NEWS RELEASE: For Immediate Release

Cleaning Validation Expert Challenges ISPE RiskMaPP Report

Kodak, TN, March 28, 2011 -- Destin A. LeBlanc of Cleaning Validation Technologies announced today that he will continue to challenge the accuracy and appropriateness of certain statements made in ISPE's RiskMaPP document regarding setting residue limits for cleaning validation protocols. The RiskMaPP document is basically a document about setting risk-based limits for highly hazardous actives, such as actives that are mutagenic or genotoxic. Mr. LeBlanc has published two critiques as Cleaning Memos (November 2010 and February 2011) on his website, www.cleaningvalidation.com.

Mr. LeBlanc agrees with the RiskMaPP that setting limits for such highly hazardous actives based on a toxicological assessment is a valid approach, since the main safety concern is not necessarily with the therapeutic effect of the active, but rather with other concerns related to issues such as mutagenicity or genotoxicity of the active. His objection to the RiskMaPP document involves statements in the RiskMaPP that current industry ways of setting limits, such as 0.001 of a therapeutic dose, are "not scientifically justified' and "arbitrary" as applied to *any* active (highly hazardous or not). Mr. LeBlanc maintains that such a description is inappropriate, and that for actives where the primary safety concern is based on the therapeutic effect of the active, such limits are appropriate with an acceptable margin of safety. Such criteria have been used by the industry for at least 18 years, and are mentioned in many regulatory guidance documents.

1128 Eagle View Drive
Kodak, TN 37764 USA

Phone: 865-932-6927
Fax: 865-932-6849

Mr. LeBlanc further has stated “The danger with these statements in the RiskMaPP document is that regulatory inspectors may challenge existing cleaning validation programs as inappropriate based on the fact that the RiskMaPP calls these methods of determining limits ‘not scientifically justified’ and ‘arbitrary’.”

Partially in response to Mr. LeBlanc’s critiques, the ISPE conducted an “independent review” of the RiskMaPP. That independent review unanimously found that the RiskMaPP was accurate, and apparently that Mr. LeBlanc’s critiques were unjustified. Mr. LeBlanc has stated, “ISPE has called for an ‘open dialogue about the concepts described in the Guide’, yet the authors of the guide will not discuss my concerns with me. Nor will ISPE share the results of the independent review, which they describe as ‘confidential’. Such an approach is not consistent with open scientific inquiry. I will continue to advocate for reasonable changes in the RiskMaPP Guide.”

Destin A. LeBlanc is recognized worldwide as a subject matter expert in cleaning validation. He has written three books on cleaning validation and has more than 20 technical publications on cleaning validation. He was a co-chair of the team that wrote PDA Technical Report #49 *Points to Consider for Biotechnology Cleaning Validation* and is currently chair of the team that is revising PDA Technical Report #29 *Points to Consider for Cleaning Validation*. He maintains the website www.cleaningvalidation.com as a resource for cleaning validation professionals. In addition, for the last 14 years, Mr. LeBlanc has trained FDA inspectors on cleaning validation in their Basic Drug School.

For further information, contact Destin A. LeBlanc, 865-932-6927, destin@cleaningvalidation.com