



B&R Compliance Associates LLC

**P.O. Box 190
Placida, FL 33946**

DOCUMENTATION OF QUALIFICATIONS

FOR

J. Robert Yeoman

President & CEO

Revision 7

June 2018

**EDUCATION:**

Temple University, Philadelphia, Pa. – Mechanical Engineering

WORK EXPERIENCE:**2002- Present**

B&R Compliance Associates LLC
Lehigh Valley, Pa

President & Chief Executive Officer

Co-owner of and managing partner of independent consulting company specializing in technical and regulatory consulting to the chemical, gases, and OTC drug firms regulated by FDA as either drug or food products. Company specializes in validation, GMP procedure development, supplier qualification, and Quality Assurance / FDA compliance program development, implementation, and auditing. Acknowledged by FDA as a qualified individual” for the following areas:

- Operating procedures
- Employee training processes
- Process validation
- Product analysis
- Computer operated distributed control systems
- Computer systems validation
- Process and product safety programs

B&R has also successfully facilitated new startup industrial companies to add a medical product line, and to successfully develop and implement a cGMP compliance program. We are also well experienced in assisting firms in managing FDA compliance actions, and have served as FDA’s qualified individual under a consent decree.

1995-2002**BOC Gases**

Division of the BOC Group, PLC
Murray Hill, NJ

Vice President Quality and Regulatory Affairs

Senior Executive responsible for Safety, Health, Environment, and Quality Assurance (SHEQ) functions in North and South America reporting to the President of Gases Americas and the BOC Group Corporate Safety Director. This position directed a staff of 40 SHEQ professionals on two continents supporting an Industrial and Medical gases business of over \$1.7 billion in annual revenues. Responsibilities included:

- Development, senior executive team coordination, and implementation of strategic plans for safety, health, fleet safety, environmental, claims management, quality systems, and Medical Gas Quality Assurance.
- Development and implementation of systems and procedures facilitating compliance management, including policies, procedure manuals, and monitoring systems.
- Development and measurement of key SHEQ performance indicators for individual business units
- Direct supervision and accountability for Quality Assurance and Quality Control functions supporting medical gas operations
- Approval of compliance strategies for business e-systems
- Provide corporate governance and monitoring of regulatory compliance through audits
- Executive team coordination for developing remedial action programs addressing compliance deficiencies and management oversight of plan action implementation and verification of completion
- Executive and administrative contact for BOC with US industry associations and trade groups



1992-1995

BOC Gases

Division of the BOC Group, PLC

Murray Hill, NJ

Director of Safety and Health

Primary responsibility for the safety, process safety, health, fleet safety, and environmental programs in the US and Canada; which included, implementation of annual plans aligned to achieving strategic goals. Responsibilities included direct supervision of program management, guidance and procedure manual development and deployment, training program deployment, program effectiveness measurement, and compliance audit program management.

1988-1992

Airco Gases

Division of the BOC Group, PLC

Murray Hill, NJ

Director Food Marketing and Field Engineering

This was a dual responsibility role which included 1) primary responsibility for marketing and support activities, technology management, application development, technical sales support, and key account development related to nitrogen food applications in the US, and 2) primary responsibility for customer systems and application engineering and installation activities. Had responsibility for management of over 50 people nationwide and activities at the small parts warehouse, as well as P&L responsibility for application equipment and parts sales.

1984-1988

Airco Gases

Division of the BOC Group, PLC

Malvern, PA

Regional Manager, Field Engineering

Responsible for managing the Field Engineering function in the eastern third of the US, including development and design of customer application storage and delivery equipment and systems. Budgeted projects, oversaw project capital procurement processes and expenditures. This position managed 12 engineers, 2 application technicians, and 4 service technicians.

1980-1984

Airco Gases

Division of the BOC Group PLC

King of Prussia, PA

Regional Engineer

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

**1976-1980**

**Amana Refrigeration Inc.
Division of Raytheon Corporation
Amana, IA**

Regional Customer Service Manager

Responsible for the administration of warranty claims processes, training for equipment service and applications, and dealer and consumer relations in the Northeast US.

1973-1976

**Elliott-Lewis Corporation
Philadelphia, PA**

Design Engineer & Construction Supervisor

Responsible for design, proposal generation, and project management of turn-key Heating, Ventilating, and Air Conditioning (HVAC) systems for commercial and industrial applications, and industrial applications for medium and low temperature refrigeration systems.

PROFESSIONAL AWARDS:

1. 2017 Compressed Gas Association Charles H. Glasier Award recipient. Award is presented annually to one individual to recognize industry and association leadership.

PROFESSIONAL MEMBERSHIPS:

1. AMERICAN SOCIETY FOR HEATING, REFRIGERATION, AND AIR CONDITIONING ENGINEERS (ASHRAE) since 1980.
2. Member COMPRESSED GAS ASSOCIATION Safety and Health Committee since 1992
3. Member COMPRESSED GAS ASSOCIATION Environmental Committee since 1993 - 2002
4. Founding Member COMPRESSED GAS ASSOCIATION Safety and Environmental Advisory (SEA) Council 1994 - 2002
5. Member COMPRESSED GAS ASSOCIATION Medical Gas and Equipment Committee since 1995
6. Chairman COMPRESSED GAS ASSOCIATION SEA Council 1997 – 2000
7. Member COMPRESSED GAS ASSOCIATION Executive Committee & Board of Directors 1997 – 2000
8. Member INTERNATIONAL OXYGEN MANUFACTURERS ASSOCIATION International Standards Harmonization Committee – 1997 – 2001
9. Chairman INTERNATIONAL OXYGEN MANUFACTURERS ASSOCIATION Taskforce to develop global industry safety statistics criteria and reporting mechanisms - 1999 – 2000
10. Founding Member of COMPRESSED GAS ASSOCIATION'S Medical Gas Regulatory and Policy (MGRP) task force – 2001 - 2009
11. Member COMPRESSED GAS ASSOCIATION'S Helium and Nitrous Oxide abuse task force 1997 - 2000
12. Member & Co-Chair Person NWSA Safety Committee – 1994 – 2001
13. Member GAWDA Safety Committee & Government Affairs Committee – 2002 – 2008
14. Non-voting member GAWDA Board of Directors 2002 – 2009
15. Member ISBT – Gases Technical Committee – 2010 – Present



16. Chairman ISBT Gases Technical Committee 2017 - Present

17. Member IBDEA – 2014 - Present

Professional Qualifications/Date

Accredited HVAC Designer –1975

Accredited Safety Auditor - 1993

ISO Lead Assessor Certified – 1995

FSSC Lead Auditor Certified – 2015

Preventive Controls Qualified Individual – 2017

Institution

ASHRAE Society

DNV Corporation

Statamatrix

Lloyds Quality Register

Food Safety Preventive Controls Alliance

TRAINING CLASSES:

1. Completed course offered by the American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE) entitled “HVAC Designer Certification” – 1974 - 1975
2. Completed Airco’s course on “Basic Properties and Applications of Gases” Presented by Dr. Taylor PhD – 1980
3. Completed Airco’s course on “Cryogenic System Design and Installation” - 1981
4. Completed Airco’s course on “Advanced Cryogenic Engineering” - 1983
5. Completed course titled “Effective Project Management” conducted by Dr. Ron LaFleur at Lehigh University - 1986
6. Completed Airco’s course on “Basic Presentation Skills” - 1987
7. Completed Airco’s course on “Advanced Presentation Skills” - 1987
8. Completed Airco’s course on “Crisis Communication Skills” – 1988
9. Completed BOC International course on “Interactive Management” – October - November 1988
10. Completed Behavioral Sciences Technology Institute’s course on “Behavioral Safety in the Workplace” - 1989
11. Completed course on “Financial Skills for Technical Managers” presented by the University of Pennsylvania – Wharton School of Business – April 1990
12. Completed BOC’s “Executive Management Program” – London England, UK – August – October 1990
13. Completed 3M Corporation’s course entitled “Total Quality Management” – 1990
14. Completed 3M Corporation’s course entitled “Total Quality Facilitator” - 1990
15. Completed the International Loss Control Institute’s course entitled “Modern Safety Management” - 1992
16. Completed the International Loss Control Institute’s course entitled “Accredited Safety Auditor Certification” – 1993
17. Accredited by the International Loss Control Institute (DNV) as an Accredited Safety Auditor - 1993
18. Completed Airco safety training courses on Energy Isolation, confined space, hazardous work permitting, overhead work, flammable / oxidizer mixing safety, and basic safety requirements for ASU & Cylinder operations - 1993
19. Completed 5 day course on behavioral safety management presented by the Behavioral Sciences Group (BSG) – 1994
20. Completed Airco 5 day Hazmat responder training course – Basic – Port Allen, LA – May 1994
21. Completed Airco 5 day Hazmat responder training & cylinder remediation course – Advanced – Port Allen, LA - November 1994



22. Completed STAT-A-MATRIX INSTITUTE course entitled “Lead Assessor Certification Workshop” – 1995
23. Completed Airco course on OSHA Process Safety Management requirements & program implementation - 1995
24. Participant in BOC’s Quality Assurance Training Program for Medical Gases: Averaged 1 session per every 2 years between the years of 1995 and 2002
25. Completed Airco’s Interaction Management (AIM) 2 day Refresher Course – 1995
26. Completed 4 day course entitled “Pharmaceutical cGMP Compliance” conducted by the Center for Professional Advancement – 1995
27. Completed 3 day course presented by Maresca & Associates entitled “Crisis Management and Communication” - 1996
28. Attended course presented by Duane Sylvia of the Food and Drug Administration hosted by the FDA Nashville District Office entitled “Fresh Air” – 1999
29. Completed 3 day course entitled “A practical approach to Compliance with 21 CFR Part 11” conducted by Taratec Development Corporation – 2000
30. Completed BOC Hazmat responder 5 day refresher course - 2000
31. Completed BOC’s course entitled “cGMP training for Auditors” conducted by Global Quality Consultants – 2001
32. Completed course entitled “Basic GMP’s for the Medical Gas Industry” conducted by Sci Lucent Corporation – 2001
33. Completed course entitled “Introduction to Process Validation” presented by the Institute of Validation Technology and The Pharmaceutical Quality Institute in cooperation with the Food and Drug Administration – 2001
34. Completed course entitled “Intermediate Validation Concepts” presented by the Institute of Validation Technology and The Pharmaceutical Quality Institute in cooperation with the Food and Drug Administration – 2001
35. Completed 3 day course entitled “Implementing the Quality System Inspection Technique (QSIT) conducted by Pharmaceutical Training Institute – 2002
36. Attended Tele-conference course presented by Immel Resources LLC entitled Part 11 and FDA’s Risk-Based CGMP Initiative – 2003
37. Attended FDA/Industry Workshop on “Drug Quality System - cGMP’s For a New Era-2004” in Chicago, IL - 2004.
38. Attended FDA/Industry Workshop on “Drug Quality System – cGMP’s for a New Era-2005” in Parsippany, NJ - 2005
39. Completed 5 day course on FMEA, FMECA, and HACCP risk assessment training presented by Dyadem Engineering Corporation in Houston, TX - 2005
40. Attended an FDA/Industry Workshop on “2008 cGMPS” in Chicago, IL. on August 4, 2008.
41. Attended 1 day seminar on Food Safety & ISO 22000 and HACCP development - by Prisim eSolutions – May 2011
42. Was invited attendee at the Food Safety Summit Meeting Hosted by McDonald’s Corporation – November 2014
43. Completed Lloyds Quality Register FSSC 22000 Lead Auditor certification course – May 2015
44. Attended 3 day PCQI certification course presented by the Food Safety Preventive Controls Alliance – April 2017
45. Certified as a Preventive Controls Qualified Individual (PCQI) by the Food Safety Preventive Controls Alliance – April 2017