Terminological Precision - A Key Factor in Product Usability and Safety

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Abstract. Precise use of terminology must be a key component in the communication amongst the product team and with end users. It is not a simple goal to have standardized terms used throughout a lengthy development process in which many people with different expertise and at different locations are involved. Terminology tools and processes used by trained terminologists enable precise use of terminology throughout the product life cycle, in all content management systems and by all contributors to the content supply chain.

Keywords: Terminology, precision, usability, terminology management system, life sciences.

1 Introduction

The natural sciences underlying the concepts in the life science industry are precise: Biology, anatomy, physiology, etc. are based on systematic research and documentation, e.g. Carl Linnaeus's nomenclature for plants, the animal kingdom, and the periodic table of elements. These sciences need organization, as organization enables precision. When a pharmaceutical company is developing a new drug or when a medical device maker is designing a new diagnostic tool, precision is a crucial component. Without precision, drugs or devices might not achieve what they are intended to, might need to be recalled, or might even harm a patient.

Precision must also be a key criterion for communication, for instance, with a patient using a medical device. Accurate communication on a small user interface depends on the correct and consistent use of technical terminology. It is not a simple goal to guarantee the usage of standardized terms throughout the device development process, though: Many contributors are involved; development might take months, if not years; documents are prepared in different systems, by different stakeholders, and in different locations.

Well-defined naming and solid documentation practices, a trained stakeholder in charge of maintaining technical terminology and a terminology management system (TMS) accessible to all project participants are critical for consistent and user-centered terminology. They provide the organization that enables reliable delivery of seemingly simple, yet highly complex products.

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After two illustrations of problems caused by unmanaged terminology in a life science field, this paper presents how precise communication with end-users can be successfully supported through terminology management practices. It describes what terminology management is and how it correlates to the product development cycle.

2 Definitions

Precision is a term with many meanings. For the purpose of this paper, precision is defined as "the quality of being sharply defined by virtue of exact detail" [1].

The language used on the user interface (UI), in supporting documentation or in instructional material falls into the category of language for special purposes. LSP is the "language used in a subject field and characterized by the use of specific linguistic means of expression [which] always include subject-specific terminology and phraseology" [2]. Examples for subject fields in life science products are medical specialties (e.g. cardiology), but also computer science in cases when the terminology appears on or refers to a device UI.

The main vehicle for transferring knowledge from a device or pharmaceuticals manufacturer to the patient is terminology. Terminology is defined as "the collection of designations, i.e. terms, appellations and symbols, belonging to a language for special purposes" [2]. Examples are 'sphygmomanometer, 'Federal Drug Administration' and ⚠, respectively.

As shown in the semiotic triangle (see in [3] and others) below, a designation, for example 'sphygmomanometer', represents a concept. In order to communicate effectively about concepts, humans agree on definitions ("A pressure gauge…" [4]).

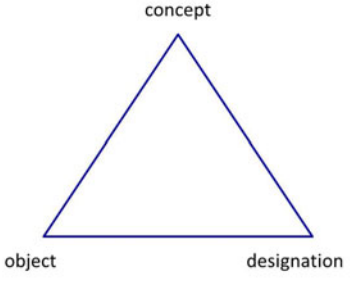


Fig. 1. Semiotic triangle

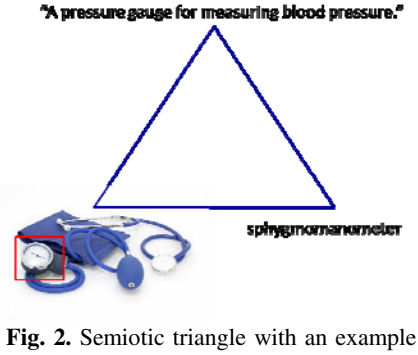


Fig. 2. Semiotic triangle with an example for a term, the corresponding object [5] and definition [4]

Terminologists use terminology principles and methods to document concepts and their corresponding designators in databases for reuse by others in written and spoken communication. The goals of managing terminology are, among others, to enable fast and safe use of a product, and to minimize additional research, misunderstandings and ultimately cost.

3 Why Terminology Management

While misunderstandings in every-day language can lead to amusing outcomes at best, misapprehensions in LSPs can result in production delays, in recalls and potentially in disasters. As the product moves through the different product life cycle stages, content is handed off to different people. R&D might have included writers and editors, for example, but even these content publishers are slightly more removed from the conceptual phase. They will hand off finished or semi-finished content to translators who are even further removed from the conceptual origin of a new device.

All of these "senders of communication" face the challenge of writing or speaking about product concepts clearly and consistently and in the language of the receiver, so that the message can be understood. Creating clear and consistent strings on a device with a user interface is a particularly daunting task, as space is limited. UX design expert, Everett McKay, not only stresses the importance of user-centered design, he says "[f]ocusing on effective communication is the single best user-centered design technique [6]".

Without a terminology strategy, problems are inevitable. Misnomers and inconsistencies are two of the most common problems. Incorrectly labeled functions, inadequately abbreviated buttons or simply poorly motivated terms are examples of misnamed concepts. Users may be slowed down in the use of the product, may need to research before using the product, may not use the product or may use it incorrectly. Specifically the latter presents a high risk for manufacturers of life science products.

According to a recent survey conducted by the International Network for Terminology, TermNet [7], inconsistent terminology is the number one factor impeding writers, editors, translators, etc. in the US information and communication technology (ICT) sector. 83% of the survey respondents said that inconsistencies between documents or within documents are consuming their time. Three participants even said that they have experienced product recall due to terminology issues. The following are examples of faulty terminology leading to incorrect study results and to a recall.

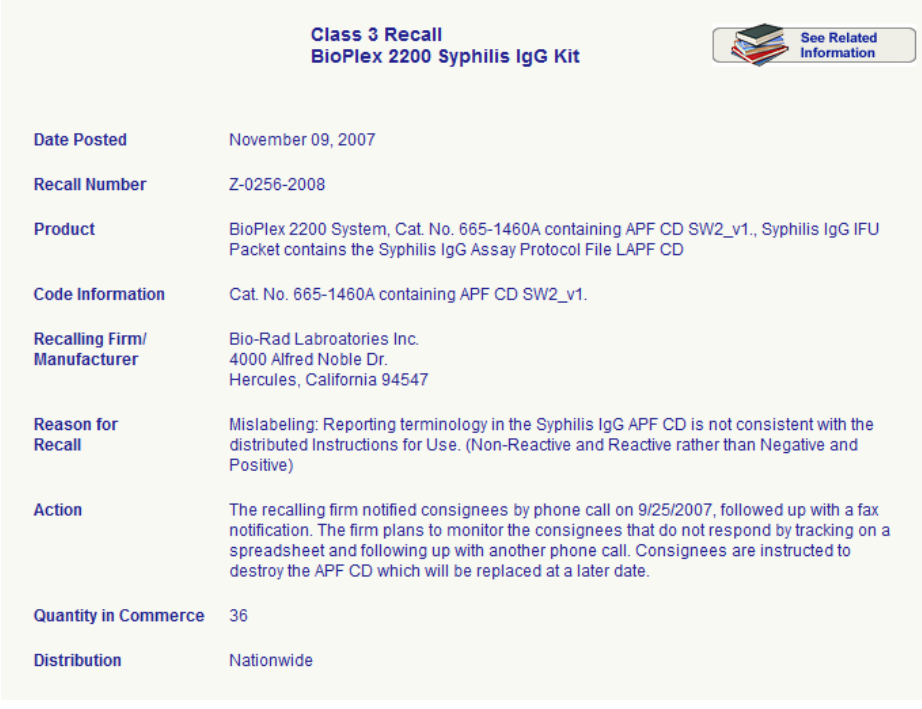
3.1 Misunderstandings

The Redbook guidance document by the Food and Drug Administration [8] recognizes the importance of defined and standardized terminology. The section "Inconsistency in Applying Diagnostic Terminology" lists the following real example:

"A study was submitted in which tissues from about one-third of the animals were evaluated by the study pathologist and the remainder were evaluated by a consulting pathologist. The diagnostic terminology was not consistent between pathologists and no attempt was made to explain the inconsistencies in the study report. Although the data appeared to show treatment-related effects, these were subsequently attributed to the way different categories of lesions were summarized." [8]

3.2 Recall Case

The FDA's recall database for medical devices contained the following instance of a recall due to a terminology error in January 2011. As Figure 1 shows, "reporting terminology in the Syphilis IgG APF CD is not consistent with the distributed Instructions for Use. (Non-Reactive and Reactive rather than Negative and Positive)"[9].



Class 3 Recall
BioPlex 2200 Syphilis IgG Kit

See Related Information

Date Posted	November 09, 2007
Recall Number	Z-0256-2008
Product	BioPlex 2200 System, Cat. No. 665-1460A containing APF CD SW2_v1., Syphilis IgG IFU Packet contains the Syphilis IgG Assay Protocol File LAPF CD
Code Information	Cat. No. 665-1460A containing APF CD SW2_v1.
Recalling Firm/ Manufacturer	Bio-Rad Labroatories Inc. 4000 Alfred Noble Dr. Hercules, California 94547
Reason for Recall	Mislabeling: Reporting terminology in the Syphilis IgG APF CD is not consistent with the distributed Instructions for Use. (Non-Reactive and Reactive rather than Negative and Positive)
Action	The recalling firm notified consignees by phone call on 9/25/2007, followed up with a fax notification. The firm plans to monitor the consignees that do not respond by tracking on a spreadsheet and following up with another phone call. Consignees are instructed to destroy the APF CD which will be replaced at a later date.
Quantity in Commerce	36
Distribution	Nationwide

Fig. 3. Entry in the Medical Device Recall Database of the US Food and Drug Administration [9]

In this case, the terminological inconsistency does not even appear to be major, after all the faulty terminology is semantically very close to the intended terms. It is easy to imagine more grave errors. At a minimum, recalls cost time and money. They could cost reputation, licenses, and, if not carried out successfully, ultimately lives.

4 Terminology Management

Terminology management is the systematic research, documentation and reuse of concepts and their terms [3]. When new concepts are first developed and described, a terminologist helps the subject matter experts, e.g. a team of cardiologists, coin designations and documents information about it in a terminology management system (TMS). Anyone, from the research staff to the writer to the translator, can then

access the centralized database and use correct terminology consistently. The following is a brief overview over skills, tools and processes necessary for successful research, documentation and reuse of standardized terminology.

Skills. Terminologists fall into two categories: The subject matter expert who has the technical knowledge of the subject area as well as enough awareness of terminology methods and principles; and the trained terminologist who has the research skills to quickly get into a subject matter [10]. There are two-year master's degree programs as well as certification programs (e.g. ECQA Certified Terminology Manager). Some of the most important terminology (vs. subject matter) skills are:

- Solid understanding of terminological and terminographical working methods
- Linguistic skills in one or more languages
- Tools and computer skills
- Problem solving and research abilities
- Communication, networking, and social competencies

Companies, such Scania, VW or Siemens, organizations, such as the European Patent Office or the European Commission, and national language centers in Finland, Sweden or Ireland have a terminologist or small teams of terminologists who support the content supply chain with expertise, for example, in term formation and terminology data management. To enable data interoperability, they are also familiar with terminology management standards set forth, for instance, in ISO documents created by Technical Committee 37.

Tools. Terminology management systems (TMS) are software applications that run on top of a relational database. One of the main criteria for a TMS is that it is concept-centered. That means that a concept, indicated by its unique ID and a definition, is the main entry. Attached to it are the designators that stand for the concept. In our example that would be the terms "sphygmomanometer" or "blood pressure meter," depending on the needs of the users and the agreed upon (=standardized) usage. It could also have the terms "Blutdruckmessgerät" for German or "tensiomètre" and "sphygmomanometer" for French attached to it in a multilingual setting.

The software interface is generally designed for the terminology expert who prepares data which is then used in content management systems, translation memory tools, machine translation systems, etc. While there are several commercial tools available, particularly software companies, such as SAP, IBM, Microsoft or Oracle, created proprietary solutions.

Processes. There are various ways to break down the terminology management process. The expert team responsible for the best practice guide of the German terminology association, *Deutscher Terminologie Tag e.V.*, lists the following four phases [11]: Terminology production, preparation and distribution, use, and maintenance.

- Terminology production is characterized by the identification of existing and the creation of new concepts. Terms that represent these concepts are collected, and new terms or names are created.

- During the terminology preparation phase, concepts and terms are being standardized and documented in a TMS along with metadata, such as definition, part of speech, context, or subject.
- As soon as the terminological entries in the database are stable, they can be released, and writers, editors, and translators among others access and use them.
- Some terminological entries might need to be changed because errors are detected or new information is available. This happens during a maintenance phase of an entry.

The main outcome of the process, established by applying the skills and in the terminology management system, is entries, such as the example in Figure 2 [12].

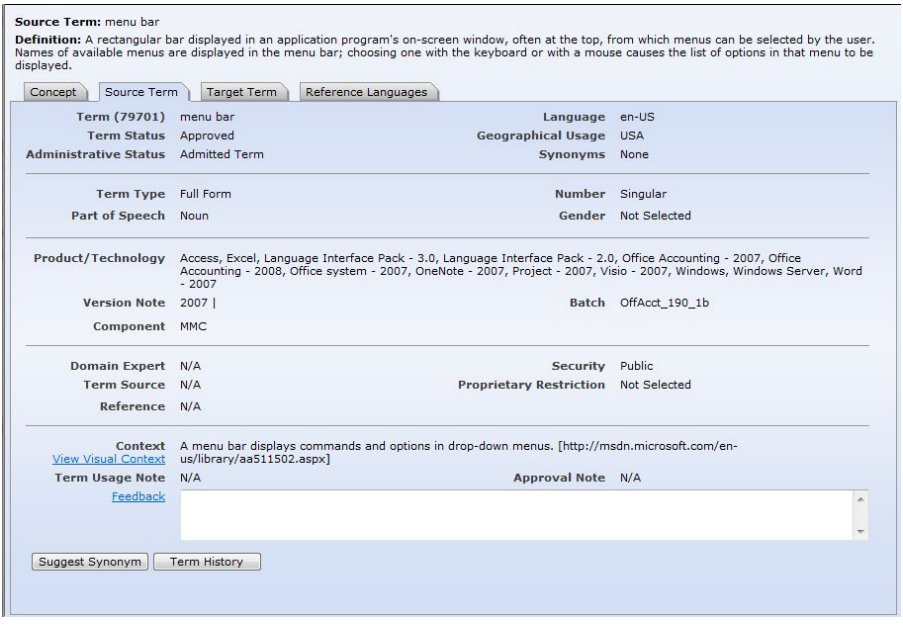


Fig. 4. Terminological entry for "menu bar" in a TMS [12]

5 Terminology and the Product Life Cycle

Depending on the industry and the device, product life cycles (PLC) take slightly different forms. This section describes how the product life cycle and the terminology life cycle are intertwined.

Figure 3 is a PLC model created by the FDA for medical devices. The phases Concept, Prototype, Preclinical, Clinical, Manufacturing, Marketing, Commercial Use, and Obsolescence are combined into Phases I, II and III below to facilitate discussion. During these phases, a variety of documents are created. The most common ones are: requirements documentation, design documentation, technical documentation, user documentation, and marketing documentation. Table 1 juxtaposes the approximate phases with the documents they produce.

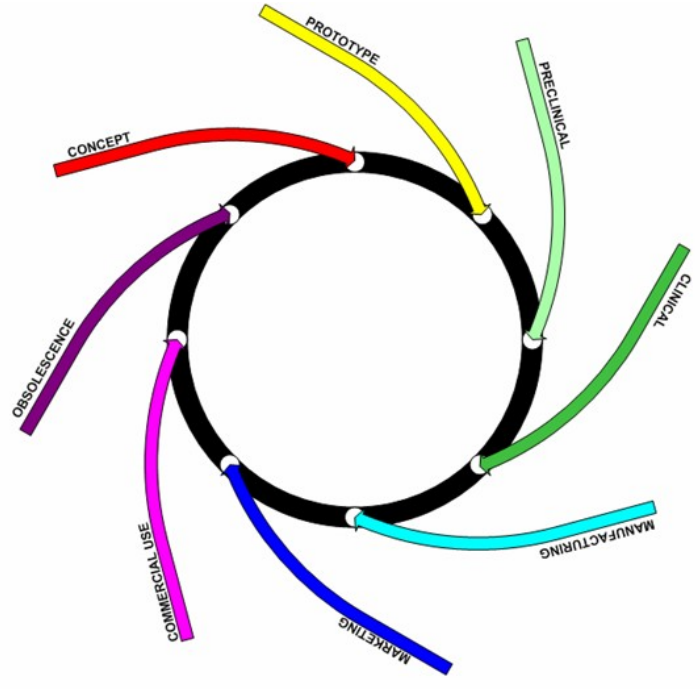


Fig. 5. Model for the total product life cycle by US Food and Drug Administration [13]

These documents contain technical terminology that is at different levels of stability during the PLC phases. Stability, for our purposes, is the quality of being free from change. Ideally, terms are stable from their inception; realistically, stability should be reached before a document is released either to the final consumer or the next step in the workflow (e.g. from content publishing to translation), so as to minimize costly changes. The next three paragraphs detail out the phases and their terminology cycle, followed by an overview in table format.

Table 1. Phases of the PLC and documentation created during these phases

Phase category	PLC Phase	Documentation
I	Concept	Requirements
	Prototype	Design
	Preclinical	Technical
II	Clinical	User
	Manufacturing	Marketing
	Marketing	
III	Commercial use	Marketing
	Obsolescence	

Phase I. Medical researchers, anthropologists, and other experts gather and analyze data. Terms and names designating these concepts might come up during patient interviews, field studies or literature reviews. They are used in drafts for requirements, design and technical documents with the understanding that they may still change. This is the phase were valuable conceptual expertise is present, but the product in all aspects, incl. terminology, is most in flux. Terminology stability is low.

Phase 2. Once problem analysis is concluded and development of a solution is well on its way, naming gets firmer. Specific attention must be placed on terminological choices on small user interfaces. Consistent and natural language is critical to usability. This is the phase when user and marketing material is written: Terms, names and labels must be locked in and documented in the TMS for everyone to use consistently. Now is also the time to research and document terms in other languages to prepare for translation. Pre-set terminology is distributed to all translators who use it during the translation of the product and all accompanying material. Questions regarding additional terms are answered and documented in the database.

Phase 3. During commercial use and obsolescence, tests for the next version of a product or a completely new product will start. Terminological problems or insufficiencies might emerge and should be noted in the terminology management system, so that better terms and names may be used in the future. Terms in the existing product are obviously not changed and stability is therefore high.

Table 2. PLC, the terminology process and stability

Phase	PLC Phase	Documentation	Terminology process	Terminology stability (ideal)
I	Concept	Requirements	Production	Low
	Prototype	Design	Production	Low
	Preclinical	Technical	Documentation, use and feedback	Medium
II	Clinical	User Marketing	Documentations, use and feedback	Medium
	Manufacturing		Use	High
	Marketing		Use	High
III	Commercial use	Marketing	Use and maintenance	High
	Obsolescence		Use and maintenance	High

6 Conclusion

Terminology errors can spoil lab data or lead to recalls. Even when they are caught before release of a product, they cause costly disruption of the content flow. And even if company terminology is locked down and documented, official FDA terminology might undergo changes, which might come during any phase of the PLC, worst of all just before release.

A terminologist may be a full-time or part-time role on the team. It may be a subject matter expert with terminology skills or a terminologist with subject matter expertise. But a database must be kept up-to-date to get the most return on

investment. Depending on the length of the product life cycle, the number of products and languages managed in the database and the number of users it supports, coordination can be done by one person or a team.

Concept-based terminology management systems allow database users to select the correct term for the target audience of their message. That may be "sphygmomanometer" when experts are communicating about the gauge only; it maybe "blood pressure meter" when the content of a blood pressure kit is described in the user documentation; or it might be "the cuff" when a nurse refers to the measuring device to a patient. Precision is user-dependent.

When precision is not present, errors will occur, if not in the source language, very likely during the translation process. A translator relies on the source material to be precise and error-free. If the text reads "cuff" when the entire blood pressure kit is meant and it is not clear from the context, the translation will be faulty. It is of utmost importance that terms and names be tracked in a database from the concept phase on and used by everyone correctly and consistently.

The above is an oversimplified process flow that in reality is impacted by tight deadlines, unexpected changes in the development cycle, and the number of stakeholders. Appropriate workflows, supported by trained terminologists and well-designed terminology management systems speed up the development process, reduce documentation and translation cost, and last, but not least, lead to precise terminology. Precise terminology as part of a products user-centered communication results in safer and more usable products and devices.

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