Gerry Migliaccio
Consultant, Pharmaceutical Quality Systems
[redacted]

Work Experience:

August 2012 – Present Independent Consultant

Consultant in the area of pharmaceutical quality systems.

July 1979 – June 2012 Pfizer Inc

2009-2012 Senior Vice President, Network Performance, Global Manufacturing, Peapack, NJ. Responsible for driving overall performance and continuous improvement across all operating units and manufacturing sites, including leadership of the following organizations; Operational Excellence, Network Performance Strategy, Technical Learning and Capability, Global Engineering, Environment Health and Safety, Supply Chain Security and Enterprise Resource Planning. Also managed the Global External Supply organization during this period.

1999-2009 Vice President/Senior Vice President, Global Quality Operations, NY, NY. Overall responsibility for quality and environment health and safety operations at Pfizer manufacturing facilities around the globe.

1997-1999 Director of Manufacturing Operations, Asia, Africa, Middle East, Latin America and Canada, Global Manufacturing, NY, NY
Management of 20 manufacturing sites in regions including overall performance, budget, staffing and capital investment.

1992-1997 Director of Production Services, US Pharmaceutical Production, NY, NY
In addition to the Technical Services activities described below, added new product planning and launch, and package design and development.

1989-1992 Manager of Technical Services, US Pharmaceutical Production, NY, NY
Responsible for change management, NDA supplement preparation, deviation investigation and technology transfer for API and drug product.

Work Experience, continued:

1987-1989 Director of Process Control, Chemical Division, New York, NY
Responsible for all compliance activities related to the manufacture of APIs and food chemicals by the Chemical Division including change management, policies, and registration activities for both quality and environment, health and safety.

1983-1987 Section Supervision, Quality Assurance, Groton, Connecticut
Quality assurance for APIs, including deviation investigation, change management, audits and batch release.

1980-1983 Development Chemist, Antibiotic Manufacturing, Groton, Connecticut
Activities included process development and troubleshooting for non-sterile and sterile antibiotic APIs and in-process laboratory supervision.

1979-1980 Staff Chemist, Quality Control, Terre Haute, Indiana
Responsibilities included modernization of analytical methodology, analytical troubleshooting and laboratory supervision.

Work Related Activities:

2002-2012 Member of the International Society of Pharmaceutical Engineers International Leadership Forum and President's Advisory Council

2009-2011 Chair of the PhRMA Technical Development and Operations Committee

1999-2009 Member of PhRMA Quality Technical Group
During this period, chaired that PhRMA GMP Task force that collaborated with FDA on the 21st Century Quality Initiative.

2004-2007 Industry Representative to the FDA Advisory Committee on Pharmaceutical Sciences.

2005-2007 Rapporteur, ICH Q10, a harmonized guideline on the Pharmaceutical Quality System.

Work Related Activities, continued:

2004-2005 Chair of the International Society of Pharmaceutical Engineers International Leadership Forum

Other Activities:

Member of the Board of Directors and Quality Improvement Committee, Middlesex Hospital, Middletown, CT

Member of the Board of Trustees and Executive Committee, The International Yacht Restoration School, Newport, RI

Education:

1979 M.S. in Medicinal Chemistry from Purdue University, West Lafayette, IN

1977 B.A. in Chemistry from the College of the Holy Cross, Worcester, MA