

UPCOMING 7 CONFERENCES

BY SYNERGUS
2008/2009

• MEDICAL DEVICE REGULATION IN CHINA

Date	Place	Subject	Speaker	Last date for Reg	
23-24 Oct 2008	Copenhagen, Denmark	MEDICAL DEVICE REGULATION AND REGISTRATION IN CHINA	Janice Ma and Lian Zhang	10 Oct	1

• SOFTWARE AND FDA REQUIREMENTS

1 Dec 2008	Copenhagen, Denmark	APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES	Alan Kusnitz	21 Nov	2
2-3 Dec 2008	Copenhagen, Denmark	FDA PRODUCTION AND QUALITY SYSTEM SOFTWARE REGULATION	Alan Kusnitz	21 Nov	3

• DESIGN AND MANAGEMENT OF MEDICAL DEVICES

10-11 Nov 2008	Copenhagen, Denmark	HOW TO APPLY DIFFERENT RISK MANAGEMENT TECHNIQUES	Erik Schwanbom	1 Nov	4
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• CLINICAL TRIALS FOR MEDICAL DEVICE IN EU/US

3 Dec 2008	Copenhagen, Denmark	ISO 14155 CURRENT AND FUTURE PRACTICES	Danielle Giroud	21 Nov	5
4-5 Dec 2008	Copenhagen, Denmark	GOOD CLINICAL PRACTICES FOR MEDICAL DEVICES	Danielle Giroud	21 Nov	6
2-3 Febr 2009	Copenhagen, Denmark	EFFICIENT AND EFFECTIVE US CLINICAL TRIALS FOR MEDICAL DEVICES	Linda Alexander	15 Jan	7

MEDICAL DEVICE REGULATION AND REGISTRATION IN CHINA

China is a fast growing market for medical devices with great potential and plenty of opportunities. However the regulation system for medical devices in China is complex, not transparent or consistent. It is also important to understand the culture and the environment in which the regulations are interpreted.

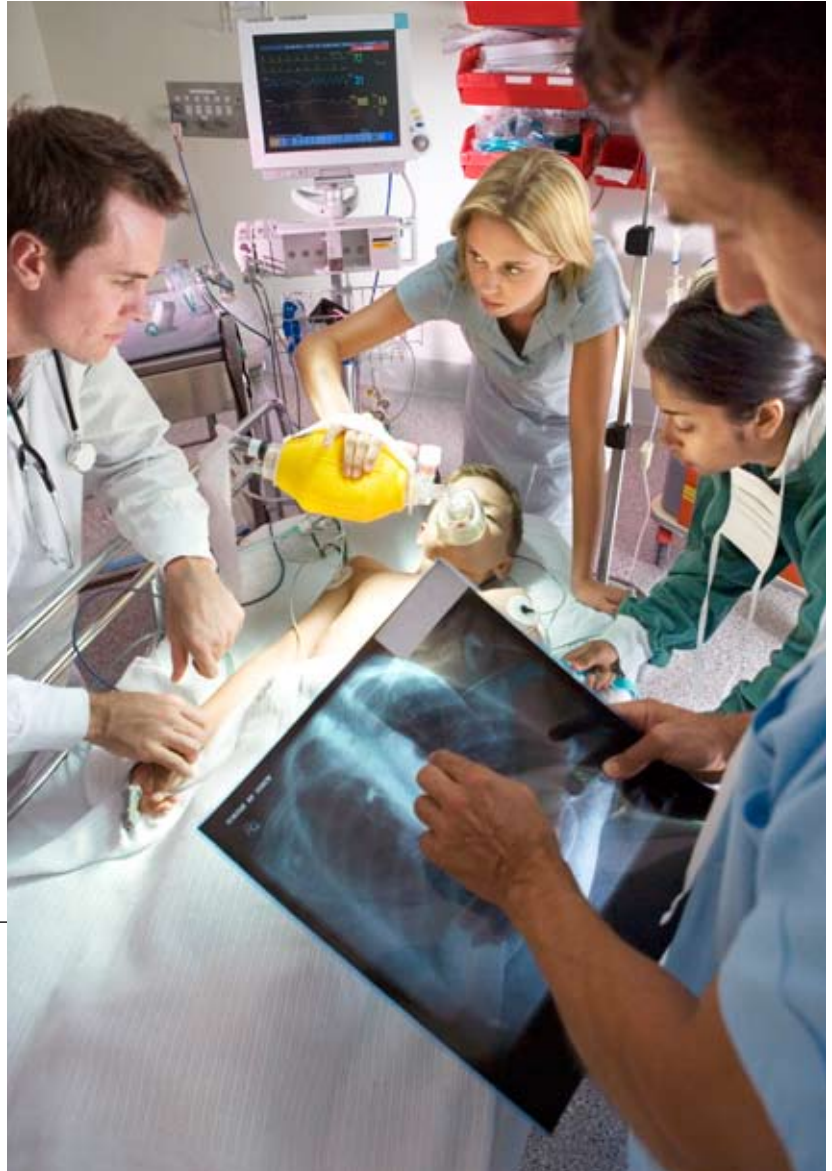
From this course you will not only have an overview with the Chinese medical device regulation and registration process, but also gain the knowledge on requirements of so-called "Product Registration Standard", type-testing, clinical study and registration dossier, as well as labeling. Some case studies will be also given.

Speakers:

Janice Ma
Dr Lian Zhang

Date Location:

October 23–24
Copenhagen Denmark



Who should attend

- Regulatory managers and specialists
- QA managers
- Marketing managers
- Project leaders
- Clinical study managers / associates
- CEOs

Speaker biographies

Janice Ma is the Managing Director and co-founder of a premium healthcare consulting company established since April 2002 which is a partner with Synergus and some others, such as Underwriters Laboratories in China, providing specialized high-quality consultancy and regulatory registration services. She has excellent experiences in medical device registration in China for many small and multinational MD manufacturers in EU.

Dr Lian Zhang is a Sr. consultant at Synergus AB. He has rich experiences with international regulatory in MD including both QA and RA. He is a specialist in regulatory issues regarding China, Taiwan and Japan.

Go to www.synergus.se for registration!

Agenda 23–24 October 2008

Day 1

- 08:30 – 09:00 Registration
09:00 – 09:15 Open Remark
Introduction to Synergus and its Chinese Partner – 10 min
Brief overview of the course – 5 min
09:15 – 09:35 MD business in China, culture and communication consideration
09:35 – 10:00 Overview of Chinese regulatory system for MD – A focus on EU MD manufactures
10:00 – 10:30 Coffee Break
10:30 – 11:00 China SFDA registration process for medical device
11:00 – 12:00 Product registration standard (company specific standard). What is the basic requirements of a Chinese product standard.
12:00 – 13:00 Lunch
13:00 – 15:00 How to arrange the sample testing in China, common problems and pitfalls in preparing product registration standard and sample testing
15:00 – 15:30 Coffee Break
15:30 – 17:00 Requirements of CCC mark, Trends in China regulatory approval. Other product entry and distributing requirements in China

Day 2

- 09:00 – 09:30 SFDA Dossier requirements for medical device
09:30 – 10:00 How to prepare the registration dossier for SFDA submission. Common mistakes and pitfall to avoid.
10:00 – 10:30 Coffee Break
10:30 – 11:00 Labeling requirements
11:00 – 12:00 Case study and normal mistakes in China registration application. Post-market surveillance requirements in China (adverse event reporting, product recall). Management of changes of registration.
12:00 – 13:00 Lunch
13:00 – 13:30 Product re-registration (sample re-testing)
13:30 – 15:00 Case Study 1 – 45 min
Case Study 2 – 45 min
15:00 – 15:30 Coffee Break
15:30 – 16:15 How to conduct a clinical trial in China
16:15 – 16:45 Q&A session
16:45 – 17:00 Round up

Registration information:

Last date for registration: October 10. Please note that the number of seats available is limited.

Conference venue

The conference will be held at Scandic Copenhagen, Vester Soegade 6, Denmark.

Accommodation

For convenience we recommend reservation of accommodation in the hotel where the conference takes place. Visit our homepage for more information: www.synergus.se

Conference fee

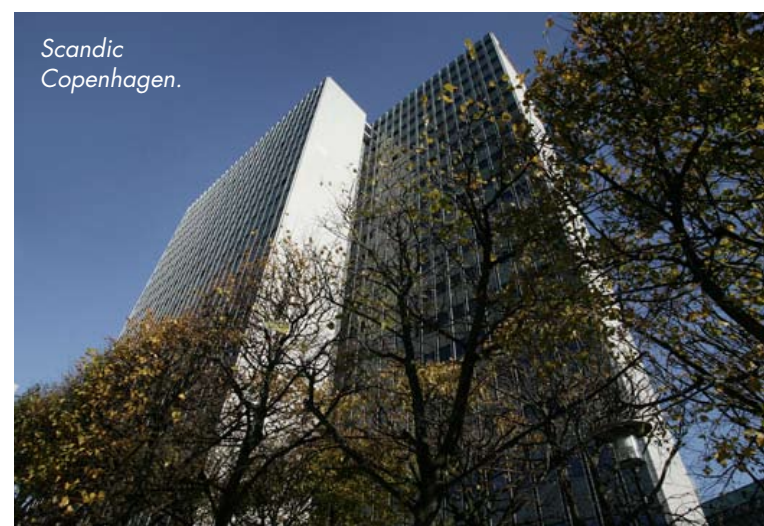
The conference fee, which will be invoiced upon registration, is:

REGISTRATIONS	BEFORE AUGUST 15	BEFORE SEPTEMBER 15	AFTER SEPTEMBER 15
1-3 persons	980 Euro/person	1350 Euro/person	1550 Euro/person
Additional persons*	300 Euro/person	400 Euro/person	800 Euro

All prices are plus VAT.

Last date for registration: October 10

(*Please note that the number of seats available is limited.)



CANCELLATION POLICY

Cancellation of registration prior to the commencement of the event:
– up to 21 days, 50 euro
– 21–14 days, 25 % of the fee
– 14–7 days, 50% of the fee
– 7 days, full fee

You have the right to replace one participant with another if you inform us no later than 3 days before the event. Courses may be cancelled by the organizer if bookings fail to reach minimum numbers. In such circumstances course fees will be refunded.

Application of risk management to Medical Device Software

December 1st 2008 – Copenhagen, Denmark

Date/Location

Monday, December 1st 2008, Copenhagen, Denmark.

Last date for registration: November 21st

Speaker

Alan Kusinitz

Program

DAILY AGENDA

8:30 Registration starts
 9:00 Start
 10:30-10:45 Coffee break
 12:30-13:30 Lunch
 15:00-15:15 Coffee break
 17:00 End

A 1 day course on performing medical device software risk management. This course will use concepts from ISO 14971, IEC 62304, and AAMI TIR32 and step through risk management activities using a series of short exercises and partial examples.

This course is best suited to those with some familiarity with the basic concepts of ISO 14971.

Course outline

- A Few Basic Concepts
 - Expectations of the FDA and the EU
 - Evolution of Standards and Future Direction
 - Short review of 14971, 62304, and TIR32 Key Risk Management Concepts

The topics below are presented through short cases and exercises for several example devices from low to high risk.

- Hazard Identification practice
- Risk Estimation practice
- Requirements and design practices for safety
- Identification of failure modes and hazard causes throughout the software lifecycle stages
- Identification of risk control measures
- Verification planning
- Tying it together in documentation and safety cases/risk summaries

Conference fee

The conference fee, which will be invoiced upon registration, is:

	REGISTRATIONS BEFORE OCT 1	REGISTRATIONS BEFORE NOV 7	REGISTRATIONS AFTER NOV 7
1-3 persons	680 Euro/person	780 Euro/person	880 Euro/person
Additional persons*	300 Euro/person	400 Euro/person	500 Euro

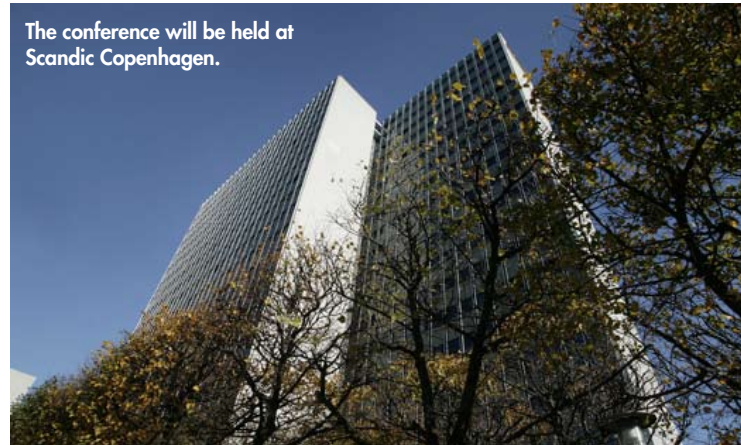
All prices are plus VAT.

Last date for registration: November 21st

(*Please note that the number of seats available is limited.)

For more registration info, please see the last page.

The conference will be held at Scandic Copenhagen.



About the speaker:

Alan Kusinitz, Managing Partner of SoftwareCPR®, is the instructor. He is lead instructor for the AAMI/FDA public courses on Software Validation with John Murray FDA's device center software compliance expert. Alan was co-chair with Paul Jones of FDA of the AAMI working group that developed TIR32 Medical Device Software Risk Management. Alan has provided internal software training at FDA and has been extensively involved in preventing and recovering from FDA enforcement actions and is involved in many standards activities.

Go to www.synergus.se for registration!

FDA Production and Quality System Software Regulation – 820.70(i) AND PART 11

December 2nd–3rd 2008 Copenhagen, Denmark

Date/Location

Tuesday-Wednesday, December 2nd-3rd 2008, Copenhagen, Denmark.

Last date for registration: **November 21st**

Speaker

Alan Kusnitz

Program

This 2 day course covers FDA regulation, guidance, and enforcement for software used to automate regulated activities under 21 CFR 820.70(i) of the quality system including as overview of current expectations for compliance with 21 CFR Part 11. Key aspects of the new AAMI TIR36 for Validation of software automated processes is also included.

This course will cover regulatory foundation and interpretation and some practical tips and approaches for a wide range of software from design tools to manufacturing equipment to IT systems. The information covered is also relevant to those in Pharmaceutical companies involved in computer system validation and to auditors.

This course is also intended to improve student's ability to articulate and defend their current approaches and understand FDA investigator's questions and intent.

FDA Production and Quality System Software Regulation - 820.70(i) and Part 11

Module 1 – Regulatory Overview

- Intent & History
- Regulation and Guidance
- Enforcement

Module 2 – Validation Basics

- 820.70(i) Scope
- Risk-based rigor
- Intended Use

Module 3 – Validation Elements and Documentation

- Requirements
- Design
- Testing coverage and evidence
- Validation Elements
- Validation Documentation

Module 4 – Validation Procedures, Lifecycles, and Operational Controls

- AAMI TIR36 Philosophy and toolbox
- General policies and SOPs
- Risk Assessment
- Validation Assurance Levels
- Configuration Management
- Security
- Mfg Engineering procedures

Module 5 – Special issues and tips

- Regression Testing
- Networks
- Spreadsheets
- IT systems
- Production Equipment
- COTS
- Legacy Systems
- Clinical Trials systems
- Design tools (compilers, CAD...)

Module 6 – FDA Inspection Cases

Module 7 – Part 11

- Current Expectations
 - Recent changes
 - Approaches to assessment
 - Predicate Rule Record Requirements
 - Paper and electronic
 - Hybrid records/paper signatures
 - Reducing overkill
 - FDA revision of the rule
- Workshops and short exercises included for specific topics.

Conference fee:

The conference fee, which will be invoiced upon registration, is:

All prices are plus VAT.

Last date for registration: November 21st

(*Please note that the number of seats available is limited.)

For more registration info, please see the last page.

DAILY AGENDA

8:30	Registration starts (first day)
9:00	Start
10:30-10:45	Coffee break
12:30-13:30	Lunch
15:00-15:15	Coffee break
17:00	End

	REGISTRATIONS BEFORE OCT 1	REGISTRATIONS BEFORE NOV 7	REGISTRATIONS AFTER NOV 7
1-3 persons	980 Euro/person	1350 Euro/person	1550 Euro/person
Additional persons*	300 Euro/person	400 Euro/person	800 Euro/person

All prices are plus VAT.

Last date for registration: November 21st

(*Please note that the number of seats available is limited.)

For more registration info, please see the last page.

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Common information

Registration, conference venue etc

3

Registration information:

Last date for registration: November 21st. Please note that the number of seats available is limited.

Conference venue:

The conference will be held at Scandic Copenhagen, Vester Soegade 6, 601 Copenhagen, Denmark. Registration starts at 8:30 am on December 1st and 2nd.

Accommodation:

For your convenience we recommend reservation of accommodation in the hotel where the conference takes place. Visit our homepage for more information: www.synergus.se

Cancellation policy

Cancellation of registration prior to the commencement of the event:

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Speaker biography

Alan Kusnitz – Managing Partner, SoftwareCPR®

Alan specializes in medical device software regulation, validation, representation, and negotiation for medical device, pharmaceutical, and biologics manufacturers. He participates in standards and software policy development and provides training internally at FDA. He is the founder and Managing Partner of SoftwareCPR® which provides consulting services related to compliance, submissions, validation, 21 CFR Part 11, project management, vendor management, crisis recovery, and process improvement. SoftwareCPR® also provides a software regulatory information and educational subscription service at www.softwarecpr.com.

Alan has 31 years of experience managing high reliability software development including 22 years of experience in medical products. He was the Medical Device Manufacturers Association representative and an executive board member on the AAMI/FDA working group for development of a medical device software standard (SW68) on which AAMI/IEC 62304 was based. He is developer and lead instructor for the AAMI/FDA Software Validation Course, co-chair of the AAMI /FDA Software Risk Management Task Group that developed AAMI TIR32 Medical Device Software Risk Management, reviewer for the AAMI/FDA TIR36 Verification and Validation working group, a trainer for the AAMI/FDA Courses on the new Quality System Regulation and Design Control, and author of the software validation chapter for the AAMI book „Current Issues in Medical Device Quality Systems“ and the 21 CFR Part 11 chapter of an AABB book on Information Technology. Alan has also provided internal training for Health Canada

Go to www.synergus.se for registration!

"How to apply different risk management techniques to the design and management of Medical Devices?"

The amendment 2007/47/EC of the medical device directive, which will have to be applied as from March 21st 2010, will enhance the role of a risk management and the use of an appropriate portfolio of risk analysis methods for various purposes during the design and management of medical devices. The aim of the seminar is to enable the participants to efficiently select and use suitable risk analysis methods in the context of an ISO 14971 risk management system and how to implement and manage them in a regulatory quality management system. Some case studies will be also given.

Speakers: Prof. Erik Schwanbom
Date Location: November 10–11, 2008 Copenhagen, Denmark



Program 10–11 November 2008

1st day: Start 9:00

Opening remarks and introduction of the participants

Risk concepts

- Background and definitions. Risk is a widely used term and depending on circumstances with different meanings. This lecture will focus on the current valid risk concept and explain its use within the regulated medical device sector and the objectives of a risk management system.

Coffe break

Regulatory, societal and individual risk perception

- Basics of the different approaches in USA and EU. The regulatory schemes for medical devices in EU changed with the introduction of the New Approach in 1987. This led to a novel approach based on a risk-benefit assessment how to the use of risk for regulatory purposes in EU.
- How to apply and meet requirements. Relevant European directives for medical devices and machinery define indirectly a comprehensive risk management system for respective devices. This lecture will identify which parts of the directives are relevant and correspond to which elements of a risk management system for efficient use in regulatory quality management systems.

Lunch

Statutory requirements and useful standards (USA and EU).

- This part will list and comment on standards and other relevant statutory requirements documents for medical devices with respect to their applicability.
- Useful tools for risk analysis. In these lectures the aim is through 'learning by doing' to understand the purpose of the tools, their advantages, disadvantages and pitfalls with the tools and learn how to efficiently put them to best use.

- FMEA
- HAZOP

Coffee in between

2nd day: Start 9:00

- ISO 14971 hazard analysis
- FTA

Lunch

When and why to use the tools

- Which tool is for use in which stage of the product lifecycle, from the conceptual design phase until final market withdrawal - limitations and advantages? With discussion, exchange of experiences and the current view of notified bodies.

Strategies for risk control and management

- Experiences with merging risk management with a regulatory quality management system. The ISO 14971 contains more than a dozen new requirements on procedures and documentations, many of which can be covered with minor extension in current existing quality management documentation leaving only a few additional documented procedures to be developed.

Coffee break

Risk evaluation and calculation

- Using numbers to quantify risk. The amended medical directive will for many medical devices open a new interface to the risk management strategies and tools of the machinery directive, where acceptable risk levels are quantitatively identified. The lecture will give an introduction into this new field.

Discussion, summary and closing.

Registration, conference venue etc

Registration information:

Date: November 10, 2008

Registration starts at 8:30

Latest date for registration: November 1st (Please note that there are a limited number of seats available.)

Conference venue:

The conference will be held at Scandic Copenhagen, Vester Soegade 6, 601 Copenhagen, Denmark.

Accommodation:

For convenience we recommend reservation of accommodation in the hotel where the conference takes place. Visit our homepage for more information: www.synergus.se

Conference fee

The cost for the conference is seen below. Prices are in Euro/person (+VAT) and will be invoiced upon registration.

REGISTRATIONS	BEFORE OCT 5	BEFORE OCT 20	AFTER OCT 20
1-3 persons	980 Euro/person	1350 Euro/person	1550 Euro/person
Additional persons*	300 Euro/person	400 Euro/person	800 Euro

(*Please note that the number of seats available is limited.)

CANCELLATION POLICY

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Speaker biographies

Dr Erik Schwanbom

Professor Safety Technology, University of Applied Sciences Luebeck, Germany.

Erik Schwanbom is professor and lecturer in safety- and risk management techniques and regulatory affairs at the University of Applied

Science in Luebeck. Since 1976 Dr. Schwanbom plays an active role in the development of safety standards for medical devices with ISO, IEC and DIN, currently focussing on the ISO/TC 210 activities concerning risk and quality management.

Dr. Schwanbom served as the convener of CEN/BTS 'Health-care', which developed EN 1441, the precursor to ISO 14971. During 1987 -1993 he served as medical device expert to the EC-Commission regarding the elaboration of the Medical Device Directives and from 1989 until 1991 as expert advisor to the IAEA, Vienna, on the management and use of Personal Protective Equipment (post-Chernobyl wrap-up).

After graduating as a chemical engineer at KTH, Stockholm in 1961, Dr. Schwanbom obtained a Dr.-Ing. degree in process engineering from RWTH, Aachen. The professional career started in 1971 in the crude oil refinery industry. In 1974 Dr Schwanbom joined Drägerwerk AG, Luebeck, where he successively became responsible manager R&D for Intensive Care Ventilators, Anaesthesia, Monitoring and Paediatric Intensive Care Products and finally for the PPE product portfolio of the Safety Division.

Before taking up his current position in 1992, he spent two years in Johannesburg, RSA, establishing a Dräger daughter company.



Go to www.synergus.se for registration!

ISO 14155 CURRENT AND FUTURE PRACTICES



ISO 14155 is currently in its final phase of second review. The document has been significantly updated in line with new regulatory requirements worldwide in the area of clinical investigations for medical devices. This course will review the ISO 14155 in detail and prompt many discussions on possible interpretations and implications of the new texts provided in the document. The course will be provided with a worldwide regulatory view in context of a global clinical investigation plan approach.

Who should attend

Clinical investigation project managers, directors, regulatory affairs managers closely involved in the implementation of clinical investigations, quality assurance managers involved in the quality systems for clinical investigations with medical devices.

Program Dec 3rd 2008 (9–17)

- Background of the ISO 14155 in context with other GCP documents
- Review of scope
- Design requirements of the clinical investigation, where to start?
- Ethics and regulatory requirements
- Roles and responsibilities
- Reporting
- Implementing the ISO 14155 in the quality system
- Discussion

Registration, conference venue etc

Date: December 3rd 2008

Registration starts at 8:30

Location: Scandic Copenhagen, Vester Soegade 6, Copenhagen, Denmark. For more details see Information in the end of the folder.

Latest date for registration: November 21st

Conference fee

The cost for the conference is seen below. Prices are in euro/person (+VAT) and will be invoiced upon registration.

	REGISTRATIONS BEFORE OCT 1 ST	REGISTRATIONS BEFORE NOV 7 TH	REGISTRATIONS AFTER NOV 7 TH
1-3 persons	680 Euro/person	780 Euro/person	880 Euro/person
Additional persons*	300 Euro/person	400 Euro/person	800 Euro

*Please note that the number of seats in this category is limited.

For more information regarding registration please see Information in the end of the folder.

GOOD CLINICAL PRACTICES FOR MEDICAL DEVICES, A PRACTICAL COURSE FOR CLINICAL RESEARCH ASSOCIATES



Clinical investigations for medical devices distinguish themselves significantly from pharmaceuticals. This course will provide practical basis for junior clinical research associates, or clinical research associates wanting to understand the differences between medical devices and pharmaceutical investigations. The course is mainly practical oriented with many exercises so that participants can find multiple examples from the experts to use in the real professional life. Very intensive course aimed to put you at ease in the profession.

Who should attend:

Clinical research associates starting in the profession or wanting to learn more substantial practical approach to monitoring.

Program Dec 4th (9:00–18:00)

Basics:

- Terminology and definitions
- Objectives of good clinical practices
- Roles and responsibilities of the different players
- Understand the different planning phases of a clinical investigation
- Efficiently read and interpret a clinical investigation plan
- Organize essential documents
- Informed consent
- Ethics committee process
- Other regulatory requirements before starting a clinical investigation
- Requirements of the device under clinical investigation

Dec 5th (8:00–18:00)

Getting started:

- Clinical investigation site selection process
- Initiation a clinical investigation in a site

Ensure quality:

- Periodic monitoring
- Source document verification
- Safety reporting
- Data flow importance of a complete case report form (both electronic and paper system will be reviewed)
- Effective monitoring reports
- Communication and trouble shooting
- Close down visit

Conclusions

Registration, conference venue etc

Date: December 4th–5th 2008

Registration starts at 8:30 on Tuesday December 3rd

Location: Scandic Copenhagen, Vester Soegade 6, Copenhagen, Denmark. More details see Information in the end of the folder.

Latest date for registration: November 21st

Conference fee

The cost for the conference is seen below. Prices are in euro/person (+VAT) and will be invoiced upon registration.

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1-3 persons	980 Euro/ person	1 350 Euro/ person	1 550 Euro/ person
Additional persons*	300 Euro/ person	400 Euro/ person	800 Euro

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For more information regarding registration please see Information in the end of the folder.

Speaker biography

Danielle Giroud

With over 20 years of experience, Ms. Giroud is widely regarded as one of the most recognized clinical research and regulatory experts within the medical device industry – having shared her extensive knowledge with multi-national corporations and start up companies from around the globe.

Ms. Giroud was the founder and CEO of D-TARGET, a leading clinical research organization specializing in medical

device clinical trials throughout the European continent. Having joined the Premier Research team in July 2007 with the acquisition of D-TARGET, Ms. Giroud ensured the transition period in the capacity of VP global strategic development for medical devices until February 2008.

Prior to founding D-TARGET, Ms. Giroud has been responsible for the successful development and implementation of worldwide clinical research as Director of Clinical Affairs for Collagen Inc. At Medinvent, she handled Trial Management and Product Manager responsibilities for the product "Wallstent", known as the very first vascular stent in the world to be placed on the market and now considered one of the major cardiovascular products.

As a Medical Research Associate in the corporate infertility department for Ares Serono, she coordinated multiple worldwide investigations, significantly contributing to Serono's placement of the world's first recombinant hormone for the treatment of female and male infertility on the market. A highly coveted international speaker, Ms. Giroud is also an active member of the ISO 14155 task force for the "Clinical investigations for medical devices and clinical investigation plan" and serves as a liaison with the Competent Authority medical device working group

Speaker at

- ISO 14155 Current and Future Practices
- Good Clinical Practices for Medical Devices, a Practical Course for Clinical Research Associates

Go to www.synergus.se for registration!

EFFICIENT AND EFFECTIVE US CLINICAL TRIALS FOR MEDICAL DEVICES



This 2 day introductory course will provide the basics of clinical study conduct for medical devices as well as strategic thinking for how to get the most value from your clinical trial efforts. Special focus will be on understanding how to start a trial in the US and how to use any clinical trial information to enhance your sales or obtain market approval. ICH and GCP requirements will be discussed and differences will be highlighted. The problem of the cost and time of clinical trials will be discussed and solutions will be presented.

This training session is ideal for clinical and regulatory personnel as well as executives and senior management of companies wanting to extend their reach to new or expanded markets.

Who should attend:

Clinical investigation project managers, directors, regulatory affairs managers closely involved in the implementation of clinical investigations, quality assurance managers involved in the quality systems for clinical investigations with medical devices.

Program Febr 2nd 2009 (9-18)

Introduction/basics of clinical trial conduct

An Overview of Clinical Trial Regulations

- Clinical Trial Terminology
- GCP vs. ICH study requirements
- US IDE regulations and Non-Significant Risk Studies

Best practices for Efficient Trials

Global Considerations – Where to bring your trial and why

Febr 3rd 2009 (9-17)

Cost and Time Issues – What hurts and what helps

Subject recruitment solutions

How to maximize the value of your clinical trial

- Publications
- Marketing materials
- Market adoption
- Achieving optimal reimbursement
- Introduction to non-significant risk studies
- Acceptance of foreign data in U.S. applications
- Technology use in clinical trials
- Partnering with a CRO

Registration, conference venue etc

Date: February 2nd–3rd 2009

Registration starts at 8:30 on Monday February 2nd

Location: Scandic Copenhagen, Vester Soegade 6, Copenhagen, Denmark. For more details see Information in the end of the folder.

Latest date for registration: January 15th

Conference fee

The cost for the conference is seen below. Prices are in euro/person (+VAT) and will be invoiced upon registration.

	REGISTRATIONS BEFORE DEC 1 ST	REGISTRATIONS BEFORE DEC 31 ST	REG AFTER DEC 31 ST
1-3 persons	980 Euro/person	1 350 Euro/person	1 550 Euro/person
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- 7 days, full fee

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Speaker biography

Linda Alexander

Ms. Alexander founded Alquest, the first dedicated medical device CRO, in 1993 with a vision to providing comprehensive, integrated services to device manufacturers. Under her leadership, the company expanded to include regulatory, clinical and compliance services for device, biologics and combination products with both national and international capabilities. She is noted for her strategic regulatory and clinical insights and has personally supported more than 100 product approvals.

Alexander's experience includes all classes and types of products including combinations such as coated stents and iontophoretic drug delivery systems. An experienced trainer and public speaker as well as quality system advisor, she is often requested to present at national conferences on topics such as combination product regulation, product approval submissions, global strategies, and FDA enforcement issues. Ms. Alexander has a B.S. in Biology from Iowa State University and M.S. in Technical Communications from the University of Minnesota.

Speaker at

- Efficient and Effective US Clinical Trials for Medical Devices

INFORMATION



Conference venue

The conference will be held at Scandic Copenhagen, Vester Soegade 6, Copenhagen, Denmark.

Accommodation

For convenience we recommend reservation of accommodation in the hotel where the conference takes place.

We have reserved a number of hotel rooms at a special price of 1 390 DKK/night (incl. breakfast and taxes) plus 50 DKK handling fee.

For reservation please contact the hotel at +45-33 757 100 or mail copenhagen@scandichotels.com.

Reservation code:

Rooms in December SYN031208.

The rooms will be available until November 1st, 2008.

Rooms in February SYN020209.

The rooms will be available until January 2nd, 2009

After the release, participants can book rooms upon availability and the hotel can no longer guarantee the agreed room rate.

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Go to www.synergus.se
for registration!

Additional clinical courses planned for 2009:

Project Management for Medical Device Clinical Investigations, a global approach

Efficient project management for medical device clinical investigations is essential to ensure quality of data as well as reliable timelines to get a medical device on the market. This course will review the global planning of a medical device clinical master plan and provide a practical approach to planning, implementation and management of each of the clinical projects involved to get a medical device on the market as well as implementing the post market phase clinical investigation activities. The course is provided in the context of global regulatory market access.

Medical devices: post market surveillance planning and setup

Regulators are constantly implementing more requirements for post market surveillance (PMS) to ensure surveillance long term safety of devices placed on the market. The course is reviewing the latest regulatory requirements worldwide for PMS. PMS is more than collecting data, the course will review possible methods to define effective PMS plans related to the risk of the device as well as provide many examples of the different elements of PMS emphasizing that PMS is more than just collecting adverse device effects.

Determine what clinical data are needed for global market access for Medical Devices

The course will review the basic elements needed to define the extend of clinical data needed to get a device to the worldwide market. Many manufacturers struggle with the decision of when a clinical investigation is needed and what should be the objectives and design of such clinical investigation. How to conduct an efficient critical literature review as part of your overall clinical data package and how to determine whether literature provides sufficient evidence to get your device to the market.