Herbal Synergy

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Herbal Synergy

Herbal Synergy is a consulting company that specializes in the food and drug regulations of the United States. Our experts have over 16 years of experience with food and drug laws and regulations.

Our expertise includes:

- Current Good Manufacturing Practices (cGMP) regulations in drugs and dietary supplements
- Validation issues
- Auditing
- Quality Control
- Meeting U.S. Pharmacopeia Standards
- Import and Export of drugs and herbal products, Labeling, and Packaging
- Clinical Trials (Pre-Clinical to Phase I) and Human Subject Protection
- Evaluation of pharmacology and toxicology of drugs and dietary supplements

The United States' food and drug regulations are complex and confusing. **Herbal Synergy** regularly assists its clients in navigating through the regulatory maze to achieve legal sale status of their products, licensing, validation of process and/or equipment, facility audit and management, planning and organizing, and training of personnel. **Herbal Synergy** has knowledge of both the United States and international markets. We have experiences in assisting clients to evaluate market potential of the products.

Richard Ko, Pharm.D., Ph.D.

Dr. Richard Ko received his undergraduate degree in biochemistry from the University of California, Berkeley and his Doctor of Pharmacy and Doctor of Philosophy from the University of Southern California, Los Angeles. His doctoral dissertation was on pharmacokinetic drug interactions. He was a Research Scientist (Food and Drug Scientist) at the California Department of Health Services, Food and Drug Branch for 16 years. In his government role, he was actively involved in regulating dietary supplements and investigating herbal products related injury and death. He has published peer review articles and has made numerous presentations in the dietary supplement area. Dr. Ko is fluent in English and Chinese.

Expert Consultant/Advisor Experience

Member of the Dietary Supplements - Information Expert Committee, United States Pharmacopeia
Commission Officer, U.S. Food and Drug Administration
Co-chair and **member** of the AOAC International Methods Committee on Dietary Supplements
Member of the Committee for the Protection of Human Subjects, California Health and Human Services Agency
Commission Officer, U.S. Consumer Product Safety Commission
Technical Advisor for the American Herbal Pharmacopoeia
Honorary Consultant for the Hong Kong Hospital Authority Toxicology Reference Laboratory, Princess Margaret Hospital
Technical Consultant for the Macao Chinese Medicine Biotechnology Research Institute, Macau University of Science and Technology
Member, Dietary Supplement Safety Surveillance Project, California Poison Control System - San Francisco.

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广 讯 司

广讯司是在美国加州注册的食品及药品专业顾问公司。我司的专家顾问群有超过 16 年的实际工作经验，不但精通美国 FDA 食物和药品条例及其工厂的现行生产质量管理规范(cGMP)法规和应用，更俱有实际审批食品和药品条例及生产工厂的 cGMP 达标与否的资格和经验。由于我司非常熟悉美国和海外市场，加上美國 FDA 食品和药品条例及 cGMP 法规的复杂性，我司会为客户提供专业指引和建议，其中包括：

- 现行生产质量管理规范 (cGMP) 法规和应用
- 设施审核和管理，计划和统筹发展，人员培训
- 质量控制
- 化验方法，仪器设备和生产过程的验证
- 药典標准
- 中西药品和保健品的包装，标签及进出口手续
- 临床实验與倫理规范法规
- 药品和保健品的药理及毒理学

高伟信， Pharm.D., Ph.D.

高伟信博士毕业于美国拍克莱大学生物科技系，在南加大（USC）荣获药济及药物双博士，是药物动力学专家。在任职于美国药品和食品加州卫生局高级科学家的十六年当中，主导了多宗药品和保健品有关伤亡事故的调查研判，并被委任和参与美国政府对药品和食品监控条例的制订。精通中英文的高伟信博士，在多家专业杂志发表和审批有关的论文，并经常为海内外政府部门，各大学及机构作现场演讲。

专家顾问群资历

- 美国药典委员会委员
- 美国食品及药品管理局(FDA)委任官员
- 国际AOAC委员会主席
- 美国加州倫理委員會
- 美国消費者委员会委任官员
- 美国草药药典专家顾问
- 美国加州中药商联会顾问
- 香港马嘉烈医院毒理化验考据荣誉顾问
- 澳门科技大学中药生物研究所专家顾问
- 美国加州毒药管制署和三藩市加大联办之中药安全监控专家