

**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

**23 February, 2010**

**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.

**Juan Muñoz** has a Master's degree in Microbiology and over 20 years of experience in quality assurance, GMP compliance, quality control, microbiological testing of medical devices, biotechnology and pharmaceutical products. He is an expert in clean room design, microbial control, environmental monitoring, sterility testing, general microbiology, microbial limits and other USP/Ph.Eur. microbial tests. Juan has held many positions of high responsibility as manager and associate director of QC of microbiology laboratories at several major biotechnology and pharmaceutical companies across the US. He has been involved in the design, commissioning and validation of several pharmaceutical and biotechnology facilities. He has set-up contamination control at several facilities. Most recently, Mr. Muñoz has managed and executed the qualification testing for a new 100,000 square ft. full service biotechnology facility (cell culture, purification, bulking and filling) and set-up the contamination control program at Abgenix Inc., located in Fremont, California. He has participated in many regulatory inspections by FDA, European, and Canadian regulatory authorities .He is one of the founders of Micro-Virology Testing Laboratories and MQA, Microbiology and Quality Associates, LLC

**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**

**23 February, 2010**

**BTEC**

Golden LEAF Biomanufacturing Training &  
 Education Center North Carolina State University  
 Centennial Campus  
 850 Oval Dr, Raleigh, NC 27606  
 (919) 513-2000

**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:	
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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 \_\_\_\_\_