McCulley/Cuppan Inc.
Enhancing regulatory communication through best practices

McCulley/Cuppan Document Standards

The standards below comprise what we at McCulley/Cuppan consider important attributes of documents developed by life science research and product development organizations. We rely on these standards when reviewing and evaluating the communication quality of documents. We have refined these standards over many years of supporting organizations in their quest for high quality research reports and registration dossiers for medical products. With appropriate modifications, we also apply these standards to the various technical and scientific documents that support the product development life cycle.

High quality documents are clearly attentive to purpose, audience, and situation:

- **Purpose** drives document development, review, and revision. What does the author/organization hope to accomplish with the document? What kind of work is the document performing? What is a successful outcome for the document?
- **Audience** suggests respect for those who must review, engage in tasks, make decisions, challenge decisions or claims, or approve some aspect of a product development program. Documents are used by professionals of varying levels of expertise, who enter at different stages of document and product development. These document users arrive with specific purposes for reading the document and take highly divergent approaches to how they engage with a document. A high-quality document is designed to facilitate highly variable reading processes, thus allowing readers to accomplish their individual purposes. Attention to audience leads to documents that support readers in the complex tasks of evaluation or work performance.
- **Situation** conditions all actions and decision making. Individual research or development documents often exist as part of large document sets that capture the history of development and must be presented to regulatory agencies to support requested marketing claims and licensure. They may be parts of large libraries of electronic documents closely reliant on extensive data sets. Very often these documents exist within a complex web of textual and statistical information.

Table 1   Document Standards - *Developing Clear Messages*

Standard	Criteria
Focus	Effective writing establishes a primary focus and sustains that focus throughout the document, section, or paragraph. Focus answers the question "so what?" Focused writing is attentive to the situation: • The primary audiences, their knowledge levels and concerns. • The purpose of the document relative to what role the document must play for the primary audience in terms of facilitating knowledge acquisition, task performance, or decision making. • The role a document may play within a family of related documents. • The challenges of analyzing and using large, complex, data-rich documents. Focus is the standard that drives all aspects of writing: • Organizational structure, level of detail, sentence length, and word choice. • Identification of anticipated reader questions that are resolved with clear messages in appropriate locations. • Conformance to relevant guidance.
Logic	A research document presents a clear logic trail. A clear logic trail makes the document coherent: • The goal/question(s) the reported work is intended to address are presented in explicit terms in the document introductory section. • Objectives (specific and measurable tasks) are explicitly stated early in the document. • Measured endpoints or parameters are defined for each objective, along with the assessment standards and analysis methods. • Results are presented for all defined endpoints/parameters. • Discussion is focused on conduct of study, including data collection and analysis. Discussion provides explicit conclusions about achievement of each study objective. • A focused "so what" statement is made at the end of the document that explicitly links to the goal/question(s) established at the beginning of the document and establishes the practical, medical, scientific, or technical merit of the work. All "so what" statements are supported by evidence and justified by reasons based on an appropriate warrant that explains why the data proves the claim. Study design and data interpretation decisions are justified with explicit rationales.
Content	The information in the document is: • Complete – includes everything necessary to support the logic trail. Provides sufficient study data to support interpretation and decision making. • Relevant – connects details to focus and objectives. • Precise – applies appropriate and consistent degrees of exactness given the focus of the work. • Accurate – contains no factual errors, contradictions, or inconsistencies.

Standard	Criteria
Context	An appropriate level of contextual information enables document users to place a section or document within the proper interpretive framework. Useful supportive information provides the context for understanding, interpreting, and accepting (or rejecting) document content. Depending on the document, useful context might include summaries of regulatory interactions, citations from regulatory guidance, the local knowledge of the scientific team gained during development, or confirming or disconfirming results from internal or published studies.

Table 2   Document Standards - *Making Messages Accessible*

Standard	Criteria
Organization	Document sections are organized with main messages, summary statements, or conclusions at the beginning of sections and paragraphs. Advance organizers are used across a document to reinforce focus by providing the reader with explicit statements on purpose and scope of an upcoming section. Within the conventions of established genres, the document is organized to accommodate reader needs and expectations. The document organization facilitates rapid information processing through multiple entry points. The organization supports navigating, skimming, scanning, seeking, comparing, answering questions, and evaluating relationships.

Presentation	Information is presented in the most appropriate form (text, table, or figure).
	• Page layout is appropriate for the document genre and makes information easily accessible.
	• Format (bullets, boldface, etc.) consistently emphasizes important details.
	• Visual displays (tables and figures) answer reader questions, emphasize or clarify important points, and offer interpretive comments that focus readers on key elements.
	• Visual displays attend to the following principles:
	  • Each display can stand on its own, with a full legend, clear labels, descriptive title, and an explanatory caption and notes as appropriate.
	  • Each display has a strong ratio of data/ink. Ink should be removed from the display to allow the meaningful relationships among the data points to emerge. The message should be salient—the trend or importance of the data should quickly become clear to the viewer. Tables should minimize the use of rules to demark table cells. Figures, plots, and other visuals should be scaled to enable the reader to see, interpret, and understand all elements.
	  • Each display can function robustly across presentation media.
	  • Each display is designed to be consistent with other displays in a document

Language	Language is appropriate for the document genre and audience. The language helps document users understand the content on first reading. The writing applies the principles of plain scientific English: • Sentences are compact, focused, and emphatic. • Sentences deliver clear, unambiguous meaning though active voice, strong subject-verb-object patterning, and effective subordinate and parallel structures, • Plain language favors phrasings, abbreviations, initialisms, and word choice appropriate to the expertise of the primary reading audience.