

5th International Conference and Exhibition on Pharmaceutical Regulatory Affairs

August 03-05, 2015 Orlando, USA



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Essential consensus and scientific definitions for advancement in pharmaceutical regulatory affairs

Disparity in basic scientific concept and theory lead to weakness in setting policy and regulatory affairs. Confusion and controversy in at least three major areas in biomedical-research and pharmaceutical development exists that compromise research efficiency, developmental cost-effectiveness and rigorous regulatory policy and affairs, namely: (1) Lack of consensus on “synergy definition and its quantification” in drug combination and treatment, especially in cancer and AIDS. (2) The terms PK/PD referred as Pharmacokinetics and Pharmacodynamics are used casually where PD is poorly defined and neglected. (3) The “care and use” legislatures for laboratory animals are good policy and regulation. However, the basic means for conservation of laboratory animals “use”, for reducing waste and minimizing data points and experimental size is poorly developed. It is proposed that all the above three serious problems can be minimized by employing the unified theory of the ‘median-effect equation’ for single entity drugs, and the ‘combination index theorem’ of drug combinations, based on the physico-chemical principle of mass-action law. Its computer software, “CompuSyn”, for automated simulation of pharmacodynamics for new drug evaluation and for synergy quantification, have already been adopted by >10,000 scientists worldwide and is growing at over 1,000 citation papers per year.

Biography

Ting-Chao Chou received MS in Pharmacology from National Taiwan University, and PhD from Yale University, and Postdoctoral Fellowship at Johns Hopkins University, School of Medicine. He joined the Memorial Sloan-Kettering Cancer Center (MSKCC) and became a member in 1988, and was a Professor of Pharmacology at Cornell University, Graduate School of Medical Sciences during 1988-2000. He was the Director of Preclinical Pharmacology Core at MSKCC, where he retired on January 06, 2013. He is the Founder of PD Science, LLC., USA. He published 273 articles that have been cited by 16,421 papers in 620 biomedical journals worldwide including Thomson Reuters Web of Science and Google Scholar Citations with 22,336 citations, h-index 65 and 38 U.S. Patents. He introduced the “Unified Theory of the Median-Effect Equation of the Mass-Action Law” in 1976 for single drug, and with Prof. Paul Talalay (JHU) in 1984, created the “Combination Index Theorem” for multiple drug dynamics. His dynamics equations and software have been utilized to advance Econo-Green Bio-Research.

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