



CURRICULUM VITAE

Bob Martin

BSc (Hons)
Senior Consultant



Recognised Areas of Expertise:

- Brings over 17 years of experience as an FDA Consultant and Consumer Safety Officer, following earlier service as a Lead for the Crime Scene Unit for Massachusetts State Police.
- Working knowledge of the following:
 - Scanning Electron Microscope
 - Inductively Coupled Plasma Spectrometer
- SKILLS:
 - Inductively Coupled Plasma Mass Spectrometer
 - Ultra-Violet/Visible Spectrometer
 - Gas Chromatograph
 - Infrared Spectrometer
 - Nuclear Magnetic Resonance (400 and 600 MHz)
 - Gas Chromatograph/Mass Spectrometer
 - Flame and Cold Vapor Atomic Absorption Spectrometer

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- WC CONSULTING, LLC Exeter, NH - Principal Consultant

Career History:

- **February 2024 – Present: WC Consulting LLC, Exeter, NH – Principal Consultant**
 - Responsibilities include providing advice and guidance to CGMP processes concerning pharmaceutical operations for both human and animal drug products
 - Auditing pharmaceutical processes and systems; auditing 503B Compounding Facilities



- Providing guidance and conducting audits for Pre-Approvals for New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs)
 - Reviewing validation activities such as process validation, cleaning validation, analytical method qualifications, and equipment and facility qualifications
 - Providing vendor or service audits reviewing and approving Production Batch Records
 - Providing education withing CGMP operations as well as mentorship, providing remediation to FDA Pharmaceutical Inspections, and proving guidance for Quality Management Systems.
- **January 2020 – February 2024: US Food and Drug Administration, Stoneham MA – Consumer Safety Officer (OPQO Region 1, Group 3)**
 - Responsibilities include: conducting technical and complex inspections/ investigations
 - Evaluating data and evidence and assessing its adherence to policy and regulatory compliance
 - Interpreting and implementing existing laws, regulations, and guidance related to pharmaceutical programs; investigating complaints of injury, illness, or death caused by an FDA-regulated product
 - Initiating actions against violators
 - Advising industry, state and local officials and consumers on enforcement policies, methods, and interpretation of regulations
 - Providing expertise in inspection/investigation procedures and developing evidence for situations that may result in regulatory action
 - Planning and directing regulatory programs
 - Negotiating and resolving issues in sensitive situations arising in highly complicated assignments
 - Developing inspection procedures and techniques
 - Providing mentorship to new investigators
 - Formulating recommendations based on background and understanding of policies, regulations and procedures related to pharmaceutical manufacturing
 - Assisting Office of Criminal Investigations with investigations into human and animal drug products when requested
 - Conducting Pre-Approval Inspections for New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs).
 - Successfully completed certification programs in Basic Drug School (DG201), Industrial Sterilization for Drugs and Devices (MP302), Active Pharmaceutical Ingredient Manufacturing (DG303), Pre-Approval Inspections (DG30 I), Process Validation of Drug Manufacturing Operations (DG307), Biological Therapeutic Manufacturing (DG306) and Level III Drug Investigator Certification Training (DG408). Certified Level U Drug Investigator (2018).

- **August 2015 – January 2020, October 2008 – May 2012: US Food and Drug Administration, Stoneham MA – OPQO Region 1, Group 3**
 - Responsibilities include: conducting technical and complex inspections/investigations
 - Evaluating data and evidence and assessing its adherence to policy and regulatory compliance
 - Interpreting and implementing existing laws, regulations, and guidance related to pharmaceutical programs
 - Investigating complaints of injury, illness, or death caused by an FDA-regulated product
 - Initiating actions against violators
 - Advising industry, state and local officials and consumers on enforcement policies, methods, and interpretation of regulations
 - Providing expertise in inspection/investigation procedures and developing evidence for situations that may result in regulatory action
 - Planning and directing regulatory programs negotiating and resolving issues in sensitive situations arising in highly complicated assignments; developing inspection procedures and techniques; providing mentorship to new investigators formulating recommendations based on background and understanding of policies, regulations and procedures related to pharmaceutical manufacturing
 - Assisting Office of Criminal Investigations with investigations into human and animal drug products when requested
 - Conducting Pre-Approval Inspections for New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs)
 - Successfully completed certification programs in Basic Drug School (DG201), Industrial Sterilization for Drugs and Devices (MP302), Active Pharmaceutical Ingredient Manufacturing (DG303), Pre-Approval Inspections (DG301), Process Validation of Drug Manufacturing Operations (DG307), Biological Therapeutic Manufacturing (DG306) and Level III Drug Investigator Certification Training (DG408). Certified Level II Drug Investigator (2018).

- **September 2014 – August 2015: Sanofi Services Inc, Cambridge, MA – Associate Director Global Quality Audit**

Responsibilities include: Ensuring that Sanofi sites and third parties achieve, maintain and improve the current level of GMP/GDP compliance through the determination of quality and compliance deficiencies, monitoring of corrective actions, providing independent advice, recommendations and solutions identification and communication of emerging GMP, Regulatory and Industry trends and identifying, promoting and communication of “best practices”. This was achieved by the following four components:

 - Evaluating and Maintaining of Quality & Regulatory Compliance by making sure that sites are prepared for Regulatory Agency Inspections,

especially FDA Pre-Approval Inspections, through FDA "Mock" inspections, audit and support activities and training; planning, preparing and performing according to the schedule; preparing Executive Summaries, issues lists and audits reports in a timely manner based upon the above and distributes to the relevant personnel; performing routine follow up of performed audits in conjunction with site management; providing immediate support in the form of possible corrective actions during the audit, and contributes to management decisions in this respect and providing effective and timely reporting of compliance status of the respective sites to the Head of Global Quality Audits and updates the relevant presentation.

- Defining, implementing and maintaining of Quality Systems & Quality Product Standards by ensuring the establishment of an appropriate timescale of corrective actions in cooperation with the audited sites, and supports follow-up as agreed with and in conjunction with the Operational Units; participating in the planning, reviewing and approving of GMP related issues of new or remodelled facility layouts, including IQ/OQ/PQ validation activities; Maintaining own knowledge of current Sanofi Quality Policies, Standards and Guidelines as well as Industry practices and incidents, Regulatory requirements, and all other related information and keeping documented records of training received.
- Managing of interfaces with Regulators & Health Authorities, Clients and Suppliers by interacting with Regulatory Agencies/Health Authorities during Regulatory inspections as part of Inspection support activities as requested by the sites and Operational Heads and interacting with internal and external clients and suppliers to communicate audit findings and provide recommendations on CAPA.
- Developing and improving of Quality by supporting and participating in training efforts as requested by Operational Units and/or sites, including PAI preparation training and Auditor Certification training and developing a "pool" of auditors throughout the Sanofi Aventis group.

As an Associate Director Global Quality Audit I frequently conducted the above mentioned activities within the sterile manufacturing facilities, vaccine manufacturing facilities, sterile combination products (drug and device), non-sterile products and manufacturing of devices.

- **May 2012 – September 2014: US Food and Drug Administration, Stoneham MA – Consumer Safety Officer (Dedicated Foreign Drug Cadre)**
 - Responsibilities include: independently investigating complaints of injury, illness, or death caused by an FDA regulated product
 - Initiating actions against violators

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GXP Assure
Supporting GxP Compliance Worldwide

- Investigating and evaluating the adequacy of complex manufacturing practices to determine compliance with cGMP regulations
 - Advising industry, foreign officials and consumers on enforcement policies, methods, and interpretation of regulations; planning and directing regulatory programs
 - Developing inspection procedures and techniques; conducting Pre-Approval Inspections for New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs) outside of the United States
 - Successfully completed certification programs in Basic Drug School (DG201), Industrial Sterilization for Drugs and Devices (MP302), Active Pharmaceutical Ingredient Manufacturing (DG303), Pre-Approval Inspections (DG301), Process Validation of Drug Manufacturing Operations (DG307), Biological Therapeutic Manufacturing (DG306) and Level III Drug Investigator Certification Training (DG408).
- **October 2008 – May 2012: US Food and Drug Administration, Stoneham MA – Consumer Safety Officer (District Drug Group)**
 - Responsibilities include: investigating complaints of injury, illness, or death caused by an FDA-regulated product
 - Initiating actions against violators
 - Investigating and evaluating the adequacy of complex manufacturing practices to determine compliance with cGMP regulations
 - Advising industry, state and local officials and consumers on enforcement policies, methods, and interpretation of regulations
 - Planning and directing regulatory programs; developing inspection procedures and techniques; conducting Pre-Approval Inspections for New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs).
 - Successfully completed certification programs in Basic Drug School (DG201), Industrial Sterilization for Drugs and Devices (MP302), Active Pharmaceutical Ingredient Manufacturing (DG303), Pre-Approval Inspections (DG301), Process Validation of Drug Manufacturing Operations (DG307), Biological Therapeutic Manufacturing (DG306) and Level III Drug Investigator Certification Training (DG408)
- **March 2007 – October 2008: Massachusetts State Police Crime Laboratory, Maynard, MA – Acting Lead Supervisor for Forensic Biology**
 - Responsibilities include monitoring and coordinating the daily operations and activities of personnel in the Forensic Biology Section consisting of the following units: DNA Analysis, CODIS, Criminalistics, and Crime Scene Response
 - Provide technical assistance to laboratory personnel concerning laboratory activities

- Provide or arrange for the training of subordinates; implement new or revised laboratory policies and procedures; perform duties such as staff meetings, letter writing, memoranda and reports; respond to enquiries about laboratory tests results,
 - Testify in court or at hearings as an expert witness
 - Accommodate changes in volume or operating budget
 - perform various personnel functions; maintain current technical knowledge in forensic disciplines
- **November 2005 – March 2007: Massachusetts State Police Crime Laboratory, Maynard, MA – Assistant Technical Manager for Forensic Biology**
 - Responsibilities included the coordination and direction of daily operations for the Criminalistics Unit and Crime Scene Response Unit.
 - Operations included the Forensic and Technology Centre and three satellite laboratories based in Western, Central, and Southeastern Massachusetts.
 - Scheduled work assignments, determined testing priorities, performed case reviews, and general work flow of staff scientists.
 - Interacted with laboratory staff of the Criminalistics Unit and field investigators of the Crime Scene Response Unit to ensure daily operations were met.
 - Provided technical assistance to laboratory personnel concerning case work, crime scene investigations, and scientific methods used.
 - Attended meetings with investigators, staff scientists, and District Attorneys to offer technical advice and assistance.
 - Ensured that accreditation standards were complied with by members of the Criminalistics Unit and Crime Scene Response Unit.
 - Coordinated with the Research and Development Unit to implement mentoring programs to assist with integration of new staff scientists and supervisors.
 - Ensured staff scientists were kept abreast of case-working procedures and protocols and that scientist's external training needs were met.
 - Assisted and proposed revised scientific and technical procedures and training. Developed and implemented training modules, exercises, and case presentations for new field investigators.
 - Ensured the availability of supplies and equipment for use in the laboratory and in the field.
 - Performed case examinations and remained proficient in current forensic expertise in the areas of Criminalistics, Trace Analysis, Bloodstain Pattern Analysis, and Crime Scene Investigation.
 - Conducted staff meetings, generated technical reports, and responded to inquiries from investigators and prosecutors concerning laboratory and field investigation results.

- Testified in court and hearings regarding agency matters. Performed personnel functions including: recommendations for hire, promotion, transfer, and disciplinary action.
- Attended annual conferences and agency committee meetings.
- **February 2001 – October 2005: Massachusetts State Police Crime Laboratory, Maynard, MA – Crime Scene Supervisor, Crime Scene Response Unit**
 - Responsible for the supervision of crime scene responding forensic scientists
 - Supervised three counties in the Commonwealth of Massachusetts including: Middlesex, Essex, and Suffolk County for major case investigations
 - Conducted on-site examinations and reconstruction of forensically complex crime scenes
 - Daily duties included crime scene case resolution and liaison with other forensics specialty units to enhance training, qualifications, and service by forensic scientists at crime scenes.
 - Provided technical advice to local law enforcement agencies on measures to properly obtain and handle evidence
 - Conferred with investigators regarding facts and suspicions pertaining to cases to determine what types of test to be performed
 - Determined probative nature of evidence and prepared detailed technical reports on examinations
 - Analysed subordinate case work and drew logical conclusions for case presentation and prosecution
 - Liaison to the District Attorney's Office for the counties supervised
 - Planned and assigned work according to the nature of the job assignment and capabilities of subordinates
 - Determined subordinates training needs and provided or arranged for such training
 - Motivated subordinates to work effectively through strong leadership examples
 - Determined the need for any disciplinary action and either recommended or initiated disciplinary action
 - Attended advanced trainings, seminars, and workshops in the areas of forensic expertise regarding crime scene investigations and Criminalistic analyses
 - Read pertinent published materials in order to keep abreast of developments in the field
- **April 1997 – June 1998, October 1998 – February 2001: Massachusetts State Police Crime Laboratory, Maynard, MA – Forensic Scientist, Criminalistics Unit**
 - Conducted chemical, physical and biological examinations in the crime laboratory and on-site at crime scenes
 - Determined probative nature of evidence such as biological stains containing DNA, glass, paint, hairs and fibres, soil and vegetative matter



- Documented, preserved, and analysed items recovered from crime scenes and submitted to the laboratory
 - Prepared detailed technical reports for investigators, district attorneys, and other authorized personnel
 - Trained in the areas of: crime scene investigation; classification of trace evidence identification of pattern evidence including: bloodstains, footwear, tire marks, fingerprints, and fabric impressions; and evidence handling and submission
 - Analysed biological evidence including: blood, semen, and saliva and the initial classification of trace evidence including: hairs, fibres, paint, and soil
 - Conducted weapon examinations; clothing for damage analysis; and gunshot residues for distance determinations in shooting cases
 - Provided technical advice and assistance to local and state law enforcement agencies on measures to properly obtain and handle physical evidence
 - Conferred with investigators regarding facts and suspicions pertaining to cases to determine what types of test to be performed
 - Attended advanced trainings, seminars, and workshops in the areas of crime scene investigation and reconstruction, bloodstain pattern analysis, identification and preservation of evidence, and expert witness testimony
 - Read pertinent published materials in order to keep abreast of developments in the field
 - Incorporated the principles of quality assurance embodied in the Crime Laboratory's policies and procedures and
 - in compliance with A.S.C.L.D./LAB
- **June 1996 – April 1997, June 1998 – October 1998: OSRAM Sylvania, Beverly, MA – Inorganic Analytical Chemist**
 - Responsibilities included the analysis of research materials by classical and instrumental chemical methods for various engineering groups; provided support to the lighting group for Mercury reduction to meet EPA TCLP requirements
- **August 1993 – September 1994: Cambridge Isotope Laboratory, Andover MA – Analytical Chemist**
 - Responsibilities included the analysis of isotopically labelled compounds using instrumental techniques such as: high field NMR, GC/MS and GC; performed chemical tests to insure the highest quality data; assisted in development of new analytical methods
- **June 1992 – December 1995, September 1994 - June 1996: Leeman Labs Inc, Lowell, MA – Standards Lab Chemist**
 - Responsibilities included the preparation and development of high purity standards and reagents
 - Develop and maintained quality control and quality assurance procedures



- Organized and created ISO 9001 documentation for the analytical procedures in the Standards Laboratory; provided technical support to customers
- Managed the collection and disposal of all hazardous waste created by Leeman Labs, Inc
- **1986 – 1994: MILITARY UNITED STATES ARMY RESERVES Lawrence, MA**
 - EXPERIENCE: HHC 3rd/18th/187th Infantry Brigade, MOS – 11B (Infantry), Grade E4 1986-1994

EDUCATION:

May 1992 - SALEM STATE COLLEGE Salem, MA: Bachelor of Science in Chemistry; Minors: Criminal Justice and Physics

CONTINUED EDUCATION

- October 2007 - West Virginia University Forensic Management Academy (NIJ)
- October 2007 - International Association of Bloodstain Pattern Analysts (Annual Conference) – San Antonio, TX
- June 2007 - 35th Annual Crime Laboratory Development Symposium
- October 2006 - International Association of Bloodstain Pattern Analysts (Annual Conference) – Corning, NY
- July 2006 - Certified, Senior Crime Scene Analyst, IAI
- April 2006 - Medical Legal Death Investigation, SLU
- December 2005 - Death Investigation, Henry Lee Institute
- October 2004 - International Association of Bloodstain Pattern Analysts (Annual Conference) – Tucson, AZ
- December 2003 - Advanced Bloodstain Pattern Analysis (TBI)
- October 2003 - Bugs, Bones, and Crime Scenes (workshop) – Henry Lee Institute of Forensic Science
- January 2003 - Hazardous/Material Response for Crime Scene Technician
- November 2002 - Certified Crime Scene Analysts, IAI
- September 2002 - Incident Response to Terrorist Bombings (NM Tech)
- November 2001 - Advanced Crime Scene Reconstruction/Major Scene Logistics
- October 2001 - International Association of Bloodstain Pattern Analysts (Annual Conference) – Harrisburg, PA
- August 2001 - Serial Number Restoration (ATF)
- August 2001 - Advanced Crime Scene Investigation (IAI)
- August 2001 - Basic Bloodstain Pattern Analysis
- April 2001 - Crime Scene Investigation and Reconstruction
- November 2000 - Crime Scene Technology III (Northwestern University)
- June 2000 - Crime Scene Investigation (Miami-Dade)

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- August 1999 - Gunshot Residue Examination (FBI)
- June 1999 - Scanning Electron Microscopy (McCrone)
- April 1999 - Forensic Hair & Fiber Microscopy (McCrone)
- March 1998 - Basic Bloodstain Pattern Analysis (Henderson)

TECHNICAL SKILLS:

Working knowledge of the following: Scanning Electron Microscope, Inductively Coupled Plasma Spectrometer, Inductively Coupled Plasma Mass Spectrometer, Ultra-Violet/Visible Spectrometer, Gas Chromatograph, Infrared Spectrometer, Nuclear Magnetic Resonance (400 and 600 MHz), Gas Chromatograph/Mass Spectrometer, Flame and Cold Vapor Atomic Absorption Spectrometer

PROFESSIONAL AFFILIATIONS:

- 2001 – 2008 - Member, International Association of Identification
- 2001 – 2008 - Member, International Association of Bloodstain Pattern Analysis
- 2024 – Present - Member, Regulatory Affairs Professional Society