# The Food and Drug Administration's (FDA's)
# 2015 ORSI Science Symposium
# April 27, 2015
***SPEAKER ABSTRACTS AND BIOGRAPHIES***

**Session 6: CORES Scientific Intramural Grant Presentations – 4:10 -5:00 PM**

| | |
|---|---|
| Speaker | **Peng Zou, Ph.D.,** |
| Title | **Chemistry reviewer** |
| Biography | **Dr. Zou is currently a chemistry reviewer at the Immediate Office, Office of Pharmaceutical Quality (OPQ). He received his Ph.D in pharmaceutical sciences from the University of Michigan in 2011 and then performed his postdoc training at the National Cancer Institute. Dr. Zou joined FDA Office of Generic Drugs in 2012 and was responsible for CMC review of nanoparticle products such as iron colloids and liposomes. His current work at OPQ focuses on CMC review of complex ANDA products, PBPK modeling of liposomal products, and internal/external grant management. He has published 40 journal articles, book chapters and three US patents.** |
| Subject | **Physiologically-based pharmacokinetic (PBPK) modeling of nanomedicine: Building clinically relevant standards for FDA-regulated nanoparticulate drug products** |
| Presentation Abstract | **Liposomal injections are a main class of nanotechnology drug products regulated by the FDA. There are multiple IND/NDA/ANDA submissions of liposomal products which are under review. To evaluate submissions related to liposomal products, a systematic understanding of the relationships between their physiochemical properties and biodistribution is critical. Physiologically-Based Pharmacokinetic Modeling (PBPK) is an ideal tool to quantitatively describe and predict the biodistribution of liposomal vesicles and drug substances. More specifically, we propose to investigate the quantitative relationships between liposome size/internal contents of ammonium sulfate and liposomal PBPK model parameters. Currently, we have developed mouse and human whole-body PBPK models which can predict the plasma and tissue concentrations and AUC of released and encapsulated doxorubicin with reasonable accuracy after i.v. administration of DOXIL®. In addition, model parameter sensitivity analysis has identified several model parameters which are critical for biodistribution of released and encapsulated doxorubicin. The next step of this study is to establish correlations between liposome size/internal contents of ammonium sulfate and critical model parameters by statistical analysis of animal biodistribution data. The established quantitative correlations will be extrapolated to humans and serve as a potential predictor of biodistribution of liposomal doxorubicin in human.** |