Martin W. Beasley, Ph.D., R.Ph.

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SUMMARY

Seasoned pharmaceutical scientist with broad experience in NDA/sNDA/ANDA product development, contract pharma development, and virtual product development. Skilled in all pharmaceutical dosage forms (oral, parenteral, topical) for small and large molecules, technical transfer, clinical and scale-up manufacturing, due diligence, patent support, FDA/regulatory and technical marketing/sales support.
Expertise includes:

- Dosage Form Design/Formulation/Evaluation from Clinical through Scale-Up Manufacturing
- Technical Transfer of clinical dosage forms to pharmaceutical sites for product manufacturing
- Patent Evaluations and Applications
- Due Diligence for acquisition of products, technologies and/or companies
- Chemistry, Manufacturing & Controls regulatory documentation and on-site meetings at FDA
- Strategic sourcing and budgeting of pharmaceutical services from internal and external partners
- Project Management/Technical Marketing/Consultative Sales Support
- Pharmacy Practice in teaching university hospital and military outpatient pharmacy

PHARMACEUTICAL CURRICULUM VITAE

Pharmaceutical Development Consultant – Cary, NC **Martin Beasley** **Jan 2012 - present**
Provide expert pharmaceutical and patent opinion to clients investigating therapeutic product development for pain, Parkinson's disease, CNS stimulation, and anti-microbial garments. Serve as Scientific Advisory Board member for NextGen Development Group LLC. Earned APHA Certificates of Achievement in Pharmacy Based Immunization Delivery, April 2013; Pharmacist and Patient-Centered Diabetes Care, June 2013; American Heart Association Certified BLS (CPR and AED) for Healthcare Providers (July 2015; July 2013).

Pfizer Pharmaceutical Development – Cary, NC **Mar 2011 - Nov 2011**
King Pharmaceuticals Research & Development, Inc. – Cary, NC **Dec 2003 - Mar 2011**
Senior Director, Pharmaceutical Development
Designed, planned and budgeted formulation development protocols; Wrote request for proposals; Supervised director of formulations, director of pharmaceutical development, and principal and senior scientists; Coordinated and evaluated dosage form development of adenosine-receptor NCEs, licensed drug delivery platforms (narcotic analgesics, transdermal patch) and managed product life cycle (patented delivery platforms) for King Pharmaceuticals' branded products. Coordinated and directed virtual CMC activities with contract development partners. Served as a King due diligence team member, and evaluated more than 200 opportunities with potential partners' intellectual property, including research and/or brand products for licensing/purchase/co-development. Transferred technology to Pfizer in 2011.

- Completed knowledge transfer of Remoxy, Bupivacaine Transdermal Therapeutic System, and Levoxyl tablets to Pfizer (three different project teams and sites) 3/2011 – 11/2011.
- Led Sub-CMC Team for Remoxy extended release capsules, following Complete Response Letter to DURECT, 12/2008. Under extreme one-year deadline, led multi-discipline CMC team through challenging dosage form attributes with external partners (in-vitro abuse deterrent tests; comparison vs. marketed reference product), manufacture of NDA resubmission batches (4Q2009), and writing Modules 2 & 3 for the eCTD.
  Result: NDA resubmission accomplished 12/2010.

- Served as a key CMC due diligence team member for 12/2008 ALPharma acquisition, targeting *Embeda* (extended release morphine sulfate and naltrexone hydrochloride), *Flector Patch*, and AL02 (extended release oxycodone hydrochloride and naltrexone hydrochloride). Coached director of formulations in the tech transfer of AL02 extended release capsules while simultaneously closing and transferring physical assets from ALPharma and negotiating multi-$million contract with external partner for technical transfer/scale-up in late 2009. **Result:** NDA submission batches successfully manufactured/delivered on-time in 4Q2010. *FDA accepted AL02 NDA submission on 13 February 2015.*
- Led SubCMC Team for Bupivacaine Transdermal Therapeutic System, licensed from DURECT (via ALPharma purchase). Led cross-functional team, including external partner. **Result:** Coordinated manufacture of Phase 2A batches for chronic lower back pain trial from late 2009 through 4/2010. Identified, selected, and negotiated tech transfer/scale-up with chosen commercial partners for Phase 3 submission batches in 2010.
- Coached principal scientist in developing Binodenosan for injection (A_{2A} agonist pharmacological stress agent for cardiac imaging).
  Result: CorVue NDA submission batches completed and Module 3 eCTD quality control executed. NDA submitted 12/2008 (FDA accepted CMC modules).
- Directed/coached senior scientist in developing Phase I hard gel/liquid fill cap (CNS)
  Result: IND filed 3Q2008. Clinical trial cancelled based on business case review.
- Coached King-St.Petersburg (FL) scientist through *Levoxyl* tablets (levothyroxine sodium) reformulation and tech transfer/scale-up at Bristol site, resulting in superior stability.
  Result: NDA supplement filed in 3Q2008 and product approved 1Q2011.
- Served as Key CMC due diligence team member for *Avinza* (morphine sulfate modified release beads) acquisition from Ligand, 02/2007. Collaborated PLCM activity with partner Elan. **Result:** 2 new SKU's (intermediate 45mg and 75mg strengths) approved 12/2008.
- Served as Key CMC due diligence team member for securing Acura tablets (Aversion platform) license, 11/2006. Coached director of formulations in Phase 3 activities/follow-on products. **Result:** Aversion licensed 11/2005; renamed *Oxecta* tablets. FDA approved 6/2011.
- Key CMC due diligence team member for securing Remoxy (oral abuse deterrent dosage form) license with Pain Therapeutics, Inc., 11/2005.
  Result: Remoxy licensed 11/2005.
  Mentored principal scientist in successfully executing collaborative Phase 3 activities and initiated plans for Remoxy follow-on products.
- Served as key CMC team member for Metaxolone PLCM activities with two external development partners, 11/2005 through mid-2009.
- Mentored director of formulations in successful completion of NDA submission batches for ramipril/hydrochorothiazide tablets (three sku's) and IND CMC submission (3/2006). NDA submission filed 4Q07 (later withdrawn).
- Mentored senior scientist and director of formulations in successful formulation of IND Ramipril tablet product with superior stability profile. IND filed 5/2004 and tech transfer/CTM manufacture completed in 3Q2006. Project terminated late 3Q 2006.
- Mentored senior scientist and director of formulations in successful formulation of NDA Ramipril/chlorthalidone combination tablet product. NDA filed 6/2004.
- Coached principal scientist in writing FDA briefing document that successfully argued for manufacturing Phase 2 MRE0094 gel product under non-aseptic conditions due to inherent, self-preserving/chemically sterile properties. Phase 2 batches manufactured (3/2006) and dosed in clinical trial. Technical transfer of analytical methods completed, but commercial scale-up ended 01/ 2008, due to non-achievement of primary clinical endpoint.

- Coached principal scientist in coordinating MRE0094 injectable formulation with Preclinical group and contract tox lab in preparation of two-year carcinogenicity study. Program cancelled after Phase 2 clinical trial completion.
- Directed and coached senior scientist in developing new modified release dosage form for *Cytomel* Tablets (liothyronine sodium). Lead prototypes with various release profiles were identified in 3 different dog PK studies (07/2004; 3Q 2005). IND filed 3/2006 and 2 test articles dosed in POC study, 05/2006. PK data revealed a potential, unique dosing pathway.
- Collaborated as a Key CMC scientist with T3 Therapeutics for investigating modified release liothyronine sodium beads. UK due diligence trip (Archimedes, 6/2005) defined IND suitability. Dosed test article in dog PK study #3 (8/2005), coordinated analytical verification activities (2005 – 2006), and advised partner for dosing beads in POC study. Coached and directed senior scientist for coordinating and reviewing analytical verification per FDA guidelines. Collaboration ended 11/2007.
- Successfully negotiated contract with Pharmaceutical Profiles for the investigation of T-62 GI absorption via gamma scintigraphy (King's first IMPD in the UK, 1Q2005). Phase 1 IMPD study completed in 2006. Coached/directed senior scientist in Phase 2 soft gel dosage formulation optimization. Optimized clinical trial material manufactured in 3/2007 and Phase 2A trial for chronic lower back pain completed in 1Q2009. Program cancelled in 2009 due to liver toxicity.
- Coached principal scientist in the feasibility development of oral dissolvable strips for *Sonata* (zaleplon). Project initiated 2004 but terminated 4/2006 due to market conditions.

KING PHARMACEUTICALS RESEARCH & DEVELOPMENT, INC Cary, NC **April 2001-Dec 2003**
Director, Pharmaceutical Development
Designed, planned and budgeted formulation development protocols; Wrote request for proposals; Coordinated and evaluated dosage form development of adenosine-receptor NCEs; Coordinated and directed virtual CMC activities with contract development partners; Coached formulation director and senior scientist development activities; Served as a King due diligence team member for evaluation and acquisition of technology.

- Led successful formulation development and IND filing of King Pharmaceutical's second Phase I NCE: T-62, an adenosine allosteric enhancer for neuropathic pain oral product. IND filed 8/2003.
- Directed successful feasibility development of stable MRE0094 Injection for nine-month toxicity study support of MRE0094 gel Phase I (2002-2003).
- Coached director of formulations in preclinical formulation support of A3 receptor antagonist identified as potential co-therapeutic oncology agent (4Q2003). Program cancelled in 2008 due to business case.
- Served as the key scientific contract negotiator for development of H2/calcium carbonate in a patented, orally disintegrating tablet platform with Eurand. In parallel, directed/coached senior scientist in successful development of stable, pleasant tasting prototype tablet with contract development partner. Project terminated in 6/2004.
- Key scientific negotiator for contract closure with SkyePharma - King Pharmaceutical's first drug delivery license - incorporating ramipril into SkyePharma's patented, modified release GeoMatrix platform. License agreement signed 5/ 2003 but project terminated 8/2004.
- Directed and coached senior scientist in successful taste masking of Tigan, an anti-emetic marketed as capsules and rectal suppositories. Stable, prototype oral solution identified in 2003. Technology archived due to project termination in 4/2004.
- Directed and coordinated transdermal patch prototype development for ramipril with drug delivery partner and transdermal consultant. Feasible prototype identified for in-vitro delivery of ramipril over 3.5 days (7/2002). Project terminated in 6/2004.

- Conceived idea for coating *Levoxyl* tablets to slow oral disintegration in direct response to consumer complaints (4Q2001). Directed/coached senior scientist in identifying feasible solvent coating process and feasible optimization of analytical methodology for prototype coated tablet. Project terminated in 6/2004.
- Served as scientific advisor/ad hoc team member for PLCM dosage form development of Phase 2/Phase 3 Sonata MR and proposed Skelaxin MR with Elan. Project terminated in late 2005.
- Directed CMC for Phase I wound-healing MRE0094 topical gel formulation, an adenosine a_1 agonist. MRE0094 was King's first NCE IND filing (4/2002).
- Provided Business Development due diligence support for more than 200 different opportunities.

AAI INTERNATIONAL - Wilmington, NC **Sep 1991 – Apr 2001**
Technical Director, Global Product Development-Pharmaceutics (Apr 1999 – Apr 2001)

Defined drug development and marketing needs for pharmaceutical clients, primarily in Eastern U.S., Michigan and Europe. Applied technical knowledge to match client needs, logistics, timeline, deliverables, and budget with AAI Pharmaceutics' capabilities. Trained sales directors and pharmaceutical scientists in consultative sales technique. Acted as key contributor for $20MM in signed Product Development (Pharmaceutics) contracts for Year 2000.

- Negotiated and coordinated marketing alliance with contract cGMP sterile manufacturer of Phase I/Phase 2a parenteral dosage forms (later acquired by AAI])
- Utilized scientific expertise to help the group grow Pharmaceutics' 1999 revenue by 14%
- Continued the growth of multi-million dollar account for Phase III periodontal microcapsule dosage form--projected revenue growth 300% by 2002 and 650% by 2005 (FDA approval 02/2001; marketed product is *Arestin)*
- Marketed product development services with clients (on-site visits and at client site), International and national scientific meetings, company sponsored seminars, and telephone conferences

Associate Director, Business Development/Process Technology, Manufacturing Services (Apr 1998 – Apr 1999)
Defined and marketed clinical trial manufacturing services and niche commercial manufacturing. Directed the Process Technology Group (Manager, Senior Packaging Engineer, Process Engineer, and Packaging Engineer) for scale-up manufacturing/packaging products:

- Mentored the scale-up NDA submission batches for Phase 3 periodontal microcapsule (marketed as *Arestin*)
- Mentored the scale-up of NDA submission batches for a Phase 3 male impotence tablet
- Coached the scale-up and validation of highly potent Azathioprine 50mg tablet. Market launch of ANDA was 1999.
- Monitored the process validation of doxycline capsule [*Periostat*] and SUPAC transfer of corticosteroid tablet that was completed/approved for 2 different clients, respectively.
- Negotiated and closed contract for market labeling of an ANDA oncology parenteral product by packaging group, the first generic on U.S. market
- Coached the upgrade and validation of the King packaging line with significantly increased bottle filling efficiency for the Azathioprine product and doxycyline product
- Co-authored MSD section of five-year Pharmaceutics Business Plan

Director, Business Development, Clinical Services Division (Feb 1997 – Apr 1998)

Identified, defined and marketed clinical trial manufacturing opportunities, helped grow the existing client base, and provided scientific dosage form development and scale-up manufacturing expertise to achieve division's revenue target.

- Scientific expertise was major factor for increasing the division's signed $ growth rate by 50% and signed contract rate by 14%, respectively, compared to 1996
- Helped grow the Business Development group from 4 to 8 associates based on increased contract demand and signed contracts, due to travel with sales force.
- Although officially transferred from operations into sales and marketing, maintained operations role as Project Leader for two ANDA projects until successful completion:
  Midazolam hydrochloride for Injection: ANDA filed 6/1997, on time-on budget, and approved for market 6/1999
  Azathioprine 50mg tablet: ANDA submitted11/1997 and approved for market 6/1999.
- Continued consulting formulation development projects/tox ratings (Safety Advisory Team)

Senior Manager, Formulations Development Laboratory (FDL) (Sept 1991 – Jan 1997)

Coordinated and directed product development activities of 8 - 18 formulation scientists for IND/NDA, NADA and ANDA dosage forms. Prepared revenue/expense forecasts, Prepared capital budget requests, met with clients and outlined project plans to exceed their expectations, trained operations and sales personnel. Served on AAI Management Team, R & D Committee, Patent Committee, Controlled Substances Committee, and Safety Advisory Team.

- Served as Project Leader for several IND teams: antiarrhythmic capsules; male impotence transurethral Pellets (*MUSE*); veterinary anti-inflammatory tablet; antiepileptic capsules
- Served as Project Leader for several ANDA teams: antibiotic caps/tab/oral powder; anesthetic injection; controlled release anti-hypertension cap/tab; Azathioprine tablet
- Managed INDs for Alzheimer tablet (*Aricept10mg*), anti-sepsis injection, antibiotic ophthalmic solution, anti-atherosclerosis injection, anti-multiple sclerosis injection, anti-sickle cell oral solution/injection, anti-viral cream, anti-inflammatory dental gel (*Apthasol*), and NDA supplement for anti-psychotic tablet (*Nardil*)
- Managed ANDAs for two anti-ulcer injections, anti-inflammatory injection, Acyclovir anti-viral tablets, Estradiol tablets, hemorheologic tablet, Azathioprine tablet, anti-asthma oral solution/inhalation solution, and cystoscope dye injection. Managed ANDA injectable compatibility studies for antibiotic, antihypertensive, narcotic analgesic, and anesthetic drugs.

APPLIED ANALYTICAL INDUSTRIES, INC. - Wilmington, NC **Jun 1988 – Sept 1991**
Manager, Formulations Development (FDL) (May 1989 – Sept 1991)

Coordinated and directed the product development activities of 19 formulation scientists. Prepared revenue/expense forecasts and prepared capital budget requests. Met with clients and outlined project plans to exceed their expectations, and trained operations/sales personnel. Prepared and coordinated development and stability reports for regulatory submission.

- Reformulated anti-acne *Stridex* product – five new SKUs approved for the OTC market
- Designed lyophilization cycles for peptide/protein parenteral dosage forms
- Tech transferred German diuretic injection into cGMP facility (*Demadex*, NDA approved)
- Appointed AAI's 1st IND Project Leader for a multi-national Pharma client's oral CNS dosage form program
- Established and coordinated summer pharmacy internship program for industrial training of students from Campbell University and University of North Carolina-Chapel Hill

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