

# Drug Safety Biomarker Services

The pharmaceutical industry continues to explore new methods to prevent costly and unforeseen safety issues during drug development<sup>1</sup>. Biomarkers are increasingly viewed by the FDA as a potential means for providing toxicity information earlier in drug development. Safety biomarkers should be quantitative, highly specific, and sensitive in order to provide insight into onset, severity, and recovery of toxicities. Nextcea specializes in the discovery, development, and GLP/non-GLP application of drug safety biomarkers to reduce late-stage drug attrition by guiding clinical development and meeting regulatory expectations.



## Nextcea, Inc.

A pharmaceutical service company dedicated to optimizing efficacy, minimizing toxicity, and ensuring the quality of drug products.

## About Nextcea, Inc.

Nextcea, Inc. is a drug development service company dedicated to optimizing efficacy and minimizing toxicity in all phases of drug development. Nextcea integrates cross-species biomarker studies with traditional PK/PD and TK/TD. In-house platforms include HPLC/UPLC coupled to mass spectrometry LC-MS and LC-MS/MS (API-6500s and and TripleTOF 6600).

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<sup>\*1</sup> Hsieh F, Tengstrand E. Detecting Phospholipidosis and Diagnosing Lysosomal Storage Disorders. US Patent 8,313,949 / Japanese Patent 5702363.

<sup>\*2</sup> Tengstrand E, Miwa G, Hsieh F. Bis(monoacylglycerol)phosphate as a non-invasive biomarker to monitor the onset and time-course of phospholipidosis with drug-induced toxicities. *Exper Opin. Drug Metab. Toxicol.* 2010; 6(5): 555-570

<sup>\*3</sup> Xu JJ, Kalgutkar, AS, Will Y, Dykens J, Tengstrand E, Hsieh F. (Chapter 15. Predicting Drug-Induced Hepatotoxicity: In Vitro, In Silico and In Vivo Approaches, Hit and Lead Profiling - Identification and Optimization of Drug-like Molecules, Vol 43, 2010) Bernard Faller and Laszlo 4 Urban Hit and Lead Profiling. Weinheim: WILEY-VCH Verlag GmbH & Co. KGaA. 345-360.

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<sup>\*5</sup> Hsieh F, Tengstrand E, Lee JW, et al. Drug safety evaluation through biomarker analysis—A toxicity study in the cynomolgus monkey using an antibody-cytotoxic conjugate against ovarian cancer. *Toxicology and Applied Pharmacology* 2007;224:12-18

\*Nextcea Publications