

# Writing for the Regulatory Reader

## ***Learn How to Effectively Communicate in the Documents You Write for the Regulatory Reader***

### **Webinar Description**

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<b>Webinar Audience:</b>	Research and development professionals who must write or review scientific, technical, and regulatory documents
<b>Webinar Purposes:</b>	To learn how reviewers at FDA and other regulatory agencies read and use your documents so that you can write more effectively for this business critical audience
<b>Webinar Length:</b>	One hour
<b>Webinar Design:</b>	90% presentation and 10% discussion utilizing examples and case histories presented through PowerPoint slides and PDF exhibits
<b>Session Dates:</b>	Various dates available, 12:00-1:00pm Eastern Standard Time

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### **Webinar Outline**

#### **Characterizing the health authority reviewer as a reader**

This portion of the webinar examines the characteristics of the health authority reviewer as a reader of scientific and technical documents submitted by industry.

- Characterizing the task-oriented reader versus other methods of reading
- Characterizing the on-screen versus paper reader
- Representing the coordinate reading style of the health authority reviewer
- Writing for the deconstructionist style of the health authority reader

#### **Consider the differences of writer-centric versus reader-centric documents**

This portion of the webinar will discuss document writing and design actions that support the health authority reviewer reading style.

- Writing issue-driven, message-focused scientific and regulatory documents
- Constructing the logic of your work in a reader-centric approach
- Understanding the importance of constructing logic trails for the reader
- Presenting information to the busy reader: organizational considerations
- How to avoid causing *information anxiety* in your regulatory reader

## About your speakers

### Gregory Cuppan

Greg is the Managing Principal of McCulley/Cuppan LLC, a group he co-founded. He has spent 15 years providing consulting and training services to pharmaceutical and medical device companies and research enterprises. Greg has personally interviewed dozens of regulatory agency staffers regarding the task of reading and using the documents submitted by drug and device sponsors.

### Philip Bernick

Philip, a senior consultant with McCulley/Cuppan LLC, has spent his career focused on improving the communication quality of complex, task-oriented documents like those submitted to regulatory agencies. Philip's expertise extends to best practices in documentation and document quality management, helping individuals and organizations improve the quality of documents.

## How to register for the webinar

Visit our website <http://www.mcculley-cuppan.com/regulatoryreaderwebinar.html>.

- 1) Complete the registration form for each registrant and click Send.
- 2) A member of our E-Learning Program staff will contact you to complete registration and process payment.

Following your registration, you will receive an emailed confirmation that includes connection instructions for the webinar.

## About McCulley/Cuppan

McCulley/Cuppan provides a full range of consulting, training, and writing support to the pharmaceutical R&D industry.

- We have worked with over 60 pharmaceutical and biotech companies worldwide.
- We interviewed, trained, and worked with the FDA to help medical officers improve the quality of their documents and document development processes.
- We have developed and conducted customized training programs and workshops for over 4000 scientists worldwide.



McCulley/Cuppan LLC  
970 Murray Holladay Road, Suite 3B  
Salt Lake City, UT 84117, USA