Herman Pieterse

SUMMARY OF EXPERIENCE:

Clinical research manager; Trainer of medical representatives; Clinical research manager for clinical pharmacology; International medical projectleader (phase I/II of clinical development of a cardiovascular research compound); Projectmanager automation with responsibility to implement office-automation for the company; Associate head of the R & D department; Medical Director ; Director of Regulatory Affairs and Research with responsibility to register medical technology products in Europe, Middle East, Australia and New Zealand and to develop new products for the company together with improvement of the existing productrange; President of PROFESS® Medical Consultancy B.V. Member of the Vision Group and the Program Planning Committee of the Society for Regulatory Affairs Professionals in Brussels and organized seminars on clinical investigation with medical devices for the fourth year now. Present activities include coaching medical department personnel, auditing of clinical quality systems and on-site audits, training and education on GCP requirements and clinical trial management and further implementation of the Dutch GCP requirements together with the Dutch GCP committee. Consultant to major pharmaceutical and medical device companies on how to perform clinical studies in compliance with Good Clinical Practice guidelines and occasionally auditing registration files. Since October 1996 Herman Pieterse is a certified GCP lead auditor to assess and evaluate Quality Systems which conform to the requirements of BS EN ISO 9000 and BS 7229/ISO 10011 standards, including Good Clinical Practice standards.
Advisor to the Dutch Ministry of Health for the implementation of the European Clinical Trial Directive.
Academic consultant to the University Medical Centers in Ghent, Amsterdam (Free University and Amsterdam Medical Center), Leiden UMC, Groningen UMC, Maastricht UMC, Erasmus MC in Rotterdam and St. Radboud UMC in Nijmegen.
Chairman of the Dutch Association for Health Information and Health care.
Professor in Clinical Pharmacology at the University of Ghent with specialization rules and regulations clinical studies.

Clinical Expertise:

General - 1572s, adverse events, central files, consent development, close-out visits, CRF development and design, CRF guidelines, data fax, data listing review, drug accountability, device accountability, electronic data capture, enrollment/recruitment issues and resolution

FDA inspection - 483s, financial disclosure, GCPs, investigator brochure development and writing, investigator/site identification, investigator/site qualification, investigator meeting planning, investigator meeting presentation, initiation visits

IRB – submission, approval, advertising, renewal, close out

Manage - sites, study, CRAs, contractors, CROs, investigator/site budget, study budget, monitoring visits, patient eligibility, pharmacy binder development, protocol development and writing, protocol deviations, protocol amendment development and writing, query resolution, regulatory binder development

Reports - site visits, study reports, annual reports, review and interpret pertinent clinical data, serious adverse event reporting, serious adverse event database and clinical database reconciliation, source documentation development, study drug blinding, study tool development, study drug preparation

Languages:

French, German, English, Dutch

WORK EXPERIENCE:

2010 - Present Professor in Clinical Pharmacology at the University of Ghent with specialization rules and regulations clinical studies.

2004 - 2010 Academic Consultant at the University of Ghent for advices on rules and regulations for clinical studies

1991 to present Managing Director of PROFESS® B.V., an independent consultancy company specialising in product development, regulatory affairs and clinical research specifically designed to assist the Health Care industry and Academic Research Groups.

1988 - 1991 Director of Regulatory Affairs and Research at Ovabloc Europe bv with responsibility for the registration of the Ovabloc procedure in Europe, Australia and New Zealand.

Director of Research with responsibility for the development of new products and the improvement of the Ovabloc products.

Manager of Clinical Affairs with responsibility for the international clinical development of a new sterilisation method, in cooperation with the World Health Organization, for European clinical studies and for the Product Surveillance program.

1986 - 1988 Member of the policy committee information of the Dutch Association of Pharmaceutical Industries.

1984 - 1988 Medical director Rhône-Poulenc Nederland bv with responsibilities for the management of the R & D department.

- Management (8 employees)
- Management of the product development process (10 products)
- In total 35 clinical studies in 7400 patients were performed according to international standards
- End responsibility for the registration process
- Medical services to support the marketing department

1984 Associate head of the R & D department of Boehringer Ingelheim.

1983 - 1984 Projectmanager automation Boehringer Ingelheim bv. Coordination and execution of respective actions for all departments.

1980 - 1984 With regard to international activities Boehringer Ingelheim appointed me International Medical Projectleader Phase I/II in September l980.

As a medical projectleader I was responsible for the international coordination of clinical studies with a cardiovascular research compound, mainly in Europe. This included also the arrangement of any further preclinical studies which deemed necessary.

Presentations of my managerial experiences in projectleadership have been given on several occasion for executives.

1980 - 1984 Clinical research manager phase I/II with full responsibility for 30 clinical pharmacology studies per year and supervision on the subdepartment which consisted of one secretary and one clinical research associate.
Other activities:

- Organisation of computer facilities with regard to literature search and documentation,
- Coordination of statistical activities by computer for all members of the research department.

1977 - 1980 Clinical research manager phase III/IV Boehringer Ingelheim bv in Alkmaar, The Netherlands.

Other activities:

- Training of medical representatives
- Organisation of an international symposium on insulin receptors
- Involvement in registration affairs with regard to pharmacological and pharmacokinetic problems
- Presentations for medical representatives and papers on international workshops
- Writing an international product manual for representative translated in German, English, French and Spanish

PROFESSIONAL AFFILIATIONS:

Drug Information Association (DIA)
Association of Clinical Research Professionals (ACRP)
Dutch Association of Research Quality Assurance (DARQA)
Dutch Association of Medical Administration (NVMA)
Dutch Federation of Physicians in the Industry (NVFG)

PUBLICATIONS:

Pieterse, H. Managing Multi-dimensional Clinical Projects. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press Inc. United States of America, pp. 67-89.

Pieterse, H. Clinical Trial Project Plan. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press Inc. United States of America, pp. 117-162.

De Jong, M.G., Pieterse, H. Quality Assurance for Good Clinical Practices. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press Inc. United States of America, pp. 163-190.

Pieterse, H. The Clinical Investigator's Brochure. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press Inc. United States of America, pp. 207-220.

Auclair, P., Pieterse, H. The Investigator Contract. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press Inc. United States of America, pp. 229-242.

Pieterse, H., Duijst, P. The Design of Case Report Forms. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press Inc. United States of America, pp. 259-272.

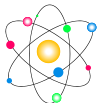
Pieterse, H. Ethics Committee Approval. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press Inc. United States of America, pp. 307-332.

Ezerman, W., Pieterse, H. Selection and Training of Clinical Trial Monitors. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press Inc. United States of America, pp. 341-354.

Pieterse, H., Serruys, P.W. How to prepare the Clinic. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press Inc. United States of America, pp. 355-372.

Pieterse, H., Van Der Velden, E.C.M. In-House Monitoring by the Clinic. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press Inc. United States of America, pp. 397-422.

Pieterse, H. Filing and Archiving. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press



Inc. United States of America, pp. 441-480.

Pieterse, H. Filing and Archiving. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press Inc. United States of America, pp. 441-480.

Pieterse, H. How to Handle Suspected Fraud. In: International Medical Device Clinical Investigations: a practical approach; second edition 1999. Herman Pieterse, Marja G. de Jong and P. Duijst (eds). Interpharm Press Inc. United States of America, pp. 521-532.

Pieterse, H. The Netherlands. In: International Clinical Trials - A guidebook and Compendium of National Drug Laws/edited by Dominique Brunier, Gerhard Nahler 1999. Interpharm Press Inc. United States of America, Volume 2: pp. 17-56.

Pieterse, H. et al. In: Internationaal Richtsnoer voor Good Clinical Practice voor het onderzoek met geneesmiddelen – Vertaling naar de Nederlandse praktijk 1998. Edited by H. Pieterse. Ministerie van Volksgezondheid, Welzijn en Sport, The Netherlands, pp.1-110.

Pieterse, H. In: Richtsnoer voor Good Clinical Practice (CPMP/ICH/135/95). Officiële Nederlandse Vertaling – Verplicht voor alle patiëntgebonden interventie onderzoek met geneesmiddelen – inclusief checklijsten voor de praktische uitvoering van WMO onderzoek – Conform Richtlijn Klinische Proeven. Tweede editie 2004. Profess Medical Consultancy B.V., The Netherlands, pp.1-129.

Pieterse, H. In: GBV Richtlijn voor klinisch onderzoek – betreffende het uitvoeren van medisch-wetenschappelijk onderzoek in Nederland. Profess Medical Consultancy B.V. , The Netherlands 1999, pp. 1-48.

Pieterse, H. In: Common Sense Guideline For Clinical Trials in The Netherlands, published by Profess Medical Consultancy B.V., The Netherlands 1999, pp. 1-63.

Pieterse, H., Cohen, A. Pols, M.A. et al. In: Instruction Manual for the Conduct of Clinical Research with Medicinal Products in the Netherlands - a practical guide for the design, preparation, conduct and reporting – To be published soon by the Ministry of Health, The Netherlands 2004, pp. 1- 80.

Pieterse, H., Franssen, G., Floor, M. et al. Source Documents: Definitions, Verification Procedure, and Archiving. Applied Clinical Trials 1994, Volume 3, No. 9, pp. 38-45.

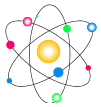
Pieterse, H. Clinical Trials with medical devices. Regulatory Affairs Journal Devices 1994: May 1994, 109-112.

Pieterse, H. EN 540 Flow Chart of Clinical Investigations with medical devices. Regulatory Affairs Journal Devices August 1994, pp. 276.

Pieterse, H. Clinical Trial Requirements in the Netherlands, European Pharma Law Centre Reports (SCRIP Report) June 1994, pp. 4-10.

Pieterse, H. Product Registration in the Netherlands, European Pharma Law Centre Reports (SCRIP Report) November 1994, pp. 9-20.

Pieterse, H. How to write a Clinical Investigator Brochure for clinical trials with medical devices, Regulatory Affairs Journal Devices November 1995, pp. 292-296.



Pieterse, H. Archiving Source Documents in compliance with GCP and Dutch Laws. GCP Journal Vol. 2, No. 5, October/November 1995, pp. 10-13.

Pieterse, H. The Future of Computerization at the Investigator Site. Applied Clinical Trials 1996; Volume 5, no. 1; pp.32-40.

Pieterse, H. The ICH GCP Guideline, What does change for Clinical Trial Practice in the Netherlands, FIAgnostic, nr. 2, May 1997, pp. 2-4.

Pieterse, H. Electronische Patiëntendossiers: Van fictie naar werkelijkheid. Conceptuur 1996: nr. 9: 24-25.

Pieterse, H. Electronische Patiëntendossiers: Tijd voor Beleid. Conceptuur 1997nr. 13. pp. 20-21.

Pieterse, H. Van Marketingplannen naar farmaceutische plannen. Transmitter 1997 nr. 10: 15-17.

Toerink, H., Pieterse, H, Van Der Linden, E., Kuit, I. European Medical Devices studies in cardiology: noncompliance with current good clinical practice guidelines and regulatory requirements. XIII World Congress of Cardiology, Rio de Janeiro, Brazil, 1998, pp.51-54.

Thesis in preparation where the various chapters are based upon publications as described below|:

Chapter One
gives an overview of the global regulatory requirements for medical devices discussing the regulatory framework.

The changing regulatory environment for the clinical evaluation of medical devices in Europe
H. Pieterse and M.G. de Jong.
Regulatory Affairs Journal Devices, Nov/Dec 2005, pp. 355-362.

Chapter Two
examines the GCP environment and its applicable to medical device trials.

The essentials of Good Regulatory Compliance.
H. Pieterse and M.G. de Jong.
Regulatory Affairs Journal Devices, Sept/Oct 2006, pp. 293-298.

Proper clinical development of medical devices to ensure continuity of care.
H. Pieterse and M.G. de Jong.
Health Information Developments in the Netherlands by the year 2006, edition 8, pp 51-55.

Een degelijke klinische ontwikkeling van medische hulpmiddelen is een vereiste om de continuïteit van zorg te garanderen.
H. Pieterse and M.G. de Jong.
Nederlands Tijdschrift voor Medische Administratie, Juni 2006, 124: 10-17.

Chapter Three
examines the methodology for conducting trials with medical devices and ethical issues in relation to regulatory environment when conducting a medical device trial.

Ethical aspects of medical device regulatory compliance.
H. Pieterse and M.G. de Jong.
Submitted to Clinical Trials.

Chapter Four
examines the clinical data from the Class I medical device trial looking at the clinical study report, statistical issues and data obtained from the trial.

Is the Migraid® device an asset in the non-pharmacologic treatment of migraine?
H. Pieterse, J.A.M. Kuster and L.M. Van Bortel.
Acta Neurol. Belg. 2007, 107, 40-46.

Chapter Five
concludes with the processes for medical device trials in terms of ethical, scientific compliance in terms of basic common sense.

A Vision for EU Device Regulation
H. Pieterse and M.G. de Jong.
Regulatory Affairs Journal Devices, Mar/April 2007, pp. 81-86.

Improving the quality of drug research or simply increasing its cost? An evidence-based study of the cost for data monitoring in clinical trials
Esther Pronker Bart F. Geerts, Adam Cohen & Herman Pieterse
Br J Clin Pharmacol. 2011; 71:3 / 467–470 / 467.

Pieterse, H. et al. Handleiding Toetsingskader en –proces voor nWMO studies.
Leden van de stuurgroep zijn in 2009 in gesprek gegaan met deskundigen en initiatiefnemers op het gebied van niet-WMO-plichtige studies. De Handleiding is het resultaat van deze gesprekken. Deze werd tijdens de FIGON Geneesmiddelendagen 2009 gepresenteerd.

Pieterse, H. et al. Rapport Voorbereiding Pilot.
In het Rapport Voorbereiding Pilot worden de resultaten van de voorbereidende fase van de Pilot Toetsingskader niet-WMO-plichtig onderzoek besproken. In deze fase zijn de toetsingsinstrumenten opgesteld, gevalideerd en geëvalueerd. 2010.

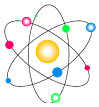
Pieterse, H. et al. Rapport Pilot Resultaten Toetsingskader voor niet-WMO-plichtig onderzoek.
In het rapport "Naar een Toetsingskader voor niet-WMO-plichtig onderzoek" vindt u een samenvatting van de reis naar een Toetsingskader voor niet-WMO-plichtig onderzoek, zijn de resultaten van de pilot studie weergegeven, waarin het Toetsingskader in de praktijk werd getest en wordt met behulp van deze resultaten antwoord gegeven op vragen zoals:Is het Toetsingskader bruikbaar?

Handboek Farmaceutische Geneeskunde. Bohn Stafleu van Loghum. Redacteuren: prof.dr. H.J. Out, dr. R.W. van Olden en P. van Meurs. Hoofdstuk Good Clinical Practices (in press).

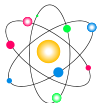
3. Editor Rapport Tweede evaluatie Wet Medisch-wetenschappelijk onderzoek met Mensen. Juli 2012. Uitgave ZONMW
http://www.zonmw.nl/uploads/tx_vipublicaties/evaluatie_wmo_webversie_17x24_-_nieuw.pdf

Disease models of chronic inflammatory airway disease: applications and requirements for clinical trials.
Zuzana Diamanta,b, Graham W. Clarkec,d, Herman Pietersee, and Juan Gispert.
www.co-pulmonarymedicine.com Volume 20 _ Number 1 _ January 2014.

Good clinical practice in clinical interventional studies.
Herman Pieterse1* and Zuzana Diamant.
European Clinical Respiratory Journal 2014, **1**: 26422 – http://dx.doi.org/10.3402/ecrj.v1.26422.



In: Quality in Nuclear Medicine edited by Andor W.J.M. Glaudemans, Jitze Medema and Annie van Zanten. Chapter 2 pages 23-59.: Good Clinical Practices in (Nuclear) Research.
Herman Pieterse and Jan Pruim.
ISBN 978-3-319-33529-2. DOI 10.1007/978-3-319-33531-5.



Spreker of voorzitter op congressen en symposia

03-06-2010	*15e EPD congress, Amstelveen*	*Klinisch onderzoek beter mogelijk met een EPD*	*Speaker* ✪
17-11-2010	*XVI IFHRO Congress Milan Italy*	*Inadequate electronic health records will have a tremendous impact on the future of scientific research; Abstract, page 34*	*Speaker* ✪
		Verschillende bijeenkomst of FIGON geneesmiddelendagen: 6-10-2010 on observational research	
2009 -2012	*Steering Committee Toetsingskader*	*DTCF Congres 5 oktober 2011: Clinical Research in the Netherlands: New initiatives to enhance the performance: Plenary session of the Steering Group Non-WMO Research in the Netherlands: Parallel workshop: Kwaliteit in klinisch onderzoek: papier of praktijk? Pieterse, H. Kwaliteit in overeenstemming met de GBV Richtlijn*	*Speaker/chairman* ✪
7-11-2012	*Annual ISPOR European Congress, Madrid, Spain*	*Workshop W16: Getting non-interventional studies over start-up hurdles in Europe: stakeholder challenges and Perspectives*	*Speaker* ✪
10-11-2011	*Chairman GaMP session on MIC Congress*	*Validation of information systems*	*Speaker/Chairman* ✪
26-01-2012	*Congress CTCM New developments in Clinical Research in Maastricht*	*Ontwikkeling Klinisch onderzoek in Nederland*	*Chairman* ✪
15-06-2012	*WEON Congress 2012 Rotterdam*	*GCP of Electronic Recordings and Submission of Clinical Data*	*Speaker* ✪
19-10-2012	*10 jarig bestaan Eenheid Dentale Therapie voor OSAS in Gent*	*Good Clinical Practices in Medical Device Clinical Investigations and other regulatory requirements for Medical Devices in Europe.*	*Speaker* ✪
2012-2015	*Several meetings lectures on GCP and rules and regulations*	*For Dutch Association of Research Quality Assurance, Dutch Hospital Pharmacist, Education for Research Nurses, etc.*	*Speaker*

AWARDS AND HONORS:

1992 Special Recognition Award by the Regulatory Affairs Professionals Society

EDUCATION:

1965 - 1970 Secondary school (HBS-B in Amsterdam)
1970 - 1977 Study Pharmacochemistry at the Free University in Amsterdam

Molecular Pharmacology on "In vitro pharmacology of 3-hydroxy-3-isopropylamino-methyl-3,4-dihydro-2H-1,5-benzodioxepine", a new beta-adrenoceptor blocking agent.

Other experience in practice during the study:
- Pharmacology department of Duphar BV, Pharmaceutical company

- Assistant scientific researcher for one year to continue pharmacological experiments

Other study subjects:
- Pharmacokinetics (5 months)
- Synthesis of biologically active substances (3 months)
- First degree in teaching chemistry
- Colloquium presentation on: The applications of fluorescence probe techniques with regard to membrane studies

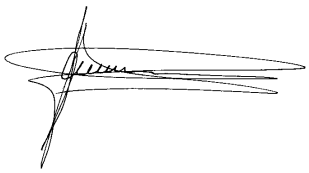
1981 - 1982 Course on middle management (one year; Institute of social sciences). Exam passed in August 1982.

1983 - 1984 Course on preparation general management (one year; Institute of social sciences) Exam passed in January 1984; judicium: summa cum laude.

1986 - 1988 Course on executive management (two years; Institute of social sciences).

April 1996 MIAQ Ltd. Certified Lead Auditor course Cert. No. 3132. Passed the examination. The course included the assessment and evaluation of Quality Systems to conform to the requirements of BS EN ISO 9000 and BS 7229/ISO 10011 standards.

29 August 2008 Ph.D degree for a thesis entitled Regulatory and Clinical Methodologies in Medical Device Clinical Trials at the University of Ghent, department of medical sciences.



16 May 2017