



The Safety and FDA
Compliance Experts
For Food, Medical
& Industrial Gases

B&R Compliance Associates LLC
P.O. Box 190
Placida, FL. 33946

**DOCUMENTATION
OF
QUALIFICATIONS**

FOR

Robert M. Sutter

**Vice President
& Chief Technical Officer**

Revision 13

December 2017



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Compliance Experts
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EDUCATION:

Spring Garden College, Philadelphia, Pa. – AS Manufacturing Engineering
Spring Garden College, Philadelphia, Pa. – BS Mechanical Engineering

WORK EXPERIENCE:

2005- Present

B&R Compliance Associates LLC

Lehigh Valley, Pa

Vice President & Chief Technical Officer

Co-owner of independent consulting company, specializing in technical and regulatory consulting to the medical and industrial gases industry. Company specializes in validation, GMP procedure development, and FDA compliance program implementation and auditing.

B&R has also successfully facilitated new startup companies and industrial companies adding a medical product line to develop and implement a cGMP compliance program, including the development and deployment of operating procedures, employee training, process and control / computer system validation, and analytical systems qualification.

BOC Gases

Division of the BOC Group, PLC

2001 – 2005, Manager Standards & Specifications

Reported directly to Director Quality Assurance. Management responsibility for the development and maintenance of the quality systems used to govern the manufacture and distribution of medical gases in North America and Canada. Responsible for decisions to ensure federal and state regulatory compliance, as well as adherence to industry guidelines and company policies.

Represented North America Gases on BOC's global medical gas standards harmonization committee.

BOC voting member on a number of CGA committees. CGA representative to the NFPA 99 committee. Performed vendor audits for firms supplying material used to produce and store medical gases.

2000 – 2001, Area Loss prevention Manager

Responsible for site audits, training and compliance assistance to field locations, ensuring compliance with safety and regulatory requirements. Job responsibilities included:

- Providing training in Med Gas QA, Safety, and Crisis Communication.
- Performing compliance evaluation and measurement through auditing in: Med Gas QA, Safety, and Engineering.
- Provided compliance assistance for site changes and upgrades, along with incident investigations.
- Provided compliance auditing for BOC customers enrolled in BOC's Med Gas QA program.

1999 – 2000, Manager Medical Systems and Standards

Manager responsible for all aspects of bulk healthcare medical gas supply systems. Specific responsibilities included:

- System design and layout
- Development of installation and maintenance procedures
- System and component qualification
- System validation & protocol development
- Development and deployment of personnel training & certification programs
- Vendor review and qualification

1990 – 1999, Manager, Installation Engineering

Management responsibility for bulk customer application storage and delivery equipment and systems. Specific responsibilities included:

- Developing systems standards and designs
- Development and deployment of personnel and certification
- Vendor interface and vendor review / approval
- Development and deployment of system installation and maintenance procedures.

1996 – 1997, Special Assignment project “Unity”

Selected by BOC senior executive committee for a one year project team assignment to redesign BOC’s business process. As part of the “Acquire the Customer Team” assigned responsibilities included the redesign of the medical gas systems installed at customer healthcare facilities. In addition to achieving targeted cost savings, was responsible to ensure compliance with applicable laws and standards, develop standard sizing methods for healthcare facilities, standard designs for the equipment being installed and standard procedures for the installation of the system.

1985 – 1990, Regional Engineer, (Airco Gases a division of the BOC Group PLC)

Responsible for project management and engineering support to Airco’s application equipment and processes, cryogenic and gas storage and distribution systems. This position also developed and delivered customer and sales specialist training in applications, storage and distribution systems and application equipment.

1984-1985

Bishops Welding Supply

Tampa, FL

Technical Service Manager

Responsible for the daily operation of a welding gases and equipment service center and the management of two service technicians. Oversaw the installation of bulk cryogenic gas systems, internal customer piping systems, large oxy/fuel cutting machines, and automated welding equipment. Managed shop employees that conducted welding machine and oxy/fuel equipment repairs. Providing support to the outside sales force during technical sales calls.

Airco Welders Supply

Division of the BOC Group PLC

Philadelphia, PA

1978 – 1984, Technical Service Manager

Responsible for the daily operation of a welding gases and equipment service center and the management of six service technicians. Oversaw the installation of bulk cryogenic gas systems, internal customer piping systems, large oxy/fuel cutting machines, and automated welding equipment. Managed shop employees that conducted welding machine and oxy/fuel equipment repairs. Providing support to the outside sales force during technical sales calls.

1977 – 1978, Outside Sales Representative

Responsible for the sale of Airco gases and equipment to customers within a specific geographic region.

PROFESSIONAL MEMBERSHIPS:

1. COMPRESSED GAS ASSOCIATION:
 - a. Medical Gas and Equipment Committee since 1998
 - b. CGA representative to the NFPA 99 committee – 2002 – 2010
 - c. Food Gases Committee – since 2012

- d. Medical Gases Certification Process – since 2012
- e. Revision to FDA Drug Regulation for Medical Gases – since 2012
- f. M-1 Guide for Medical Gas Installations At Consumer Sites, Task Force since 2002
2. AMERICAN SOCIETY FOR HEALTHCARE ENGINEERS (ASHE) since 1998
3. NATIONAL FIRE PROTECTION ASSOCIATION (NFPA) since 1999
 - a. NFPA HEALTHCARE SECTION since 2001
 - b. Principle voting member of the NFPA 99 Healthcare Facilities Technical committee on Piping Systems, 2002-2010
 - c. Principle voting member of the NFPA 99 Healthcare Facilities Technical committee on Gas Delivery Equipment, since 2002
 - d. Principle voting member of the NFPA 99 Healthcare Facilities Technical committee on Medical Equipment, since 2007
 - e. Principle voting member of the NFPA 55 Technical Committee on Industrial and Medical Gases, since 2016
4. MEDICAL GAS PROFESSIONAL HEALTHCARE ORGANIZATION (MGPHO) since 1999
 - a. Special expert since 2005
 - b. Board of Directors 2013 - 2016
5. AMERICAN SOCIETY OF SANITARY ENGINEERS (ASSE) SEIRIES 6000 COMMITTEE
Professional qualification Standards for Medical gas Systems Installers Inspectors, Verifiers, maintenance Personnel and Instructors since 2002

Qualifications/Date

Institution

ASSE 6010, Certified medical Gas Installer – Since 2016	MGTC
ASSE 6020, Certified Medical Gas Inspector– Since 1999	NITC/MGTC
ASSE 6035, Certified Bulk Medical Gas System Verifier – Since 2013	MGPHO
ASSE 6055, Certified Bulk Medical Gas System Instructor – Since 2007	NITC
Accredited Safety Auditor – 2000	Det Norske
ISO Auditor – 2000	LRQA
Certified Brazier – Since 2005	WTII
Medical Gas Piping endorsement, License #185	State of Montana
Certified Lokring Inspector #144728	Lokring

SIGINIFICANT TRAINING COURSES:

1. 3M Corporations course entitled “Total Quality Management” – 1990
2. BOC’s course on “BOC Hydrogen” – 1990
3. BOC’s course on “Carbon Dioxide” – 1991
4. BOC’s course on “Cryogenic System Design and Installation” - 1991
5. BOC’s course on “Brazing Certification” - 1997
6. Airco’s course on “Basic Presentation Skills” - 1987
7. BOC’s Quality Assurance Training Program for Medical Gases
8. Food and Drug Administration “Fresh Air” by Duane Sylvia – 1998
9. American Hospital Association “Medical Gas Systems” – 1998

10. American Hospital Association on “JACHO Environment of Care Standard” – 1998
11. ASTM Technical & Professional Training course on “Fire Hazards in Oxygen Systems” - 1998
12. BOC’s course on “Lock out Tag Out” – 2000
13. BOC’s course on “Confined Space” – 2000
14. “Medical Gas Inspectors” by NITC – 2000
15. “A practical approach to Compliance with 21 CFR Part 11” conducted by Taratec Development Corporation - 2000
16. BOC’s course, “cGMP training for Auditors” conducted by Global Quality Consultants – 2001
17. “Basic GMP’s for the Medical Gas Industry” conducted by Sci Lucent Corporation – 2001
18. “OSHA Standards 1910 Level I &II” training presented by American Safety Training – 2001
19. “ISO 9001:2000 Lead Auditor” training presented by LRQA – 2001
20. Det Norske Veritas (DNV) course on auditor training – 2001
21. “ Hazardous Incident Response Training” – 2002
22. “Implementing the Quality System Inspection Technique (QSIT) conducted by Pharmaceutical Training Institute – 2002
23. FDA/Industry Workshop on “Drug Quality System-cGMP’s For a New Era” in Newark, NJ. – 2003
24. “Executive and Senior Management CGMP” training – 2003
25. “Validation protocol Execution Training” – 2003
26. “Code of Conduct” training – 2004
27. FDA/Industry Workshop on “Drug Quality Systems–cGMP’s For A New Era” in Parsippany NJ. – 2005”
28. FMEA, FMECA, and HACCP risk assessment training presented by Dyadem Engineering Corporation in Houston, TX. (5 day course) – 2005
29. FDA/Industry Workshop on “2008–cGMP’s” in Chicago, IL. – 2008”
30. FDA/Industry Workshop on “Preparing Electronic Drug Establishment Registration and Dug Listing Submissions” in Rockville, MD. – June 2009”