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Qualifikationszentrum
LIFE Sciences Hamburg

SEMINAR

21 SEPTEMBER 2006

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Seminar-No. QZ-

SEMINAR am 21 September 2006
In Vitro Diagnostics as Medical Products

Relevance of the IVD guideline for bringing into circulation and operating IVD products

Programme organisation as regards content: Verein zur Förderung der Klinischen und Experimentellen Molekularen Endokrinologie (Society for the Promotion of Clinical and Experimental Molecular Endocrinology), Prof. Dr. Wolfgang Höppner, Hamburg

Fees: For participants from Hamburg, fees are 200 Euro plus VAT; for participants from outside of Hamburg fees are 314 Euro plus VAT. The seminar is supported with subsidies funded by the City of Hamburg; for this reason, different fees are charged. Fees include a comprehensive documentation as well as beverages during break times and a lunch snack.

Registration and eligibility requirements: After receipt of the written registration, you will receive an invoice which also serves as registration confirmation. To cancel the registration, a written notification is required. Cancellation is only possible up to two weeks prior to the respective seminar date and requires a processing fee of 50 Euro plus 16% VAT. In the case of cancellations up to one week prior to the beginning of the seminar, 50 percent of the seminar fees are due; after that date, and in the case of non-attendance of the participant, the seminar fees are due in full unless a substitute participant is named. Rebookings are treated the same way as cancellations. If the organiser cancels the seminar for organisational reasons or otherwise, all fees paid are reimbursed in full. Any and all further claims are ruled out.

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Date, Signature

In Vitro Diagnostics as Medical Products

Relevance of the IVD guideline for bringing into circulation and operating IVD products

SPEAKERS

Dr. Oliver Eikenberg
Human Gesellschaft für Biochemica und Diagnostica mbH, Magdeburg

Dr. Brigitte Gallert
Dekra Intertek Certification GmbH, Stuttgart

Prof. Dr. Wolfgang Höppner
Bioglobe GmbH, Hamburg

Dr. Jürgen Mikoleit
Ministerium für Gesundheit und Soziales des Landes Sachsen-Anhalt (Ministry for Health and Social Affairs of the State of Saxony-Anhalt), Magdeburg

Dr. Sigrid Nick
Bundesamt für Sera und Impfstoffe (Federal Ministry for Sera and Vaccines), Paul-Ehrlich-Institut, Langen

Prof. Dr. Rüdiger Siekmeier
Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Pharmaceuticals and Medical Products), Bonn

Dr. Folker Spitzenberger
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (Federal States´ Central Office for Health Protection with respect to Medicaments and Medical Products), Bonn

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Freie und Hansestadt Hamburg
Behörde für Wirtschaft und Arbeit
Behörde für Wissenschaft und Gesundheit

Europäischer Sozialfonds

Dieses Projekt wird aus Mitteln des Europäischen Sozialfonds kofinanziert

one-day seminar

in Hamburg

In Vitro Diagnostics as Medical Products

SPEAKERS

Dr. Oliver Eikenberg
Human Gesellschaft für Biochemica und Diagnostica mbH, Magdeburg
Dr. Eikenberg worked in the field of biosensors and biochemical environmental analysis and acquired deep analytical background in assay validation for several years. He was laboratory manager at ABETA GmbH, where IVD-Testsysteme for the diagnostic of Alzheimer diesease are developed, CE-marked and produced. Moreover, he consult small biotechnological and diagnostic companies during their CE conformity process with the special focus on technical dokumentation for immunochemical tests. Since January 2005 Dr. Eikenberg is responsible for the development and production of ELISA tests at the Human GmbH. The focus of his work is the generation of reliable technical data, which is an essential requirement for CE-marking of IVD tests-systems.

Dr. Brigitte Gallert
Dekra Intertek Certification GmbH, Stuttgart
After her university studies in chemistry, Dr. Gallert developed in vitro diagnostics in the industrial sector. She was active as lead auditor and field expert and is currently working at the Dekra Intertek Certification GmbH as branch in-charge for non-active medical products and IVD.

Prof. Dr.Wolfgang Höppner
Labor für Molekulare Genetik der Bioglobe GmbH, Hamburg
After his university studies in chemistry and the graduation in Hamburg, Professor Wolfgang Höppner has been engaged in fundamental research in the field of endocrinology for the past twelve years. In 1991, he habilitated in the subject biochemistry/molecular biology and continued his scientific work at the private Institute for Hormone- and Reproduction Research. In 2001, he became self-employed with the foundation of Bioglobe GmbH, a bio-analytics company focussing on DNA analyses. For the German Society for Endocrinology, he worked in the GLP Commission of the ALM, and he is active as member of the Sector Committee 5 of the Federal States´ Central Office for Health Protection with respect to Medicaments and Medical Products in Bonn. Professor Höppner is co-founder and chairman of the keme e.V., Society for the Promotion of Clinical and Experimental Molecular Endocrinology. The society supports, amongst others, advanced training courses in the field of molecular endocrinology and provides information about quality management in the field of molecular diagnostics.

Dr. Jürgen Mikoleit
Ministry of Health and Social Affairs in Saxony-Anhalt, Germany
Dr. Mikoleit studied physics at the Technical University in Magdeburg. He has graduated at the Humboldt-University in Berlin in the field of medical physics. After the graduation he gathered experience for many years in a hospital while working together with medical doctors. He was head of the pysical department dealing with all matters of medical devices. In 1992 he joined the Ministry of Health and Social Affairs in Magdeburg; responsible for medical devices law and radiation protection. During 2002 until 2006 he was the chairman of the working group „Medical Devices“ where representatives of the „Länder-Authorities“ for surveillance on medical devices discussed all relevant matters related to the medical devices market.

Dr. Sigrid Nick
Federal Ministry for Sera and Vaccines, Paul-Ehrlich-Institut, Langen
Dr. Nick studied biology at the Johannes Gutenberg University in Mainz and graduated in 1986 in the Department for Experimental Virology. From 1986 to 1991, Dr. Nick was heading the immunological and the diagnostic laboratory in the Department for Virology and Immunology of the Deutsches Primatenzentrum in Göttingen. Subsequently, she worked as scientific assistant in the Institute for Clinical and Molecular Virology, and since April 1995 as scientific assistant in the Sector 2/3 (Diagnostics) of the Paul-Ehrlich-Institut in Langen. In 2001, Dr. Nick took over the supervision of the test laboratory for in vitro diagnostics of the Paul-Ehrlich-Institut.

Prof. Dr. Rüdiger Siekmeier
Federal Institute for Pharmaceuticals and Medical Products, Bonn
Professor Siekmeier is heading the section In Vitro Diagnostics in the Department for Medical Products of the Federal Institute for Pharmaceuticals and Medical Products (BfArM). His fields of responsibility include the scientific evaluation of vigilance cases. Professor Siekmeier studied at the Clinical Centre of the J.W. Goethe University Frankfurt to become Doctor of Laboratory Medicine, and he also attended the Carl Gustav Carus Clinical Centre of the Technical University Dresden to graduate as Clinical Chemist. After habilitating in the subject Clinical Chemistry and Laboratory Medicine at the TU Dresden, he changed to the BfArM.

Dr. Folker Spitzenberger
Federal States´ Central Office for Health Protection with respect to Medicaments and Medical Products, Bonn
After the completion of his university studies in chemistry, Dr. Spitzenberger received a PhD at the Institute for Pharmacology of the University of Heidelberg in the field of Molecular Biology. In 2001, he completed a scientific sojourn at the Yale University, Medical School, Section Endocrinology, in New Haven, CT, USA. Since 2002, Dr. Spitzenberger is scientific assistant in the Section for Medical Products of the Central Office of the Federal States for Health Protection with respect to Medicaments and Medical Products (ZLG). His fields of responsibility include the establishment and continued updating of scientific bodies of legislation in the field of accreditation according to the European regulations for medical products as outlined in the Medical Device Directives 98/79/EG, 93/42/EWG, 90/385/EWG and the Norms DIN EN ISO/IEC 17025 and DIN EN ISO 15189.

PROGRAMME 21 SEPTEMBER 2006

9.00 h Registration and welcome coffee
Introduction and presentation of the participants

9.30 h Prof. Dr. Wolfgang Höppner
Overview of processes and procedures in medical laboratories

10.00 h Dr. Folker Spitzenberger
“IVD directive”
Legal foundations: New conception and global concept, 98/79/EC and Medical Products Act 2nd amendment, basic requirements and harmonised standards, accreditation and notification

11.15 h Dr. Jürgen Mikoleit
Surveillance of Medical Devices in Germany - authorities, tasks and vigilance-system

12.30 h Lunch break

14.00 h Dr. Brigitte Gallert
“CE marking and placing on the market”
Development of a certification procedure: basic requirements, classification and conformity assessment procedure, evaluation of performance

15.00 h Dr. Oliver Eikenberg
What must be done in practice to meet the criteria of the IVD-directive 98/79/EG? Implementations for CE-marking of immunochemical test systems

15.45 h Coffee break

16.15 h Prof. Dr. Rüdiger Siekmeier
Vigilance – experience by BfArM (= Federal Institute for Drugs and Medical Devices) so far with the notification of faults in respect of in-vitro diagnostics

17.15 h Dr. Sigrid Nick
Risk products in accordance with Annex II, 98/79/EC: Joint technical specifications, batch release, Report from the test laboratory of PEI (Paul-Ehrlich Institute)

18.15 h End

SEMINAR

Goals of the seminar

When the Medical Product Act took effect on 1 January 2002, the in-vitro diagnostics directive of 27 October 1998 was implemented as national law. Since 7 December 2003, at the latest, the initial placing on the market and the further placing on the market as well as the implementation of in-vitro diagnostics is thus subject to the regulations of the Medical Product Act.

The seminar is to convey the requirements of Directive 98/79/EC of the Medical Product Act. An overview of the development of the IVD directive and its implementation in Germany will be provided as well as of the respective authorities and notified bodies. The procedure for the acquisition of the CE mark is described in detail and illustrated using real-life experiences.

Target group

The seminar is oriented toward start-ups as well as small and medium sized businesses that are active or are planning to become active in the area of in-vitro diagnostics. The programme is oriented toward members of the management team and to the respective staff responsible for Regulatory Affairs, approvals, quality management, production management and legal affairs.

Schedule

21 September 2006 from 9 am to approx. 6.30 pm.

A coffee break as well as a lunch break during which a snack will be offered have been scheduled for the seminar day.