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Aggregate Resume

SUMMARY

Physician-Scientist with more than 20 years' experience in big Pharma and Biotech. Proven technical and managerial leadership within clinical departments and cross-functionally in highly matrixed environments. Goal is to contribute to the development of new therapies via integration of experience in clinical pharmacology, pharmacovigilance/risk management, and safety of drug/device combinations and management of risks associated with product quality findings.

Areas of expertise are complementary. Experience in clinical pharmacology provides tools to understand the science behind novel therapeutic mechanisms, including use of biomarkers, optimization of experimental design and proper analysis of data. Clinical safety expertise includes consideration of signal detection methods and signal management for multiple products. Assessment of delivery device safety and understanding of product quality issues applies at each stage of pharmaceutical product life cycle, including integration between and across areas of expertise. Clinical medicine and pharmacology expertise comes full circle to understanding risk(s) to patients of hazards related to device misuse and malfunctions.

Clinical Pharmacology

Vanderbilt-trained Clinical Pharmacologist, with 18+ years' experience managing, conducting, interpreting and communicating clinical pharmacology studies and their results.

- Diverse therapeutic area experience and expertise ranging from antihypertensives to disorders of gastrointestinal motility to antibiotics, and other therapeutic classes.
- More than 200 studies conducted, many allowing clean Go/NoGo decisions and initial dose selection for patients.
- Experienced in development of biomarkers and their use in focused translational mechanistic studies; example: planning/implementation and conduct team for PET receptor occupancy studies for NK_1 receptor antagonists.
- Worked extensively with internal experts and therapeutic area and clinical pharmacology KOLs in planning mechanism studies.
- Conducted and communicated results of multiple studies investigating product characteristics such as pharmacokinetics, formulations, and drug interactions
- Responsible for data necessary for approval of 9 NDAs.

Led data analysis and writing teams for multiple successful INDs, NDAs and ex-US applications. Experience with FDA/EMEA meetings and FDA Advisory Committee presentations.

For drug delivery device safety evaluations, led medical team which provided scientific input to human factors research and study interpretation.

Clinical Safety Experience

Thirteen years' experience in management of product safety within Safety organizations and cross-functionally focusing on:

The collection and analysis of safety data from all sources for signals of new risks and the characterization of previously identified risks. Including:

- Evaluation of pre-clinical safety data
- Management of product safety data during development, including preparation of integrated safety summaries
- Post-marketing surveillance, medical case review, signal detection, and signal evaluation
- Development and application of processes for safety assessment of product quality/device safety issues, including consequent risk management activities of global safety teams
- Working cross-functionally to develop safety processes applicable to pharmacovigilance for biosimilars
- Signal validation, risk identification, assessment, and mitigation
- Conducting risk assessment and management processes for patient data in relation to potential safety signals derived from product pharmacology, and product quality findings.
- Appropriate management of risks associated with patient adverse events from multiple sources

Device Safety/Product Quality Experience

During most recent 5-year period, conceptualized and established innovative Safety Group focused on product quality and device safety. Developed and applied skills to management of the full spectrum of potential safety issues and their communication to therapeutic area groups, and Regulatory, Product Quality/Manufacturing and Drug Delivery engineering groups.

- Built strong links to the Global Product Quality organization to understand and facilitate investigation and management of product quality findings and device complaints
- Identified potential risks and safety signals related to quality issues and device misuse and malfunctions
- Performed formal safety and benefit-risk evaluations, including Health Hazard Evaluations
- Evaluated and managed safety issues related to medical impact and necessary actions to resolve product/device quality findings and manufacturing issues, including participation in CAPAs
- Applied cGMP, international standards, and Medical compliance requirements to life-cycle management of the safety of drug delivery devices
- Provided continuous medical safety input to cross-functional teams assessing device hazards and risks and consequent human harms

Communicated device safety issues cross functionally, to assure understanding of patient risk and the need for mitigation

Implemented necessary device safety and complaint monitoring in combination product clinical trials

Experienced with multiple drug delivery device combination products, including pre-filled syringes, auto-injectors and novel on-body patch pumps

Incorporated high scientific standards to the development and interpretation of Human Factors Engineering studies and Phase 0 device evaluations

PROFESSIONAL EXPERIENCE

CTIBIOPHARMA, Seattle, Washington **2015 – Current**
Consultant, Clinical Trial Operations

Management of operational aspects of pharmacokinetic sub-study for Phase 3 study

MICHAEL R. GOLDBERG, CONSULTANT, Westlake Village, CA **2015 – Current**
Clinical Pharmacology and Global Safety Professional/Consultant
Principal

Completion of Consultant and Contract assignments for issues related to Clinical Pharmacology, including pharmacodynamics, pharmacokinetics, translational medicine, data review and interpretation (including PK/PD relationships), and document preparation/review. Completion of consultant and contract assignments related to large and small molecule safety issues, and issues related to drug delivery device combination products. Safety roles include single and aggregate case review, aggregate analysis and signal detection, as well as drug and delivery device risk management activities.

Leading cross-functional interaction, team support, and mentoring activities.

AMGEN, INC., Thousand Oaks, CA **2009 – 2014**
Global Safety Executive Medical Director

Established and recruited a new functional group to manage safety issues related to 1) manufacturing deviations and product quality issues, including product complaints; 2) drug-device combination products, including risk assessment activities and monitoring of device safety in investigational studies and post marketing use; and 3) biosimilar safety. Led Global Safety Team evaluations and management of related issues, including risk assessment.

With respect to the above issues provided safety advice across the Amgen organization with respect to patient risk assessment and evaluation of findings, including actions to be taken such as recalls.

MRG MD, PHD; CLINICAL PHARMACOLOGY, LLC, San Francisco, CA **2009 – 2009**
Principal, Clinical Pharmacology Consultant

Provided leadership and technical support to clients on clinical pharmacologic evaluation of novel drug products

THERAVANCE, INC., South San Francisco, CA **2005 – 2008**
Vice President, Clinical Pharmacology

Member of Senior Management Team. Responsible for establishment of Clinical Pharmacology Department. Leadership and hands-on roles in management of clinical programs for all therapeutic areas (e.g., antimicrobial agents and gastrointestinal drugs). Conducted First-in-human safety/biochemical efficacy and Phase 2 proof of concept studies. Prepared documents for regulatory submissions and potential partnering opportunities

MERCK AND COMPANY, Merck Research Laboratories, West Point, PA **1988 – 2005**

Senior Director, Worldwide Product Safety /
Clinical Risk Management and Safety Surveillance 2001 – 2005

Directed team responsible for and conducted evaluation of safety signals on multiple product classes. Management of actions to be taken for validated signals. Led and conducted individual case review, aggregate analyses, preparation of PSURs,responses to regulatory queries, risk management documentation, support of subsidiary filings (especially Japan). Chair of Safety Sub-team of Product Development Teams. Responsible for integrating and aligning of product safety assessments by Japanese subsidiary with Merck policies and procedures.

Director, Senior Director, Clinical Pharmacology 1988 – 2001

Overall responsibilities included managing the Clinical Pharmacology Department in Pennsylvania, studies for new programs, and leading interdisciplinary teams to achieve readiness for initial human studies. Additional management role was as Merck leader for interactions with the Jefferson Medical School Clinical Pharmacology Unit, a unique Industry-Academic collaboration. With respect to the Clinical Pharmacology Department, grew and managed group consisting of 4 MDs, a Pharm. D., and 10 support staff. In multiple therapeutic areas, managed Phase 1 programs through:

Pre-clinical-clinical transition

Establishment of methodologies for translation of pre-clinical mechanism studies into useful, quantitative data to advance programs

First-in-human safety / proof of concept studies

NDA pharmacokinetic, formulation, drug interaction, special mechanism studies.

Completion of study reports and summary sections of marketing applications.

ELI LILLY AND COMPANY, Indianapolis, IN **1983 – 1988**

Clinical Pharmacologist/ Clinical Investigator 1983 – 1988

Managed Phase III studies and program for antihypertensive, including NDA preparation, conducted Phase I studies for early phase compounds.

Completed and presented to open FDA Advisory Committees on 2 occasions: presented plans for conduct and analysis of first factorial design study to determine optimum combination of antihypertensive with diuretic; Safety presentation in support of NDA approval

Wrote approved NDA and participated in approvability negotiations with FDA,

Education

Clinical Associate Physician, Clinical Research Unit, Clinical Pharmacology, Vanderbilt University School of Medicine, Nashville, TN

Fellow, Clinical Pharmacology, Vanderbilt University School of Medicine, Nashville, TN

Intern / Resident (Internal Medicine), Tulane Hospitals, New Orleans, LA

PhD, Pharmacology, Tulane Graduate School, New Orleans, LA

MD, Tulane Medical School, New Orleans, LA

BA, Biology, Clark University, Worcester, MA

Society Memberships

American Society for Clinical Pharmacology and Therapeutics, Member, 1991

Parenteral Drug Association, Member, 2011

Academic / Professional Honors

BA, *cum laude*, Biology, Clark University

Diplomate, American Board of Internal Medicine

American Chemical Society Award for Team Innovation (Losartan)

Licensure / Certification

Louisiana State Board of Medical Examiners (inactive)

American Board of Internal Medicine

State of Tennessee Licensing Board for Healing Arts (inactive)

State of Indiana Medical Licensing Board (inactive)

Publications

3 books, 4 book chapters, 1 review and more than 100 peer-reviewed publications (full list available on request)

Representative/significant publications:

1. Manini ML, Camilleri M, Goldberg M, Sweetser S, Mckinzie S, Burton D, Wong S, Kitt MM, Li Y-P, Zinsmeister AR. Effects of Velusetrag (TD-5108) on gastrointestinal transit and bowel function in health and pharmacokinetics in health and constipation. Neurogastroenterol Motil. 2010; 22, 42–50
2. Goldberg M, Li Y-P, Johanson JF, Mangel AW, Kitt M, Beattie DT, Kersey K, Daniels O. Clinical trial: the efficacy and tolerability of velusetrag, a selective 5-HT4 agonist with high intrinsic activity, in chronic idiopathic constipation – a 4-week, randomized, double-blind, placebo-controlled, dose–response study. Aliment Pharmacol Ther; 2010; 32:1102–1112
3. Lehman HP, Chen J, Gould AL, Kassekert R, Beninger PR, Carney R, Goldberg M, Goss MA, Kidos K, Sharrar RG, et al. An evaluation of computer-aided disproportionality analysis for post-marketing signal detection Clin Pharmacol Ther; 2007; 82:173-180.
4. Bergstrom, M; Hargreaves, RJ; Burns, HD; Goldberg, MR; Sciberras, D; Reines, SA; Petty, KJ; Ogren, M; Antoni, G; Langstrom, B; Eskola, O; Scheinin; M, Solin, O; Majumdar AK; Constanzer ML; Battisti WP; Bradstreet TE; Gargano C.; Hietala J. Human positron emission tomography studies of brain neurokinin 1 receptor occupancy by aprepitant. Biological Psychiatry. 55(10):1007-12, 2004

5. Majumdar, AK; McCrea, JB; Panebianco, DL; Hesney, M, Dru, J; Constanzer ,M; Goldberg, MR, et al. Effects of aprepitant on cytochrome P450 3A4 activity using midazolam as a probe. Clin Pharmacol Ther 74(2): 150-156 (2003)

6. Goldberg, MR; Sciberras, D; De Smet, M; Lowry, R., Tomasko, L; Lee, Y; Olah, TV; Zhao, J; Vyas, KP; Halpin, R; Kari, PH; James, I. Influence of beta adrenoceptor antagonists on the pharmacokinetics of rizatriptan, a 5-HT1B/1D agonist: Differential effects of propranolol, nadolol and metoprolol. British J. Clinical Pharmacol 2001; 52:69-76

7. Goldberg, MR; Lo, M-W; Christ, DD; Chiou, R; Furtek, CI; Amit, O; Carides, A, Biollaz; J, Piguet V; Nussberger, J; Brunner, HR: DuP 532, an angiotensin II receptor antagonist: first administration and comparison with losartan. Clin Pharmacol Ther 61:59-69, 1997

8. Goldberg, MR; de Mey, C; Wroblewski, MS; Li, Q; Schroeter, V; Belz, GG: Differential effects of oral losartan and enalapril on local venous and systemic pressor responses to angiotensin I and II in healthy men. Clin Pharmacol Ther 59:72-82, 1996

9. Goldberg, MR, et al.: Biochemical effects of losartan, a non-peptide angiotensin II receptor antagonist, on the renin-angiotensin-aldosterone system in hypertensive patients. Hypertension 25:37-46, 1995

10. Sciberras, DG; Reed, JW; Elliott, C; Blain, PG; Goldberg, MR: The effects of a peripherally selective 2-antagonist, MK-467, on the metabolic and cardiovascular response to exercise in healthy man. Br Journal Clin. Pharmacol. 37:39-44, 1994

11. Goldberg, MR, et al.: Dose-effect and concentration-effect relationships of pinacidil and hydrochlorothiazide in hypertension. Clin. Pharmacol. Ther. 46:208-218, 1989

12. Goldberg, MR; Offen, WW; Rockhold, FW: Factorial design: An approach to the assessment of therapeutic drug interactions in hypertension J. Clin. Res. Drug Dev. 2:215-225, 1988

13. Robertson, D; Goldberg, M.R., et al.: Isolated failure of autonomic noradrenergic neurotransmission: evidence for impaired ß-hydroxylation of dopamine. New Eng. J. Med. 314:1494-1497, 1986

14. Goldberg, M.R., Hollister, AS; and Robertson, D: Influence of yohimbine on blood pressure, autonomic reflexes and plasma catecholamines in humans. Hypertension, 5:772-778, 1983

15. Goldberg, MR; Kadowitz, PJ: A comparison of the effects of 5- and 6-hydroxydopamine on isolated canine saphenous veins. Circ. Res., 43