

REGISTRATION

ROUND TABLE DISCUSSIONS AT ICSE 2008

Return answer by fax to +49 6128 744-9400

Name, first name _____ Company _____
Phone _____ E-Mail* _____
Fax _____ *Receipt will be confirmed via e-mail

Please tick the required dates!

Direct Your Extractable and Leachable Assessment (language: English)

(Speaker: Dr. Andreas Nixdorf, SGS Germany GmbH)

In recent years, the requirements for the assessment of substances that can potentially leach into the drug product in the course of its shelf-life have increased considerably. Extractable and leachable studies are designed to ensure that packaging material does not negatively impact the stability and activity of the drug, or even worse actively harm the end user. Leachables can vary from organic common oligomers and special plasticizers, to minerals or catalyst residues. Within the scope of the presentation, relevant aspects of leachables and extractables testing will be addressed ranging from regulatory requirements to the extractables testing for quality control.

Tuesday, September 30, 2008 / 3:00pm - 3:30pm

Harmonizing quality compliance within pharmaceutical supply chains (language: English)

(Speaker: Dr. Eize de Boer, SGS NEDERLAND B.V.)

The pharmaceutical industry is faced with increasing legislation and guidance on efficacy, quality, and safety during the entire life cycle of their products. As a result, quality and compliance departments in the sector are expected to control compliance of the entire supply chain, from incoming goods to the delivery of final product to the patient. Therefore, the quality management staffs are increasing their focus in the area of internal quality, safety self-inspections, and external vendor qualifications. The presentation will provide an overview of the wide range of outsourced, third-party Good Manufacturing Practices (GMP) solutions for the entire pharmaceutical and bio-tech industries, including drug manufacturers, suppliers and regulators. Furthermore, how these services can be provided in a globally consistent and independent manner, while at the same time understanding and appreciating the cultural and regulatory differences from country to country, will be covered.

Wednesday, October 1, 2008 / 3:00pm - 3:30pm

Harmonized Pharmaceutical Microbiology (language: English)

(Speaker: Dr. Christof Siersdorfer, SGS Germany GmbH)

The new United States Pharmacopeia (USP), European Pharmacopeia (EP) and Japanese Pharmacopeia (JP) harmonized microbial limits test method has been available for some time. Although the USP will make it a requirement in May 2009, the EP will already require its use by January 2009. Although these dates are some months out, preparation for the change must begin now to ensure proper implementation. Depending on the product line, there may be a need to purchase additional equipment, media, and micro-organisms. Most manufacturers will need to re-validate test methodology, and advanced planning will ensure no delay in production and release requirements. The presentation will assist attendees in performing their own gap analysis.

Thursday, October 2, 2008 / 2:00pm - 2:30pm

SGS Germany GmbH

Im Maisel 14

D-65232 Taunusstein

t +49 6128 744 230

f +49 6128 744 203

de.qualitycontrol@sgs.com

www.de.sgs.com/lifescience

WHEN YOU NEED TO BE SURE

SGS