



GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Peter Savin

BSc (Hons), MRSC, C.Chem
Senior Consultant



Recognised Areas of Expertise:

- Experienced Pharmaceutical Consultant having supported over 70 companies, globally.
- Over 48 years experience in the pharmaceutical industry, 35 years of it in multi-national pharmaceutical companies; including 25 years in the leadership of global functions
- Leadership of the development and implementation of quality, compliance, risk and corporate governance processes including:
 - Quality Management Systems, development and implementation
 - Risk Management and Risk Registers
 - Auditing, internal and external
 - Simplification, processes and documentation
 - Deviations, Investigations and CAPAs
 - Training, including senior management briefings and coaching
 - Organisational Design & Change Management
- Strategic business perspective of quality, compliance, auditing, risk management and corporate governance processes across R&D, manufacturing and commercial operations
- Extensive experience of UK IAG, US Warning Letter and Consent Decree remediation activities
- Development of Human Error Prevention, Quality Culture and Behavioural GMP

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Director of independent GMP consultancy providing services for multiple pharmaceutical companies



Career History:

- **2010 to Present: Independent Pharmaceutical Consultant**
 - Providing Consulting, Audit and Training services to over 60 companies globally.
 - Specialising in Quality Systems and Corporate Governance
 - Remediation including Quality culture and Human Error reduction with focus on behavioural GMP, deviations and investigations.
- **2011 to 2020: Editor, GMP Review, Euromed Communications**
 - Editorial responsibility for “GMP Review”, a quarterly publication circulated in Europe that analyses and provides expert comment on the effect of new and existing regulations on Compliance and Quality Professionals and operations of their companies.
- **2001 to 2009: Vice President - Global Quality Assurance, GlaxoSmithKline**
 - Reporting to the Company Secretary & SVP Quality, responsible for the Global Quality Assurance function:
 - Corporate Audit Function providing governance oversight and risk management of product quality and regulatory compliance across manufacturing, marketing and strategic 3rd party contractor network
 - The development and implementation of Quality Management Systems, Audit processes and Risk Modelling
 - Experience of Warning Letter and Consent Decree remediation and the establishment of Corporate Governance processes for Quality & Compliance
 - Preparation of Manufacturing and Development functions for regulatory inspections
- **1995 to 2001: Director, International Quality Assurance, Glaxo Wellcome**
 - Definition, development and ongoing review of corporate Quality Policies and QMS
 - Management of the corporate compliance audit function and technical function providing quality support to manufacturing and supply operations
 - Anticipation of emerging regulatory requirements and preparation of companies for regulatory inspections
 - Provision of Due Diligence service for product and company acquisitions
- **1985 to 1995: Manager, Quality Co-ordination Dept, Wellcome Foundation**
 - Internal and External Audit functions covering manufacturing sites, contractors and suppliers
 - R&D Quality function and release of CT materials



- **1975 to 1984: Various roles, Wellcome Foundation (1975 - 1984)**
 - New Product Introduction – sterile formulations of new antiviral drugs
 - Section head, International QC Laboratory
 - Analyst in Analytical Development

Education:

- BSc(Hons) Chemistry
- MRSC
- C.Chem