MAWA EVENTS

Address: No. 857, Block A2. Leisure Commerce Square - No 9., 46150 Petaling Jaya, Selangor, Malaysia

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TECHNICAL REPORT WRITING & STATISTICAL ANALYSIS FOR THE PHARMACEUTICAL INDUSTRY

"Enhancing Scientific Communication and Data Integrity in Pharma Documentation"

Schedule

Date	Venue	Fees
24 – 26 Jun 2026	Dubai, UAE	USD 2495 per delegate

► **Available delivery methods:** Face-to-Face & Online Training

Introduction

In the pharmaceutical industry, the clarity and accuracy of technical documents—such as study reports, regulatory submissions, and quality control summaries—can directly impact product approval, compliance, and operational success. Equally critical is the proper analysis and presentation of statistical data, ensuring scientific integrity and regulatory acceptability.

This intensive 3-day course is designed to strengthen the technical writing and statistical interpretation skills of professionals working in pharmaceutical R&D, clinical trials, regulatory affairs, and quality assurance. The course blends best practices in scientific writing with hands-on instruction in descriptive and inferential statistical methods commonly applied in pharmaceutical reporting.

Objectives

By the end of this course, participants will be able to:

- Write clear, accurate, and structured technical reports for scientific and regulatory audiences
- Apply proper statistical methods to pharmaceutical data sets
- Interpret statistical outputs and integrate them meaningfully into reports
- Ensure compliance with ICH, FDA, and EMA reporting requirements
- Improve data presentation through tables, figures, and visual summaries

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Why Attend

- Enhance the quality and clarity of technical documentation
- Learn to interpret and report pharmaceutical data with confidence
- Avoid common pitfalls in statistical reporting and writing for regulatory bodies
- Strengthen credibility in audits, inspections, and peer reviews
- Gain practical skills to meet global documentation standards

Target Audience

This program is designed for:

- Pharmaceutical scientists and medical writers
- Regulatory affairs and quality control professionals
- Clinical research associates and data managers
- R&D and formulation development personnel
- Statisticians and technical documentation specialists

Individual Benefits

Key competencies that will be developed include:

- Effective planning and structuring of scientific reports
- Selection and application of appropriate statistical tools
- Regulatory-compliant writing and data presentation techniques
- Graphical and tabular representation of analytical results
- Scientific argumentation and critical review of data

Organizational Benefits

Upon completing the training course, participants will demonstrate:

- Improved documentation quality for submissions and audits
- More accurate and transparent reporting of pharmaceutical data
- Reduced delays in regulatory approvals due to clearer communication
- Enhanced internal review and compliance mechanisms
- Stronger alignment with ICH, GxP, and FDA/EMA guidelines

Instructional Methodology

The course follows a blended learning approach combining theory with practice:

- Technical Lectures – Writing structure, scientific tone, and compliance
- Hands-On Statistical Exercises – Descriptive, comparative, and regression analysis
- Report Review Workshops – Critique and edit sample reports
- Case Studies – Regulatory writing successes and failures
- Templates & Tools – Reporting formats, statistical analysis checklists

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Course Outline

Training Hours: 7:30 AM – 3:30 PM Daily Format: 3–4 Learning Modules | Coffee Breaks: 09:30 & 11:15 | Lunch Buffet: 01:00 – 02:00

Day 1: Fundamentals of Technical Writing in Pharma

- Module 1: Principles of Effective Technical Writing (07:30 – 09:30) • Clarity, precision, structure, and audience focus • Common errors in scientific writing
- Module 2: Writing for Regulatory and Scientific Audiences (09:45 – 11:15) • ICH guidelines, CTD format, and regulatory expectations • Tone, objectivity, and documentation integrity
- Module 3: Structure of Technical Reports and Dossiers (11:30 – 01:00) • Abstracts, methods, results, conclusions, and appendices • Data reporting vs data interpretation
- Module 4: Workshop – Rewriting a Poorly Written Section (02:00 – 03:30) • Group editing and feedback

Day 2: Statistical Tools and Interpretation

- Module 5: Introduction to Descriptive Statistics (07:30 – 09:30) • Means, medians, ranges, standard deviations • Data visualization (histograms, box plots, control charts)
- Module 6: Comparative Analysis and Inferential Statistics (09:45 – 11:15) • T-tests, ANOVA, confidence intervals, p-values • Appropriate application in pharma trials and QC
- Module 7: Regression, Correlation, and Trend Analysis (11:30 – 01:00) • Simple linear regression and trend forecasting • Interpreting R^2 and significance
- Module 8: Workshop – Analyze and Summarize Sample Data (02:00 – 03:30) • Write statistical results section based on provided dataset

Day 3: Integration, Review, and Compliance

- Module 9: Integrating Statistical Results into Reports (07:30 – 09:30) • Choosing the right charts and language • Avoiding misinterpretation or overstatement
- Module 10: Regulatory and Compliance Considerations (09:45 – 11:15) • FDA, EMA, and ICH E6/E3 expectations • Documentation audits and data integrity principles
- Module 11: Final Report Writing Exercise (11:30 – 01:00) • Compile sections of a technical report from mock trial data
- Module 12: Review, Feedback, and Certification Exam (02:00 – 03:30) • Peer review, final corrections, and knowledge test

Certification

Participants will receive a Certificate of Completion in Technical Report Writing & Statistical Analysis for the Pharmaceutical Industry, validating their ability to create clear, compliant, and data-driven documents suitable for scientific, operational, and regulatory use.

Why Choose MAWA Events

- **Global Expertise:** More than 17 years of experience in professional training and consulting.
- **Industry-Leading Faculty:** Courses delivered by seasoned professionals with hands-on experience.
- **Practical Insights:** Learn to turn theory into actionable strategies for real-world business impact.
- **Client-Focused Solutions:** Customized programs designed to achieve your organisation’s unique goals.

In-House / Customized Training Interested in running this course for your team? Please contact us:	TEL: **+601116373203**	EMAIL: **info@mawaevents.net**