

**UNDERSTANDING COMPRESSED GASES USED IN FDA REGULATED AND HEALTHCARE  
INDUSTRY**  
**EQUIPMENT, VALIDATION, SAFETY, REGULATIONS, TESTING AND RISK ASSESSEMENT**

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

**14 July, 2009**

**COMPRESSED GASES - EQUIPMENT, VALIDATION, SAFETY**

- Commonly used gases in the Pharmaceutical, Biotechnology and Medical Device Industry
  - Oxygen
  - Nitrogen
  - Argon
  - Carbon Dioxide
  - Helium
  - HCl
  - SF<sub>6</sub>
  - Chlorine
  - CDA
- Equipment Configurations for these gases
  - Cylinder Supply
  - MicroBulk Supply
  - Bulk Supply
- Ancillary Parts
  - Storage Vessels
  - Piping and Piping Components, Materials of Construction
  - Vaporizers
  - Pressure Control
  - Switchover Manifold
  - Gas Cabinets
  - Telemetry
- Validation
  - Equipment (IQ)
    - Vessel Preparation
    - Purge Procedure
    - Pressure / Retention Testing
    - Helium Leak Testing (if necessary)
  - Product (OQ)
    - NF Nitrogen
    - USP Oxygen
    - CO<sub>2</sub>
    - Product Stewardship
      - 3<sup>rd</sup> Party Validations
      - FDA Certification
      - ACC info
    - Delivery Documentation
      - C of A
      - C of C
      - Special Customer Requirements
- Safety Issues
  - Cryogenic Gases
  - Pressure Hazards
  - Expansion Hazards
  - Storage Requirements
    - NFPA
    - CGA

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**COMPRESSED GAS SYSTEMS TESTING – REGULATORY DISCUSSION**

- Discussion of various types of compressed gases and related applicable testing
  - Outline and discussion of regulatory bodies:
    - International Organization for Standardization
    - European Union Annex
    - U.S. Food and Drug Administration
    - National Fire Protection Association
- Guidance on types of testing required by each regulatory body
  - Outline of priority tests to satisfy regulatory bodies:
    - Airborne viable particulate testing
    - Non-viable particulate counting
    - Dew point measurement
    - Total hydrocarbon testing
    - Additional relevant test types
- Question & Answer Session

**COMPRESSED GAS SYSTEMS TESTING – TECHNICAL SESSION**

- Review of priority test types
  - Discussion of available equipment used in testing CGS systems
  - Discussion of preferred test equipment and test methods
    - Airborne viable particulate testing
    - Non-viable particulate counting
    - Dew point measurement
    - Total hydrocarbon testing
- Summary of test methods and equipment
- Question & Answer Session

**UNDERSTANDING THE RISK OF CONTAMINATED COMPRESSED GASES**

- Discussion on the use of compressed gases in participant technologies
- What are direct product contact and indirect product gases and points of use
- Using a risk based approach to establish a monitoring strategy
- How can particulates, microbes, moisture or hydrocarbons affect your product or process

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**ABOUT THE PRESENTERS**

**Jeffrey Bombich** has over 10 years of Engineering and Commercial experience with Air Products and Chemicals, Inc. Prior to beginning his career, Jeffrey received his Bachelor's Degree in Electrical Engineering from Bucknell University. During his time with Air Products and Chemicals Inc, Jeffrey worked as a Project Engineer supporting Packaged Gases, Helium, and Electronics customers before transitioning to a Commercial position. As a project engineer, Jeffrey's responsibilities included design, installation, and commissioning activities for gaseous and cryogenic supply systems for both internal and external customers.

**Allan Bier** combines years of experience in field testing compressed gas systems with an in depth understanding and knowledge from work in the medical device industry. Mr. Bier serves as a Technical Field Support Specialist at Technical Safety Services, Inc. corporate headquarters. Mr. Bier is a member of ISPE and is NSF Accredited.

With over fifteen years of experience in technical and engineering support of the biopharma and medical device industries, **Matt Smyers** brings together both the technical knowledge and practical application of controlled environment testing and certification. Mr. Smyers serves as the Safety Manager for Technical Safety Services, Inc. – the premier provider of controlled environment services. Mr. Smyers holds a B.S. in Physics from Chico State University.

**Ziva Abraham** has over 25 years of academic, research, clinical and industrial experience in Microbiology, and Quality Assurance. She has trained personnel from various industries in microbiology techniques and methods. Ziva has received her Master's Degree in Microbiology and has conducted research on developing Microbial Insecticides. She has established clinical laboratory systems in Israel, Microrite, Inc. a consulting company based in San Jose, CA and Microrite Training Center in Santa Clara, CA. Microrite helps Pharmaceutical, Medical Device, Biotechnology and Combination Product Companies in the areas of Quality Assurance, Validation, Process Development and Microbiological Quality Control. Ziva has also developed "BACTISPELL" a microbiology spellchecker to spell check genus and species names of microbes and other microbiology related terms. She is a member of PDA, ISPE, AAMI, and PMF and is an active mentor for graduate students at Stanford University working through the American Woman in Science Organization (AWIS). She is involved in Expanding Your Horizons, a program through the Math and Scientific Network to educate young girls about careers in science. Ziva serves on the editorial board of Pharmaceutical Microbiology Forum (PMF) Newsletter

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**SCHEDULE AND VENUE**

**July 14, 2009**

**Microrite Training Center  
 2338 B Walsh Avenue  
 Santa Clara, CA**

**PROGRAM**

Registration and Light -Breakfast	8.00 AM to 8.30 AM
Commonly used gases in the Pharmaceutical, Biotechnology , Medical Device and Healthcare Industry - Equipment Configurations	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Validation and Safety Issues related to Equipment	10.15 AM to 11.45 PM
<i>Questions and Answers</i>	11.45AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Compressed Gas Systems Testing – Regulatory Discussion	1.00 PM to 2.15 PM
Break	2.15 PM to 2.30 PM
Compressed Gas Systems Testing – Technical Session	2.30 PM to 3.45 PM
Understanding Risk of Contaminated Compressed Gases-Discussion	3.45 PM to 4.30 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: \$900.00 (US)**

**Discounts: 10% discount**      **Applicable when two or more attendees register from the same company**

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.**

Confirmation of registration will be sent via email if payment is made by check or PO. For credit card payment on website, a payment receipt will be considered as confirmation of registration. For credit card information faxed to Microrite an email confirmation will be sent with a copy of payment receipt. Please call 408-445-0507 in due time if confirmation is not received after payment.

**Cancellation Policy:** Your notice of cancellation must be received by in writing by letter, facsimile or email 10 working days prior to the Seminar date. Fax: 408-445-1236 Email: [sales@microrite.com](mailto:sales@microrite.com) or [info@microrite.com](mailto:info@microrite.com). A 10% cancellation fee is applicable for credit card payments

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**SUGGESTED AIRPORT AND HOTELS**

**Closest Airport**

Norman Y. Mineta San Jose International Airport (SJC)  
1732 N 1st St # 600  
San Jose, CA 95112  
Distance from Microrite Training Center  
Estimated Driving Time: 9 minutes Estimated Distance: 4.77 miles

**Accommodations-Suggested Area Hotels**

**Holiday Inn Express 1700 El Camino Real**

Santa Clara, CA 95050  
877-410-6681  
1.35 miles away from Microrite Training Center

**Hawthorn Suites-Santa Clara**

2455 El Camino Real  
Santa Clara, CA 95051  
408-241-0514  
1.19 miles away from Microrite Training Center

**Howard Johnson**

2499 El Camino Real  
Santa Clara, CA 95051  
408-244-9610  
1.19 miles away from Microrite Training Center

**Embassy Suites**

**2885 Lakeside Drive**

Santa Clara, CA 95054  
408-496-6400  
1.19 miles away from Microrite Training Center

**Biltmore Hotel and Suites**

2151 Laurelwood Road  
Santa Clara, CA 95054  
408-988-8411  
0.96 miles away from Microrite Training Center

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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 \_\_\_\_\_