GXP Assure
Supporting GxP Compliance Worldwide

# CURRICULUM VITAE

# Martin Moore

**BSc (Hons) Chemistry**
**Senior Consultant, GxPAssure**

**Recognised Areas of Expertise:**

- Highly experienced pharmaceutical quality and manufacturing specialist with a proven ability to identify and assess risk across complex manufacturing sites, including leadership effectiveness, operational culture, strategic alignment, internal controls, supply chain robustness, and current and future business needs. Demonstrated success in remediating sites operating under FDA Consent Decrees, Warning Letters, critical MHRA findings, adverse regulatory outcomes, and significant quality-performance issues.
- Expertise spans quality management system (QMS) design, quality and data integrity investigations, data governance frameworks, GxP compliance, and comprehensive site audit programmes, including Due Diligence assessments. Extensive experience preparing facilities for Pre-PAI, FDA, MHRA, EMA, and Rest-of-World regulatory inspections, as well as leading the development of effective, timely responses to inspectional observations.
- Technical background covers APIs, terminally sterilized and aseptically filled products, biopharmaceuticals, vaccines, topical formulations (ointments and creams), liquids, and solid-dose manufacturing. Brings thirty-eight years of pharmaceutical industry experience, including over twenty-five years in management and leadership roles.

**Current Employment:**

- Independent Consultant working on behalf of GxPAssure Limited
- MSM Pharmaceutical Consulting LLC

**Career History:**

- **January 2022 – Present: MSM Pharmaceutical Consulting LLC**
  - Performed GMP audits to identify compliance risks at US/EU manufacturing sites.
  - Written deficiency responses to 483's and Warning Letters.
  - Developed improvement plans to support remediation of quality activities in response to regulatory observations and/or prior to regulatory submissions.
  - Improvement plans due to regulatory observations, warning letters and significant 483's, have changed regulatory status of sites from OAI to VAI.

- **February 2021 – December 2021: Glaxo Smith Kline, Nebraska - Remediation Director, Lincoln Quality and Culture Remediation and Improvement Program**
  - Providing the structure and mechanisms enabling the site to coordinate cGMP remediation processes.
  - Developing and managing a detailed plan to deliver the necessary corrective and preventive actions to ensure sustainability of improvements.
  - Assessing senior leadership, managers and shop floor to evaluate site culture and developing action plans for improvement.
  - Work with the site leadership team, particularly the Site Director & Senior Leadership Team to demonstrate progress of the site transformation and overall remediation plan to senior management within GlaxoSmithKline.
  - Interfacing and overseeing activities of third-party consultants supporting remediation activities.
  - Tracking and reporting progress to Consumer Healthcare and Executive Steering Teams.
  - Providing cross-functional subject matter expertise to the understanding, communication, management and the development of corrective measures.
  - Providing structure and co-ordination of verification processes with the corporate audit. Manage remediation cost centre's tracked costs and provide projections to Senior management.

- **January 2016 – February 2021: Glaxo Smith Kline – Ethic and Compliance Director, Consumer Healthcare Quality and Supply Chain**
  - Lead the implementation of a values-based, effective and pragmatic compliance culture through guidance, policies, training, investigation and advice in order to prevent, detect and correct violations of company policies and regulatory requirements.
  - Being a strategic advisor and partner with the business to develop compliant solutions for Consumer Healthcare Quality and Supply Chain.
  - Partnering with senior Supply Chain leadership to influence their strategies, risk management processes and strategic decision- making.

- Assessing leadership capability and culture at manufacturing sites. Working with senior supply chain leadership to develop mitigation plans to correct capability and culture risks.
- Performing data integrity investigations to identify contributing factors which lead to the event.
- Ensuring governance frameworks were established and there was clearly defined links and escalation mechanisms to and from each governance board within the business unit.
- As a key member of governance boards, encouraging discussion of relevant, significant risks and ensured that issues and conclusions were escalated.
- Developing of tools for the identification of risk within internal and external manufacturing sites and across the Consumer Healthcare manufacturing supply chains.

- **December 2014 – January 2016: Glaxo Smith Kline - Head, Compliance and External Audit**
  - Provided leadership, direction and of a team of 90 that included Corporate Audit Directors & Audit Manager that performed and managed GMP compliance audits of Pharmaceutical (sterile and non-sterile), BioPharma, Consumer, API, Vaccine manufacturing sites, Third Party Contractors supplying GSK, Logistical Service Providers, Research and Development Centres and Local Operating Companies. My responsibilities included:
  - Developing and managing a comprehensive risk-based approach to the auditing of these entities; and provided senior management with assurance that risks are being identified and managed sufficiently to ensure the protection of patients, customers, shareholders, regulatory compliance and GSK's reputation.
  - Assessing leadership capability and culture at manufacturing sites. Working with senior supply chain leadership to develop mitigation plans to correct capability and culture risks.
  - Leading the development and execution of the Internal and external site Quality and Culture Remediation and Improvement Programs of sterile and non-sterile manufacturing sites.
  - Performing data integrity investigations to identify contributing factors which lead to the event.
  - Assessing and preparing of pharmaceutical (sterile and non-sterile), consumer, biopharma, vaccine manufacturing sites for Pre-PAIs, FDA, MHRA and EMA inspections.
  - Leading and performing Due Diligence Audits of potential acquisitions of manufacturing sites and products.
  - Overseeing quality integration of acquired sites into the manufacturing supply chain.
  - Reporting of regulatory compliance risks to senior and executive management.

- Influencing quality and compliance activities across the GSK supply chain.
- Mobilizing experts to investigate and resolve critical quality and compliance problems such as product recalls, critical or significant findings or Warning Letters.

- **March 2012 – December 2014: Glaxo Smith Kline – Director, Compliance Audit Group**
  - Provided leadership, direction and management of a team of 30 that included Corporate Audit Directors and Audit Managers that performed and managed GMP compliance audits of Pharmaceutical (sterile and non-sterile), Biopharma, Consumer, API, Vaccine manufacturing sites, Research and Development Centres and GSK Local Operating Companies. My responsibilities included:
  - Developing and managing a comprehensive risk-based approach to the auditing of these entities and providing senior management with assurance that risks are being identified and managed sufficiently to ensure the protection of patients, customers, shareholders, regulatory compliance and GSK's reputation.
  - Assessing leadership capability and culture at manufacturing sites. Working with senior supply chain leadership to develop mitigation plans to correct capability and culture risks.
  - Leading the development and execution of the Internal and external site Quality and Culture Remediation and Improvement Programs of sterile and non-sterile manufacturing sites.
  - Assessing and preparing of pharmaceutical (sterile and non-sterile), consumer, biopharma, vaccine manufacturing sites for Pre-PAIs, FDA, MHRA and EMA inspections.
  - Leading and performing Due Diligence Audits of potential acquisitions of manufacturing sites and products.
  - Overseeing quality integration of acquired sites into the manufacturing supply chain.
  - Reporting of regulatory compliance risks to senior and executive management.
  - Influencing quality and compliance activities across the GSK supply chain.
  - Mobilizing experts to investigate and resolve critical quality and compliance problems such as product recalls, critical or significant findings or Warning Letters.

- **August 2011 – February 2012: Glaxo Smith Kline – Quality Director, Central America Quality**
  - Led the development and execution of the Quality and Culture Remediation and Improvement Programs for the Panama and Costa Rica supply sites.
  - Led and managed teams performing compliance assessments at Panama and Costa Rica supply sites which resulted in ceasing of manufacturing and supply of product and a recall of all liquid/solid dose products for the USA.

- Developed Quality System Diagnostic process to assess total site risks to business unit. Process included evaluation of site culture, Quality, Technical and Risk Management capabilities.
- Interface with key senior supply chain stakeholders on a regular basis to update on Quality and supply issues.

- **January 2005 – August 2011: Glaxo Smith Kline - Audit Director, External Supply Audit, North Central and South America**
  - Provided leadership, direction and management of a team of 10 that included Corporate Audit Directors and Audit Managers that performed GMP compliance audits of the North, Central and South America, and Third-Party contractors supply sites.
  - One of the Directors leading the development and execution of the Cidra Consent Decree Remediation and Improvement Programs.

- **April 2000 – January 2005: Glaxo Smith Kline - Quality Manager, Global Quality Assurance – GMP Auditor**

- **November 1994 – April 2000: Glaxo Smith Kline - Research Scientist Analytical Sciences**

- **April 1990 – November 1994: Carter- Wallace Inc./Wallace Laboratories, Cranbury NJ – Senior Research Scientist**

- **April 1985 – April 1990: Warner Lambert Co./ Morris Plains, NJ - Parke-Davis Pharmaceutical Research and Development - Senior Associated Scientist**

- **February 1983 – March 1985: Luitpold Pharmaceuticals Inc., Shirley, NY - Senior QC Chemist**

**Education:**

- 1982: Bachelors of Science, Chemistry - State University of New York
- College of Environmental Science and Forestry, Syracuse, NY