GRACE V. MILTON GOWDA, M.Pharm., Ph.D., RAC

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I. Education/Certification

RAPS Executive Education Program, Kellogg Business School, 2016
Regulatory Affairs Certification, USA, 2008
Clinical Post-Doctoral fellow, CNS, 1994
Ph.D. (Pharmacology and Toxicology), The University of Texas at Austin, 1993
Foreign Pharmacy Graduate Equivalency, USA, 1992
Master of Pharmacy (Pharmacology), University of Nagpur, Nagpur, India, 1986
Bachelor of Pharmacy, University of Madras, Madras, India, 1984

II. Professional Experience

Merial Inc., now part of Boehringer-Ingelheim **2017-2018**
Merial Limited, a sanofi Company **2012-2016**
Head of RA Operations and Policy/Government and Strategic Affairs, Global Regulatory Affairs, R&D

Strengthened relationship with regulatory authorities and progressed policy agenda in trade associations (e.g., Compounding, ADUFA performance goals). Represented company in global (Health for Animals), and national (Animal Health Institute - AHI) trade associations and interacted with intra-governmental organizations (e.g., CODEX – ivermectin MRL's) to protect company interests. Served as the regulatory expert on strategic business initiatives (e.g., due diligences) and projects (trade association strategy).

- Chair of the ADUFA working group in AHI and member of the ADUFA III and IV industry user fee negotiating team with FDA. Vice-Chair of the AHI-ADS steering committee. Member of multiple working groups (Trade, Compounding, Pharmacokinetics, Antimicrobial - past, Statistics - past, etc.).
- Co-Chair the Regulatory Strategy team, Chair of Data Protection/Data exclusivity working group, member of the CODEX working group and past-member of the Science to Policy and Politics team and Trade Agreements (TPP and Transatlantic) team in Health for Animals.
- Representing AHI on the VICH Steering Committee.

Managed global regulatory affairs operations team supporting information systems (regulatory databases and tools), harmonizing policies and procedures across regulatory groups worldwide, communication (website, newsletters and tips), coordinating regulatory intelligence and trends, industry benchmarking (US, EU, China and Brazil) and functional excellence (e.g., KPI's, e-learning) activities.

- Led R&D Knowledge Management and RA Knowledge Management Teams to enhance accessibility to information, collaboration and prepare for future.
- Represented Merial in the Big Data Workshop and WINS project when we were part of Sanofi

Merial Limited, a sanofi Company **2004-2011**
Director, Regulatory Affairs New Projects North America, R&D

Defined the overall (pre-clinical, clinical and CMC) regulatory strategy for new product development and post-approval indications. Liaison with FDA and obtain necessary agreements for products in development and registration. Managed the preparation of dossier, respond to queries during registrations and negotiate label/FOI with agency.

- Three NADA approval (EQUIOXX® paste and injection for horses, ZACTRAN® Injection for Cattle) and three supplemental NADA approvals for new indications (PREVICOX® Chewable Tablets for dogs - 2 claims and ULCERGARD® - 1 claim).
- Experienced in therapeutic areas such as pain and inflammation, osteoarthritis, ulcer, and infectious disease (bacteria and parasites).
- Represented Regulatory Affairs globally in interdepartmental project teams
- Co-chair of the AHI/FDA companion animal review cycle team and member of the ADUFA II (User fees) industry negotiation team with FDA. Member of multiple working groups (MUMS, VMAC, PK, Compounding, ADUFA)

Merial Limited, a sanofi Company **2001-2004**
Senior Manager, CMC, Worldwide Pharmaceuticals, R&D

Defined technical and regulatory strategy for development of products to market globally in the area of chemistry, manufacturing and controls (CMC). Managed implementation of technical and regulatory requirements for development projects by functional areas such as R&D, Manufacturing and QA. Prepared and reviewed CMC technical sections (new marketing applications, incomplete letters and supplements/variations) for submission to regulatory agencies worldwide including USA (e.g. IND/NDA), EU (Centralized/Mutual Recognition Procedure), and international markets (Japan, Canada, Australia, New Zealand, etc.).

- Areas of expertise include new chemical entities (e.g., coxibs, macrolides), established API (e.g., enalapril, avermectins) and innovative technology products (e.g., chewable tablets, pastes, aerosols, long-acting injectables etc.).
- Provided oversight for CMC on Specifications Committee
- Represented Merial in trade association working groups (e.g., Active Drug Substance Working Group – AHI)
- Developed compendial monographs with USP, BP etc. for establishment of public standards for drug substance and drug products.
- Vital Difference Award

Solvay Pharmaceuticals, Inc. **1998-2001**
Manager, Clinical Trial Materials, R&D

Managed the Clinical Trial Materials (Phase I-IV) department. Departmental responsibilities include: planning and coordinating in-house activities with related departments, packaging, labeling and distribution of clinical supplies, identifying, managing and negotiating contracts. Management responsibilities included:

preparation of yearly budgets, personnel reviews and individual career development plans and plans for long-term departmental growth. Worked extensively with Regulatory Affairs on CMC issues for IND's/NDA's related to clinical supply.

- Led a multi-departmental team in the implementation of Quality Standards
- Planned and implemented departmental reorganization to sustain long-term growth and in-house technical expertise.
- Integrated quality systems concept into departmental procedures to reduce errors, strengthen quality and ensure long-term compliance.

Dialysis Clinic, Inc. **1994-1998**

Research Scientist

Managed research projects (animal pharmacology and ADME) on targeted delivery of cytokine neutralizing antibodies, antisense oligonucleotides and NCE's using microencapsulation technology. Expert in biochemical and molecular biological techniques to evaluate efficacy and mechanism of action, and animal models of septic shock, glomerulonephritis, pulmonary granulomas and transplant rejection. Collaborated with researchers in Emory University (Yerkes Primate Center), V.A. Medical Center, Mercer University, Vanderbilt University, Harvard School of Public Health, Monash University in Australia, St. Marianne University in Japan. Wrote proposals and grants; analyzed data for statistical significance; and prepared documentation for publications.

- Developed a peritonitis model of septic shock in non-human primates

Mercer University **1993-1994**

Clinical Post-Doctoral Fellow

Managed the conduct of **clinical trials for drugs used in the treatment of psychosis and Alzheimer's disease**. Sub-investigator for clinical trials on Zotepine, Risperidone, Nimodipine, Mentane and Metrifonate. Preceptor for Pharm.D. students.

University of Texas at Austin **1987-1993**

Graduate Research/Teaching Assistant

Evaluated the acute, chronic and aging effects of ethanol on the **brain (meso-limbic system)** using behavioral models in animals. Taught the laboratory pharmacology course for undergraduate pharmacy students.

Tablets (India) Ltd. **1986-1987**

Product Development Scientist

Worked on various new and marketed solid and liquid dosage formulations. Provided technical support for manufacturing on in-process and quality issues for marketed products.

Medopharm **1984-1985**

Quality Control Chemist

Qualitative and quantitative analysis of raw materials, in-process materials and finished dosage forms.

III. Lectures and Presentations

Lecturer (Pre-recorded), M.S. Regulatory Affairs, UGA Athens Spring 2009 to date
- Submission of Animal Health Products (EPA/USDA/FDA) and Regulatory Intelligence

Moderator and Panelist, AHI Regulator Day November 2015
- ADUFA III Update

Moderator, AHI Regulator Day February 2014
- Overview of ADUFA III

Presenter, AHI Regulator Day October 2012
- IFAH Global Benchmarking Survey

Global R&D Meeting, Merial Limited April 2012
- Regulatory Trends and Challenges

Speaker, Regulator Day November 2008
- Companion Animal Review Cycle team (AHI/FDA) Annual Update

Co-chair and Presenter, AHI Workshop October 2008
- Companion Animal Protocol and Data Submissions to CVM, FDA

Speaker, AHI Regulator Day November 2007
- Companion Animal Review Cycle team (AHI/FDA) Annual Update

Moderator, Panel Discussion for DIA Tutorial June 2007
- The Changing Landscape of Pharmaceutical Product Launches: Bridging Functional Gaps for Success

Lecturer, RAC Study Group September 2006
- Generic Drug Submissions

Moderator, AAPS 2004 RS Open Forum November 2004
- Investigational Drug Products: Opportunities & Implications of Risk-based Approaches

Speaker, RAPS - Atlanta Chapter June 2004
- Organization of CTD: An Overview with Emphasis on M4Q

Lectures, Mercer University March 1997 and August 2001
- Basics of molecular biology, recombinant DNA technology, monoclonal antibodies, gene therapy, transgenic and antisense oligonucleotide therapeutics
- Renal Anatomy and Physiology

Lecture, Georgia College May 1996
- Psychopharmacology

IV. Honorary Positions and Memberships

Honorary Position

1994-1998	Adjunct Faculty, Department of Pharmaceutical Sciences, Southern School of Pharmacy, Mercer University, Atlanta, Georgia.
1995-1998	Adjunct Collaborative Scientist, Department of Pathology and Immunobiology, Yerkes Regional Primate Research Center, Emory University, Atlanta, Georgia
1993-1994	Adjunct Faculty, Pharmacy Practice, Southern School of Pharmacy, Mercer University, Atlanta, Georgia

Committee Memberships

Member of the Curriculum Committee - University of Georgia Reg. Affairs Graduate Studies, 2018

Master's Thesis Committee Member – University of Georgia, Regulatory Affairs Program (Patricia Keszler) 2015

Publication Committee Member, American College of Clinical Pharmacology (ACCP), 2010 – 2016

Board Member (Past-President - 2010, President - 2009, President-Elect - 2008, Vice-President – 2006/2007, Mentoring Committee Chair -2011-2012), Healthcare Business Women's Association, Atlanta Chapter 2006 – 2012

Publications Reviewer, Journal of Clinical Pharmacology, 2008 – 2009

Public Policy Committee Member, ACCP, 2002 – 2009

Dissertation Committee Member - Mercer University, 1997 – 2009 (Wenkai Tong; Zhaowei Jin alias Bruce, Henry Nutty, Dinesh Haswani, Nima Akhavein and Karyn Ines Cotta)

Member, Regulatory Sciences Membership Committee, American Association of Pharmaceutical Scientists (AAPS), 2006 – 2009

Treasurer/Secretary, Regulatory Sciences Section, AAPS 2006 – 2008

Membership Strategic Oversight Committee Member, AAPS**,** 2004 - 2007

Chair, Regulatory Sciences Membership Committee, AAPS, 2006 – 2007

Program Committee Member, Regulatory Affairs Professional Society, Atlanta Chapter, 2003 – 2006

Education Committee and Public Policy Committee Member – RS Section, AAPS**,** 2003 – 2005

Chair, RS-Open Forum, AAPS Annual Meeting, 2004

Treasurer, ACCP, Atlanta Chapter from 1995 - 1999

V. Awards

- Chapter **Leadership Award**, Healthcare Businesswomen Association, 2009
- Regulatory Sciences **Service Award**, AAPS – 2008 and 2009

- **University First** in Master of Pharmacy Degree, Awarded by Nagpur University, India 1987
- Prof. Rathanagiriswaran Medal for **top score in Pharmaceutical Chemistry**, Awarded by Indian Pharmaceutical Association, Madras, India, 1984

VI. Publications

Abstracts

1. **Milton, G. V.** and Chopde, C. T.: *GABA and the Mechanism of Antidepressants*. Ind. J. Pharm. Sci. 49(3):124 (1987) [Oral - The National Conference of Indian Pharmaceutical Association]
2. Erickson, C. K., McCarter, S., Taylor, T., Erickson, D., and **Milton, G. V.**: *Studies on a New Rat Line Sensitive to Low Doses of Ethanol*. Alc. Clin. Exp. Res. 12:307 (1988) [Poster]
3. Popp, R. L., Erickson, C. K., Post, Z. M., **Milton, G. V.**, and Omar, M. A.: *Ethanol Effects and Blood Ethanol Parameters in Four Ages of Fisher Rats*. Alc. Clin. Exp. Res. 14:330 (1990) [Poster]
4. Erickson, C. K., Popp, R. L., **Milton, G. V.**, Post, Z. M., and Smith, T. E.: *Brain Area Acetylcholine and Opioid Peptide Changes After Ethanol in Several Ages of Fisher Rats*. Alc. Clin. Exp. Res. 14:286 (1990) [Poster]
5. **Milton, G. V.** and Erickson, C. K.: *Effects of Ethanol and Discomfort on Brain Met-Enkephalin Levels in Male Sprague-Dawley Rats* Alc. Clin. Exp. Res. 15:327 (1991) [Poster]
6. **Milton, G. V.** and Erickson, C. K.: *Effect of Ethanol on Drug-Induced Locomotor Activity*. Society of Neuroscience, (1992) [Poster]
7. Oettinger, C. W., D'Souza, M. and **Milton, G. V.**: *Comparison of Ccytokine Release by OKT3, ATGAM and ATS in vitro: Inhibition of Cytokine Release by Microencapsulated Neutralizing Antibodies (MCNA)*. XIVth Annual Meeting of the North American Society for Dialysis and Transplantation, (1995) [Oral]
8. Oettinger, C. W., D'Souza, M. and **Milton, G. V.**: *Interleukin-1beta Microencapsulated Neutralizing Antibodies Protect Rats from Experimental E.Coli Peritonitis*. 35th Interscience Conference on Antimicrobial Agents and Chemotheraphy, San Francisco, California (1995) [Poster]
9. Oettinger, C.W., **Milton, G.V.** and D'Souza, M.J.: *Microspheres Containing Neutralizing Antibodies to TNFa and IL-1b Prevent Lethality in Gram Negative Peritonitis Model of Sepsis*. European Cytokine Network 7:234 (1996) [Poster]
10. **Milton, G.V.**, Shah, A., Oettinger, C.W. and D'Souza, M.J.: *Distribution Profile of Microspheres Containing Cytokine Neutralizing Antibodies in Normal and Infected Rats.* Pharm. Res. 13:S95 (1996) [Poster]
11. **Milton, G.V.**, Shah, A., Oettinger, C.W. and D'Souza, M.J.: *Intracellular Targeting and Release of IL-1b Neutralizing Antibodies from Albumin Microspheres.* Pharm. Res. 13:S97 (1996) [Poster]
12. Oettinger, C.W., Tipping, P., D'Souza, M.J. and **Milton, G.V.**: *Macrophage depletion with microencapsulated clondronate alters anti-glomerular basement membrane glomerulonephritis.* J. Am. Soc. Nephrol. 8:480A (1997) [Oral]

13. Oettinger, C. W., **Milton, G. V.**, D'Souza, M. and Tracey K.: *Microencapsulation of cytokine neutralizing antibodies, CNI-1493 and clondronate enhances inhibition of endotoxin-stimulated cytokine release in vitro*. 37th Interscience Conference on Antimicrobial Agents and Chemotheraphy, Toronto, Ontario, Canada (1997) [Poster]
14. **Milton, G. V.**, Oettinger, C. W., D'Souza, M., Shah, A. and Weller, D.: Inhibition of cytokine release in vitro is potentiated by microencapsulation of tumor necrosis factor antisense morpholino oligomers. 7th International TNF Congress: Conference on tumor necrosis factor and related molecules: Scientific Advances and Medical Applications. Hyannis, Massachussets May 17-21 (1998)

Papers

1. **Milton, G. V.**, Randall, P. K. and Erickson, C. K.: *Low-Dose Effect of Ethanol on Locomotor Activity Induced by Activation of the Mesolimbic System*. Alc. Clin. Exp. Res. 19:768-776 (1995)
2. **Milton, G. V.** and Jann, M. W.: *As Needed Administration of Antipsychotic Drugs: Pharmacokinetic Considerations*. Clin. Pharmacokin. 28:494-504 (1995)
3. Gerber, D. A., Oettinger, C. W., D'Souza, M., **Milton, G. V.**, Larsen, C. P. and Pearson, T. C.: *Prolongation of Murine Cardiac Allograft Survival by Microencapsulated TNFa and IL-1□ Neutralizing Antibodies.* J. of Drug Targeting. 3:311-315 (1995)
4. Oettinger, C.W., D'Souza, M.J. and **Milton, G.V.**: *In Vitro Comparison of Cytokine Release from ATS and OKT3: Inhibition with soluble and Microencapsulated Neutralizing antibodies.* Transplantation 62:1690-1693 (1996)
5. Huang, X.R., Tipping, P.G., Apostolopoulos, J. Oettinger, C., D'Souza, M., **Milton, G.**, Holdsworth, S.R.: *Mechanisms of T cell induced glomerular injury in anti-GBM glomerulonephritis in rats.* Clin. Exp. Immunol.109:134-142 (1997)
6. D'Souza, M.J., Oettinger, C.W., Shah, A., Tipping, P.G., Huang, X.R. and **Milton, G.V.**: *Macrophage depletion by albumin microencapsulated (MC) clondronate: Attenuation of cytokine release and glomerulonephritis in rat.* Drug Develop. Ind. Pharm. 25:591-596 (1999)
7. Oettinger, C.W., D'Souza, M.J. and **Milton, G.V.**: *Targeting macrophages with microspheres containing cytokine neutralizing antibodies prevents lethality in gram negative peritonitis*. J. Interferon Cytokine Res. 19:33-40 (1999)
8. D'Souza, M.J., Oettinger, C.W., and **Milton, G.V.**: *Evaluation of Microspheres Containing Neutralizing Antibodies in Endotoxemia*. Drug Develop. Ind. Pharm. 25: 727-734, (1999)
9. D'Souza, M.J., Oettinger, C.W., **Milton, G.V.** and Tracey, K.J.: *Prevention of Lethality and Suppression of Proinflammatory cytokines in Experimental Septic shock by Microencapsulated CNI-1493.* J. Interferon. Cyt. Res. 19: 1125-1133 (1999)
10. D'Souza, M.J., Oettinger, C.W., **Milton, G.V.** and Tracey, K.J.: *Microsperes containing Neutralizing Antibodies to Tumor Necrosis Factor-□ and Interleukin-1□ Protect Rats from Staphylococcus aureus-induced Peritonitis.* J. Interferon. Cyt. Res. 20: 907-913 (2000)