Bridge Associates International LLC

"Partners for Quality and Manufacturing Excellence"

Ferdinando Aspesi, Ph.D.

Managing Partner

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Dr. Aspesi advises clients and their Management on Quality, Manufacturing, Regulatory and Compliance Strategies as well as organizational design with particular attention to proactive strategies and plans.

Dr. Aspesi has more than 35 years of experience in the Pharmaceutical Industry. He has worked in API and Drug Products Quality Assurance and Quality Control, in Pharmaceutical Research and Development and Analytical Development.

Dr. Aspesi has held positions as Global Head of Quality for Aventis and Wyeth Pharmaceuticals and led the Wyeth Pharmaceuticals Global Regulatory Affairs Chemistry and Control organization.

In Novartis from 2010 to2016 has held the position of Global Head Development QA leading the cGxP Quality and Compliance Sustainability Program for Pharma Development and the re-design of the Pharma Development Quality organization. He has become later the Global Head of OTC QA. From 2013 he has been the Senior Advisor for the Novartis Quality Head in charge to define the Company Quality Strategy and organize the External Engagement Group.

Dr. Aspesi has worked in the United States, South Africa, UK, Germany, France and Italy.

He has led up to 5,000 people Quality Organizations and has been part of Executive Management in three major Pharmaceutical Companies Aventis, Wyeth and Novartis

Over many years Dr. Aspesi has been active in external Industry Initiatives. He engaged with the US FDA on Process Analytical Technology and FDA 21st Century GMP's Initiative and was recognized by the US FDA as Industry Leader for the implementation of PAT and Manufacturing Science approaches.

He is a Member of PDA and ISPE where he contributed to the design of the Quality Metrics Pilot and where he is Member of the Global Pharmaceutical Manufacturing Forum.

He is Vice Chair of the ASTM E55 Subcommittee for "Pharmaceutical and Biopharmaceutical Manufacturing". He is also serving on the ASTM Board of Directors to advise about opportunities for ASTM in the Pharmaceutical Industry.

Dr. Aspesi holds a degree in Organic Chemistry from University of Milan/Italy

Background and Accomplishments

- 39 years experience in Drug Substance and Drug Product Quality Assurance, Development GxP QA, Quality Control, in Pharmaceutical Research and Development and in Analytical Development
- Work experience in the United States, Germany, France, UK, South Africa and Italy
- Led Global Quality Organizations with up to 5,000 people
- Part of the Executive Management in three major Pharmaceutical Companies: Aventis, Wyeth, Novartis
- Worked in different regulatory environments: US- Food and Drug Administration (FDA), European Union and South Africa
- Interfaced personally with EMA, Italian, French and Irish Boards of Health on major quality and compliance projects
- Engaged with the FDA on Process Analytical Technology and FDA 21st century GMP's initiative
- Contributed to the Design of the ISPE Quality Metrics Pilot
- Championed Quality and Regulatory Excellence in Industrial Operations and in different organizations
- Fostered implementation of Quality as well as Total Quality Management Systems in Industrial Operations
- Fostered implementation of Laboratory Information Management Systems and Lean labs on Global basis
- Led Regulatory Affairs CMC organization and implemented Global CMC change control systems linking plants and Affiliates
- Led Environment, Occupational Health and safety Strategy for Aventis Pharma (2001 - 2004)
- Vice chair of the ASTM E55 on "Pharmaceutical and Biopharmaceutical Manufacturing" Committee
- Member of the ASTM Board of the Directors (2016-2018)

Career History

- From November 1, 2016 Bridge Associates International LLC Princeton, NJ USA

  Pharmaceutical and Medical Devices Manufacturing and Quality consulting firm working internationally to identify and solve manufacturing quality and regulatory issues for the Pharmaceutical/Biopharmaceutical/food ingredients companies of all sizes

  Senior Partner

- 08/2014 – 09/2016 Novartis Pharmaceuticals East Hanover, NJ USA

  VP, Senior Advisor to Novartis Group Quality

  Contributed to the design of Novartis Advanced Quality Master Program

  Continued to serve as Vice Chair of the ASTM E55 "Pharmaceutical & Biopharmaceutical Manufacturing" Committee

  Member of the ASTM Board of Directors (2016-2018)

  Member of the Organizing Committee of the IFPAC Cortona Conference on Manufacturing and Quality Innovation.

- 09/2012 – 08/2014 Novartis Pharmaceuticals East Hanover, NJ USA

VP, Senior Advisor to the Novartis Global Quality Head

Responsible to design the Novartis Quality 2016 and organizing the External Engagement Group to properly represent Novartis in external Professional Bodies and with the Regulators

- 09/2011 – 08/2012 Novartis Consumer Health Parsippany, NJ USA

  VP, Novartis Consumer Health Quality Assurance Global Head

  Direct responsibility for approximately 400 Quality professionals covering Quality Control, Quality Assurance, Analytical Sciences & Technology and OTC Development GxP Quality Assurance

- 03/2010 – 08/2011 Novartis Pharmaceuticals East Hanover, NJ USA

  VP, Global Head Pharma Development Quality Assurance

  Direct responsibility for approximately 200 Quality Professionals covering Technical Development, Clinical Development and Pharmacovigilance

- 06/2007 – 10/2009 Wyeth Pharmaceuticals Collegeville, PA USA

  Senior VP, Global Quality and Compliance

  Direct responsibility for approximately 4,500 Quality Professionals in five platforms, Proteins, Vaccines, Small Molecules, Consumer Products, Infant Formula

  Global Sales: $ 22 Billion

- 04/2006 – 06/2007 Wyeth Pharmaceuticals Collegeville, PA USA

  Senior VP, Global Regulatory Affairs CMC and Compliance Auditing

- 02/2005 – 03/2006 Wyeth Pharmaceuticals Collegeville, PA USA

  Group Vice President, Global Compliance Operations

  Global sales: $ 17 Billion

- 01/2002 – 12/2004 Aventis Pharma Frankfurt, Germany

  Senior Vice President, Global Quality Operations, Environment, Health and Safety

  Global Sales: $ 18 Billion Quality Operations & EHS 6,000 people

- 07/2000 – 12/2001 Aventis Pharma Paris, France

  Vice President, Europe, Middle East Africa and Asia Pacific

  Regional sales: $ 7 Billion Quality Operations 1,500 people

- 12/1999 – 6/2000 Aventis Pharma Bridgewater, NJ USA

  Vice President, Quality Operations Americas and Asia Pacific

  Regional Sales: $ 6 Billion Quality Operations 1,100 people

- 08/1999 – 11/1999 Hoescht Marion Roussel Frankfurt, Germany

  Vice President, Global Quality Operations

  Global Sales: $ 7 Billion Quality Operations 1,650 people

- 07/1997 – 07/1999 Hoescht Marion Roussel Frankfurt, Germany

  Vice President, Quality Operations Europe, Middle East and Africa

  Regional Sales: $ 3.5 Billion Quality Operations 850 people

- 01/1996 – 07/1997 Hoescht Marion Roussel Kansas City, MO USA
  Vice President, Quality Operations North America
  Regional Sales: $ 2.3 Billion Quality Operations 500 people
- 01/1994 – 01/1996 Marion Merrell Dow Kansas City, MO USA
  Director, Quality Operations North America & Quality Hub North America
  Project Leader for Design and Implementation of Merion Merrell Dow Global LIMS
  Regional sales: 1.8 Billion Quality Operations 400 people
- 10/1991 – 12/1993 Marion Merrell Dow Cincinnati, OH USA
  Director, Quality Assurance (Quality Operations)
  Plant Sales: $ 800 Million Quality Assurance 60 people
- 02/1990 – 09/1991 Marion Merrell Dow Anagni, Italy
  Director, Quality Operations and Technical Director (Responsible Pharmacist)
  Plant Sales: $ 250 Million Quality Operations: 75 people
- 06/1985 – 02/1990 Marion Merrell Dow Anagni, Italy
  Manager, Quality Control and Support Leader, Quality Assurance Technology Center
- 10/1982 – 06/1985 Merrell Dow Johannesburg, South Africa
  Manager, Quality Control and Quality Assurance
- 06/1981 – 06/1982 Merrell Dow (Lepetit) Garessio, Italy
  Manager, Quality Control
- 01/1979 – 06/1981 Dow Lepetit Research Center Milan, Italy
  Research Chemist
- 03/1977 – 01/1979 Farmitalia Carlo Erba Research Center Milan, Italy
  Research Chemist
- 09/1975 – 03/1977 University of Milan – Statale Milan, Italy
  Research Chemist

Special Skills

Regulatory

- Knowledge of US Code of Federal Regulations for Drug and Biologics, FDA Guidelines and Policies on technical and FDA Compliance issues
- Understanding of the FDA interpretations and expectations of guidelines and policies for Drug Products and Biologics
- Knowledge of the FDA enforcement approach and expectations for GMP's and Submission Regulatory Compliance in the US and overseas
- Knowledge of the NDA filing requirements
- Understanding of the DEA and ATF Regulations

- Knowledge of the European Union GMP's and Marketing Authorization Application requirements
- Understanding of the Regulatory enforcements practices of the major European Health Agencies in particular UK, France Germany and Italy
- Understanding of the Japanese Regulatory and GMP's requirements
- Understanding of the EH&S and programs to achieve Excellence

Technical

- Knowledge of pharmaceutical technology
- Knowledge of different regulatory environment
- Knowledge of analytical and instrumental chemistry and microbiology
- Knowledge of manufacturing systems

Non-technical

- Excellent teamwork, people management, TQM and problem solving skills
- Fluent in English, Italian, French understanding

Membership

- Member of ISPE, PDA, ASTM and AAPS

Education

- 1969 -1975 University of Milan – Statale Milan, Italy

University Degree (Laurea) in Organic Chemistry

Thesis: "Photochemistry of Cyclohexanones Biciclo (6.3.1) Dodeca – 11ene-10one – Mechanism of Reaction"