

**CORRECTIVE ACTIONS PREVENTIVE ACTIONS
CAPAs**

Who should attend: Quality Assurance, Quality Control, Operations, Regulatory and Manufacturing Supervisors, Cleanroom Operators and Facilities Personnel

Benefit from Microrite.'s expertise in Quality Assurance Management and Training. Learn how to identify, evaluate, investigate, analyze, establish action plans and follow up procedures for CAPAs

23 March, 2009

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This half day seminar will address:

- Introduction and Definitions
- Requirements for CAPA
- Analysis in the CAPA System
- Investigations in the CAPA System
- Documentation, Records, and Tools
- Cause Analysis: Investigating Causes and Solving Problems
- Problem Prevention: Ensuring Successful Implementation
- Simulations and Case Studies
- CAPA System from an FDA Perspective
- Effectiveness Checks and Timeliness
- Management Oversight and Review

ABOUT THE PRESENTER

Steven Drake is a Quality Consultant with over 20 years experience in successfully managed cGMP, cGLP, QSR and ISO 9000 quality system development and implementation. He has an in depth knowledge of regulatory compliance issues related to production and analysis of regulated products including biologics, drugs, devices, diagnostics and parenteral solutions. With a strong background in Quality Control, Quality Assurance/Compliance Steve has held senior positions in pharmaceutical, biotechnology and stem cell research companies. As a consultant Steve establishes and manages quality systems and helps companies through acquiring State Licensure.

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SCHEDULE AND VENUE

23 March, 2009

San Jose Biocenter
 5941 Optical Court
 San Jose, CA 95138
 TEL: (408) 960.3807
 FAX: (408) 960.3822

PROGRAM

Registration and Light -Breakfast	8.00 AM to 8.30 AM
Introduction and Definitions	8.30 AM to 8.45AM
Requirements for CAPA	8.45 AM to 9.15 AM
Analysis in the CAPA System	9.15 AM to 9.45 AM
Investigations in the CAPA System	9.45 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Documentation, Records, and Tools	10.15 AM to 10.30 AM
Cause Analysis: Investigating Causes and Solving Problems	10.30 AM to 10.45AM
Problem Prevention: Ensuring Successful Implementation	10.45 AM to 11.00 AM
Simulations and Case Studies	11.00 AM to 11.15 AM
CAPA System from an FDA Perspective	11.15 AM to 11.30 AM
Effectiveness Checks and Timeliness	11.30 AM to 11.45 AM
Management Oversight and Review	11.45 AM to 12.00 PM
Questions and Answers	12.00 PM to 12.30 PM

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REGISTRATION FORM

Personal Information of One Registrant

Last Name: Mr. Ms. Dr. First Name: _____

Title: _____ Organization: _____

Mailing Address: _____

Telephone: (Area Code) _____ Facsimile: (Area Code) _____

Email: _____

Fees: \$500.00 (US)

Additional Attendees					
Last Name:		First Name:		Title:	
Last Name:		First Name:		Title:	
Last Name:		First Name:		Title:	
Last Name:		First Name:		Title:	

Method of Payment: Check, Credit Card or Purchase Order
Fax : 408-445-1236

Checks payable to Microrite, Inc.
5019, New Trier Avenue
San Jose, CA 95136

Confirmation of registration will be sent via email.

Cancellation Policy: Your notice of cancellation must be received by in writing by facsimile or email 10 working days prior to the Seminar date.

Fax: 408-445-1236 Email: sales@microrite.com or zabraham@microrite.com

A 10% cancellation fee is applicable for credit card payments

Accommodation: Seminar attendees requiring hotel accommodation should contact
Dolce Hayes Mansion
San Jose's Best Historic Hotel less than 10 minutes drive or taxi ride to the seminar venue
200 Edenvale Ave, San Jose CA 95136
Tel. 1.888.274.6918-ask for San Jose.com rates
Holiday Inn San Jose-Silicon Valley- 1.5 miles from seminar venue
399 Silicon Valley Blvd.
San Jose, CA 95138
Tel: 877-410-6681

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Business name: _____

CREDIT CARD INFORMATION

Credit Card Payment may be made on the Micro rite's website-<http://www.microrite.com>
Or this form may be faxed to 408-445-1236

Choose one: VISA Master Card American Express

Card Holder's Name _____

Address of Card Holder **Please note Company Address if it is a Corporate Card and
Personal Address if Personal Card**

Street _____

City _____

Zip Code _____

Country _____

Contact Phone Number _____

Card Number: _____

Expiration(Month/Year): _____

Name on Card: _____

Amount (US Dollars): _____

Signature: _____

Name of Attendee(s) _____

City and Date of
Seminar _____