LGC Standards

Excellence through measurement

INVITATION

LGC Standards
together with
Analytical Instruments
invites you

to the

Pharma-Seminar

Date: Thursday, 26th of March 2015

Venue:

Analytical Instruments SA
9, Tzavella str.
GR-15231 K. Chalandri

Application deadline: 20 March 2015

Please return the enclosed application form by email!

LGC Standards

Excellence through measurement

Pharmaceutical seminar Program
26th March 2015

9.00 Registration

9.15 Welcome address - Analytical Instruments

9.30 LGC Standards – company presentation, John Ball, Director of Sales EMEA , Izabella Razman (LGC Standards)

9.50 Reference standards and (certified) reference materials (60 minutes)
Reference materials and standards are used in wide fields of analysis. Due to different guidelines and users, there is often some confusion in the use of all the relevant terms. This presentation gives an excursion into the field of reference materials, with an attempt to classify them. Definitions for primary and secondary reference materials are given, mainly for pharma purposes, but also from a metrological point of view.

10.50 Reference materials and standards: Certificates of analysis (30 min)
Most reference materials and standards include a certificate of analysis. These certificates can be highly different in the quantity and quality of information. To give an insight into the usage of a certificate, CRMs from different suppliers and for primary and secondary reference standards are shown. Also we will explain the difference between an impurity reference standard and a research material.

11.20 Refreshment break

11.40 Impurities in drug substances and products (part 1, 45 min)
Impurities are always present in drug products in trace quantities. Limit and threshold values are provided by official bodies, i.e. pharmacopoeias and ICH (their guidelines). Dedicated reference standards for impurities can help in development and validation of analytical methods for impurity control, and are also used in the routine analysis of drug products. The use of such standards can also prevent cost and time intensive qualification studies according to ICH guidelines (e.g. by animal experiments). The presentation describes the different approaches to impurities, and how the EP limits must be interpreted.

12.25 Impurities in drug substances and products (part 2, 20 min)
Content please see below under part 1.

12.45 Refreshment break

13.00 Use of reference materials in the validation of pharmaceutical applications (40 min)
This presentation summarises how legislation/regulations, i.e. the main international pharmacopeias and the ICH guidelines address validation issues. Examples will be given as well, which will highlight certain validation parameters, some of those with the help of reference standards, e.g. impurity materials.

13.40 Impurities: Selected case studies from contract analysis (20 min)
As a manufacturer of reference standards for impurities, the laboratories of LGC Germany are often contacted for special inquiries in contract analysis as well. May it be questions about the identity of reference materials sourced elsewhere, or impurities in drug substances and drug products that could not yet be identified, or simply misunderstandings and ambiguities in the naming of chemical substances: The expertise of our staff in Luckenwalde is often used apart from our catalogue products as well.
This presentation gives some insight into the not-so-daily work of a company working on impurities and standards thereof, by the means of a few interesting case studies on complaints and other queries from its customers.

14.00 Final Q&A, end of seminar

APPLICATION FORM

Please return to:

Analytical Instruments SA
email: rgeorgiou@analytical.gr

I apply for the
"Pharma Seminar"
Thursday, 26th March 2015

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Analytical Instruments SA
9, Tzavella str.
GR-15231 K. Chalandri

Please complete in block letters!

First Name:_____

Surname:_____

Company:_____

Post code/City:_____

Address:_____

Phone/Fax:_____

E-Mail:_____

Date: :_____

NOTE : THE SEMINAR IS FREE OF CHARGE