



ABDELLAH SENTISSI, Ph.D.

SUMMARY

Ph.D., Chemist, Pharmacist and Biologist with 25 years experience in creating and managing quality control laboratories and quality assurance systems for biotechnology companies. Strong relationship builder recognized for leadership success in start-up, technology transfer, partnership and M&A environments. Accomplished in quality affairs and in supporting process optimization, process validation, new drug development and clinical trials; demonstrated expertise in Clinical Laboratory Medicine. Over nine years experience as Biotechnology lecturer at Northeastern University-School of Pharmacy.

- cGMP expert for investigational and marketed drugs and biologics in broad range of clinical and biopharmaceutical fields.
 - Clinical fields: Oncology, neurological disorders, hormonal replacement therapy, and infectious diseases.
 - BLAs, INDs and DMFs in biopharmaceutical fields; plasma derivatives, vaccines, novel drug delivery systems, xenotransplantation therapy, autologous cell therapy and drug targeting.
 - Quality representative in 17 FDA-CBER/HPB-Canada inspections
- Documentation and Compliance (CFR, USP, PTCs, FDA, cGMPs, GCPs, GLPs, ICH)
- Validation of equipment, processes and methods (SOPs and protocols)
- Expert in Aseptic Processing (Sterile fills and lyophilization processes)
- Microbiological testing (Sterility, Environmental, Bioburden and Personnel Monitoring)
- Pyrogen testing (LAL, USP Rabbit assay, etc.)
- Raw materials, in-process and final product testing and disposition
- Product release, lot summary, label control, inventory control
- Modern analytical instrumentation operation (GC, LC, IR, DSC, Dissolution testing, etc.)
- Statistical evaluation of data trends (licensed products and INDs)
- Change Control Procedures and OOS/Non-Conformance/Investigation Procedures (CAPA)
- Technology and Method transfer and Material Specifications determination
- GMP training expertise
- GLP and GMP auditing expertise
- GCP expertise (generation of all required SOPs, manuals and documents for clinical trials)

PROFESSIONAL EXPERIENCE

ANTERION, INC, Salem, MA (*New drug delivery systems, implant manufacturing*) 2008-present, GXP consultant – provided expertise (CMC, Validations and Analytical work) to meet FDA requirements for phase 1 clinical trial.

TOKAI PHARMACEUTICALS, INC., Cambridge, MA (*An oncology company*) 2010, GXP Consultant – developed GLP questionnaire to facilitate GLP audits. Conducted GLP audits in the US (PA) and Scotland. Reviewed Batch records for starting materials, in-process materials, bulk crude products and final product.

TRANSMOLECULAR, INC, Cambridge, MA (*An oncology company*) 2005-2010. Vice President of Quality Systems, Manufacturing and Chairman of New Drug Development – successfully transferred manufacturing technology and operations from Alabama to Massachusetts. Built and established strong teams for Quality and Manufacturing. Led production, testing and distribution of products and optimized manufacturing processes. Directed new drug development and supported Phase 1 and 2 clinical trials.

- Improved and optimized the radiolabeling manufacturing process and trained and qualified over 40 nuclear pharmacists in 24 nuclear pharmacies in the US to ensure readiness for clinical trials
- Implemented Quality and Manufacturing SOPs, protocols, and logistics for cGMP operations
- Supervised the production, testing and distribution of 441 radiolabeled doses to 19 clinical sites to treat 160 patients in Phase 1 and Phase 2 trials.
- Designed and validated a DOT7A transport system for frozen doses delivery to nuclear pharmacies
- Trained the nuclear chemists at a commercial radiopharmaceutical CMO (Draxis-Canada) and transferred the process successfully for the patch model/scale-up prequalification work
- Successfully qualified a second major peptide vendor and designed the qualification/scale-up plan for Phase 3 and commercial scale production
- Developed a strong CMC document (CTA) for submission to Health Canada for Phase 2 trials and to FDA for phase 3 trials. No objection was received on the CMC section and TransMolecular was approved to conduct trials in Canada and in the US
- Developed the oncology drug targeting platform concepts and designed drug conjugates for TransMolecular, chaired the new Drug Development Committee

BIOVEST INTERNATIONAL, INC, Worcester, MA (*An Autologous Vaccine Company*), 2005, Vice President of Quality Systems – Instrumental in a successful MAB technology transfer of manufacturing and control from Charles River Laboratories, Malvern, Pa to Biovest. Created an efficient QA/QC department

- Participated in the planning and execution of the phase 3 trial for Biovaxid, an autologous anticancer vaccine developed by Biovest and NCI

- Organized the validation of QC methods, the validation of aseptic manufacturing suites and the validation of the aseptic fill and finish manufacturing process
- Developed a facility release document after the completion of all validation and qualification activities

GENVEC, INC/DIACRIN, INC, Charlestown, MA (*A Cell and Gene Therapy Company*) 1995-2005, Vice President of Quality Systems – successfully built and established a strong A/QC/GMP documentation team. Led the QC methods validation, testing, release and distribution of clinical trials materials. Played a key role in discussions with FDA reviewers, and in the joint-venture and merger-acquisition meetings and final decisions.

- Created a strong quality department at GenVec, Inc. by hiring, training, developing and validating assays, implementing a mandatory GMP in-house training program for the entire company, designing, and orchestrating multiple validation programs (autoclaves, processes, facilities, cleaning methods, etc), saving the company several thousand of dollars.
- Key player in the creation of the GenVec-Genzyme LLC and validation of a Phase III facility and a manufacturing process for the LLC's joint-venture in xenotransplantation.
- Managed the entire manufacturing, testing, and release of a monoclonal antibody at a contract manufacturing facility for GenVec, Inc. and wrote the Master file for FDA submission.
- One of the three key players in the merger-acquisition between Diacrin and GenVec and technology transfer operations for gene vector manufacturing from the Maryland labs to the Massachusetts's GMP plant.
- Managed the validation work, manufacturing, formulation, fill, and testing of several lots of gene vector products developed by GenVec for cancer therapy and antimalarial vaccine therapy.
- Managed the technology transfer operations for cell therapy products from GenVec to Terumo-Japan.
- Generated and implemented the corporate Quality Plan and Quality Manual for GenVec

ENDOCON, INC, South Walpole, MA (*A Drug Delivery Company*) 1992-1995, Director of QC/QA and Technical Affairs – Built and led a new QC/QA/Technical affairs group from ground zero. Key members of team in the merger-acquisition meetings which led to a successful collaboration and share acquisition by Wyeth-AHP

MASSACHUSETTS BIOLOGICAL LABORATORIES, Jamaica Plain, MA (*A Biological Company; Vaccines and Plasma Derivatives Manufacturing*), 1985-1992, QC Manager (Chief of QC Labs) – Reorganized, staffed and trained the QC/QA departments at the Massachusetts Biologics Laboratories to support the manufacture and distribution of four licensed blood products (Human albumin and Immunoglobulins) and three licensed adult and pediatric vaccines.

- Participated in the R&D, testing and FDA licensing of two Massachusetts Biologics Labs blockbuster immunoglobulin products (CMVIG and RSVIG) which were acquired by Medimmune
- QC/QA representative in 17 FDA/Health Canada inspections

EDUCATION

Ph.D., Clinical Chemistry, Northeastern University, Boston, MA

Master, Med Lab Sciences, University of California-San Francisco, San Francisco, CA

Bachelor of Science, Pharmacy, University Paul Sabatier, Toulouse, France

U. S. PATENTS

- **Treatment of metastatic tumors**, USSN: 12/466599, May 2009.
- **Chlorotoxin as Drug Carriers**, USSN: 61/954409, International patent application # PCT/US 0872524, Aug 2008.
- **Inhibition of Anti-Angiogenesis**, International patent application # PCT/US 08/76740, Sep 2008.
- **Repetitive Hit-and-Run Immunoassay**, US Patent 4801726, Jan 1989.
- **Anti-Angiogenic effects of Chlorotoxin**, US patent 61/954409.