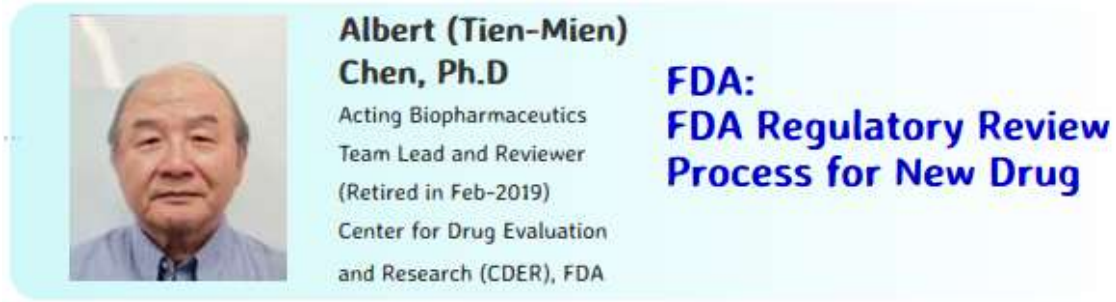
Taiwanese American Association of Pharmaceutical Sciences

台美藥劑學會

2019 TAAP Symposium

Speaker Introduction



Bio

Dr. Chen received his BS in Pharmacy from Kaohsiung Medical University and Ph.D. in pharmacokinetics from University of Illinois at Chicago. He joined FDA in 1991 and served as a reviewer in OCPB (Office of Clinical Pharmacology and Biopharmaceutics) from 1991-2009. He was then transferred to Division of Biopharmaceutics (DB) under Office of New Drug Product (ONDP)/Office of Pharmaceutical Quality(OPQ).

His experiences have been built on reviews of pharmacokinetics (PK) in OCPB and Biopharmaceutics in OPQ to fulfill the daily review tasks and to tackle the new review challenges.

Dr. Chen was appointed as an acting Biopharmaceutics team leader in 2015. His roles were to mentor new reviewers, help transformation of the old ONDQA (Office of New Drug Quality Assessment) to the modern OPQ, and to actively involve in interactions/meetings with drug companies for thorough discussions on Biopharmaceutics issues.

He had received numerous awards from FDA during his service from 1991 till he retired in Feb, 2019.

Abstract

The objectives of this presentation are to familiarize the audience with the FDA review process, to learn the review challenges, and to understand the insights during the regulatory review process.

The speaker will give a brief overview of FDA regulatory review process mainly on INDs (Investigational New Drugs), NDAs (New Drug Applications), and ANDAs (Abbreviated NDAs for generic drugs), but not on biologics (biologic medical products).

Several review cases will be presented. The insights on review challenges will also be briefly discussed.