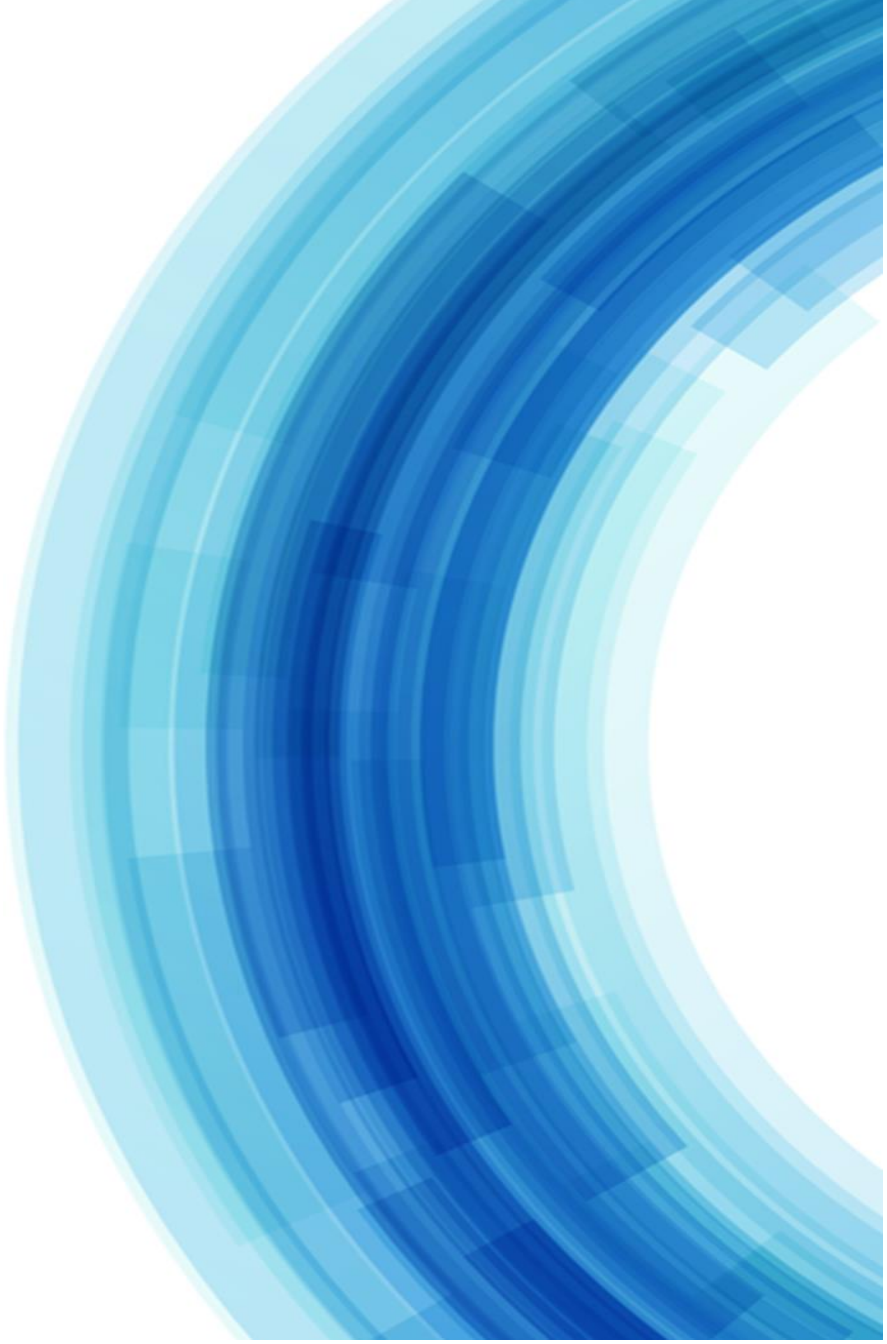

CCMS Starter Kit

Life Sciences

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1 INTRODUCTION AND OVERVIEW

TransPerfect's "GlobalLink CCMS" technology provides unparalleled efficiency to organizations in all industries struggling to produce high quality content in multiple languages and in multiple formats. However, organizations operating in the Life Sciences market have the added burden of regulatory compliance, which imposes additional costs in both quality management and audit tracking not borne by unregulated companies on a content production process. It is in these strict environments and market segments where GlobalLink CCMS solutions are indispensable.

"GlobalLink CCMS" refers to a segment within the GlobalLink suite of products. GlobalLink itself is TransPerfect's turn-key, cloud-enabled platform for managing a Life Science organization's entire supply chain for content production. It comprises modular, flexible systems that work equally well as an integrated platform or as standalone components. "GlobalLink CCMS" is the system built particularly for managing components of XML content.

"CCMS" is an acronym for "Component Content Management System" where "component" refers to reusable content encoded in XML. A "component" might be an XML[1] file. It might also be a paragraph, or a table, or a procedural sequence within an XML file. Components are reusable snippets of information. A CCMS ensures that components are well formed, properly linked, and protected against accidental or malicious modification.

This document describes TransPerfect's GlobalLink CCMS Starter Kit for Life Science organizations. It explains how TransPerfect prepares customers to adopt a GlobalLink CCMS system, including preparation of People and Content to adjust to a more efficient and cost-effective process for producing highly accurate content in a regulated environment. It then describes how GlobalLink CCMS modules are pre-configured with templates, workflow, and permissions designed specifically for the needs of Life Sciences organizations. It also explains how GlobalLink CCMS modules connect seamlessly into the GlobalLink Globalization platform itself.

2 PREPARING PEOPLE AND CONTENT

When a Life Science company acquires a GlobalLink CCMS system, TransPerfect's initial effort is always with the people who will work in the system every day. We begin with a service call **Process Refinement**, which includes the following activities:

- The GlobalLink CCMS Content Consulting Practice studies the client's existing content lifecycle practices, looking at how content teams have implemented daily, weekly, and monthly procedures to satisfy regulatory requirements.
- GlobalLink consultants then map out those tasks and reports that are automated by the GlobalLink CCMS system.

  RESULT: the client receives a customized roadmap marking the ways in which the GlobalLink CCMS reduces manual, error-prone activities while still collecting and delivering the necessary controls and audit trails required by regulatory bodies.

[1] XML: eXtensible Mark-up Language. It allows organizations to encode content in a layout-neutral, vendor-independent format that is easy to translate and transform into specific types of output.

Once people are comfortable with the roadmap, TransPerfect leads the customer through three activities that prepare content for use in the GlobalLink CCMS system. These activities are as follows:

- **Information Modeling**: Consultants from the GlobalLink CCMS Content Consulting Practice map existing content into XML structures.

  RESULT: the client receives as a guide for authors to create and modify content encoded in XML. The client also receives detailed instructions on a Life Science's oriented metadata and content-reuse strategy.
- **Content Conversion**: GlobalLink consultants convert the customer's existing data into XML-encoded data. Consultants and the client work together to ensure that conversion rules generate content that loads efficiently into the CCMS.

  RESULT: the client's content is ready for import into the GlobalLink CCMS system.
- **Content Migration**: GlobalLink consultants manage the import of the customer's content into the GlobalLink CCMS system.

  RESULT: Files are available in the CCMS with all reuse references intact and with content placed into folders according to the client's requirements.

3 CONFIGURING SOFTWARE AND TEMPLATES

As People and Content are preparing to adopt a GlobalLink CCMS system, TransPerfect's GlobalLink CCMS Operations personnel are configuring the CCMS for operational use. Configuration activities comprise the following tasks:

- **Installing Life Science Content Templates**. TransPerfect has content templates for the following package inserts: patient information leaflet (PIL) or instructions for use (IFU)[2], and summary of product characteristics (SmPC) or prescribing information (PI). TransPerfect also has templates for informed consent forms (ICF). Customers may adjust logos, fonts, and colors in a template without altering the validation status of the template or its content.
- **Installing Output Templates for PDF and HTML**. GlobalLink CCMS systems are preconfigured to generate PILs, IFUs, SmPCs, PIs, and ICFs. Output may be as a PDF or as an HTML file, and the layout of each output will be correct for all languages in which the output is generated.

  NOTE: all output complies with emerging standards for electronic versions of paper documents.
- **Configuring a regulatory-compliant Workflow**. GlobalLink CCMS systems include a standard workflow comprising the following content states: Draft, In Review, In Rework, Pending Acceptance, Accepted, Pending SOR[3] Approval, Approved. Furthermore, the GlobalLink CCMS is configured to capture an **electronic signature** as content moves into the Approved state,

[2] In the United States, labeling for patients and/or caregivers includes "Medication Guides", "Patient Package Inserts", and "Instructions for Use". This document uses "Instructions for Use" as a synonym for all three designations.

[3] SOR: System of Record

- **Configuring roles and permissions**. TransPerfect creates roles for authors, reviewers, translation coordinators, and content publishers. The CCMS automatically tracks all activities by any user operating in any of these roles. Furthermore, the CCMS ensures that a user inhabits at least one role and also cannot perform any operation without inhabiting a specific role.
- **Configuring reports required by regulators**. TransPerfect adds the customer's logo to standard reports that showing that required corrections have been completed and that all internal reviews have been completed. The CCMS also allows an approver (or an external auditor) to display the change history of any content.
- **Connecting to GlobalLink Project Director**. When a Life Science customer operates the GlobalLink CCMS system as part of the GlobalLink Globalization platform, TransPerfect's GlobalLink CCMS Operations personnel configure the connector that joins the GlobalLink CCMS to GlobalLink Project Director. The connector allows a translation coordinator working in the CCMS to send translation projects directly to Project Director. The connector also provides automatic updates on progress of the translation project directly to the CCMS user interface. A translation coordinator may also update or cancel an in-progress translation project from the CCMS user interface.

4 TRAINING AND ON-GOING SUPPORT

Once its People, Content, and the CCMS are prepared, a Life Science organization is ready to into production with a GlobalLink CCMS system. TransPerfect aids this transition with training and on-going support. Training covers these subjects:

- Guide for data input and composition (style guide)
- Workflow states and what they mean
- Customizable items (logos, colors, font)
- How to locate and link to reusable content
- Sending content for translation

NOTE: Training sessions extend over several days and may be recorded for later reference.

TransPerfect also organizes regular check-in meetings with the client. These meetings, which usually happen weekly when a customer goes into production and change in frequency as the client so decides, allow TransPerfect and the client to discuss and resolve specific system-adoption and production-operation issues, or examine and refine best practices for workflow and content usage.