

# *LexaMed*

## *Curriculum Vitae*

### **SENIOR CONSULTANT, CHEMISTRY**

### **RAMON A. BURNS, JR., PH. D.**

Phone: 541-761-0557

#### **Summary of Qualifications**

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Ramon has over thirty years of experience providing expertise in pharmaceutical sciences in the biopharmaceutical and medical devices industries. He is a six-sigma black belt and has an impressive thirteen patents as well as over twenty publications or published meeting abstracts. Specifically he has actively worked on and/or led consulting projects in the following areas:

- **Biologics**

Stability Data (Study Design, Protocol, Analysis and Reports), Product Shipping Validation Studies, CMC (Chemistry, Manufacturing and Controls) Writing, Reference Standard Qualification and Container / Closure Issues.

- **Drugs**

Kinetic Modeling of Stability Data, SR and CR Tablet Manufacturing Process Troubleshooting, Injectable Product Formulation Survey, CTD Module 3 Writing, Development History Reports, Stability Data Analysis/Reports, Assay Validation, Product Shipping Validation Studies, Blow-Fill-Seal Product Development, Formulation Development, CMC Writing, Scientific Problem Solving, Drug Product Filtration Issues, Container/Closure Issues, SOP Writing.

- **Medical Devices**

Assay Validation, Specification Justification, SOP and Protocol Writing, Collagen Formulation Development and Analysis, Stability Data Analysis/Reports, Container/Closure Issues.

#### **Professional Experience**

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##### **SENIOR CONSULTANT, *LexaMed, Ltd.***

Ramon provides consulting services for clients from pharmaceutical and medical device companies. Responsibilities to date include technical guidance with respect to chemistry, biologics qualifications and validation studies, pharmaceutical product

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development, stability studies, shipping validations, and medical device closure issue resolution.

#### **Tablet Manufacturing Process Troubleshooting**

- Analyzed release and stability Dissolution results versus manufacturing process parameters using Covariance and Quadratic Fit Regression Analysis to identify process parameters related to erratic dissolution results.
- Projects involved one sustained release and one controlled release product.

#### **Prefilled Syringe Research and Development Support**

- Surveyed current parenteral products for commonly used injectable formulations appropriate for testing in pre-filled syringes.
- Identified nine formulations that were the basis for more than half of the 167 liquid injectable products surveyed.
- Surveyed generic and compendial injectable products and identified eight drugs in six therapeutic classes for study in the prefilled syringe.
- Identified testing to be performed on these drug/ formulation/ syringe systems in stability studies.

#### **Stability Data Analysis for an Oral Liquid Product**

- Analyzed product stability data in SLIMStat following ICH Q1A (R2) and ICH Q1E to support a product shelf life extension.
- Used analysis of covariance (ANCOVA) to demonstrate equivalence of upright and inverted configurations.

#### **Analytical Support for a Nutritional Supplement Company**

- Implementation of a Quality System in the QC Laboratory, SOP and Protocol Writing, HPLC Method Development.

#### **ASSOCIATE DIRECTOR, PHARMACEUTICAL SCIENCES DEPARTMENT, *Celtrix Pharmaceuticals***

Responsibilities involved management of the formulation development and pharmacology groups. These efforts included:

- Diverse formulation development activities for transforming growth factor- $\beta$ 2 (TGF- $\beta$ 2) and insulin-like growth factor I/insulin-like growth factor binding protein-3 (IGF-I/IGFBP-3) complex,
- Development of several injectable formulations for direct application to the retina, intravenous and intradermal injectable formulations, topical creams and ointments, oral rinse solutions, and high dose injectable toxicology formulations, and
- Participation in Drug Product technology transfer to manufacturing, liaison with contract manufacturing sites, and Drug Product fills for clinical studies.

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**ASSOCIATE DIRECTOR, PHARMACEUTICAL AND ANALYTICAL CHEMISTRY DEPARTMENT, *Collagen Corporation***

- Managed a department that performed a variety of distinct activities, including:
  - Basic pharmaceutical formulation development and stability studies,
  - Development of parenteral controlled release formulations for proteins utilizing collagen as the device matrix,
  - Development of novel collagen products, and
  - Execution of basic physical studies and method development for collagen based materials.

**STAFF RESEARCHER II, PARENTERALS/CONTROLLED RELEASE DEPARTMENT, INSTITUTE OF PHARMACEUTICAL SCIENCES, *Syntex Research***

- Projects focused on the pharmaceutical development of several parenteral controlled release systems for peptides, and aspects of pharmacology, polymer and colloid chemistry affecting these systems:
  - A luteinizing hormone releasing hormone (LHRH) agonist microencapsulated in the biodegradable polymer poly(lactide-co-glycolide),
  - A matrix implant containing the LHRH agonist RS-49947, yielding one year of drug release,
  - Theoretical aspects of drug release from matrix implant systems, and
  - Pharmacological modeling of drug release profiles from controlled release systems.

**RESEARCH SPECIALIST, AGRICULTURAL FORMULATIONS GROUP, *Monsanto Agricultural Products Company***

- Studied the physical chemistry of Lasso Micro-tech; a water based microencapsulated formulation of Lasso herbicide (U. S. Patent 4,280,833). This product was commercialized in the 1985 growing season. My goal in this position was to determine the basic principles affecting Lasso Micro-tech performance. These studies included:
  - Isolation and characterization of the microcapsule polymeric shell wall,
  - The role of dispersants in formulation suspendability and herbicide active release rates, and
  - The effect of the herbicide active on the microcapsule polymerization.

**RESEARCH TECHNICIAN, DEPARTMENT OF BIOCHEMISTRY AND BIOPHYSICS, *University of Pennsylvania***

- Water proton relaxation rate and electron paramagnetic resonance studies of protein / paramagnetic metal ion complexes.
- Isolation of several proteins following known procedures.

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## Education

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- ◆ Ph. D. in Chemistry, Massachusetts Institute of Technology, Cambridge, Massachusetts
  - Concentration in Biological Chemistry.
  - Thesis: Short Chain Phospholipid Micelles: A Useful Biological Membrane and Lipoprotein Model System.
- ◆ B. A. in Biophysics, University of Pennsylvania, Philadelphia, Pennsylvania.
  - Graduated *magna cum laude* with distinction in the major.

## Honors

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- ◆ Whitaker Health Sciences Fund Predoctoral Fellowship
- ◆ Syntex Achievement Award

## Patents

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U. S. Patents only shown, some of these are also filed as European, World or Country-Specific Patents:

1. Lynda M. Sanders, Ramon Burns, "Delivery System for the Controlled Administration of LHRH Analogs," U. S. Patent 5,028,430, Issued July 2, 1991.
2. Woonza Rhee, Don Wallace, Alan Michaels, Ramon Burns, Louis Fries, Frank DeLustro, Hanne Bentz, "Collagen-Polymer Conjugates," U. S. Patent 5,162,430, Issued November 10, 1992.
3. Woonza Rhee, Donald G. Wallace, Alan S. Michaels, Ramon A. Burns, Jr., Louis Fries, Frank DeLustro, Hanne Bentz, "Composition for Bone Repair," U. S. Patent 5,264, 214, Issued November 23, 1993.
4. Woonza Rhee, Donald G. Wallace, Alan S. Michaels, Ramon A. Burns, Jr., Louis Fries, Frank DeLustro, Hanne Bentz, "Collagen-Polymer Conjugates," U. S. Patent 5,304,595, Issued April 19, 1994.
5. Woonza Rhee, Donald G. Wallace, Alan S. Michaels, Ramon A. Burns, Jr., Louis Fries, Frank DeLustro, Hanne Bentz, "Method of Augmenting Tissue with Collagen-Polymer Conjugates," U. S. Patent 5,306,500, Issued April 16, 1994.
6. Woonza Rhee, Donald G. Wallace, Alan S. Michaels, Ramon A. Burns, Jr., Louis Fries, Frank DeLustro, Hanne Bentz, "Biologically Inert, Biocompatible-Polymer Conjugates," U. S. Patent 5,324,775, Issued June 28, 1994.
7. Woonza Rhee, Donald G. Wallace, Alan S. Michaels, Ramon A. Burns, Jr., Louis Fries, Frank DeLustro, Hanne Bentz, "Collagen-Polymer Conjugates," U. S. Patent 5,328,955, Issued July 12, 1994.
8. Woonza Rhee, Donald G. Wallace, Alan S. Michaels, Ramon A. Burns, Jr., Louis Fries, Frank DeLustro, Hanne Bentz, "Method of Augmenting Tissue with Collagen-Polymer Conjugates," U. S. Patent 5,376,375, Issued December 27, 1994.

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9. Woonza Rhee, Donald G. Wallace, Alan S. Michaels, Ramon A. Burns, Jr., Louis Fries, Frank DeLustro, Hanne Bentz, "Collagen-Polymer Conjugates," U. S. Patent 5,413,791, Issued May 9, 1995.
10. Woonza Rhee, Donald G. Wallace, Alan S. Michaels, Ramon A. Burns, Jr., Louis Fries, Frank DeLustro, Hanne Bentz, "Collagen-Polymer Conjugates Containing an Ether Linkage," U. S. Patent 5,446,091, Issued August 29, 1995.
11. Woonza Rhee, Donald G. Wallace, Alan S. Michaels, Ramon A. Burns, Jr., Louis Fries, Frank DeLustro, Hanne Bentz, "Method of Preparing Collagen-Polymer Conjugates," U. S. Patent 5,523,348, Issued June 4, 1996.
12. Woonza Rhee, Donald G. Wallace, Alan S. Michaels, Ramon A. Burns, Jr., Louis Fries, Frank DeLustro, Hanne Bentz, "Implants Coated With Collagen-Polymer Conjugates," U. S. Patent 5,543,441, Issued August 6, 1996.
13. Woonza Rhee, Donald G. Wallace, Alan S. Michaels, Ramon A. Burns, Jr., Louis Fries, Frank DeLustro, Hanne Bentz, "Polymer Conjugates Ophthalmic Devices Comprising Collagen-Polymer Conjugates," U. S. Patent 5,550,188, Issued August 27, 1996.

## Publications

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1. "Investigation of Anion Binding Sites in Transition State Analogue Complexes of Creatine Kinase by Infrared Spectroscopy," George H. Reed, Clyde H. Barlow, and Ramon A. Burns, Jr., *J. Biol. Chem.* 253 (1978) 4153-4158.
2. "C-13 Nuclear Magnetic Resonance Studies of Short Chain Lecithins: Motional and Conformational Characteristics of Micellar and Monomeric Phospholipid," Ramon A. Burns, Jr., and Mary Fedarko Roberts, *Biochemistry* 19 (1980) 3100-3106.
3. "Physical Characterization and Lipase Susceptibility of Short Chain Lecithin/Triglyceride Mixed Micelles: Potential Lipoprotein Models," Ramon A. Burns, Jr., and Mary Fedarko Roberts, *J. Biol. Chem.* 256 (1981) 2716-2722.
4. "Characterization of Short-Chain Alkyl Ether Lecithin Analogues: 13-C NMR and Phospholipase Studies," R. A. Burns, Jr., J. M. Friedman, and M. F. Roberts, *Biochemistry* 20 (1981) 5945-5950.
5. "Cholesterol Solubilization by Short-Chain Lecithins: Characterization of Mixed Micelles and Cholesterol Oxidase Activity," Ramon A. Burns, Jr., and Mary F. Roberts, *Biochemistry* 20 (1981) 7102-7108.
6. "Monomer-to-Micelle Transition of Dihexanoyl Phosphatidylcholine: 13-C NMR and Raman Studies," Ramon A. Burns, Jr., Mary F. Roberts, Richard Dluhy, and Richard Mendelsohn, *J. Amer. Chem. Soc.* 104 (1982) 430-438.
7. "Kinetic model for surface-active enzymes based on the Langmuir adsorption isotherm: Phospholipase C (*Bacillus cereus*) activity toward dimyristoyl phosphatidylcholine/detergent micelles," Ramon A. Burns, Jr., Maha Y. El-Sayed, and Mary F. Roberts, *Proc. Natl. Acad. Sci. (USA)* 79 (1982) 4902-4906.

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8. "Using Short-Chain Lecithins to Study the Surface Behavior of Lipolytic Enzymes," Ramon A. Burns, Jr., and Mary Fedarko Roberts, *Biophysical Journal* 37 (1982) 105-106.
9. "Structural Analysis of Short-Chain Lecithin/Triglyceride Micellar Particles," R. A. Burns, Jr., J. M. Donovan, and M. F. Roberts, *Biochemistry* 22 (1983) 964-973.
10. "Dependence of Phosphatidylcholine 31-P Relaxation Times and 31-P [1-H] NOE Distribution on Aggregate Structure," R. A. Burns, Jr., R. E. Stark, D. A. Vidusek, and M. F. Roberts, *Biochemistry* 22 (1983) 5084-5090.
11. "Methyl Branching in Short Chain Lecithins: Are Two Chains Necessary for Optimum Phospholipase A-2 Catalysis?" C. D. DeBose, R. A. Burns, Jr., J. M. Donovan, M. F. Roberts, *Biochemistry* 24 (1985) 1298-1306.
12. "Micellar Systems for Defining the Active Site of Phospholipase A-2: Methyl Branching in Short Chain Lecithins," C. D. DeBose, R. A. Burns, Jr., and M. F. Roberts, in *Surfactants in Solution*, Vol. 5, K. L. Mittal, P. Bothorel, ed., Plenum Press, New York, (1986) 917-929.
13. "Short Chain Lecithin/Triglyceride Mixed Particles: Physical Studies of the Surface Accessibility of Triglyceride and Correlation with Lipase Kinetics," R. A. Burns, Jr., J. M. Donovan, C. D. DeBose, and M. F. Roberts, in *Surfactants in Solution*, Vol. 5, K. L. Mittal, P. Bothorel, ed., Plenum Press, New York, (1986) 931-941.
14. "Use of Poly(ortho esters) for the Controlled Release of 5-Fluorouracyl and a LHRH Analogue," J. Heller, S. Y. Ng, D. W. Penhale, B. K. Fritzing, L. M. Sanders, R. A. Burns, M. G. Gaynon, S. S. Bhosale, *J. Controlled Release*, 6 (1987) 217-224.
15. "Design and Performance of Controlled Release Biodegradable Delivery System of Nafarelin: An Overview," Lynda M. Sanders, Georgia McRae, Karen Vitale, Ramon Burns, Philip Hoffman, and Efraim Shek, *J. Pharm. Sci.* 78, 11 (1989) 888-890.
16. "Nafarelin Controlled Release Injectable: Theoretical Clinical Plasma Profiles from Multiple Dosing and from Mixtures of Microspheres Containing 2%, 4% and 7% Nafarelin," Ramon A. Burns, Jr., Karen Vitale, and Lynda M. Sanders, *J. Microencapsul.* 7, 3 (1990) 397-413.
17. "A One Year Controlled Release Implant for the Luteinizing Hormone Releasing Hormone Superagonist RS-49947. I. Implant Characterization and Analysis of *In Vitro* Results," Ramon Burns, Kristen Peterson, and Lynda Sanders, *J. Controlled Release* 14 (1990) 221-232.
18. "A One Year Controlled Release Implant for the Luteinizing Hormone Releasing Hormone Superagonist RS-49947. II. Clinical Performance Results," Ramon Burns, Georgia McRae, and Lynda Sanders, *J. Controlled Release* 14 (1990) 233-241.

## Published Meeting Abstracts

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1. "A One Year Controlled Release System for the LHRH Agonist RS-49947," Ramon Burns, Georgia McRae, and Lynda Sanders, Proceedings of the 15th International Symposium on Controlled Release of Bioactive Materials, J. Heller, F. Harris, D.

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- Lohmann, H. Merkle, J. Robinson, eds. Controlled Release Society, Lincolnshire, Illinois, (1988) 64-65.
2. "Multi-dose Modeling of Plasma Profiles from Nafarelin Controlled Release Injectable," Ramon Burns and Lynda Sanders, Proceedings of the 15th International Symposium on Controlled Release of Bioactive Materials, J. Heller, F. Harris, D. Lohmann, H. Merkle, J. Robinson, eds. Controlled Release Society, Lincolnshire, Illinois, (1988) 452-453.
  3. "Clinical Performance of Nafarelin Controlled Release Injectable: Influence of Formulation Parameters on Release Kinetics and Duration of Efficacy," Lynda Sanders, Ramon Burns, Karen Vitale, and Philip Hoffman, Proceedings of the 15th International Symposium on Controlled Release of Bioactive Materials, J. Heller, F. Harris, D. Lohmann, H. Merkle, J. Robinson, eds. Controlled Release Society, Lincolnshire, Illinois, (1988) 62-63.
  4. "Development of an Injectable Formulation for Transforming Growth Factor Beta-2," Edwin S. Kamemoto, Julie Pon, Ramon A. Burns, Jr., *Pharm. Res.* 7, 9 (1990) s-200.