John Hlavaty, Ph.D.

Senior Analytical Services Consultant

Core Competencies

- Analytical Strategy
- Antibodies/Proteins
- Method Authoring
- CMO Selection
- Automation in Analytics
- Validation Protocols
- Small and Large Molecule

Products

- Julia®
- Palforzia®
- MicroCor® products

Professional Summary

Dr. John Hlavaty is an accomplished scientist with over 20 years of both small and large molecule drug substance and drug product Analytical and QC experience. He has hands-on experience in a wide array of methods, including over 20 years of HPLC/UPLC, used to analyze molecules from early stage R&D to commercial stages. In addition, he has over 15 years of successfully managing and guiding teams through a product launch.

Dr. Hlavaty has led cross-functional team meetings by interacting with manufacturing, QA, supply chain, and RA teams. He has authored SOP's and CMC sections of IND, NDA, and BLA filings (includes FDA approved drugs), reviewed data, and interacted with FDA on CMC issues, including "Phase 4" projects (post-approval). He was responsible for all OOS/OOT results and ensured laboratory accuracy per USP, ICH, FDA, DEA, EA, and TGA guidelines.

Education

Ph.D.	Biochemistry	University of Notre Dame
M.S.	Biochemistry	University of Notre Dame
B.S.	Chemistry	Loyola University of Chicago

Professional Experience

Design Space InPharmatics, LLC **2020 – Present**
Independent Consulting

Senior Analytical Services Consultant

- Managed the QC team responsible for the chemical and microbiological testing of raw materials, in-process supplies, and R&D through commercial level (and post-launch) drug products.
- Wrote and implemented new company SOP's. Wrote, reviewed, and optimized analytical methods and validation protocols and reports per cGMP, FDA, USP, and ICH guidelines.

- Performed analytical and QC work and reviews, as well as regulatory authorship for numerous products, including the successfully launched Jublia® and Palforzia®. Worked on multiple MicroCor® transdermal drug delivery products.
- Guided projects (HPLC-UV, UPLC, Dissolution, GC-FID, Karl Fisher Titration, UV/Vis, FTIR, etc.) Provided troubleshooting for method and instrument issues.

Aquestive Therapeutics **2019 - 2020**

Manager Quality Control

- Managed the cGMP Quality Control (QC) team (8 people) that was responsible for chemical, microbiological, and *in vivo* testing of raw materials, in-process materials, and finished products for medicinal oral strips.
- Performed as a Contract Research Organization (CRO) and Contract Manufacturing Organization (CMO) for the development of products for partners from Phase 1 through commercial activities.
- Utilized knowledge of cGMP's, FDA, DEA, TGA, EMA and other relevant regulations for drug development and submissions. Established QTPP's and CQA's for client and internal products.
- Strategized QC department planning in terms of scheduling, capital expenditures, and validation needs.
- Worked closely with manufacturing, supply chain, and all out-sourced work (CRO) for the timely release of all raw materials and finished product. Tests focused on chromatographic and compendial (USP, EP, etc.) assays and included HPLC, SEC, Viscosity, FTIR, XRPD, particle size, dissolution, GC, microbial, etc.
- Oversaw the out-of-specification (OOS) and out-of-trend (OOT) testing results.
- Utilized ISO 9001:2015 techniques as part of the QMS system to ensure quality while performing internal audits and subsequent Corrective/Preventative Actions (CAPA). Provided troubleshooting for root cause analyses and performed non-conformance investigations.
- Authored, reviewed and approved QC SOPs, policies, analytical test methods, protocols and reports. Guided all additional method development, validation and transfers.
- Identified and addressed technical and validation gaps in analytical methods and QC testing for FDA and MMA submissions. Ensured compliance with all USP/FDA cGMP tasks, such as 21 CFR 210/211, etc.

Aimmune Therapeutics **2016 - 2018**

Director of Analytical Development & Quality Control

- Managed and developed members of the Analytical Development (AD) & Quality Control team for the development of allergenic products (large molecules) for the treatment of food allergies.
- Oversaw all activities associated with QC and stability testing of Aimmune's API and pharmaceutical products at CMOs and Contract Testing Labs (CTLs). Performed risk assessments for regulatory documents and advanced and managed internal product specification systems.
- Served as a section author and reviewer of CMC sections related to analytical methods and method validation, specifications, and stability in INDs, IMPDs, NDAs, BLAs, and other regulatory submissions.
- Partially authored the CMC section of the BLA for the recently FDA approved Palforzia®, the first approved drug to treat peanut allergies.

- Managed the development, validation, and transfer of analytical methods at and between CMOs and CTLs for protein API's. These included HPLC, ELISA, and total nitrogen combustion methods. Reviewed data for all Endotoxin tests for raw materials and stability/clinical products.
- Prepared and maintained Quality Agreements between Aimmune and contract entities.
- Audited (GMP) new CTLs and CMOs suitable for commercial stability and QC release.
- Interacted closely with other departments (Quality Assurance and Regulatory) in the development of product.,
- Established QTTP's and CQA's for internal products.
- Managed CTLs and CMOs to devise and implement improvements in analytical methods for BLA/MAA submissions and product commercialization.

Dow Development Labs **2015 - 2016**

Principal Scientist

- Managed analytical and QC activities for client activities (CRO/CMO). Developed and validated stability indicating methods for drug products (topical and transdermal) for both large and small molecules.
- Maintained and operated QC testing equipment, standards, and procedures in compliance with cGMP standards.
- Managed all external contract lab work (CRO, CMO, and CTL) associated with projects.
- Performed OOT and OOS investigations, testing of stability samples, and release of drug products,
- Reversed engineered topical formulations (including developing methods for excipients),
- Interacted with and provided scientific and timeline updates to clients,
- Guided feasibility and GLP testing. Performed Phase 1, 2 and 3 GMP analyses for Regulatory FDA submissions (included ANDA). Authored protocols and reports.

Corium International **2014 - 2015**

Principal Scientist II

- Managed a team of 13 scientists (M.S. and B.S. levels). Performed all analytical and QC functions,
- Guided the analytical and QC development of all MicroCor® transdermal delivery systems (for the delivery of proteins and small molecules). This included method development, quality control assessments, validations and stability testing of drug product batches,
- Authored analytical SOP's, test methods and forms,
- Executed QC tasks such as release of raw materials, OOT and OOS investigations and subsequent CAPA's, and stability tests,
- Guided feasibility and GLP testing, and Phase 1 and Phase 2a GMP analyses for Regulatory FDA submissions (achieved successful Phase 2a results),
- Interacted with collaborating partners providing updates, budgets and timeline information,
- Developed and validated methods for both small and large molecules used in GMP commercial release,
- Performed audits on CMOs and CROs.

Bausch Health (formerly Valeant Pharmaceuticals International) **2006 - 2014**

Senior Principal Scientist

- Managed analytical and QC team of eight scientists, including Ph.D. level scientists for client-based drug development. Guided as many as ten active projects simultaneously.
- Authored Regulatory CMC sections of Briefing Books, BLA, IND, IMPD, NDA and ANDA filings for multiple clients.
- Led the team development of all methods and QC/stability support for the product, Jublia®.
- Directed an analytical and QC team for the development, validation, and transfer of methods for both small and large molecules (e.g., oligonucleotides, peptides and proteins) for multiple clients.
- Performed QC tasks for the release of raw materials and drug products; analyses of stability samples; and executed OOS and OOT investigations (and corresponding CAPAs).
- Prepared analytical and QC team for successful regulatory inspections and audits. No FDA 483 violations observed in the analytical and QC group in over 8 years.
- Guided analytical aspects for GLP toxicity studies and Phase 1, 2, 3 and 4 GMP studies.
- Developed and validated methods currently used in GMP commercial release. These included HPLC, FT-IR, ELISA, SDS-PAGE, LC-MS, Western Blot, and cell-based methods.
- Increased company revenue by bringing in new services (SDS-PAGE, ELISA, amino acid analysis, Western Blotting, etc.) that attracted new clients.
- Established QTTP's and CQA's for client and internal products.
- Reversed engineered formulations using analytical techniques (e.g., HPLC).
- Provided scientific, budgetary and timeline updates to clients.

GlaxoSmithKline (formerly ID Biomedical; formerly Shire Biologics, Inc.) **2003 - 2006**

Scientist

- Developed, validated and transferred new HPLC methods to determine the purity and state of aggregation of protein vaccine formulations. Wrote and implemented all new SOP's, protocols and reports.
- Designed and implemented a new Western Blot method (semi-dry blotting) for the evaluation of membrane-bound proteins.
- Characterized proteins and evaluated methods of characterization using Capillary Electrophoresis (CE), SDS-PAGE, Western Blot, N-terminal amino acid sequencing, amino acid analysis, and some LC-MS.
- Performed GMP compliance aspects of the company, such as method and instrument qualifications, validations and SOP authorship.
- Executed audits on collaborating companies.
- Managed lab coordinator duties, including the proper maintenance of all instruments.
- Worked with production on fermentation and bio-processes to optimize cell growth.
- Facilitated ID Biomedical's ISO 14001 certification.

Curagen Corporation **2002 - 2003**

Senior Research Scientist

- Authored analytical sections of the CMC section for the first electronic IND submission.
- Developed new HPLC (SEC and RP) methods to determine the concentration, purity, stability and state of aggregation of protein therapeutic formulations (in oncology treatment).
- Developed antibody assays for quantitation (using SEC and Protein A/G columns).
- Performed or reviewed data for all Bioburden and Endotoxin tests for raw material, in-process, and stability or clinical products. Optimized cell growth in conjunction with fermentation/bio-process team.
- Developed improved methods (e.g., Western, protein concentration) to optimize performance and results.

Matritech **2000 - 2002**

Manager

- Discovered and identified a potential prostate cancer serum biomarker using proteomic techniques such as HPLC, MALDI-TOF, SELDI (Surface Enhanced Laser Desorption/Ionization mass spectroscopy – biochip technology), gel electrophoresis (SDS-PAGE and 2D-IEF), Western blots, protein purification and ELISA.
- Developed protein purification methods for cancer biomarkers from blood sera and plasma, including immunological methods to remove IgG proteins.