Dr. Pier Mario Boso

Verbania
Italy
(M) +[redacted]
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CAREER SUMMARY

Highly accomplished and respected Senior Quality Director with 30+ years of experience that reflects achievements in pharmaceutical manufacturing and quality assurance. Europe Region South AbbVie Commercial QA Lead. Head of Business Unit Sanofi. Novartis Quality Director, Chair of the Steering Committee for Data Integrity Novartis with direct management of regulatory inspections worldwide, which includes overseeing governance and compliance oversight through audits, compliance upgrade projects and inspection management. Deep knowledge of GXP requirements and recognition for outstanding leadership skills after overseeing large global project teams (30,000+ personnel).

- *Global Compliance*
- *Quality Assurance*
- *Inspection Management*
- *Head of Business Unit*
- *Regulatory Affairs*
- *Corporate Governance*
- *Operating Procedures*
- *Technical Presentations*
- *Audit Preparations*
- *Quality Systems*
- *Project Management*
- *Mentoring*

CAREER ACCOMPLISHMENTS

- Director Quality Commercial Europe Region South and Qualified Person QP (FvP) for Switzerland Affiliate at AbbVie AG and Qualified Person (FvP) at Allergan AG
- Head of Quality EMEA Region at Soho Flordis International, Bioggio TI Switzerland
- Head of Business Unit Sanofi at Soho Flordis International, Switzerland (50 Mio CHF turnover)
- Director Quality, Senior GXP Auditor, Global Compliance and Auditing, Corporate QA Auditor (15+ years)
- Qualified Person EU
- Team Leader Quality Assurance
- Site Quality Director of Novartis Excellence Center for Stability Studies
- Technical Director granted by Swissmedic
- Novartis Signatory Authority (10 Mio CHF)
- Company Attorney (approve budgets and contracts)
- Member of Novartis Emergency Management Team
- Moderator of 30+ FDA, 20+ Swissmedic, 5 EMEA, 5 ANVISA , Russia, China FDA, Korean, Turkish and miscellaneous HA inspections with active HA networking
- Remediation lead of projects following consent decree and Warning Letters
- Extensive technical and management background - Completed various executive leadership & financial training
- Dynamic presenter capable of projecting a strong, credible, articulate and engaging personal presence
  - Invited speaker to multiple GMP presentation
- Established capability to manage relationships in multicultural environments
  - Languages: Italian (mother tongue), English and German (fluent written and spoken), Spanish (technical)
- 6x Italian canoeing champion (Olympic candidate for the 1984 Los Angeles Games) and 5x Italian champion at the Masters Game

PROFESSIONAL EXPERIENCE

AbbVie AG, Cham, Switzerland — **Sep 2019 - current**

QA Director Europe Region South Abbvie and Allergan Aesthetics Inc.

- Provide governance and compliance oversight of AbbVie Affiliate QA (Portugal, Switzerland, Lichtenstein, Austria, Greece, Malta, Cyprus, Turkey Israel and Palestine) ensuring adequate, time effective quality support for uninterrupted supply of medicines. Direct oversight of 4 manufacturing sites and TPMs.

Soho Flordis International, Bioggio, Switzerland **2018 – Aug 2019**

Director Quality, Head of Quality Assurance of EMEA Region

- Provide governance and compliance oversight of SFI manufacturing sites and affiliates (Pharma, CMOs, distributors and suppliers) trough audits, compliance upgrade projects and inspection management.

- *Head of Business Unit Sanofi , revenue of about 50 Mio CHF*

Novartis Pharma AG, Basel, Switzerland October **1989 - 2017**

Director Quality, Senior GXP Auditor, Global Pharma QA Compliance & Auditing (July 2012 – Dec 2017)

- Provide governance and compliance oversight of Novartis Pharma (Pharma, Biopharma, CMOs, CROs and suppliers) trough audits, compliance upgrade projects and inspection management (150+ audits performed as Lead Auditor)

- Compliance Director at Pharmaceutical Operation CH Stein sterile and solids (2000+ FTEs) including Supplier Qualification, Manufacturing support, Quality Upgrade Plans, Site Risk Assessments and preparation for Health Authorities Inspections (20+/year)
- Training and Certification of Auditors at different seniority level.
- Mentor of young Talents
- Mock PAI, for cause audits and Site preparation for regulatory inspections.
- Special audit program developed and performed on behalf of Business Compliance Office for malpractice verification.

- **Chair of Global Pharma Steering Committee for Data Integrity** (2010 - Present)
  - Manage and coordinate the activities of Group level Executives and Managers
    - The project covered the quality upgrade of 32 manufacturing sites, 80+ CPOs (Country Pharma Organization), 87 CMO and all clinical and research departments worldwide
  - Oversee and set companywide standards and procedures including:
    - Quality Manuals, Directive and Information Letters for data integrity
    - Author of Quality Manual for Novartis Group for Analytical Testing, Stability Testing, GDP, OOS Investigations and Computerized System Validation in analytical environment.
  - Implement a high-performance culture and best practice mentality within the global organization
  - Worldwide involvement in senior QA oversight in Pharma facilities, mock PAI, routine GMP, verification audits and quality remediation's
  - Business Project Manager implementation of SAP Novartis worldwide
  - Member of Expert Committee for AQWA (Trackwise) implementation

Site QA Director (February 2009 - July 2012)
- Responsible for all QA Governance including overseeing the assessments and certifications of new auditors
- Site Head at the Novartis Pharma "Center of Excellence", Locarno
- Authored multiple Quality Modules and Quality Directives for Novartis Group
- Member on site of the **Global Remediation Project for the Division OTC (Lincoln, Nebraska). Consent Decree**
- Certified global GMP Lead Auditor
  - Led cross-divisional worldwide audits at the senior level
  - Delivered verification audits and site preparations for health authority inspection including the FDA, ANVISA etc.

GMP Officer/ Lead Auditor Certified (February 2006 - January 2009)

- Professor of GMP at the Superior School SUPSI Southern Switzerland (2009)
  - Taught and mentored students completing their last year of specialization
- Successful achievements of Lead Auditor Certification by the Global Quality Organization (2008)
- QA Team Leader for the "Center of Excellence", Locarno
  - Accountable for all aspects of QA in the switch of reporting line from TechOps CH to Pharma QA (2006)
- Member of the **Marburg Novartis Vaccine & Diagnostics Remediation Project following a FDA Warning Letter**

GMP Officer (February 1999 - January 2006)

- Managed and oversaw all aspects of QA including:
  - Self-inspection, SOP redaction and approval, audit preparation and CAPA
- Compliance Team of PharmOps CH Switzerland, Stein
- Delivered on-site support for HA Inspections in related manufacturing sites (Swissmedic, FDA and Anvisa)
- Company Records Management Coordinator - Comprehensive knowledge of the Sarbanex-Oxley Act
- Selected PDA Trainer on GMP topics at the Italian Inspectorate of Ministry of Health
- Nominated as the Deputy Site Head of Locarno
- Invited speaker at multiple European stability conferences (2x Dublin and Prague)

QC Department Head (February 1995 – January 1999)

- QC of Raw Materials, Active Ingredients, Excipients and GC Lab for release analysis and stability testing
- Responsible for audit preparations and acknowledged as the SPOC for Health Authority Inspections
- Member of GMP Committee of Novartis Pharma

QC Manager (February 1992 - January 1995)

- Laboratory Head for the GC analysis of Drug Products, Active Ingredients, Raw Material and Excipients
- Head of the Method Development Project responsible for testing monograph upgrades of Raw Materials, mainly chiral molecules separation

Analyst (1989 - January 1992)

- QC Analyst for the release of Drug Products, Raw Material and Excipients

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EDUCATION & QUALIFICATIONS

- **Dr. Pharmacy** (1984 - 1990)
  - Università degli Studi di Pavia, Italy

Additional Executive Training:

- Product Management (Executive Education)
- Leadership Course I, II & III (Executive Education)
- Leading Teams (Executive Education, Novartis Basel)
- Finance Management and Pharma Budgeting (Executive Education, Novartis Basel)
- Improvement Action (Executive Education, Novartis Basel)
- Project Management Fundamentals (The George Washington University, Washington DC)
- Effective Presentation Skills (Executive Training & Develop Center, Novartis Pharma Basel)
- Emergency Management (Novartis Emergency Management)
- Media Communicator (Novartis Emergency Management)

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