B&R Compliance Associates LLC

P.O. Box 190
Placida, FL 33946

DOCUMENTATION
OF
QUALIFICATIONS

FOR

Stephen C. Kerecman

Senior Associate

Revision 1

August 2017

EDUCATION:

Utah Technical College – Provo, Utah – Associates Degree in Electronics & Instrumentation

WORK EXPERIENCE:

2017- Present
Senior Associate, B&R Compliance
Easton, Pa

Senior Associate, B&R Compliance

Owner 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 as a qualified individual" for the following areas:

- Operating Procedures
- Employee training processes
- Process validation
- Computer operated distributed control systems
- Computer systems validation
- Process and personnel safety programs

2015 - 2016
Linde LLC
Operations Certification & Proficiency Mgr.
Bridgewater, NJ.

Served as Regional Process Owner (RPO) for the Regulatory Training and Compliance for Linde Cylinder Supply

Responsible for Medical Compliance and Quality Process functions in North and South America reporting to the Head of Cylinder Supply Chain Management. This position oversaw a staff of 350 Medical Site Managers and Staff in North America, Canada and the Caribbean supporting an Industrial and Medical gases business of over $1.7 billion in annual revenues. Responsibilities included:

- Created and established strategic continual training plans to ensure technical competence of the Cylinder Supply workforce.
- Developed, implemented and ensured compliance to theory and practical testing to ensure trained and qualified operators for US Healthcare, US PGP, CA Helium and the Caribbean
- Updated and maintained all new hire onboarding process and required training, utilizing LiMSS to ensure a standardized process for all employees within CSCM.
- Implemented Train-the-Trainer program for all salaried employees within Cylinder Operations for North America to ensure regulatory and compliance, to include cGMP.
- Implement a certification program for all hourly employees to ensure they are in regulatory compliance for the role they are assigned.
- Created and identified for each job function of operations employees, the Critical to Quality (CTQ) procedures and the critical HOME Chapters – e.g. Interaction with Patients, Patient Privacy, and the HCCG, and related podcasts for which the employee must understand and demonstrate competency before being permitted to perform his/her job.
- Reviewed and updated CSCM employee training profiles to ensure every individual's profile is aligned with his/her job function and all Critical Chapters are included in the employee's profile.
- Developed, trained and implemented a train-the-trainer program for each plant manager and supervisor to train his/her employees in cGMP. Include a method to assess the competency of the manager/supervisor and employee. Documented relevant certification and competency of each individual as applicable to their job function.

- Audited select sites against deliverables and kpi's associated with trained and implemented materials.
- Ensured compliance and sustainability of Individual Cylinder Control (ICC) processes.

2012 - 2015
Linde LLC.
Director of Medical & FDA Compliance
Murray Hill, NJ

Medical & FDA Compliance Manager

Responsible for overall compliance, validations, auditing and licensing for medical products manufactured and distributed in Region North America for approximately 150 medical sites, with over 500 employees. Own and provide direction to the business regarding compliance to State and Federal Medical Compliance associated with 21 CFR Parts 210, 211, 820 and Part 11. Responsible for the development, implementation, sustainability and champion all medical operations and quality assurance strategies, processes and standards to include industrial, medical, food, electronic and specialty gas products.

- 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 Linde with US industry associations
- Train all employees on medical and quality related issues and responsibilities with regard to GMP and regulatory compliance.
- Recognized as Subject Matter Expert on bulk supply and represented Linde as the vice chairman of the MGRP committee in the CGA.
- Championed Region North America and Linde customers to develop, implement and sustain bulk and packaged medical and industrial strategies, policies, standards, guidelines, processes and best practices
- Directly manage medical licensing and validation operations and implementation

2002 - 2012
BOC Gases
Manager, Quality Control
Murray Hill, NJ

Manager, Quality Control

Management of Quality Control for US operations including applications associated with Air Separation and CO2 operations and compliance with FDA Regulations. Create, develop and provide technical training and documentation for LiMSS implementation. Worked collaboratively with most lines of business within and outside of the organization. Served as North America Team of Expert for ASU, CO2 Quality and PGP Compliance. Led the development and implementation of Medical Regulatory Audit Question Set and conducted medical compliance audits of all BOC Gases Bulk Medical Locations.

2001 - 2002
BOC Gases
Assistant Operations Manager
Vancouver, WA

Assistant Operations Manager

Responsible for managing the day to day operations of four ASU's along with ensuring cGMP Compliance. This position managed 25 employees.

1978 - 2002

Air Liquide America
Operations & Transport Manager
Provo, UT

Operations & Transport Manager

Air Liquide was the largest manufacturer of industrial gases globally, with over $10 billion in annual sales. Promoted to Operations Manager with responsibility for the safe, efficient and reliable operations of Utah's Air Separation plants as well as bulk distribution. Coordinated the Orem facility construction and start-up operations. Ensured compliance with all government regulations. Supervised, trained and coached engineering, distribution and production staff. Led a team for the development and training Air Liquide's initial National Site Quality Control Unit.

TRAINING CLASSES:

1. Completed BOC's course on "Basic Presentation Skills" - 2002
2. Completed BOC's course on "Advanced Presentation Skills" - 2003
3. Completed BOC's course on "Crisis Communication Skills" – 2003
4. Completed 3M Corporation's course entitled "Total Quality Management" – 2003
5. Completed 3M Corporation's course entitled "Total Quality Facilitator" - 2004
6. Completed BOC's 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 - 2006
7. Completed BOC's 5 day Hazmat responder training course – Basic – Port Allen, LA – 2004
8. Completed BOC's 5 day Hazmat responder training & cylinder remediation course – Advanced – Port Allen, LA - November 2004
9. Completed BOC's course on OSHA Process Safety Management requirements & program implementation - 2002
10. Participant in BOC's Quality Assurance Training Program for Medical Gases: Averaged 1 session per every 2 years between the years of 2002 and 2004
11. Completed 4 day course entitled "GMP By the Sea" conducted by Pharma Conference Inc. – 2002, 2003 & 2007
12. Completed BOC's course entitled "cGMP training for Auditors" conducted by Global Quality Consultants – 2003
13. Completed course entitled "Basic GMP's for the Medical Gas Industry" conducted by Sci Lucent Corporation – 2002
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 – 2002
15. Attended FDA/Industry Workshop on "Drug Quality System – cGMP's for a New Era-2005" in Parsippany, NJ - 2005