



Thomas Göbel  
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## Curriculum vitae

### Personal data

Name: Thomas- Jürgen Göbel

Function: Clinical Research Associate - Freelancer

Date of birth: 18.01.1962

Nationality: German

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## **Education**

**Freelancer / Clinical Research Associate**  
**September 2009 – present**

*Working Areas : Clinical Monitoring, Study Management, Project Management, Marketing Authorization, Pharmacovigilance, Pharmaconsulting*

**Network for Health GmbH**  
**Clinical Center Berlin Friedrichshain**  
**January 2012 – present**  
**Clinical Trial Conduct / Medical Documentation**

*Responsibilities: Clinical monitoring, data management and medical documentation in oncology studies.*

**Allied Clinical Management GmbH**  
**May 2009 – March 2010 / Contract Consultant**  
**Clinical Trial Applications / Medical Documentation**

*Responsibilities: Consultant on submission packages and medical documentation issues for III quarter 2009 and IV quarter 2009 studies on a contractual basis.*

**Bayer Schering Pharma AG, Berlin**  
**February 2007 – December 2008 / Head Coordinator of Global Safety Committee**  
**Department: Global Development Operation / Medical Governance Committees**

*Responsibilities: Coordination of Global Safety Committees, communication concerning all safety issues between the departments of Bayer Schering Pharma, organization and leading of GSC meetings, distribution of safety documentation in GSC database, creation of GSC processes, creation and maintenance of GSC website, leader of GSC trainings*

**Schering AG, Berlin**  
**January 2006 – January 2007 / Global Safety Committee Coordinator**  
**Department: Global Medical Safety Surveillance Operation**

*Responsibilities: Coordination of Global Safety Committees, distribution of safety documentation in GSC database, creation of GSC processes, creation and maintenance of GSC website, leader of GSC trainings*

**Schering AG, Berlin**

**January 2005 – December 2005 / Product Group Coordinator**

**Department: Global Medical Safety Surveillance Assessment**

*Responsibilities: support of pharmacovigilance in the creation of Periodic Safety Update Reports (PSURs), creation of expert statements for product renewals, coordination and standardization of PSURs and Annual Safety Reports (ASRs) according to the EU Clinical Trial Directives, support of global electronic archive of PSURs, training in writing of PSURs*

**Schering AG, Berlin**

**Education as training supervisor locally in the range of commercial development 2001**

**Further education in Project management November 2001 – 2003**

**Schering AG, Berlin**

**January 2001 – December 2004 / Global Publishing Coordinator**

**Department: Clinical Operations – Submission Logistics**

Worldwide Compilation of Submissions

*Responsibilities: in charge of compilation of dossiers needed for submissions, compilation of all documentation for CTAs in electronic form (CTD, eCTD), cooperation with Schering subsidiaries worldwide to create country specific submission dossiers, provided support to users of internal document database. Close cooperation with Project management.*

**Schering AG, Berlin**

**January – December 2000 / Clinical Data Manager**

**Department: COE DATA MANG.EU**

Evaluation of Clinical Data concerning Diagnostic Studies

*Responsibilities: familiarization with study protocol and amendments, review of data, maintenance of tables documenting protocol violations, responsible for creation of plausibility checks. Close cooperation with Study- and Project management.*

**Schering AG, Berlin**

**February 1995 – December 1999 / Clinical Research Associate**

**Department:** SGE Diagnostics – Clinical Development / DG+RP CORP.CLIN.DEV  
CRA for Diagnostic Studies ( liver cell cancer and metastases ) throughout the EU

*Responsibilities: Planning and conduct of clinical studies, preparation and conduct of monitoring visits (site selection-, initiation-, monitoring- und close-out-visits ) according to ICH/GCP, site management, maintaining ISF and Monitor File, maintaining trial documentation covering AEs, SAEs and SUSARs.*

*Planning and conduct of investigator meetings and trainings. Cooperation with the Study management: support in preparation of study protocol and CRF. Support in communication with EC and BfArM and compilation of all necessary documents for study applications EC and BfArM.*

*Support of Project management and take over from Lead CRA responsibilities as required.*

**Schering AG, Berlin**

**July 1986 – January 1995 / Senior Laboratory Assistant**

**Department:** Endocrine Pharmacology II / Oncology / ASSAY DEVEL. & HIGH THROUGHPUT SCREENING

Development of methods in cell cultures concerning male prostate carcinoma

*Responsibilities: Testing of substances with endocrinological test assays, establishing and propagating tumor lines in vivo, histological and statistical evaluation of test results using ELISA and RIA*

**Schering AG, Berlin**

**October 1983 – June 1986 / Laboratory Assistant II**

**Department:** Endocrine Pharmacology I / FEM. HEALTH CARE-2

Pharmacology Investigations concerning Gestagenes / Antigestagenes in guinea pigs, rats , rabbits

*Responsibilities: Planning, preparation, conduct and statistical and histological evaluation of animal tests*

**Schering AG, Berlin**

**February 1983 – September 1983 / Junior Laboratory Assistant**

**Department:** Pharmacokinetics / PRECLINICAL PHARMACOKINETICS

Pharmacology Investigations concerning Prostaglandins in rats and monkeys

*Responsibilities: Analysis using TLC, HPLC and RIA, compilation and documentation of test results, archiving of test results, creation of new analysis methods*

**Schering AG, Berlin**

**September 1979 – February 1983**

Development as Biological laboratory technician

## Summary

- 14 years of experience in Clinical Research and Development
- 12 years of experience in Research and Development

## Global Safety Committee Therapeutic Areas

- Diagnostic Imaging:  
X-ray contrast media, contrast agents for magnetic resonance imaging
- General Medicine:  
Bacterial infections, men's healthcare, pulmonary hypertension, cardiovascular and metabolic diseases, thromboembolic diseases
- Specialty Medicine:  
Hemophilia, drugs for solid-tumor therapy and for treating diseases of the central nervous system, age-related eye diseases
- Women's Healthcare:  
Contraception, menopause management, gynecological therapies

## Project management area

- Women's Healthcare:  
Contraception, menopause management, gynecological therapies

## Studies conducted as Monitor since 1995 until now

- Contrast media in radiological imaging for demonstration of Liver cell cancer and metastases ( Multicenter Studies Phase II and Phase III )
- Symptomatic treatment of acute bronchitis accompanied coughing in children ( Multicenter Study Phase III )
- COPD - Chronic Obstructive Pulmonary Disease Study ( Multicenter Study Phase III b)
- PILOT INVESTIGATION of IBD - Inflammatory Bowel Disease ON THE IMMUNOPURE MEDICAL DEVICE
- NON-interventional Study in iPD patients with GastroIntestinal symptoms

## Therapeutic areas of PSUR compilation:

- Betaferon - multiple sclerosis
- Ilomedin - cardiovascular disease
- Ventavist - cardiovascular disease
- Nerisona - psoriasis
- Skinoren - acne
- Nexavar - liver and kidney cancer
- Noctamid - sleeping disturbance
- Campath - b-cell lymphatic leukaemia
- Bonefos - bone metastases
- Fludara - lymphoma

## Languages

- German - native
- English - fluent
- Russian - beginner

## Computer skills

- Internet tools, Microsoft Office XP (Word / Excel / Power Point),
- CoreDossier (Publishing tool)
- GlobeDoc (Archiving tool)
- Score MISO Vision and SigmaPlot (Statistic tools),
- Lotus Notes Sametime (Communication and Meeting tool)

## Certificated Trainings:

- Drug Development
- Rhetoric
- Training Clinical Research Associates / Lead Clinical Research Associates
- Clinical Trial Monitoring Web – Based Training
- RDC Web – based Training for CRAs
- GCP Compliance Course
- GCP – CRA Refresher Course
- GCP – Fundamentals Web-based Training
  - Module 1 : Overview of GCP
  - Module 2 : Recruitment and Selection
  - Module 3 : Informed Consent
  - Module 4 : Documentation Requirements
  - Module 5 : Investigational Products
  - Module 6 : Data Collection and Reporting
  - Module 7 : Safety Reporting
  - Module 8 : Sponsor Monitoring and Audits
- Education in Project management – Efficiently Project management
- Market Authorization EU
- Application Submissions
  1. Publishing with Core Dossier
  2. Publishing eCTD format
- Drug Safety Course
  1. Pharmacoepidemiology
  2. Literature
  3. ARGUS – Medical DATA Base
  4. GCP Theory and Practice
- Pharmaceutical Drug Safety
- Compilation PSURs
  
- Intensive Course English in Dublin
- English for Professional Communication
- English for Business
- Russian Compact Course