B&R Compliance Associates LLC

7956 Eagle Valley Pass
Indianapolis, IN 46214

DOCUMENTATION OF QUALIFICATIONS

FOR

RONALD E. BALL

Vice President
Managing Director

EDUCATION:

Graduate of Purdue University; West Lafayette, In. (1980) BA

WORK EXPERIENCE:

2002-Present
B & R Compliance Associates, LLC
Lehigh Valley, PA

Vice President & Managing Director

Co-owner and managing partner of independent consulting company specializing in regulatory compliance for the medical and industrial gases industry. Company specializes in validation, GMP procedure development, and FDA compliance program implementation and auditing. Served as FDA's "qualified individual" as part of remediating a major consent decree over a 7 year period. Responsibilities included certifying to FDA the firm's compliance activities met all relevant cGMP requirements for the following areas:

- Operating Procedures
- Internal audit programs
- Analytical systems qualification
- Analytical methods validation, including computer systems

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.

1999-2002
BOC Gases
Division of the BOC Group, Inc.

Manager/Loss Prevention Services

Oversaw (by providing direction & assistance) Loss Prevention Services Staff (6-8 ALPM's) responsible for maintaining BOC compliance programs.

Function included:

- System development (Procedures & Policies)(participated on several Manual Rewrite Project teams)(Active participant in IMSS initiative)
- Training (Med Gas QA/Numerous Safety/Crisis Communication)
- Performance Measurement (various audit functions: Med gas QA/Safety/Engineering)(active participant in integrated audit & audit manager initiative)
- Site Assistance (site projects/on-site hands on training/incident investigations)

1994-2002
BOC Gases
Division of the BOC Group, Inc.

Manager/Distributor Regulatory Affairs

Manage the development, marketing, implementation, and maintenance of BOC Gases Americas Distributor Regulatory Services program. This position actively promotes the adoption and use of BOC's loss prevention programs among BOC's independent distributors. This position works with division executives and distributor principals to establish plans, goals, and objectives. Programs significantly strengthen the perceived value of a BOC distributor franchise.

1993-1994
Airco Gases
Division of the BOC Group, Inc.

Compliance Coordinator, Gases

Responsible for maintaining the Airco/BOC Compliance Program in accordance with federal and state regulatory standards, industry guidelines, and internal company policies; within assigned geographical territory; with optimal efficiency and economy.

1982-1993
Airco Gases
Division of the BOC Group, Inc.

Regional Manager, Quality Assurance, Gases

Responsible for maintaining the Airco/BOC QA Program applicable to medical, food grade, and specific industrial gases in accordance with federal and state regulatory standards, industry guidelines, and internal company policies; within assigned geographical territory; with optimal efficiency and economy

1970-1981
Eli Lilly and company
Lafayette, Indiana

Senior Laboratory Technician
Analytical and Quality Control Laboratory (6 years)

Responsible for a full range of analytical and quality control procedures servicing production of major pharmaceuticals, antibiotics, and agricultural products.

Senior Laboratory Technician
Technical Services Laboratory (4 years)

Responsible for a wide range of troubleshooting and maintenance activities for ongoing manufacturing processes. Also responsible for scale-up of new production processes from laboratory sized reactions through pilot plant scale and into plant production.

Chemical Operator Manufacturing Plant (1year)

Involved in general chemical production work, including manufacture of pharmaceuticals, antibiotics, and agricultural products.

PROFESSIONAL MEMBERSHIPS:

1. AMERICAN SOCIETY FOR QUALITY CONTROL (ASQC) since 1986.
2. REGULATORY AFFAIRS PROFESSIONALS SOCIETY (RAPS) since 1988.
3. Member COMPRESSED GAS ASSOCIATION Medical Gas and Equipment Committee since 1999

Professional Qualifications/Date	**Institution**
Accredited Safety Auditor - 01/20/1994	DNV Corporation
ISO Lead Assessor Certified – 12/13/91	Statamatrix

TRAINING CLASSES:

1. Completed Perry Johnson, Inc. course for "Implementing SPC Effectively" on 9/18-20/90 in Detroit, MI.
2. Completed ASQC course for Quality Auditor Training on 1/31-2/1/91 in Indianapolis, IN.
3. Completed STAT-A-MATRIX INSTITUTE course entitled "Lead Assessor Certification Workshop" Conducted in Edison, N.J. on 12/9-13/91.
4. Completed Airco's Loss Control Performance Standards certification program in Lisle, IL. On 11/17/93.
5. Completed DNV's course for "Modern Safety Management" on 12/1-3/93 in Atlanta, Georgia.
6. Completed DNV course entitled "Accredited Safety Auditors" conducted in Atlanta, Georgia on 12/6-9/93.
7. Completed Airco's course on "Engineering Orientation" on 1/10-11/94 in Murray Hill, N.J.
8. Completed NSC course entitled "Principles of Occupational Safety and Health" conducted in San Francisco, CA. on 1/24-28/94.
9. Completed Airco's Interaction Management (AIM) Program on 2/18/94 in Lisle, IL.
10. Completed OSHA Training Institute course entitled "A Guide to Voluntary Compliance in Safety & Health" conducted in Kansas City, Mo. on 7/18-22/94.
11. Completed course entitled "A practical approach to Compliance with 21 CFR Part 11" conducted by Taratec Development Corporation on 2/14-15/00 in Philadelphia, Pa.
12. Completed BOC's course entitled "cGMP training for Auditors" conducted by Global Quality Consultants on 3/1-2/01 in Murray Hill, NJ.
13. Completed course entitled "Basic GMP's for the Medical Gas Industry" conducted by Sci Lucent on 12/12/01 in Murray Hill, NJ.
14. 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
15. 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

16. Completed course entitled “Implementing the Quality System Inspection Technique (QSIT) conducted by Pharmaceutical Training Institute on 5/20-21/02 in Chicago, IL.

17. Completed Course entitled “Process Hazard Analysis, FMEA & HACCP Training” conducted by Dyadem International Ltd. On 6/13-17/2005 in Houston, TX.

18. Completed Course entitled “Designated Representative and Exemptee Certification Class for the California Board of Pharmacy” conducted by Skills Plus International on 2/5/2010 via internet.

19. Completed Course entitled “FDA’s cGMP for Human Food” conducted by Caliso Corporation on 4/22/2011. (8 hour online training course)

WORKSHOPS:

1. Participant in workshop titled “Inspections and After” sponsored by the Food and Drug Law Institute on 6/26/84 in New York, N.Y.

2. Participant in workshop titled “Drug Development” sponsored by Regulatory affairs Professionals Society on 6/12-14/85 in Arlington, Virginia.

3. Participant in workshop titled “Basic Drug Laws” sponsored by Food and Drug Law Institute on 2/11-13/86 in Washington, D.C.

4. Participant in ASQC workshop entitled “Process Validation Update” on 10/15-16/87 in Chicago, IL.

5. Participant in Airco workshop on “Presentation Skills”, on 6/22-23/89 in Murray Hill, N.J.

6. Participant in ASQC course on “Fundamentals of Probability & Statistics in Indianapolis, In. During January and February of 1990.

7. Participant in QAI Limited workshop entitled “ISO 9002 Awareness Training” conducted in Murray Hill, N.J. on 12/16/91.

8. Participant in Airco Workshop on “Introduction to Industrial Hygiene” in Middlesex, N.J. on 1/12/94.

9. Participant in Airco Workshop on “MHRP” in Middlesex, N.J. on 1/13/94.

10. Participant in Airco Seminar on “Loss Control Training” in Lisle, IL. on 4/11-13/94.

11. Participant in JBF Associates workshop on “Process Safety Management” in Lisle, IL. on 4/14/94.

12. Participant in BOC Workshop on “Environmental Policies & Procedures” in New Orleans, La. on 9/26-30/94.

13. Participant in BOC Workshop on “Effective Driver Management” in Nashville, TN. on 12/7-8/94.

14. Participant in NSC professional development seminar “Grass Roots Safety Leadership, Culture Based Safety Improvement Strategies”, in Dallas, TX. on 11/9/95.

15. Participant in NSC professional development seminar “Executive Leadership in Safety & Health: Putting safety & Health on Senior Management’s Agenda”, in Dallas, TX. on 11/10/95.

16. Participant in BOC professional development seminar “Validation Issues in the Medical Gases Industry” in Toronto, Canada on 6/6/02

17. Completed course entitled “Implementing the Quality System Inspection Technique (QSIT) conducted by Pharmaceutical Training Institute – 2002

18. Attended Tele-conference course presented by the Regulatory Affairs Professional Society entitled Turbo EIR – 2003

19. Attended Tele-conference course presented by Immel Resources LLC entitled Part 11 and FDA's Risk-Based CGMP Initiative – 2003

20. Attended an FDA/Industry Workshop on "Drug Quality System-cGMP's For a New Era-2004" in Chicago, IL. on August 9, 2004.

21. Attended an FDA/Industry Workshop on "Drug Quality System-cGMP's For a New Era-2005" in Parsippany, NJ. on June 6, 2005.

22. Attended an FDA/Industry Workshop on "2008 cGMPS" in Chicago, IL. on August 4, 20008.