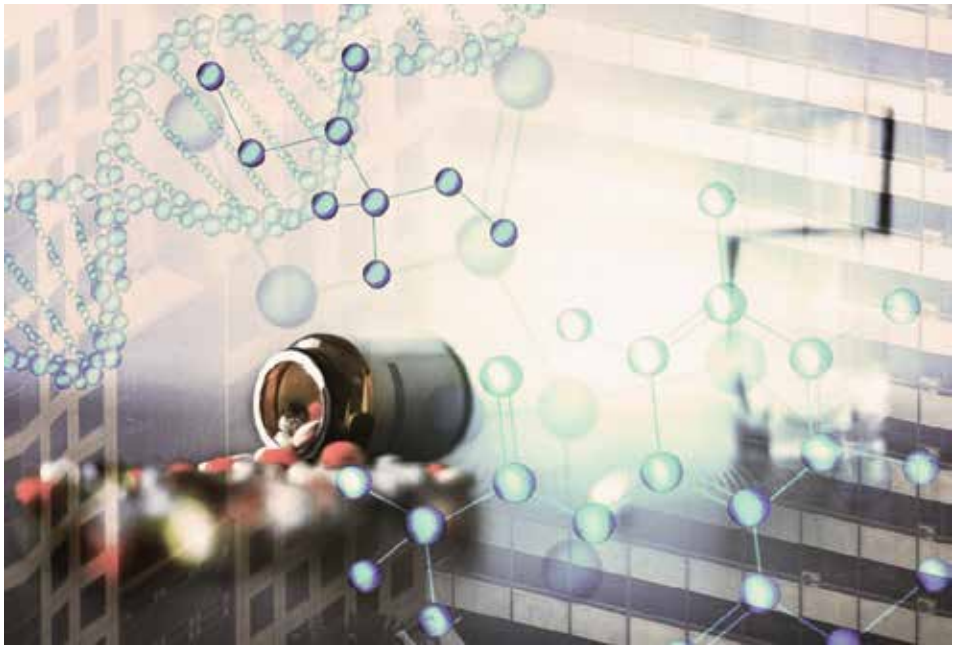
Compliance Online
The Largest GRC Advisory Network

2-Day In-Person Seminar

Technical Writing for Pharma, Biotech and Med Devices

By: **Mark Powell,** Director, Mark Powell Scientific Limited

Location: Boston, MA | June 11-12, 2020



SPEAKER

Mark Powell, Director, Mark Powell Scientific Limited

Dr Mark Powell a Fellow of the Royal Society of Chemistry (RSC) with over thirty years' experience as a senior analytical chemist. Mark was Honorary Treasurer of the RSC's Analytical Division and led a working group on continuing professional development until July 2016. He has worked at a senior level in a number of companies with responsibility for method development and equipment qualification. In 2010 Mark was appointed Scientific Manager of a UK-based pharmaceutical CRO, with responsibility for guiding the direction of drug development programs as well as establishing collaborations with academia and instrument manufacturers. His work resulted in a number of published papers and presentations at international scientific conferences. In 2013, he set up his own company to provide training and consultancy services to pharmaceutical professionals. His consultancy work has involved, amongst other things, managing the analytical aspects of pharmaceutical development programs and conducting data integrity audits. He is in demand as a trainer in topics such as chromatography, spectroscopy, pharmaceutical dissolution testing, data integrity, control of impurities, stability/stress studies and sample preparation, as well as technical writing.

LEARNING OBJECTIVES

- Information required in regulatory submissions
- eCTD format and style
- The fundamentals of effective writing: accuracy, brevity and clarity
- Common mistakes in written English
- Effective use of figures and tables
- Correct methods of citing literature sources in technical documents
- Types of data distribution
- Statistical treatment of experimental data
- Design of Experiments (DoE)
- Writing effective procedures

COURSE DESCRIPTION

The quality and clarity of written technical documents is vital to the success of pharmaceutical companies. Such documents are used in regulatory submissions, to report the outcome of development work to clients, to record the results of investigations and to guide the direction of internal projects. In this course, participants will learn how to analyze and present technical data in a clear and concise manner. The use of visual tools such as graphs and flow charts will be covered, together with the design of effective tables. Statistical tools for data reduction and analysis will also be covered. The elements of effective standard operating procedures will also be explained. A large part of the course will be spent in a workshop setting, where attendees will produce technical content for comment and evaluation. The workshop can either be based on participants' own data or model data provided by the trainer.

Attendees will be expected to bring a laptop computer. By the end of the course, attendees will be able to:

- Understand the expectations of regulators when reviewing a NDA/BLA/MAA
- Edit documents to remove superfluous words or phrases
- Identify and correct ambiguous text
- Write effective technical reports and procedures that cater to the needs of their target audience
- Present complex experimental data in a logical, clear and concise manner making optimal use of graphs, charts and tables
- Follow the conventions of scientific writing to support explanations and arguments
- Ensure technical documents achieve maximum impact by efficiently structuring the data and avoiding common mistakes in written English
- Analyze experimental data using statistical principles

AGENDA

Day 1 (8:30 AM - 4:30 PM)

08:30 AM – 08:59 AM – Registration Process, Meet & Greet

9:00 AM - 10:30 AM

- Regulatory expectations
- ICH, US FDA and EMA guidance on eCTD submissions
- How much information to include

10:30 AM - 10:45 AM Break

10:45 AM - 12:00 Noon

- Writing appropriately for the audience – who will read your report?
- Organization and structure of technical reports
- Use of templates
- Conventions and style in scientific writing
- Correct use of English
- Length and structure of sentences
- Citing scientific literature
- Exercise: identifying and correcting poor writing

12:00 Noon - 1:00 PM Lunch

1:00 PM - 3:00 PM

- Statistical methods
- Types of data distribution
- Basic statistical terms and techniques
- Tests for normality
- Outliers
- Analysis of variance
- Introduction to experimental design
- Exercise: using appropriate statistical techniques

3:00 PM - 3:15 PM Break

3:15 PM - 4:30 PM

- Graphical presentation of data
- Options for presenting data in technical documents
- Designing effective figures and tables
- Use of error bars
- Graphics tools in Microsoft Excel®
- Exercise: selecting appropriate data presentation methods

Day 2 (8:30 AM - 4:30 PM)

8:30 AM - 8:59 AM Attendees arrive

9:00 AM - 10:30 AM

- Writing effective procedures
- Differences in style between technical reports and procedures
- SOP structure
- Developing an effective procedure – risk-based approach
- Use of diagrams and pictures
- Procedure lifecycle management
- Regulatory observations
- Exercise: reviewing a SOP

10:30 AM - 10:45 AM Break

10:45 AM - 12:00 Noon

- Workshop/group exercise: review of example reports – identifying good and bad practice

1:00 PM - 3:00 PM Report-writing workshop

3:00 PM - 3:15 PM Break

3:15 PM - 4:15 PM Report-writing workshop (continued)

4:15 PM - 4:30 PM Final questions, feedback and close

WHO WILL BENEFIT

- Regulatory affairs professionals
- Project managers
- Technical staff with responsibility for report/procedure writing
- Quality management

Registration Form

Registration Information:

- **Register Online**. Click Here Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-201 871 0474.
- Call 201 871 0474 or Fax your PO: 253 663 7224 Pay your check to "PMA Conference Management" and Mail the check to: PMA PO Box 2303, Falls Church VA 22042. Please fill this form with attendee details and payment details and fax it to 253 663 7224

Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ 201 871 0474 or email us @ register@pmaconference.com

Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $300 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($300) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Seminar Topic: Technical Writing for Pharma, Biotech and Med Devices

Date & Location: Boston, MA | June 11-12, 2020

Attendee Details Registration Fee $1799:

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization .....

.....

Address .....

.....

City .....

State ..... Zip.....

Country .....

Phone ..... Fax .....

Payment Options

☐ Check enclosed,

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....

Total amount $ .....

Signature .....
(Signature required on credit card and bill-me orders.)

Print name.....

☐ Bill me/my company $ .....

Purchase order # .....

(Payment is required by the date of the conference.)
Please fill this form with attendee details and payment details and fax it to 201 871 0474