Courses approved by:

- The Royal Colleges of Physicians, UK
- IPULS
TFS Academy

- Knowledge
- Experience
- Expertise
- Excellence

Having worked with clinical research training for more than 10 years, we at TFS Academy appreciate the importance of providing training that is up-to-date and relevant to your staffing needs.

ICH GCP requires that “Each individual involved in conducting a trial should be qualified by education, training and experience” and since the implementation of EU Directive 2001/20/EC training has now become a legal requirement for clinical research staff and investigators throughout the EU.

At TFS we offer an extensive selection of courses to match the wide range of roles and functions involved in clinical research. We have the knowledge, the experience and the expertise to deliver the training your staff need.

Publically available EudraCT statistics show a recent dramatic rise in the number of inspections taking place - with over 1200 inspections being conducted in Europe between September 2010 and September 2011.

Inspectors look for evidence of training – at both Sponsor and Investigator sites. TFS Academy has experience of training staff at both Sponsors and Investigators on a worldwide basis so as to ensure that they have the knowledge and skills to conduct clinical trials to the highest standards that are expected today and to meet the expectations of the inspectors.

Lecturers
We resource our lecturers from a faculty of very experienced trainers who have many years of actually working in clinical research and who can help clients develop the understanding and skills they need to perform in today’s highly regulated environment.

We expect and ensure excellence from all our lecturers. Feedback from our participants demonstrates that we achieve this.

Courses
We offer the most comprehensive range of courses in Europe for clinical research personnel. In addition to training in GCP, we offer training in such diverse topics as Project Management, Application to Ethics Committees, Pharmacovigilance, and also courses for those working with Medical Devices.

As well as the courses in this catalogue we offer in-house training solutions to suit your company’s individual needs – the most cost-effective and targeted way to train your staff.

We have a special well-documented and verifiable expertise in training Investigators.
Locations
TFS Academy courses are scheduled regularly in Sweden, Spain, the Netherlands and throughout Central and Eastern Europe, but we are happy to arrange courses anywhere in the world.

Certification
A number of our courses are now approved by the Faculty of Medicine of the Royal Colleges of Physicians of the UK and by IPULS in Sweden. See individual courses for details.

Cost (unless otherwise indicated)
- ½ day courses – 200 EURO plus VAT (225 when applying within 1 month of the course)
- 1 day courses – 375 EURO plus VAT (400 when applying with one month of the course)
- 2 day courses – 750 EURO plus VAT (800 when applying with one month of the course)

Prices include morning/afternoon coffee and sandwiches or lunch as appropriate.

Discounts
Discounts are available on the above prices.

How to apply
If you wish to apply for any of the courses in this brochure you may do so via our website www.tfsacademy.com or by contacting us directly to discuss your training requirements.

Contact Information
Alistair Bone
Director Global Quality Assurance
TFS, Sweden
Phone: + 46 (0)46 280 19 60
Email: alistair.bone@tfscro.com

Sheelagh Corcoran
Global Training Manager
TFS, Sweden
Phone: + 46 (0)46 280 19 62
Email: sheelagh.corcoran@tfscro.com

Marita Höstberg
Quality Assurance and Training Associate
TFS, Sweden
Phone: + 46 (0)46 280 19 61
Email: marita.hostberg@tfscro.com

Stella Hermans
Board Secretary / Office Manager
TFS, The Netherlands
Phone: + 31 (0)412 40 70 70
Email: stella.hermans@tfscro.com

Merce Ferrer
Secretary
TFS, Spain
Phone: + 34 (0)93 185 02 18
Email: merce.ferrer@tfscro.com
GCP for Investigators

This course is approved by the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK and been awarded 6 CPDs. The course is also certified by IPULS (The Institute for the Professional Development of Physicians in Sweden).

Investigators are required to have documented knowledge of ICH GCP guidelines. This course is normally a one day course but the duration and content can be customised to meet client’s needs or requirements.

Description
- History of GCP
- Declaration of Helsinki
- Principles of GCP
- Ethics Committee
- Investigator’s responsibilities
- Sponsor’s responsibilities
- Safety reporting (AE, SAE, SUSAR)
- Informed Consent
- Protocol and Amendments
- Investigator’s Brochure
- Essential documents

Target group
Investigators and other research personnel working with clinical trials.

Date/location
As requested by customer or at TFS office.

Language
Swedish or English, as agreed with customer. Contact us for further discussion.

Tailor made courses

- Are your staff/investigators adequately trained as required by ICH E6 GCP Guidelines?

- Do you have the time, experience and trainers to deliver a full range of internal training programs?

TFS Academy has been providing customised training for our clients for 10 years and have the experience, knowledge and trainers to provide an extensive range of tailor-made courses for clinical research professionals, both for Sponsors and Hospital staff.

You can choose any of our courses and we will adopt them to your specific needs and requirements.

In the last year we made several tailor made courses including:
- A brief overview of clinical trial processes in Europe, for an American company at their HQ un the USA.
- A one day course for an office in Spain - combining an Introduction to Clinical Research and GCP, with an overview of the EU Directives and their implementation in Spain.
- A course to improve and optimise interaction between Sponsor and Investigator staff.
- A GCP course for Paediatricians who are new to clinical research.
Effective Site Management
-2 days

It is not a simple job for Clinical Research Associates (CRA) to monitor and manage investigational sites. CRA’s need - besides “technical knowledge” - to have special skills, which they can use to manage the site in order to ensure that the site staff do things that have to be done.

This 2-days course has been set up to develop these skills.

Description

Topics:
- Communication with investigators
- Motivation and behaviour
- Negotiation and how to prevent misunderstandings and conflicts
- Leadership styles

Objectives:
- To be able to recognize communication pitfalls for yourself and others:
  - To be able to use a result-oriented communication model
- Insight in the motivation process;
  - Insight in your own strengths and weaknesses
- Insight in negotiation and in how to handle conflicts
- Make participants aware that there are more leadership styles, than your own preferred style;
  - To be able to leave your own style, if this style should not be effective

Contents:
- Communication
  - Exercises to make pitfalls visible
  - Tools and techniques
  - Result-oriented communication model, how to ask questions, giving feedback and act assertively
- Introduction to motivation
  - Herzberg case
  - Introduction on the Porter theory
  - Exercises
- Negotiation
  - Introduction to the Harvard method
  - Negotiation exercises
- Introduction on how to manage (the site) and leadership styles
  - Leadership style test
  - Exercises
  - Flexibility test

Target group

Number of participants
The number of participants for this course is limited to 14.

Cost
The Cost for the course is EURO 850 + VAT when applying one month prior to the date of the course. An application after that date costs EURO 900 + VAT.
GCP
This course is approved by the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK and been awarded 6 CPDs. The course is also certified by IPULS (The Institute for the Professional Development of Physicians in Sweden).

The aim of this course is to provide a practical introduction to GCP as described in the ICH E6 guideline. Participants will learn about the ethical issues, requirements for subject safety and the roles and responsibilities of those working in clinical research.

Description
• History of GCP
• Declaration of Helsinki
• Principles of GCP
• Ethics Committee
• Investigator’s responsibilities
• Sponsor’s responsibilities
• Safety reporting (AE, SAE, SUSAR)
• Informed Consent
• Protocol and Amendments
• Investigator’s Brochure
• Essential documents

Target group
Individuals who have recently started working in clinical research, either in the pharmaceutical industry or as investigational site staff.

This one-day course can be combined with a web-based examination. For further information please contact us.

GCP Update
The aim of this course is to provide participants with an update to previous GCP training.

Description
A series of quizzes and exercises are used to test participants’ knowledge and remind them of the key GCP issues.
• Why GCP is needed
• The ICH process
• The Principles of GCP
• Ethics Committees and Informed Consent
• Safety Reporting
• Monitoring
• The IMP
• Essential documents

Target group
This course is suitable for those working within the pharmaceutical industry or at investigator sites, who have previously undertaken GCP training but need a refresher.

This one-day course can be combined with a web-based examination. For further information please contact us.
Monitoring, basic
- 2 days

This course is approved by the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK and been awarded 12 CPDs.

The aim of this course is to provide training on how to monitor in compliance with the requirements of GCP. Each type of monitoring visit will be discussed in detail so that participants can learn how to manage sites and deal with issues that may arise during monitoring.

**Description**
- Monitor’s role
- Investigator’s role
- Site selection visit
- Site initiation visit
- Routine monitoring visit
- CRF and data review
- Investigational Product handling
- End of study visit
- Reporting

**Target group**
Newly appointed monitors and clinicians who have recently started working in the pharmaceutical industry.

---

Monitoring, advanced

The aim of the course is to provide participants with deeper insight into monitoring and common monitoring issues.

**Description**
- Team work
- Site Management
- Investigator meeting
- Monitoring issues
- Data quality and fraud
- Tracking tool
- Time Management

**Target group**
Monitors with at least 1 year working experience.
Application to Ethics Committee

The EU directive 2001/20/EC has resulted in a harmonised and simpler application process within the EU. To clarify and facilitate the interpretation of the requirements the EU commission has published a guidance document.

The course will look at the guidance document together with national requirements to give participants a better understanding of how to apply to Ethics Committees.

Description
- EudraCT form
- Application form
- Application process
- Attachments
- Practical aspects
- Document and attachment
- Contact with Ethics Committees
- EU guidelines

Target group
Persons who want to have better insight in the application process.

This course is country specific.

Introduction to Clinical Research

This course is approved by the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK and been awarded 6 CPDs.

The aim of the course is to provide participants with an overall picture of the clinical study process so that they are better prepared for working in the clinical research environment.

Description
- Background to clinical trials
- Clinical trial phases I-IV
- Guidelines and regulations
- Basic GCP elements
- Study design
- Key documents

Target group
All who have recently started working in clinical research, either in the pharmaceutical industry or as investigational site staff.
Clinical Study Protocol Writing

The aim of the course is to introduce participants how to write a clinical study protocol including study synopsis.

Description
• Clinical plan, product development
• Study design
• Laws, rules and guidelines
• Content according to ICH guidelines
• Objectives, patient population
• Investigational medicinal product
• Registration of efficacy/safety
• Cooperation with data management/biostatistics
• Quality control and quality assurance

Target group
The course is designed for anybody who is planning to or already has started to write Clinical Study Protocols. The course will also benefit anybody involved in the review of Clinical Study Protocols e.g. Project Managers, Clinical Research Managers, Monitors, Investigators and other site personnel.

Patient Information

The aim of the course is to provide participants with a better understanding of how to produce Patient Information and Informed Consent Forms that comply with ethical and regulatory requirements.

Description
• Laws, rules and guidelines
• Ethics Committee
• Genetic samples
• Content
• Data protection act
• Informed Consent
• Signatures
• Version control and changes
• Practical exercises

Target group
Professionals who need a better understanding of the Patient Information and Informed Consent process.
Biostatistics for non-statisticians

The aim of the course is to give participants a better understanding of the statistical issues in clinical trials to make their interaction with study statisticians more effective.

Description
- Basic concept of statistics
- Estimation and hypothesis testing
- Statistical principles for design of trials
- Measuring effect and effect size
- Sample size calculation
- Protocol deviations, missing data and other special issues
- Discussion examples

Target group
Physicians and other personnel engaged in conducting clinical trials, who work with statisticians and want to get a basic understanding of the role of statistics as applied to clinical trials. Participants are expected to have some experience of clinical trials and preferably also some basic statistical training.

Number of participants
The number of participants for this course is limited to 15.

Cost
The Cost for the course is EURO 400 + VAT when applying one month prior to the date of the course. An application after that date costs EURO 425 + VAT.

Audits and Inspections

The EU Directive requires that each member country has its own inspection programme with its own inspectors.

ICH GCP guidelines require that Sponsors/CROs have their own quality system with audit programmes. Thus, audits and inspections are an integral part of work with clinical trials.

The aim of this training course is to provide participants with an increased understanding of what it means to be audited and inspected. Furthermore, the course will provide an increased understanding of what can be done to prepare for an audit or inspection and how one should respond to an audit report.

Description
- What is an audit?
- What is an inspection?
- Regulations
- Preparing for an audit/inspection
- Following up an audit/inspection
- Common findings during audits and inspections

Target group
Project Management for Clinical Research - 2 days

This course provides participants with an understanding of the principles of project management. Participants will learn how to apply project management principles to clinical research projects.

Description
The course covers the five basic project management functions:
• Project planning
• Organisation and staffing
• Directing and leading
• Controlling
• Reporting

More details of the content of this course may be found on our web site.

Target group
Newly appointed project managers, experienced monitors wishing to understand the principles of project management and medical staff who have recently joined the pharmaceutical industry.

Number of participants
The number of participants for this course is limited to 14.

Cost
The Cost for the course is EURO 850 + VAT when applying one month prior to the date of the course. An application after that date costs EURO 875 + VAT.

Contracts and Agreements

The aim of the course is to provide participants with knowledge about the agreements in clinical trials and EU directives.

Description
• Aim of contracts and agreements
• Rules and laws
• Principles of agreements
• Investigator’s and Principal’s view on agreements between sponsor and investigator/study site
  - Content of agreement with the investigator
  - Compensation to the investigator
• Principal agreements
  - Additional agreements
  - Administrative costs
• Payment

Target group
All who needs further knowledge and understanding of how to establish contracts and agreements in clinical trials.

This course is country specific.

Cost
The Cost for the course is EURO 400 + VAT when applying one month prior to the date of the course. An application after that date costs EURO 425 + VAT.
Clinical Study Report Writing

The aim of the course is to teach participants how to write clinical study reports including the synopsis and appendices in such a way that they fulfil the regulatory requirements.

Description
The course includes a comprehensive survey of ICH E3 with tips on how to avoid the most common problems, how to simplify the writing process and how to structure quality control and review. The course will also briefly discuss when a complete clinical study report is not necessary and what to include in a report written under such circumstances.

- ICH E3
- Data presentation
- Quality control & review
- Preparation of appendices
- “Abbreviated clinical study reports”

Target group
The course is designed for anybody who is planning to or already has started to write clinical study reports. The course will also benefit anybody involved in review and quality control of clinical study reports and other medical documents. The course will be of most value to those who already have some experience in clinical development.

Pharmacovigilance

The aim of the course is to provide participants with a basic understanding of pharmacovigilance and the rules and guidelines regulating safety reporting.

Description
- Background
- Definitions
- Laws and regulations in clinical trials
- Sponsor’s responsibility
- Laws and regulations post-markering
- The responsibility of the Marketing Authorisation holder

Target group
People needing a basic knowledge of pharmacovigilance, such as Safety Assistants, Clinical Research Managers, Project Managers and Monitors.
Data Management for non-Data Managers (including CRF-design)

The aim of the course is to provide participants with a basic understanding of how to design CRFs and how data are processed.

**Description**

**CRF-design**
- The aim of the CRF
- CRF vs Protocol
- CRF vs Medical Record
- Instructions to investigators
- ICH GCP
- Monitoring of CRFs
- Source Document
- Paper vs electronic CRFs

**Data Management**
- Planning
- Database
- Verification and validation
- Queries
- Clean File/Database lock

**Target group**
Clinical Research Managers, Monitors, Data Assistants and new Data Managers.

---

e-CRFs and e-Source Data

The aim of the course is to provide participants with a basic understanding of how e-CRFs are designed, how they should be used and monitored at-site and how to manage sites and perform source data verification when the source data are electronic.

**Description**

- The aim of the CRF
- CRF vs the Protocol
- CRF vs the Medical Record
- Instructions for the Investigators
- How to Monitor eCRFs
- Paper vs eCRFS
- How to monitor as sites were the source data are electronic

**Target group**
Clinical Research Managers, Monitors, Data Assistants and new Data Managers.
EU Directives and latest guidance documents

This course is approved by the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK and been awarded 6 CPDs.

Clinical Research conducted in the European member states is now regulated by a number of Directives and guidance documents. The aim of this course is to provide participants with a clear understanding of the contents and implications of these documents.

Description
The following Directive and documents will be reviewed in depth.

- **Clinical Trials Directive (2001/20/EC)**
The Directive is a legal document, published in 2001, which sets out how clinical trials investigating the safety or efficacy of a medicinal product in humans must be conducted within the European Union. This document is the basis for clinical trial legislation in member states.

Lays down the principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products.

- An overview will be provided of GMP Directive (2003/94/EC) and Data Protection Directive (95/46/EC)

**Guidance documents applying to clinical trials:**
- Application to competent authorities
- Application to ethics committees
- Eudract database
- Collection of Adverse Reactions reports
- Eudravigilance database

**Target group**
All clinical trial professionals.
Non-Interventional Studies  
- ½ day course

The aim of this course is to provide participants with an overview of the conduct of non-interventional studies.

Description

Topics covered include

- Non-interventional vs interventional studies
- Need for Ethics Committee approval and Informed Consent
- Post-authorisation safety studies (PASS) and Risk Management Plans (RMPs)
- Quality Assurance
- Good Epidemiological Practice (GEP)

Target group

This course is suitable for those working in research within the pharmaceutical industry or may be involved with non-interventional studies.

Clinical Trials in the Paediatric Population

The aim of the course is to provide participants with an overview of the Paediatric Regulation (1901/2006) and an understanding of the issues involved in conducting trials in children.

Description

- Background to the Regulation
- Details of the regulation
- The Paediatric Investigation Plan (PIP)
- The Paediatric Committee
- Ethics of trials in the paediatric population, including consent/assent
- ICH Guideline E11
- Paediatric trial information in the EudraCT database
- EU Paediatric Networks
- Global perspectives
- Pharmacovigilance in the paediatric population

Target group

Anyone who is interested in finding out more about the issues surrounding research in children in the EU.
Regulatory Affairs

The aim of this course is to provide some basic understanding of regulatory affairs and the processes involved when applying for marketing authorization of a medicinal product.

**Description**
- Laws/Directives/Rules
- Role of authority
- Development of a drug
- Approval procedure
- Application documentation
- CTD module 1-5
- Life cycle of a product
- Product Information

**Target group**
People needing a basic knowledge of the regulatory process, such as regulatory affairs assistants, clinical research managers and monitors.

**Cost**
The Cost for the course is EURO 400 + VAT when applying one month prior to the date of the course. An application after that date costs EURO 425 + VAT.

Presentation Skills

The aim of the course is to provide an overview of the various skills involved in giving a successful presentation.

Participants will be asked to prepare a pre-course self-assessment, and will receive individual feedback from the course leader.

**Description**
- Preparation and planning, main message and knowing the audience
- Essential elements of presentations
- Getting off to a good start, handling nerves.
- How to finish
- Getting people’s attention and keeping it
- Body language
- PowerPoint skills, making good slides
- Being understood, being brief and being memorable
- Storytelling

**Target group**
Everyone who is involved in giving formal presentations as part of their working life.

**Cost**
The Cost for the course is EURO 400 + VAT when applying one month prior to the date of the course. An application after that date costs EURO 425 + VAT.

**Number of participants**
The number of participants for this course is limited to 10.
Introduction to Clinical Research for non clinical staff

The aim of this course is to provide participants with an overview of clinical research and the drug development process.

Description
- Drug development from discovery to market place – the different phases of clinical trials
- A typical trial – what’s involved?
- What is ICH?
- An overview of the ICH Guidelines
- Introduction to Good Clinical Practice
- EU Directives
- Essential Documents
- Abbreviations, jargon and terminology explained!

Target Group
Those working within the pharmaceutical industry or at investigator sites – but in non-clinical/non-technical roles (eg administrators) who would benefit from a basic understanding of clinical trials and Good Clinical Practice.

Medical and Scientific Writing

The aim of this course is to provide tools for effective and clear scientific writing.

Description
- Structuring sentences
  - Basic sentence structure (subject-verb-object)
- Verbs (active, passive, active linking)
- Punctuation
- Writing clear concise sentences
  - Word choice (simple versus complex)
  - Repeating key terms
  - Verb choice, releasing trapped verbs
  - Parallelism
  - Avoiding wordiness
- Structuring paragraphs
- Targeting your audience (patients versus professionals)
- Effective document review: Strategic and inspectional.

Target group
- Pharmaceutical industry - Clinical Research professionals
- Health care - doctors and other health professionals
- Academia - scientists and PhD students

Number of participants
The number of participants for this course is limited to 10.
Medical Devices - Clinical Investigation Plan

The aim of this course is to provide an overview of the requirements for Clinical Investigations of Medical Devices

**Description**
- Overview of European and USA regulations
- Annex 10 of European MD Directive
- Meddev 2.7.1
- When to Perform a Clinical Investigation?
- Risk analysis
- Objectives of clinical investigations
- The ISO 14155 guideline
- Scope
- Investigator’s Brochure
- Ethics and Regulatory approval
- The Clinical Investigational Plan
- Requirements for Clinical Investigations
- Safety reporting
- Investigations with Non-CE marked and CE-marked devices
- FDA requirements
- Summary of similarities and differences between clinical trials and clinical investigations

**Target Group**
People working with Clinical Investigations of Medical Devices.

Medical Devices

The aim of this course is to give participants a basic knowledge of the rules and laws regulating the development of Medical Device focusing on how and when to do Clinical Investigation.

**Description**
- General
  - MDD - Medical Device Directive
  - National requirements
  - Notified Bodies
  - Reporting - requirements
- Country specific experience of working in:
  - Europe (different countries within EU)
  - USA
- Registration of a product
  - CE-labeling (Europe)
  - 510k/PMA (USA)
- Classification of a product
- Risk analysis
- Instructions for use and labelling
- Clinical Investigations when, where and why
  - When to do a Clinical Investigation
  - Differences between Europe and US
  - Ethical Aspects
  - ISO 14155 -1 and 2
  - Clinical Evaluation
- Group work and presentations

**Target group**
People working for CROs, medical device manufacturers, hospitals and clinics, who need an overview of the European and USA regulations related to medical devices, with a focus on clinical evaluation of medical devices.
Biostatistics, advanced

The aim of the course is to provide participants with an in-depth understanding of biostatistics.

**Description**
- Demonstrating efficacy
- Group-sequential studies and other adaptive designs
- Multiple testing
- Methodology for safety and tolerability
- Dose-response and dose-finding

**Target group**
Biostatisticians, programmers with experiences from clinical research.

**Number of participants**
The number of participants for this course is limited to 10.

**Cost**
The cost for the course is EUR 400 + VAT when applying one month prior to the date of the course. An application after that date costs EUR 425 + VAT. The price includes morning and afternoon coffee as well as lunch.

---

Comments from participants

“The GCP lady was excellent. She presented the topic (which is usually perceived as boring) in a very attractive and engaging way. This was mainly because of her huge experience coming from over 30 years of practice in clinical trials. Everything was supported by good presentation skills, good atmosphere and language that was comprehensible even for non-native English speakers.”

Adam G, GSK Oncology

“Very good and useful. If all courses are as good as this one we (Topotarget) will participate more often”

Anne B-N, Topotarget

“I personally liked the approach, by using quizzes as discussion openers and to trigger attendees engagement and active participation. Thank you”

Jordi M, Amgen

“It was a wonderfully dynamic class! This material can be dense but it was presented in a creative form. Thank you!”

Carmen C, Amgen
**COURSE LEADERS**

**Alistair Bone, Director Global Quality Assurance, TFS**
Alistair has been working with clinical trials since 1989 in a number of different roles. Alistair is currently working as Director of Quality Assurance and Training at TFS where he has set up and developed the Quality Assurance and Training department at TFS. He has held numerous training sessions in many different areas including audits, GCP, the European Directive, monitoring etc.

**Hanna Liedman, PhD, Medical Writer, TFS**
Hanna has been working as a Medical Writer at TFS for nearly 6 years. Hanna has a PhD in immunology from the University of Lund and has previously worked as a researcher within the fields of immunology and inflammatory diseases, both at the university and in the pharmaceutical industry. She has also been teaching several courses at the university.

**Anne Hallgårde, MSc, Senior Clinical Research Associate, TFS**
Anne has been working as a CRA for 5 years and has an MSc in Medical Biology from Linköping University. From 2005 until 2007 she worked in the pharmaceutical industry in New York City where she was involved in developing SOPs and staff training. She has worked in several therapeutic areas and in clinical trials from application through to “Clean File”

**Margareta Svensson, MSc, Team Leader Clinical Drug Safety Manager, TFS**
Margareta has a MSc in Pharmacy. She has worked in various positions at AstraZeneca for many years and she is well-experienced in pharmacovigilance/adverse event reporting. She is today responsible for pharmacovigilance, in post-marketing as well as in clinical studies.

**Sheelagh Corcoran, BSc, Global Training Manager, TFS**
Sheelagh has worked in the pharmaceutical industry for nearly 30 years - in many roles including data management and as a CRA. Her main experience is in training, and she has trained both industry staff and investigators. She has taught widely throughout the EU and Eastern Europe, and also in the USA, Japan, Australia and Brazil.

**Bernhard Huitfeldt, PhD, Statistician, BH Statistik-konsult**
Bernhard has earlier worked as senior lecturer at the Statistics Department of Uppsala University. He has for over 30 years worked in different statistical roles at AstraZeneca and Pharmacia, most recently as Global Skills Leader Biostatistics at AstraZeneca.

**Katarina Ortfelt, Senior Regulatory Affairs Manager, TFS**
Katarina has extensive experience of working within Regulatory and Clinical affairs within the Medical Device industry.

**Per Lundström, Legal expert and economist, Öhman Partners Ekonomi och Juridik**
Per is one of Sweden’s “most famous persons” in contracts and agreements in clinical trials. He has been working with internal and external training for staff in the pharmaceutical industry and country councils since the beginning of 1990. He has long experience of commercial and business laws working with different types of agreements in the pharmaceutical area.
Marc Surtees, PhD, Quality Assurance Manager and Advisor, TFS
Marc gained his PhD in 1985, the year he started to work in the pharmaceutical industry. His experience includes 3 years in preclinical development performing drug assays and pharmacokinetic analyses. Since 1990 he has worked in clinical development as a study monitor and then as an international study manager in both France and the UK. He also has experience in continuous process improvement, writing and reviewing SOPs and international clinical operations. Marc is fluent in French and has a diploma in medical statistics awarded by the University of Paris.

Theo van Delft, Quality Assurance Manager and Advisor, TFS
Theo has been working with clinical trials since 1998, first as a Quality Officer and later in a number of different roles (such as Manager QA, Manager Clinical Research and interim, Trainer, Project Manager and Consultant). Before that (since 1984) he was working as consultant and trainer, manager, project manager and scientific researcher in different organisations and sectors.

Rhiannon Sanders, Consulting AB
Rhiannon Sanders has a broad background in life sciences starting with 10 years in cancer research (PhD), followed by 10 years in the diagnostics industry. She has held positions from project leader to line manager to director of business development. After a further five years working with education issues and entrepreneurship for biotechnology, Rhiannon started her own company in 2007 to teach advanced presentation technique for leaders, specialists and for challenging situations.

Helene Rahdevi, RN, Unit Manager Clinical Operations TFS
Helene has been working with clinical trials as a Study Nurse, CRA, Project Leader since 1995. She has worked in Sweden, Denmark and Finland. Since September 2008 Helene is employed by TFS as a Unit Manager for Clinical Operations in Sweden.

Vibeke Bjerregaard, Senior Regulatory Manager, Novo Nordisk
Vibeke has worked in regulatory affairs since 1980, joining Novo Nordisk A/S in 1988. She has a master of science in pharmacy and diplomas in biological sciences and business administration. Vibeke works with global regulatory affairs, developing new products as well as lifecycle management. Her responsibilities involve the company’s diabetes and growth hormone treatments’ and include project - and life cycle planning to ensure the company’s authorisations on a global basis.

Ulrika Hägg, Medical Writer, TFS-Lund
Ulrika has a PhD in cardiovascular physiology. Before starting out as a Medical Writer two years ago, she was a researcher at the Department of Physiology, University of Gothenburg. She has published 11 scientific articles. Ulrika is a member of the European Medical Writers Association, and currently enrolled in their Professional Development Programme. She is also a lecturer at the medical faculty in Gothenburg.

Catherine Heddle, Medical Writer, TFS-Stockholm
Catherine Heddle, BSc, PhD, Medical Writer, TFS Trial Form Support Catherine is a native english speaker and has a PhD in Bioscience. Catherine has been working as a Medical Writer for a number of years. Before that she worked as a research scientist at AstraZeneca’s biotechnology laboratory and at the Department of Oral and Dental Science at the University of Bristol.