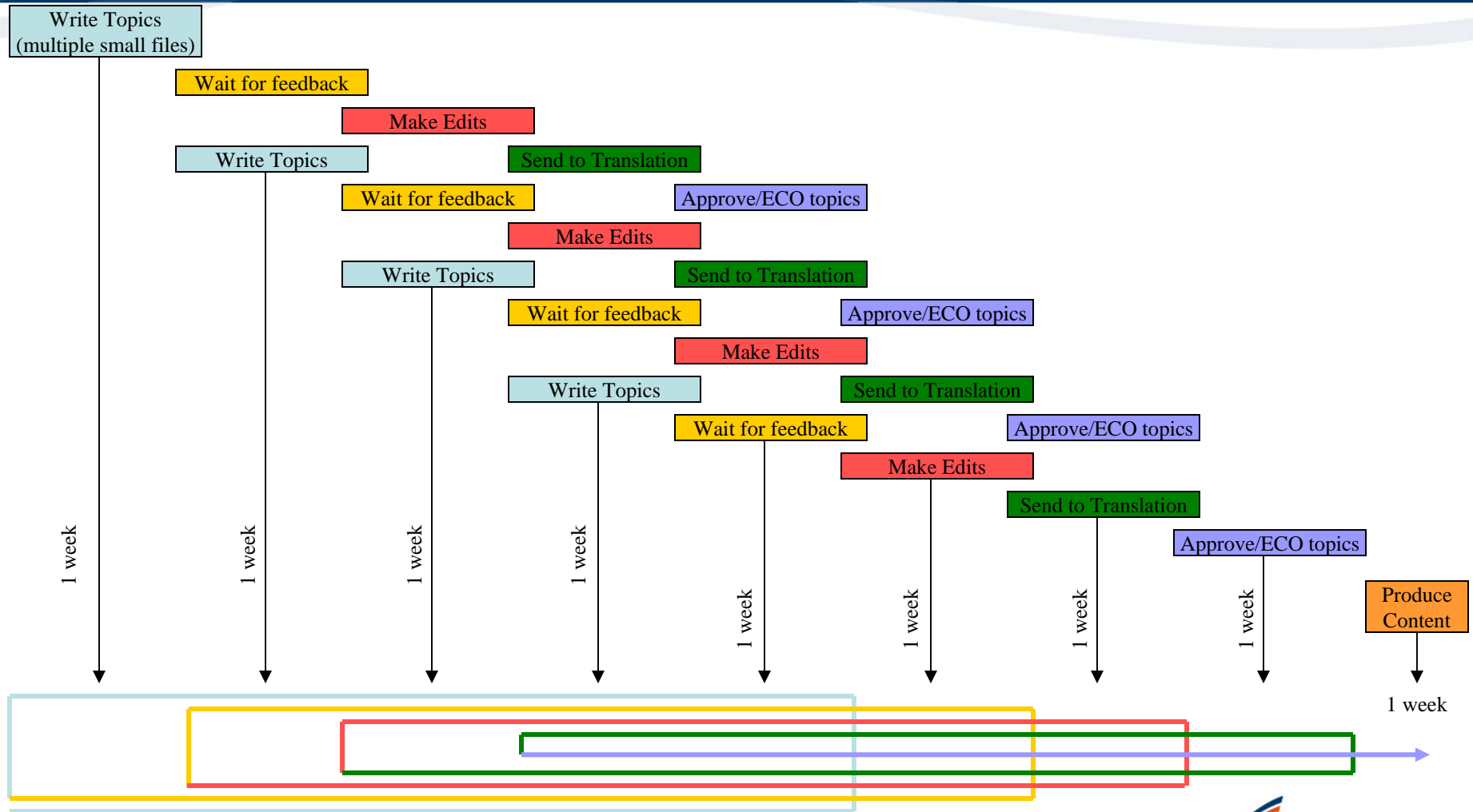
Document-based Process



TIMELINE (Linear and sequential) : 28 weeks



DITA Topic-based Process



TIMELINE (Spiral and concurrent): 9 weeks

Building a business case

- Efficiency: automation, ease of use, parallel processing, faster to market
- Re-use: author once, translate once, review once, release multiple outputs multiple times
- Consistency: multilingual terminology, style, branding, regulatory, legal and IP messaging
- Cost savings: see all of the above
- Higher quality: after all, we are authoring and translating complex concepts that impact lives and well-being

Implementing the supporting tools

- Content Management System
 - Central storage location for all authors and departments to access
- Translation Management System
 - Manages our translated content (TMs)
 - Improves term consistency (TDs)
 - Automates manual steps in the L10n workflow
 - Promotes vendor-independence and portability
- DITA (topic-based) authoring
 - Improves reuse
 - Improves time-to-market
 - Improves consistency in deliverables

Implementing standards

Authoring Standards:

- DITA
- XSL
- SVG
- Unicode (utf-8 & utf-16)

Localization Standards:

- XLIFF
- Translation Memory eXchange (TMX)
- TermBase eXchange (TBX)
- Segmentation Rules eXchange (SRX)
- ISO 639 and ISO 3166
- SAE J2450 Quality Metric

Benefits of using standards:

Portability/Flexibility
– migration between different tools/vendors

Consistency
– authoring and formatting

Common Knowledge and Terminology
– Training

Regulatory Compliance
– less validation needed for industry-wide standards vs. proprietary technology

Regulatory Constraints

- External Standards:
 - Code of Federal Regulations (USA)
 - Medical Device Directive (EMEA)
 - Canadian Standards Association/Health Canada (Canada – electrical standards accepted in most countries)
 - Pharmaceutical Affairs Law (Japan/APAC)
 - International Electromechanical Commission (IEC)
 - International Organization for Standardization (ISO)
- Notified Bodies:
 - FDA, BSI, KEMA, SFDA
- Internal Standards:
 - CaridianBCT Quality Management System
 - Standard Operating Procedures

Regulated vs. Non-Regulated

Non-regulated

- Output flexibility
 - Allows for more dynamic deliverable creation and delivery options
- Quick roundtrip translations
 - No ICR (in-country review) required
- Customer responsibility to retrieve needed information



Bottom Line: There are more detailed considerations required to implement a topic-based authoring and translation environment in a regulated industry

Regulated

- Thorough output approval
 - Every deliverable hierarchy and format must be reviewed.
 - Engineering Change Orders (ECOs) required.
 - PDF/Print needed vs. electronic delivery
- In-country review
 - Complicates integrated workflows between CMS/TMS
- Proactive communication to customers
 - Not only are we regulated, our customers are as well.
 - It is our responsibility to provide thorough documentation of changes from version to version to the customers.

What does it all mean...



...from a regulatory perspective?

- Consistency!!!
 - We no longer have to update multiple sources when regulations change
- Eliminate manual creation of change lists
 - We can now more easily create change lists for our regulated customers using topic and map comparison on different versions.
- Expanded language base
 - Using these systems and technologies, we increase the number of languages without drastically increasing the cost.
 - Most of our target locales will not accept English

Time and Resources

Time:

- About 3 years to purchase, implement, test and deploy both CMS and TMS
- First end-to-end pilot completed in 2008
- All Ops Manual and multilingual IFU content is converted to DITA
- All members of Tech Comm department are fully trained
- It is imperative to take a phased approach
 - In a regulated environment, there is little margin for error

Time and Resources

Resources:

- In addition to Technical Communications team, required involvement from Regulatory, Marketing, Clinical, Tech Support, Training, Operations, R&D and IT departments, Master Document Control (MDC)
- Extensive resource involvement had a direct impact on cost and time – but it was mandatory
- During the implementation process and beyond, we have 2 dedicated resources for system administration

GIM Environment – Known Benefits



More control over authoring directly impacts translation

- Translation cost savings of nearly \$5,500/language/deliverable
 - Eliminated desktop publishing
 - Decreased translation costs because of TM leverage and internally managing previously-translated content
 - PM costs reduce as well
- Reuse
 - Reuse content at the topic level by referencing the different topics into hierarchical maps to create deliverables.
 - Write once, Edit once, Review once, Translate once, Produce multiple times.
 - Process efficiency is greatly improved.

GIM Environment – Known Benefits (cont.)

- **Flexibility**
 - Create different types of deliverables for different audiences, locations, media (HTML vs. Print), and in many different languages
 - Conditional filtering - authoring and translating nearly similar content and filtering only what is needed in-house to publish specific deliverables for specific product version or audiences.
- **Portability**
 - More than just technical documentation can use these technologies
 - Marketing, Training, Web Development, and other departments can use this method for creating information and keeping it consistent throughout all deliverables.

Bottom Line: In the pilot project, CaridianBCT is producing 24 deliverables from one source and one translation project. Because of reuse, conditional filtering, and publishing in-house, CaridianBCT is saving nearly \$100,000



GIM Environment – Current/Future Concerns

- User Acceptance
 - Some LSPs resist shift to “in-sourcing” many localization tasks (TM management, DTP, etc.).
 - Some in-country reviewers have difficulty consistently accessing online review environment
 - Translating and reviewing topics, rather than documents, can create contextual challenges and more change management
- “In-sourcing” requires new skill-sets and more overhead
 - Creation and maintenance of style sheets and information architecture
 - Management of TMs, TDs and workflows
 - Administration of system configuration and troubleshooting
 - Training requirements (internal and external)

Lessons Learned & Best Practices

- Impact of GIM implementation is widespread
 - Content developers, PMs, translators, reviewers, etc.
- Understand the user base
 - Global users may not have reliable access or fast connection speeds to online systems
 - All users may not be technologically savvy
- Change management
 - Radical change can be difficult to those used to doing things a certain way
 - Remind users how they can benefit
- Testing and proof of concept
 - Don't try to test all use cases at once, take an iterative approach
 - Aim for quick wins

Lessons Learned & Best Practices (cont.)

- LSP selection
 - Find LSPs that are willing to partner with you
 - Find LSPs that know the technology or are willing to learn
 - This may not always include your current suppliers!
- In-country review
 - Re-define scope of ICR process based on new environment and content architecture
 - Assess current resource pool and refine minimum requirements if necessary
- Internal resources
 - Hire dedicated resources with the right skill sets
 - System administration and training is not a part-time job

Best Practices and Lessons Learned (cont.)

- Streamline the global content lifecycle
 - Include source content development and localization in the same department if possible
 - Content creation and translation are not independent processes and should be thought of as an integrated workflow
- Work cross-functionally
 - Engage all stakeholders in advance, including internal teams, translation suppliers, and reviewers
 - Know what other internal departments/personnel are impacted (Regulatory, Quality, Marketing, etc.)

Questions?



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