Ralph A. Lessor, Ph. D.

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During my 32+ years in the pharmaceutical industry, I have built a history of significant accomplishments and broad experience across virtually all facets of the drug development, manufacturing and marketing process. My record of technical experience and innovation spans drug discovery, chemical manufacturing process development and validation, preclinical and clinical demonstration of new product safety and efficacy, planning and management of complex product development and improvement programs, intellectual property expertise including extensive litigation of patents in US, EU, Japanese and United Kingdom venues, and successful development and submission of global regulatory filings for new pharmaceutical products and container/closure systems and for manufacturing process changes for marketed products. My excellent written and verbal communication skills have made me an effective technical partner for manufacturing, marketing, regulatory affairs, medical affairs/product safety and product quality functions within a global pharmaceutical business organization.

Professional Experience

Baxter Healthcare, Round Lake, IL

Principal Scientist, Anesthesia Science 6/2013-3/2019

Global technical leader for Baxter Anesthesia product line, supervising activities in chemical process research and development for manufacture of inhaled anesthetic products, container/closure and delivery device interface and validation, as well as all life cycle and technical maintenance activities for globally marketed, >$500MM anesthetic product portfolio. Chemical process improvements implemented resulted in >$6MM reduction in annual production cost for sevoflurane and net 8% increase in production capacity with minimal capital investment. Team developed, validated and launched an improved closure/interface system for Suprane inhalation anesthetic, as well as Baxter's first integrated closure/vaporizer interface system for sevoflurane.

Principal Scientist, Pharmaceutical and Process Sciences 7/2012-6/2013

Led establishment of anesthesia R&D operations at Round Lake campus to support transfer of Baxter Anesthesia business operations from New Providence, NJ to Illinois, including design and construction of state-of-the art laboratories for anesthetic chemical process research and analysis. Supported innovation initiatives and business development opportunities within Baxter R&D portfolio.

Baxter Healthcare, Global Anesthesia and Critical Care, New Providence NJ

Director, Research 12/2010-6/2012

Technical lead for life cycle management and product improvement programs for inhaled anesthetic products; technical evaluation of business development opportunities; planning and supervision of internal and contract research programs on existing and future pharmaceutical agents.

Baxter Healthcare, Baxter Pharmaceuticals and Technologies, New Providence, NJ

Director, Product Development, 10/07-12/2010

Led internal Baxter non-clinical R&D and innovation efforts on Hylenex and related products, integrating R&D plans for new products and enhancements with global product strategy and Long-Range Plan. Responsible for project management and technical aspects of production planning, process improvement and revalidation efforts, and cross-functional investigation and resolution of product quality issues. Provided technical and litigation support for Anesthesia business based on prior experience and involvement in inhaled anesthetic programs. Planned and initiated two exploratory programs in Hylenex/drug coformulation area, leveraging Baxter internal resources at three geographic locations and one external contract laboratory. Led multidisciplinary team assessing scientific, clinical and regulatory feasibility of hyaluronidase-assisted subcutaneous drug administration.

Baxter Healthcare, Anesthesia/Critical Care and Oncology, New Providenc,e NJ

Director, Proprietary Project Management, 5/04-11/07

9/05-11/07: Following strategic decision to focus business on enhanced delivery of therapeutic agents (rather than new drug development), responsibilities shifted to support of litigation activities related to sevoflurane (including coordination of all Baxter technical support activities for litigation and preparation of expert statements and testimony, culminating in US and UK verdicts favoring Baxter), global technical support for regulatory and customer initiatives to drive introduction of Baxter's sevoflurane anesthetic product, and new role as technical leader for development partnership with Halozyme Therapeutics (starting 2/07), focused on strategic planning, research and development budgeting, and execution of product enhancement and new market development activities for a recombinant human hyaluronidase product (Hylenex®).

5/04-9/05: Supervised three proprietary drug development projects within the Anesthesia, Critical Care and Oncology business unit. Global Project Leader for

the preclinical and clinical development of atilmotin, a peptide drug for treatment and prophylaxis of postoperative ileus and other gastrointestinal motility disorders, with overall responsibility for global program design and planning (including overall product NPV and market assessment), budgeting and program execution, utilizing project management and financial modeling tools including Microsoft Project and Excel-based NPV/market models for multiple project scenarios; led a multidisciplinary team through pre-IND gap analysis against global regulatory requirements, gap remediation, IND preparation and filing, Phase I clinical program and post-Phase I FDA meeting preparation and execution. Additional responsibilities included business development activities (technical and business assessment of opportunities; identification of new business opportunities; participation in strategic planning activities) and coordination of technical staff activities related to sevoflurane patent litigation.

Director, Chemical Development and Chemical Analysis, 11/01-5/04

Research Director, supervising organic synthetic chemistry, process and analytical research in support of inhalation anesthetics business and drug development programs. Chemistry team developed and implemented two significant patented improvements to isoflurane/desflurane anesthetic manufacturing processes, increasing process yield by approximately 10% and increasing plant capacity by approximately 15%, delaying need for capital expansion.

Parallel role as Global Project Leader for preclinical and clinical development of BAX-ACC-1638 (later designated as atilmotin), a peptide drug for the treatment and prophylaxis of postoperative ileus and other gastrointestinal dysmotility conditions; led team that developed proposal for resumption of product development, including market assessment/project financial model, and successfully presented proposal to Baxter management. Also responsible for technical and business evaluation of business development and partnership opportunities.

Associate Director, Chemical Development and Chemical Analysis, 8/99-11/01

Supervised process and analytical research and development activities on inhalation anesthetics; developed and implemented research strategies. Led chemistry function during process scale-up, plant design and construction, and ANDA filing for Baxter's generic sevoflurane inhalation anesthetic product.

Section Manager, Chemical Development, 4/98-8/99

Process research on inhalation anesthetics: supervision of process research and development activities.

Ohmeda PPD/Anaquest, New Providence, NJ

Section Manager, Chemical Development, 1/97-4/98

Process research on inhalation anesthetics and Ohmeda ketorolac synthesis, including synthesis of ketorolac-related degradants and process impurities; supervised process research and development activities, including: development and scale-up of a new synthesis of sevoflurane; synthesis of process impurities and degradants related to atracurium, propofol, and midazolam; process troubleshooting activities in support of inhalation anesthetic production facility at Guayama, P. R.; development of new spectroscopic analytical technologies for use in production of inhalation anesthetics. Primary chemical process R&D representative in discussions of pilot and production plant design for sevoflurane process; ad hoc representative to Ohmeda PPD Patent Strategy Committee.

Principal Scientist, 11/93-12/96

Process research on synthesis of halogenated ether anesthetics and classical medicinal agents; acting manager of Chemical Development Section, 5/95-12/96, supervising synthesis of process impurities, metabolites and degradants of compounds of interest to Ohmeda and process research/process improvement efforts for production of enflurane, isoflurane and desflurane at Guayama production facility.

BOC Group Technical Center, Health Care R&D, Murray Hill, NJ

Lead Scientist, 12/90-11/93

Synthesis, purification and characterization of motilin-related peptides; synthesis of process impurities, metabolites and degradants related to nalmefene hydrochloride, a narcotic antagonist. Won Ohmeda President's Award for developing synthetic methods for production of nalmefene-related Reference Standard materials required to enable analytical method development and validation, NDA filing and product launch.

Senior Research Chemist/Senior Scientist, 6/86-12/90

Synthesis and characterization of new local anesthetic compounds, including conformationally constrained analogs of known anesthetics and compounds specifically targeted for metabolic inactivation in the bloodstream; solid-phase synthesis, purification and characterization of motilin-related peptides with gastrointestinal stimulatory activity.

National Institutes of Health, NIADDK, Bethesda, Md.:

Staff Fellow, Section on Medicinal Chemistry, Laboratory of Chemistry, 10/83-6/86

Synthesis of biochemical probes based on compounds with central nervous system activity: Alkylating and acylating irreversible ligands for CNS receptors for opiates, phencyclidine, and other CNS drugs under the supervision of K. C. Rice and A. E. Jacobsen.

Education

Massachusetts Institute of Technology, Cambridge, Ma. :
B. S. Chemistry, 1978

University of Illinois at Urbana-Champaign:
Ph. D. 1983
Doctoral Thesis: Synthesis and Characterization of Deoxyribonucleotide Analogs
Thesis Advisor: N. J. Leonard
Eli Lilly Chemistry Fellowship, 1980-1981

PUBLICATIONS AND PATENTS

1. Lessor, R. A. and Leonard, N. J. Synthesis of 2'-deoxynucleotides by deoxygenation of ribonucleosides. J. Org. Chem., **1981**, 46, 4300-4301.

2. Lessor, R. A., Gibson, K. J. and Leonard, N. J. Synthesis and biochemical evaluation of 2'-deoxy-lin-benzoadenosine phosphates. Biochemistry, **1984**, 23, 3868-3873.

3. Bhatnagar, D., Hartl. F. T., Roskoski, R., Lessor, R. A. and Leonard, N. J. Adenosine cyclic 3',5'-monophosphate-dependent protein kinase: nucleotide binding to chemically modified catalytic subunit. Biochemistry, **1984**, 23, 4350-4357.

4. Bhatnagar, D., Glass, D. B., Roskoski, Jr., R., Lessor, R. A. and Leonard, N. J. Interaction of guanosine cyclic 3',5'-phosphate dependent protein kinase with lin-benzoadenine nucleotides. Biochemistry, **1985**, 24, 1122-1129.

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