

KB COMM Project Profiles

Assessing, Mapping, and Rewriting Quality System Documentation

Industry	Pharmaceutical Manufacturer
Problem	Quality system documentation for the client's global IT function was incomplete and poorly structured and organized, resulting in findings in an FDA audit.
Solution	<p>A visual map was created to logically depict the processes and sub-processes supporting the quality elements identified in the Quality Manual.</p> <p>All quality system documents were analyzed and categorized according to the processes and sub-processes they supported. Individual maps were then created to visually depict all the documents related to specific processes and sub-processes. Gaps, inconsistencies, redundancies, and obsolete documents were identified.</p> <p>Procedures and work instructions were rewritten to improve comprehension and usability. The restructured documents were shorter and more modular, making it easier for readers to quickly find the instructions they need to complete specific tasks.</p> <p>Guidelines for writing policies, procedures, and work instructions were developed to explain the different types of documents in the hierarchy and the information and level of detail that should be included in each.</p>

Developing a Product Installation Guide from Illustrations

Industry	Specialty Window Manufacturer
Problem	European manufacturer seeking to introduce product line in North America needed a product installation, use, and safety guide with step-by-step, written instructions. Their current guide consisted entirely of illustrations, which did not adequately address the complexity and safety issues associated with product installation and use.
Solution	Developed a detailed guide for safely installing and using the product, working solely from illustrations and phone conversations with technical staff in Europe.

Developing a Communication Style Guide

Industry	Healthcare Diagnostics Manufacturer
Problem	Communications varied in style, structure, and voice; used product and business names, trademarks, and other terminology inconsistently; and contained compositional, grammatical, and punctuation errors.
Solution	Developed a communication style guide for the enterprise that specified correct usage of names, trademarks, and terminology and addressed the most common compositional, grammatical, and punctuation errors.

Providing Ongoing Editorial Desk Services

Industry	Healthcare Diagnostics Manufacturer
Problem	Sales and marketing collateral produced for different product lines varied considerably in style, structure, and voice, resulting in inconsistent and sometimes confusing presentation of the company's products, services, and brand to the marketplace.
Solution	Established an Editorial Desk service through which all the global enterprise's sales and marketing collateral is routed prior to publication. Documents are reviewed and edited for consistency in style, structure, voice, and compliance with corporate publishing standards, as well as for grammar, spelling, and punctuation. The service is designed for high-volume throughput, with typical turnaround times from one to two business days after receipt of material.

Based on the its success in improving sales and marketing collateral, the client has since expanded the scope of the Editorial Desk to include all enterprise communications, including customer letters, executive and employee communications, and public relations.

Developing and Delivering Personalized Microsoft Office® Training

Industry	Real Estate
Problem	Client needed to self-produce sales and marketing collateral and web sites using Microsoft Office® applications but lacked the skills to do so.
Solution	Authoring, editing, and formatting tasks were identified, analyzed, and prioritized. Personalized, hands-on training was developed to address the specific tasks and MS Office applications required to produce the desired materials. Training was delivered using the client's hardware and software in a one-on-one, live setting.

Reducing Manual Data Entry in Microsoft Excel® Spreadsheet

Industry	Pharmaceutical Manufacturer
Problem	Extensive and unstructured manual data entry was required to populate an Excel workbook, resulting in reduced productivity and inconsistent presentation of information.
Solution	A data entry form and supporting macros were developed to provide a fast, structured, and consistent way for team members to enter data into the Excel spreadsheets of the workbook. The result was faster, more accurate data entry and consistent presentation of information in the populated spreadsheets.

Developing and Delivering Customized Microsoft Word® 2007 Training

Industry	Pharmaceutical Manufacturer
Problem	Staff members were struggling to author, edit, and format documents after an upgrade from MS Word 2000 to Word 2007. Existing “off-the-shelf” training did not address the unique requirements and tasks of this very specialized documentation environment.
Solution	<p>Document authoring, editing, and formatting tasks were identified, analyzed, and prioritized. Instructor-led, customized training was developed to address the most commonly performed and time-critical documentation tasks. The instructional strategy was to translate or map staffers’ existing knowledge and skills using Word 2000 into the Word 2007 environment.</p> <p>Training was delivered to small groups of 5-6 learners. Sessions were structured to allow plenty of time for hands-on practice, one-on-one interaction with the instructor, and learner questions.</p>

Simplifying Quality System Documentation

Industry Pharmaceutical Device Manufacturer

Problem The policies and methods associated with the Quality Manual were difficult to understand and use, partly because too many cross-references were included.

Solution Policies and related documents were reviewed to identify required information, theoretical and nice-to-know information, and redundant information. A new design for policy documents and easy-to-use templates were developed. The method template included process flow with corresponding steps, responsibilities clearly identified in each step, and only the information relevant to the task at hand.

Three components of the quality system were revamped as a result of the project: Change Control, Validation, and Sterilization. Over 70 procedures were rewritten. The amount of content in the documents was minimized by reorganizing information, eliminating redundancy, and capturing valuable information not essential to a procedure in a separate guidance document.

Streamlining Office Workflow

Industry Veterinary Clinic

Problem The four-doctor practice moved to a larger facility and doubled their staff. Essential procedures were not documented, and there was concern that office workflow would be compromised by the newer, less-experienced staff.

Solution A series of interviews was conducted and the staff was observed performing tasks during peak hours. Findings were documented and recommendations for improving and streamlining critical procedures were developed and communicated.

Coordinating Translation of Technical Documentation

- Industry** Device Manufacturer
- Problem** The existing User Manual needed to be translated from American English to seven languages.
- Solution** The User Manual was rewritten using controlled vocabulary to facilitate translation. Descriptions and procedures were reworked to make them clear, usable, and useful; reduce sentence and paragraph length; and implement consistent use of terminology. A Glossary of terms to be translated was created. Translation firms were identified and RFQs prepared and disseminated.

Creating User Instructions for Employment Web Site

- Industry** High-Tech Manufacturer
- Problem** HR purchased and implemented a new, web-based application for identifying job opportunities and applying for positions. The employment web site proved to be confusing and difficult to use by potential candidates.
- Solution** Developed task-based instructions for using the employment web site to identify job opportunities and apply for open positions. Deployed the instructions as pdf files accessible through a link on the web site.

Creating Role-Based Change Management Training

- Industry** Pharmaceutical Device Manufacturer
- Problem** The Change Management process was complex and difficult to understand and execute. Online training was developed but proved to be overwhelming and inadequate.
- Solution** Designed and developed instructor-led, classroom training to be facilitated by subject matter experts at each plant location. Facilitator guides were fully scripted, so personnel with no experience delivering training could serve as facilitators. Training curricula were role-based and task-oriented, so learners were presented only with information required for the tasks they needed to perform. Training modules included numerous hands-on exercises derived from common change management scenarios, so learners were able to practice performing change management tasks in the context of actual situations they encountered in the workplace.