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Focus on: Terminology management

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Terminology Management

Neglect It At Your Own Peril

by Uwe Muegge

Effective terminology management is an essential risk-management strategy for biopharmaceutical organizations. With a terminology management strategy in place, organizations of all sizes can use the same terms consistently within and across the various documents and labeling that accompany a product or service. Because such documents are typically created in a collaborative environment, terminology management is the most efficient solution for ensuring that the organization as a whole uses the same terms to describe the same features and functions.

With comprehensive, project-specific “termbases” available at the beginning of a project, team members are free from the tedious task of researching terms on their own. The availability of a project termbase also reduces the risk of multiple coworkers inadvertently coining multiple terms for the same feature, which, if undetected, can confuse users or cause unnecessary expense and delays for terminology harmonization later on.

More Efficient External Communication: It is a defining characteristic of the biopharmaceutical industry that its products and services typically have an immediate impact on the lives and well-being of people they treat. So any communication with end users — whether clinicians or patients — must be as comprehensible as possible to ensure that documentation and labeling do not interfere with the intended use of a product or service. Consequently, labeling and instructions



for use must not only be terminologically consistent, but their writers must also use the most common and most easily understood terms.

THE RISKS OF NOT MANAGING TERMINOLOGY

Liability Issues: Without an infrastructure in place for ensuring consistent use of approved terminology by each member of every team that contributes material for external communication, discrepancies between terms are inevitable. Inconsistencies between what users see while interacting with a product and what they find in user assistance texts such as instructions for use, online help, and tutorials can negatively affect their experiences with products or services.

This type of issue should particularly concern the biopharmaceutical industry because usability issues can have serious legal consequences. Even if patients are

unaffected, terminological inconsistencies certainly reflect poorly on otherwise excellent products. Equally important, inconsistent terminology can lead to unnecessary and costly calls to support and customer service centers.

LOST OPPORTUNITIES

Managing terminology does cost money (Figure 1), but not managing terminology can cost even more. By having project-specific termbases in place, companies can ensure that all communicators — including researchers, developers, writers, and translators — use only approved terms. Best of all, compliance with a corporate glossary can be checked using automated tools. Without a glossary, a product, its labeling, and every other text associated with that product must be checked manually for consistency. Because of the complexity of that task, not every inconsistency will necessarily be discovered.

The need to correct terminological consistency in existing documents — and the negative impact that has on a project's budget and release schedule — is not even the worst-case scenario. A postponed launch caused by delays in regulatory approval because of incorrect and/or inconsistent terminology in the submission documents is much worse. I know of a submission that was rejected outright by a foreign regulatory body because of translation and terminology issues, which resulted in lost revenue of several million dollars.

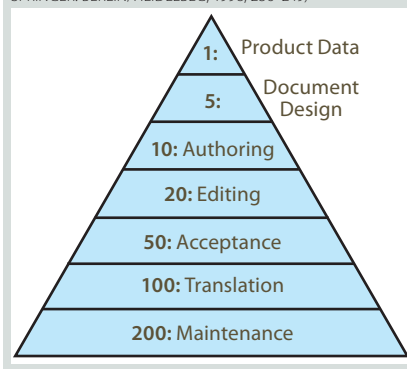
WHERE TO BEGIN?

Terminology Research: It's no easy task to identify words that are important enough to mandate their consistent use within and across documents. If an organization has a team of terminology stakeholders (e.g., representatives from R&D, operations, technical and marketing communications, and legal), then the challenge is to reach consensus among all those groups and interests.

Entry Creation: Once the issue of which terms should go into a termbase has been resolved, the next question to answer is how much additional information to enter. It is debatable whether collecting anything beyond simple term lists makes good business sense. ISO 12620 catalogs almost 200 possible data categories for a terminological entry. At the same time, ISO 12616 lists only three of these data categories (*term*, *source*, and *date*) as mandatory. For many if not most organizations, the most practical solution is a data model made up of fewer than two dozen data categories.

Unfortunately, most companies today have no terminology team in place. Many documents (including specifications, clinical studies, software, instructions for use, regulatory documents, and marketing collateral) are generated by different groups. In such cases, it may be difficult to analyze all documents connected with a launch for consistent terminology. Even if all those documents were available in one place,

Figure 1: Terminology cost pyramid (SOURCE: SCHÜTZ J, NÜBEL R. EVALUATING LANGUAGE TECHNOLOGIES: THE MULTIDOC APPROACH TO TAMING THE KNOWLEDGE SOUP. MACHINE TRANSLATION AND INFORMATION SOUP. SPRINGER: BERLIN/HEIDELBERG, 1998; 236–249)



the sheer volume of text might be too high for human processing.

All major terminology standards treat definitions as an optional data category. Writing a definition can easily be the most time-consuming and expensive part of creating an entry, and the definition is typically also the most valuable part of that entry. This is especially true when a terminology database is being used as the universal knowledge base that it can be. The definition helps technical staff members choose correct terms from a range of options, and it helps new employees understand unfamiliar concepts better than any other information in the entries.

For those who struggle with writing definitions, a terminological definition and an encyclopedic entry are two very different things. A good, standards-compliant terminological definition is a concise statement no longer than one sentence that identifies a more generic group to which a given term belongs and the characteristics that distinguish it from related terms. For example, the term *phytochemical* would be defined as a chemical substance derived from plants.

Termbase Review and Approval:

There simply isn't a way around having subject matter experts review monolingual and multilingual termbases before publication and use. Terminological collections are normative documents that should be used as references by all communicators within an organization as well as by its external vendors of

DEFINITIONS

Glossary: Collection of words that have special meaning in a project

Synonym: Word that has the same meaning as another word

Term: Word that has a special meaning in a given subject field

Termbase: Database that contains a collection of words that have special meaning in a given subject field

Terminology: Collection of words that have special meaning in a given subject field

Terminology management system:

Type of software application that enables users to efficiently collect, process, and present terminology

THE STASH MODEL

Here's a good model for effective outsourced terminology management:

Strategy: Terminology management is part of the overall launch plan for a product, drug, or service

Timing: Terminology development effort is initiated at the earliest possible time

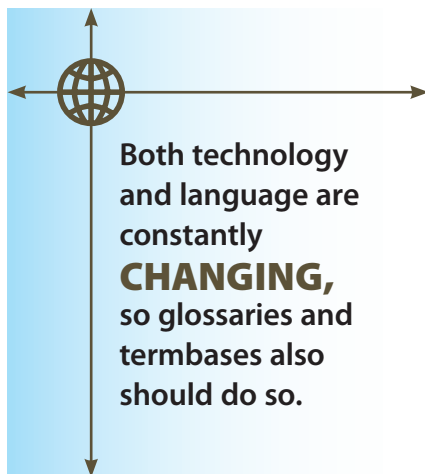
Allocation: Subject matter experts are made available during key phases of terminology project

Selection: Language service provider has experience in terminology management

Hand-offs: Glossary is available as a resource to all internal and external contributors to a launch

communication services such as marketing, advertising, and translation agencies. For that reason, it is imperative that each person familiar with both the domain the termbase cover — and that the sponsoring organization review — and approve each and every entry.

The reviewer's job is to evaluate the accuracy of definitions and, if an entry contains more than one term (*synonyms*), decide which terms are desirable and should be used (*preferred terms*) and which aren't and shouldn't (*deprecated terms*). Translated glossaries should be reviewed by bilingual subject-matter experts who work in the country where the target language into which the glossary was translated is spoken.



Both technology and language are constantly **CHANGING**, so glossaries and termbases also should do so.

Termbase Maintenance: The adage that “the only constant in the business world is change” certainly applies to terminology management. Because both technology and language are constantly evolving, glossaries and termbases also should do so. To be able to provide internal and external communicators with the up-to-date terminology they need, terminological collections must not only be continuously expanded, but their existing entries have to be reviewed and updated regularly.

WHEN TO START A TERMINOLOGY PROJECT

The best time to start developing terminology for a specific project is before the first source document in a global campaign is written. An organization’s terminology “circle” should formalize an initial glossary of new terms for features and functions at the specification stage. Such a glossary will grow and mature as a new product, drug, or service evolves. Initiating terminology management any later, for example by extracting terms from existing documents, inevitably means changing some or all of those existing documents to harmonize their terminology.

That approach would by necessity be expensive and time-consuming. A study conducted in the automobile industry indicates that a terminology change at the maintenance stage (after publication) is 200 more expensive than a change at the product data stage (at the specification stage).

ISO TECHNOLOGY STANDARDS

The International Organization for Standardization (ISO) has created several standards that provide best practices in terminology management.

ISO 704:2000 Terminology Work — Principles and Methods: This 38-page document is an excellent introductory text to terminology management and includes guidelines for writing definitions.

ISO 1087-1:2000 Terminology Work — Vocabulary, Part 1: Theory and Application is another overview text that describes the major concepts used in terminology management.

ISO 12616:2002 Translation-Oriented Terminography provides information on managing terminology specifically for translation environments.

ISO 12620:1999 Computer Applications in Terminology — Data Categories specifies data categories that should be used to ensure easy data exchange among systems that store and process terminology.

Glossary Sources

The following are examples of the many ISO standards that contain monolingual and multilingual glossaries relevant to the biopharmaceutical industries:

ISO 14644-6:2007 Cleanrooms and Associated Controlled Environments — Part 6: Vocabulary

ISO 15225:2000 Nomenclature (specification for a nomenclature system for medical devices for the purpose of regulatory data exchange)

ISO/TS 27687:2008 Nanotechnologies (terminology and definitions for nano-objects: nanoparticles, nanofibers, and nanoplates)

International Standards for Terminology Management: The International Organization for Standardization (ISO) has created several standards that provide best practices in terminology management, as listed in the “ISO Terminology Standards” box. Additionally, many national standardization bodies and governmental and nongovernmental organizations publish extensive domain-specific glossaries that may be helpful in jump-starting a terminology management project.

INFRASTRUCTURE FOR MANAGING TERMINOLOGY

Managing Terminology Internally:

Some organizations have developed sophisticated internal terminology management capabilities. Medtronic (www.medtronic.com) is a good example of a biotechnology company that has spent well over a million dollars on hiring full-time terminologists, developing proprietary software, and translating terminology assets in-house. For multibillion-dollar organizations with local resources in most of the markets they serve, such a model makes perfect sense.

Outsourcing Terminology

Management: For smaller organizations that are less experienced in globalization issues or elements, it may make more sense to use an external vendor for most terminology tasks. These service buyers provide two types of resources to the outsourced relationship: subject matter experts for tasks such as ranking of synonyms (e.g., preferred, admitted, deprecated/do not use) or writing/reviewing definitions and the means for sharing terminological information, typically a searchable site on the organization’s Intranet.

FURTHER READING

Schütz J et al. Controlling Language in Multilingual Documentation. *Proceedings of the 1998 EAMT Workshop: Translation Technology: Integration in the Workflow Environment*, Geneva, Switzerland, 2–3 April 1998. European Association for Machine Translation (EAMT): Geneva, Switzerland, 1998; 55–63.

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