

Statement of Qualifications



McCulley/Cuppan LLC

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McCulley/Cuppan LLC

- We have been in business since 1993.
- We focus on writing and documentation work practices as applied in Pharmaceutical R&D.
- We examine the *practice* of document development not the *process*.
- We work extensively with CMC and Clinical regulatory documentation.



McCulley/Cuppan Experience

- We have worked with over 50 pharmaceutical companies worldwide.
- We have worked with more than 40 project teams in all the major therapeutic areas.
- We have developed customized training solutions for over 25 clients in the US, Europe, and Japan.
- We have reviewed and written hundreds of regulatory documents.
- We have consulted to FDA on improving writing quality and meeting management.
- We have conducted numerous interviews with regulatory authorities regarding submission document usability.



McCulley/Cuppan Consultants

- We work with trained scientists in various medical and CMC areas.
- We are experienced communication experts with knowledge in product development, compliance, clinical research, regulatory management, technical communication, information design, collaborative writing, and training development.



McCulley/Cuppan Services

- Consulting
- Special Projects
- Skills Development Workshops



Intended Services Outcomes

- Improved problem-solving skills
- Improved writing and planning processes
- Improved review processes
- Improved understanding of document quality
- Improved documentation outcomes
- Improved productivity



Consulting

- Our consulting services are focused on improving document quality, development processes, and skills.
- We define problems and develop solutions to a wide range of documentation problems.



Special Projects

- Our tools and processes help drive projects and quality improvement programs for better document outcomes.
- We coach project teams to develop new skills and processes or we support teams when extra resources are needed.



Skills Development Workshops

- Our skills development workshops are tailored to the specific needs of our clients.
- We base all our training on adult learning principles to maximize outcomes.
- We ensure new skills and approaches are transferred immediately to the workplace.



McCulley/Cuppan Key Objectives

- To help clients exploit and improve the document development process
- To help clients understand and build quality documentation
- To help clients take an issue-focused and message-driven approach in documents



Exploit and Improve the Document Development Process

- By sharing information to create consensus, define positions, and finalize decisions early in the process.
- By planning and prototyping documents to keep document focused on key issues and ensure messages are displayed in prominent positions.



Help Clients Improve Document Quality

- By using document standards
- By applying well defined document development processes
- By conducting usability analyses
- By analyzing and improving work practices



Make Documents Issue-driven and Message-focused

- By defining issues, responses, and rationales
- By keeping track of the target package profile and evolving issues and responses
- By identifying and resolving gaps in support of the label or development issues
- By placing key messages in prominent positions



McCulley/Cuppan Approach

We use writing as a *conceptualizing*,
constructive activity versus simply as a
recording activity.



Objectives of this Approach

- To help organizations become more aware of their own “thinking and doing processes.”
- To convey the concept of quality thinking leads to quality writing.
- To present writing as a tool that helps clarify and invoke better thinking or reveal flaws in the thinking, scientific design, or argument.



We Help Our Clients

- Improve productivity through the use of writing tools.
- Understand document quality and how to create it consistently.
- Apply work processes that ensure high quality documents.
- Reduce review cycles and late-stage rework of documents.
- Use a mapping tool to define messages, issues, responses, and support for development programs.
- Maximize the value of research data through effective documents.
- Evaluate documents to establish strengths and weaknesses.
- Promote a structured, team-based approach to document development.
- Exemplify high quality writing through the use of model reports and other reference tools.
- Migrate documentation outlines and templates to a highly usable, CTD-compliant format.

