CLIII CONSULTING LLC

Integrating Toxicology Expertise. Advancing Drug Development.

CLIII Consulting, LLC provides toxicology, non-clinical, and drug development consulting to the pharmaceutical, biotechnology, government, and academic communities on a global basis.

Services include:

- Scientific advisory services on portfolio management & compound progression
- Discovery & early-stage drug development strategies
- Design/peer review of non-clinical development plans, study protocols, & regulatory submissions
- Contract research organization selection, study placement, monitoring, & reporting
- IND, CTA, & eCTD submissions
- Preparation of responses to Health Authority queries, briefing documents for Health Authority meetings, integrated summaries, & expert reports
- Representation for non-clinical discipline at Health Authority meetings
- Authorship of position/white papers on clinical relevance of non-clinical study findings
- Safety assessment literature reviews
- Participation/consultation on drug registration defense preparations, FDA Advisory Committee meetings, & package insert negotiations
- Qualification strategies for impurities, degradants, leachables, & excipients
- Drug target evaluations, drug product in-licensing reviews, & due diligences
- Assistance with preparation of out-licensing packages

CharlesLindamoodIII, PhD, DABT

Managing Director

Dr. Lindamood is a toxicology and drug development expert. He has 30 years of experience in pharmaceutical and biopharmaceutical toxicology, including small and large molecules, multiple administration routes, and diverse therapeutic areas. Dr. Lindamood's expertise includes study and program design and execution, contract research organization selection and oversight, regulatory submissions and health authority interactions, in-licensing reviews, and due diligences.

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Over his career, he has addressed and resolved a wide variety of study and program findings to the satisfaction of regulatory agencies, resulting in numerous drug approvals. This diverse experience makes him uniquely qualified to advise clients on non-clinical safety findings, study designs, drug development programs, regulatory strategies, portfolio management, and business development opportunities.

Dr. Lindamood has supported business development, drug discovery, drug development, global drug registration, and lifecycle programs of approved compounds, including indication extension and new formulations. These activities involved the psychiatry, neurology, gastrointestinal, cardiovascular, metabolic disorders, endocrine, women's health, anti-infective, respiratory, inflammation disorders, and oncology therapeutic areas. His accomplishments include major contributions to 13 NDA/eCTD approvals, including Celexa®, Benicar®, Namenda®, Lexapro®, Bystolic®, Savella®, Daliresp®, Viibryd®, Teflaro®, Combunox®, Aerospan®, Trudorza®, and Linzess®.

Dr. Lindamood worked for more than 15 years at Forest Laboratories, Inc. (now Allergan), most recently as Executive Director of Early Development. His responsibilities included oversight of the discovery and early stage development portfolio, as well as full administrative and technical responsibility for the discovery, pharmacology, DMPK, toxicology, and clinical pharmacology disciplines.

Dr. Lindamood began his career at Southern Research Institute, where he worked for 10 years as client interface and study director in the full range of toxicological studies in rodents and large animals conducted under GLP and global regulatory guidelines. Additionally, he worked for four years at Solvay Pharmaceuticals (now AbbVie). At Solvay, he provided the US subsidiary with core expertise in pharmacology and toxicology — both investigative and regulatory — and served as the primary non-clinical liaison to the FDA for the US and all international subsidiaries.

Dr. Lindamood earned a BS in Chemistry from California State University, San Diego, and a PhD in Pharmacology and Toxicology from West Virginia University Medical Center. He completed a post-doctoral fellowship at the Chemical Industry Institute of Toxicology (recently Hamner Institutes). Being very active in professional development, he has held various officer and committee membership roles in professional societies and trade associations, and has assisted government institutes with grant and policy reviews.

Investigative & Regulatory Toxicology

Discovery & Early Stage Drug Development Strategies

Drug Product In-Licensing Reviews & Due Diligences

Regulatory Submissions & Health Authority Interactions

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