Bob Malone
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Skills

- Problem solving professional with extensive experience in multidisciplinary and multinational project teams capable of supporting product development through all phases and commercialization.
- 25+ years of pharmaceutical product development, quality and commercialization experience from virtual companies to billion-dollar global companies.
- 18+ years in Quality with increasing responsibilities including oversight of numerous development programs and in leadership and management roles.
- Strong technical background (B.S. in chemistry and M.S. in analytical chemistry) with the experience and ability to contribute broadly across a wide variety of functional areas.
- Constructed and modified company quality management systems in leadership roles.
- Directed product development in leadership roles from pre-IND through phase 3.
- Authored/reviewed/approved; SOP's; quality agreements; supply agreements; audit reports; test methods; specifications; regulatory submissions; master and executed batch records; process validation protocols and reports; media fills; master validation protocols and reports; complaints investigations; cleaning validation; stability study protocols; change control preparation, review and approval; OOS and product investigations.
- Identified, qualified, managed and audited contract manufacturers (including aseptic manufacturers) and suppliers to meet internal needs and timelines. Participated in PAI readiness and 483/warning letter remediation.
- Personally managed tens of millions of dollars of stability testing including data trending and investigations.
- Extensive experience in the preparation of NDA's (5), IND's and other regulatory submissions.
- Experienced with the development of combination products, including molding of plastic components and validation.
- Experience with solid orals, solutions, suspensions, blow fill seal inhalation products, inhalation and topical aerosols, injectables and sterile ophthalmics.
- Experienced with respiratory (asthma, COPD, allergy), CNS (depression, restless leg, anti-seizure) and other (anti-emetic, weight loss, ED) clinical development programs.
- Developed and managed validation of dry heat and gamma sterilization methods for drug substances.
- Self-starter and a team player with a customer service based approach and dedication to the company's goals, objectives and core values.
- Managed numerous Ph.D. level scientists both internally and externally.
- Managed annual budgets over $5MM/yr.
- Experienced world traveler.

Career Highlights

- CMC author/reviewer for five NDA's responsible for quality related sections. Three first round approvals including the first ever for a metered dose inhaler (MDI). Most were eCTDs with electronically submitted stability data.

- Headed quality and supported product development, process validation, launch and the first two years of Aerospan® Inhalation Aerosol sales. Authored supplements which reduced release and stability testing costs by 25%. Directed a critical technical investigation (unknown contaminant) preventing an impact to the product launch date and authored the investigation report.
- Managed $3MM of Aerospan stability data and authored the CMC section for submission that supported the subsequent sale of Acton to Meda for $135MM.
- Justified avoiding cold shipments of a refrigerated product from distributors to pharmacies, saving millions of dollars over the product life cycle.
- Outsourced and managed quantification and characterization of unknown particulate matter in Xopenex Inhalation Aerosol. First ever MDI approval with no question or commitment related to particulate matter. Developed an innovative approach to identifying elastomeric particulates via SEM/EDX after one of the best microscopy labs in the country (McCrone) said they did not know how it was possible.
- Led a multidisciplinary CMC team which developed a phase 1 clinical trial material for a new seizure medication and prepared the CMC section of the IND for submission in under a year.
- Managed quality, methods validation, stability and authored NDA sections for tecastemizole, which was not approved for safety reasons. Meant to be a competitor to Claritin, the development program consisted of three strengths of capsules, two strengths of capsules in combination with pseudoephedrine, three flavors of oral syrup and a rapidly disintegrating tablet program.
- Fixed a quality issue with an aseptically manufactured suspension for phase 3 studies, managed subsequent media fills and manufacture of a dozen batches on schedule.
- Supported method validation and process transfer for four marketed topical aerosol foam products to a new CMO.
- Identified several viable commercial aseptic manufacturers for clients and managed the quotation processes and technical interactions.

Work Experience

1/2015 – present Principal – Malone Pharma Consulting, Inc.

Provide drug product development and QA/QC consulting services. Experience from raw materials through drug substance and drug product.

- Directed product development and quality for a pharmaceutical company with two aseptically filled products in phase 3 for ten months after their successful IPO.
- Directed product development and quality for a local pharmaceutical company developing biodegradable polymer depot products for human use for six months.
- Directed product development and quality for a virtual pharmaceutical company developing a prefilled syringe in an autoinjector for a 505(b)(2) submission. Prepared the CMC portions of the Pre-IND briefing package.
- Supported quality and technical operations for Meda, including Aerospan and tech transfer of four marketed topical aerosol products to a new CMO.

10/2013 - 12/2014 Senior Director of Quality – Meda Pharmaceuticals Inc.

Oversaw process validation and the launch of Aerospan Inhalation Aerosol in March of 2014. Supplied quality oversight for batch releases of drug product and components, investigations and deviations, change controls, complaints and the supply chain. Developed and implemented cost control projects which significantly reduced testing costs. Supported retrospective development of the design history file.

12/2011 - 10/2013 Senior Director of Quality – Acton Pharmaceuticals

Developed the quality management system including the quality manual and SOPs in support of the product development and commercialization of Aerospan® Inhalation Aerosol. Helped re-establish the global supply chains (one with a warning letter and under an import ban) and qualified a new ex-US vendor for drug substance. Managed the revalidation of molding operations for the Aerospan® actuator spacer and development of the defect library for it and other device components. Managed collection of $3MM of stability data and authored much of the NDA supplement, including a complete stability package with extensive leachables data. There were no questions on the submission from FDA and it enabled the subsequent sale of Acton to Meda for $135MM.

2007 - 2011 Director of Development Quality Assurance – Sepracor Inc. / Sunovion

2003 - 2007 Associate Director of Technical Quality Assurance – Sepracor Inc.

Managed internal and external QA/QC resources supporting numerous developmental programs. Responsible for review and approval of batch records, media fills, process and method validation, release and stability testing, stability protocols and batch release. Managed product and OOS investigations and clinical complaints. Prepared quality and stability related parts of the CMC sections of IND's, IND Annual Reports and NDA's (including several eCTDs). Headed and served on multidisciplinary project teams, including international teams, representing Quality. Served on the global quality integration team. Provided quality oversight for phase 4 activities and technical support for the commercial products Brovana®, Xopenex®, Omnaris® and Alvesco®.

1999 - 2003 Quality Control Manager / Project Coordinator - Sepracor Inc.

Managed internal and external resources performing QC testing for numerous developmental programs. Prepared quality and stability related parts of the CMC sections of IND's, IND Annual Reports and NDA's (including in eCTD format). Served on multidisciplinary project teams to represent Quality.

1992 - 1999 Senior Analytical Chemist / Analytical Chemist- Sepracor Inc.

Developed and validated analytical methods for ICH/FDA compliance.

1989 - 1992 Research Associate – Sepracor Inc.

Experience with tangential flow filtration from bench to commercial scale for chemical and biological reactions.

Education

University of Massachusetts	M.S. – Analytical Chemistry	1999
Framingham State University	B.S. – Chemistry (Math minor)	1989

Publication

"First preparation of enantiomerically pure sibutramine and its major metabolite, and determination of their absolute configuration by single crystal X-ray analysis," Q. K Fang; C. H. Senanayake; Zhengxu Han; C. Morency; P. Grover; R. E. Malone; H. T. Butler; S. A. Wald; and T. S. Cameron, *Tetrahedron Asymmetry* 10 (1999) 4477-4480.