**报告人简介：**

古丽　博士，FDA驻华办公室主任

**Leigh Verbois, Ph.D.**

**FDA Country Director, China**

Leigh Verbois, Ph.D. is currently the Country Director for the U.S. Food and Drug Administration (FDA) for the People’s Republic of China. Before this she served as Director of the Office of Regional and Country Affairs within the Office of International Programs at FDA where she oversees regulatory engagement with countries in the Asia-Pacific (excepting China and India), Middle East, Africa and Canada.  Dr. Verbois began her FDA career as a reviewer in Center for Drug Evaluation’s Office of New Drugs. She then developed and directed strategies, activities, and policies to reduce threats to the global drug supply chain through increased transparency and accountability, effective enforcement, and promotion of proactive industry vigilance and voluntary compliance in CDER’s Office of Compliance.  Dr. Verbois then served in the Office of Global Regulatory Operations and Policy as Senior Advisor, Acting Assistant Commissioner for Compliance Policy in the Office of Regulatory Affairs and Acting Deputy Director of FDA’s China Office.  In these capacities she guided multidisciplinary teams to facilitate strategic decisions, develop policy that is data driven and risk-based and manage resources. Dr. Verbois received her undergraduate degree from Tulane University, her Ph.D. in Pharmaceutical Sciences from the College of Pharmacy at the University of Kentucky and completed her postdoctoral training at the National Institutes of Health.

柯雷恩　博士，FDA驻华办公室助理主任（药品）

**Lane Christensen, Ph.D.**

**Assistant Country Director, FDA China Office**

Dr. Lane Christensen is an Assistant Country Director of the China Office in the Office of International Programs (OIP) at the US Food and Drug Administration (FDA) where he serves as the International Program and Policy Analyst (IPPA) for Drugs. Before joining the FDA China Office, he was a Branch Chief in the Office of Process and Facilities (OPF), in the Office of Pharmaceutical Quality (OPQ), CDER, FDA which is tasked with the review of manufacturing process and established facility inspections for abbreviated and new drug applications (A/NDAs).

Previously he was with the Office of Generic Drugs (OGD) as a Team Leader in a review division and as a Chemist with the Immediate Office having various responsibilities related to Chemistry Manufacturing Control activities such as ANDA review, Control Correspondences, Citizen Petitions, and policy development. Lane was extensively involved in various initiatives related to OPQ reorganization and new user fee implementation under GDUFA including the lead for hiring efforts and involvement with risk-based review efforts. He received his Ph.D. in Pharmaceutics and Pharmaceutical Chemistry from the University of Utah followed by a post-doctoral fellowship within the pharmaceutical industry. Lane began his FDA career with the CDRH Office of Compliance.

艾丽西亚·莫萨西奥，FDA药品评价与研究办公室药品质量办公室监管官员

**Alicia Mozzachio, Regulatory Officer, OPPQ/OPQ, CDER/FDA**

Alicia Mozzachio has been with FDA for 23+ years in various roles including field drug investigator and CDER compliance officer. She became a Branch Chief within Office of Compliance responsible for evaluating FDA’s international drug inspections and determining actions to be taken against firms failing to comply with CGMPs. Currently, she is the Senior Advisor for International Activities in the Office of Policy within the Office of Pharmaceutical Quality in CDER. Alicia serves as a technical lead on GMP-related policy projects focusing on those policies with a global impact. She represents the interests of CDER/OPQ while working with international organizations such as PIC/S.