MOSAIQUIES and U.S. FDA describe detection of drug-induced side effects in early phase animal models

11.05.2009 - Drug-induced toxicity represents a significant problem in health care delivery: Over 100,000 people die per year from adverse effects of medications in the U.S. (Starfield, JAMA 2000, 284: 483-485). This has led to an intense awareness of drug-induced side effects, which may hamper the development of new therapeutic agents. Initial assessment of possible side effects in animal models is certainly preferred over discovering side effects in a clinical study - if not worse after approval - in human.

Now mosaiques diagnostics demonstrated the capability of its proprietary CE/MS technology by the early and reliable assessment of drug-induced side effects in animal models. The data clearly indicate that CE/MS analysis is able to display drug-induced changes in the urinary proteome. To reveal drug-induced alterations (or the absence thereof) with high statistical significance opens an avenue towards screening for potential side effects with limited or reasonable effort during preclinical research.

The results also indicate that the number of individuals required for statistically sound results is by far less in laboratory animals in comparison to human. Furthermore, the found similarity to human beings, strongly supports the notion that urinary proteome analysis is a very valuable tool not limited to assessing drug toxicity and unwanted side-effects in preclinical investigations, but also to reduce the risk for appearance of such side effects later in clinical studies, or even after approval.