

# CURRICULUM VITAE

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Karin Friis Bach

## Personal Information:

Date of Birth: 14. March 1965

Nationality Danish

Marital Status: Married to Christian Friis Bach  
3 children (born 1991, 1993 and 1999)

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## Education:

Aug. 1990 MSc. Pharm., Royal Danish School of Pharmacy  
(Since 2012: Faculty of Health and Medical Science, University of Copenhagen)

June 1983 High School graduation, Niels Steensens Gymnasium, Copenhagen

## Work Experience

Nov. 2012 – Sep 2015	Research Assistant, Dept. of Pharmacy, Faculty of Health and Medical Science, University of Copenhagen
Sep. 2012 – Nov.2012	External Course Lecturer, Faculty of Health and Medical Science, University of Copenhagen
Dec. 2002 – Aug.2012	Head of GCP-Unit, Copenhagen University Hospital
Jan. 2002 – Dec. 2003	Teaching assistant, Royal Danish School of Pharmacy (Preparation of syllabus for the new Specialist Education in Hospital Pharmacy)
Nov. 2000 – Dec.2004	External pharmaceutical advisor, Netdoktor.dk
Mar. 2000 – Nov. 2002	Information scientist, Institute for Rational Pharmacotherapy (IRF), Danish Medicines Agency.
Oct. 1997 - Aug. 1999	Pharmacist, Dept. of Clinical Pharmacology, Bispebjerg University Hospital, Copenhagen.
Jan. 1997 - Sep. 1997	Auditor, Dept. Of Clinical Quality Assurance, Novo Nordisk A/S
Apr. 1996 - Dec. 1996	Regulatory Affairs pharmacist, Amternes Lægemiddelregistreringskontor I/S
Nov. 1990 - Dec. 1994	Regulatory affairs and information scientist, Zeneca AS (since 2005 AstraZeneca A/S)
Dec. 1988 - Feb. 1990	Student position, Amternes Lægemiddelregistreringskontor I/S
1986, -87, -88	Temporary positions as pharmacy assistant at Hørsholm Pharmacy

## Other Activities

1993– 1994	Opened non-profit shop "Butik Salam", Skindergade, Kbh. K
1995	Lived one year in Washington D.C., USA
1998 -	Part-time farming, Vejgaard

## Voluntary or Honorary Activities

Jan 2014 -	Member of the Regional Council, Capital Region. Chairman of the Health Committee.
June 2012 – May 2014	Member of the Regional Committee, The Danish Cancer Society
May 2010 – Aug.2012	Member of Advisory Group, Nordic University Hospital Research Conference (NRCnetwork.com)
Dec. 2004 – Aug.2012	Member of ECRIN, European Clinical Research Infrastructures Network (ECRIN.org)
Apr. 2007 – Aug. 2008	Member of the Research Council, Gentofte University Hospital, Copenhagen
Jan 2007 – Dec 2009	Member of the board in a non-profit housing association (Ledøje-Smørum Almennyttige Boligselskab). Representing Egedal City Council.
Jan 2007 – Dec 2009	Member of Egedal Business Council. Representing Egedal City Council.
Jul 2006 – Jun 2010	Member of the Social Complaints Board, The Regional State Administration, The Capital Region of Denmark.
Jan. 2006 – Dec 2009	Member of Egedal City Council on behalf of the Danish Social/Liberal Party (Radikale Venstre). - Chair of the Committee of local democracy/citizen involvement - Member of the Committee of health care and prevention - Member of the Committee of business, industry and tourism
Dec. 2003 – Aug 2004	Member of a Working Group in the Council related to standardization of medical terminology (det Nationale Begrebsråd). Established by the National Board of Health.
Feb. 2003 – Sep 2004	Member of the Committee on Health Politics in The Social/Liberal party of Denmark (radikale venstre).
Mar 2001 – Mar 2005	Member of the board, The Pharmaceutical Society of Denmark
Apr. 1999 – May 2005	Member of the board in the Section for Clinical Pharmacy, The Pharmaceutical Society of Denmark. Since March 2003 Chair of the board.
Dec. 1997 – Apr. 1999	Member of the working group regarding evaluation of the possibility of introducing analogue substitution between pharmaceutical products marketed in Denmark (established by the Danish Medicines Agency).
1990 – 1992	Member of the board, U-landsimporten

## Courses

Feb – June 2017:	European Womens Academy, ALDE
Aug. 2011:	Course in Employee influence and involvement (MED-kursus) for the GCP-Unit. Arranged by the Capital Region of Denmark.
Apr. 2011:	Communication Workshop. Arranged by the GCP-units.
Aug-Sep. 2010:	Education in Working Environment. The Capital Region.
Dec. 2007 – 2009:	Mentor Program – a pilot project arranged by the Capital Region of Denmark (participated as a mentee).
Nov. 2007:	“Internal course on research methodology and statistics”. Arranged by the GCP-units in Denmark.
Nov. 2005:	Phosco Workshop. Rigshospitalet. Open Source program for Electronic DataCapture in clinical drug research.
Nov. 2004:	”Management on time – strategy and management in transission”. A conference for managers in the County of Cph.
Oct. 2004:	Methods in Clinical Intervention Research. DIRAC (Danish Clinical Intervention Research Academy)
Jun. 2004:	”Galileo” – a development course for managers, arranged by the County of Copenhagen.
Jan. 2004:	Course in Research Statistics. Signifikans Uddannelse.
Apr. 2003:	Diploma Course in “GCP monitoring – Clinical drug research in Denmark”. The Danish Association of the Pharmaceutical Industry. Exam passed.
Mar. 1999:	Postgraduate educational course for medical doctors in Clinical Pharmacology: Pharmcoepidemiology and pharmacoecconomy. University of Southern Denmark.
Oct. 1998:	Postgraduate educational course for medical doctors in Clinical Pharmacology: Measuring drugs. Methods of analysis, Therapeutic Drug Monitoring (TDM) and clinical toxicology”. Bispebjerg Hospital.
May 1998:	Postgraduate educational course for medical doctors in Clinical Pharmacology: ”Pharmacodynamics, Effect modles and dose-effect – relationsship.” Aarhus University.
Apr. 1998:	Ph.d. course ”Clinical Research Methodology”. Bispebjerg Hosp.
Nov. 1997:	Course in conductance of surveils. DIEU, Hørsholm.

## Active participation in organizing scientific meetings:

- 7-9. May 2012 Co-organizer and speaker at the main conference and organizer/moderator of the workshop: "The Nordic Monitor Network". Nordic University Hospital Research Conference (NRC), Bergen.
23. Feb. 2012 Co-organizer of the workshop: "Medical Research Methodology. The Randomised Clinical Trial – are there alternatives?" Center for Medical Research Methodology, Faculty of Health and Medical Sciences, University of Copenhagen.
- 11-13. Apr. 2011 Organizer, moderator and speaker at the workshop: "Monitoring - The Nordic Network". Nordic University Hospital Research Conference (NRC), Bergen.
29. Sep. 2010 Host, organizer and moderator at the Annual Meeting of the GCP-Unit "Change of the requirements for clinical drug research". Bispebjerg University Hospital.
- 3-4. Jun. 2010 Chairman and co-organizer of the conference "Clinical Trials in the Nordic Region - challenges and opportunities" Arranged by the Danish Association of the Pharmaceutical Industry. (Lif Uddannelse) and the Association of Professionals in Pharmaceutical Science (PharmaDanmark). Copenhagen.
- 10-12. May 2010, Organizer and moderator of the preconference: "GCP monitoring and Research Quality". Nordic University Hospital Research Conference (NRC), Bergen.
21. Sep. 2009 Host, organizer and moderator at the Annual Meeting of the GCP-unit: "Does GCP contribute to a higher quality of academic research?" Bispebjerg University Hospital.
- 4-6. May 2009 Organizer, moderator and speaker at the preconference: "Monitoring of Investigator Initiated Trials". Nordic University Hospital Research Conference (NRC). Bergen.
13. Nov. 2003 Co-organizer and speaker at the meeting "Good Clinical Practice – New Regulations for Clinical Drug Research". Organized together with the Danish Society for Internal Medicine and the Danish Society for Clinical Pharmacology. Rigshospitalet, Copenhagen.

## Invited speaker at other meetings

- 8 dec. 2011 Speaker at the meeting: "The good protocol", arranged by the section for clinical drug development, The Pharmaceutical Society of Denmark.
28. okt. 2011 Speaker at the meeting "Barriers to Clinical Research", arranged by The Medical Society, Copenhagen.
1. Maj 2009 Speaker at the springmeeting for regionally employed medicinal consultants, arranged by Institute for Rational Pharmacotherapy. Gl. Avernæs.
5. feb. 2009 Speaker at a session regarding clinical research arranged by The Ethics Committees in The Capital Region of Denmark, Hillerød.
27. april 2007 Speaker at "Forskningens døgn" (the annual "day of research"), arranged by Hillerød Hospital.
6. okt. 2005 Speaker at "Studiestartens Temadag" (thematic session when starting the education). Faculty of Pharmacy, University of Copenhagen.
- 16-17. dec. 2004 Speaker at a workshop arranged by the European Clinical Research Infrastructure Network, ECRIN. Bruxelles.
- 2003 + 2004 Speaker at staff-meetings at 5 hospitals in total (Hvidovre, Glostrup, Herlev, Amager, Gentofte)
6. nov. 2003 Speaker at a session regarding research, arranged by the Hospital Cooperation of Copenhagen (H:S), Frederiksdal
4. sept. 2003 Speaker at "Forskningens Dag" (the "annual day of research"), Glostrup University Hospital
- 26-29. maj 2002. Oral presentation: "Rational Pharmacotherapy" at Nordisk Läkemedelskongress (nordic conference on medicinal products). Stockholm.

## Teaching experience

2010	Teached at the course "Advanced Clinical Research Training for students", WHO Collaborating Centre, Bispebjerg University Hospital
2009	Arranged a teaching session for research nurses at the Cardiac Lab. Gentofte University Hospital..
2007 – 2016 (repeated once yearly)	Teached in clinical drug development and GCP at the 3rd semester of the Cand. Scient. San. Education, Faculty of Health Science, University of Copenhagen.
2007	Teached at the course: "Introduction to Clinical Research" . The GCP-unit in Odense.
2007	Teached at the course: "Methods in Clinical Intervention Research". Danish Clinical Intervention Research Academy, DIRAC
2007	Teached at the Ph.D. Course "Clinical Epidemiology". Institute of Preventive Medicine.
2007 - 2009 (repeated once or twice yearly)	Teached in monitoring at "Diploma Course in GCP for research nurses". The Danish Association of the Pharmaceutical Industry (Lif Uddannelse).
2005- 2006 (repeated once yearly)	Teached in GCP at the course "Basic research for medical doctors and others". Health Administration, The County of Roskilde. Roskilde Hospital.
2005 - 2011 (repeated once yearly)	Teached at the course "GCP in Clinical Cancer Research". The collaboration of cancer departments in Denmark, SKA
2005 - 2011 (repeated three times)	Teached in GCP at the course "Development and investigation of medicinal products and administrative pharmacology" (postgraduate education for medical doctors).Danish Medicines Agency.
2005 – 2011 (repeated three times)	Teached in GCP at the Course "Benign Hematology" (postgraduate education for medical doctors). Herlev University Hospital.
2004 - 2012 (repeated once yearly)	Teached at the course "GCP and investigator-initiated drug trials". Arranged by the GCP-unit in Århus. From June 2010 the course has been a Ph.D. course at the Dept. of Clinical Medicine, Aarhus University.
2004 - 2012 (repeated once yearly)	Teached in "Quality Assurance of Clinical Trials" at the Ph.D. course "Clinical Evaluation of Medicinal Products", Faculty of Pharmacy, University of Copenhagen.

## Establishment of new courses

2011 – 2014 (planned to be repeated in 2012)	Course director and teacher at the course: Clinical drug research and GCP. Faculty of Pharmacy, University of Copenhagen. <i>7,5 ECTS – please see attachment 1 for at description of the course</i>
2009 - 2010 (Repeated four times)	Course Director and teacher at the course "GCP and investigator-initiated drug research". A one-day course for medical doctors arranged by the GCP-Unit in Copenhagen..
2006 - 2008 (repeated twice)	Planned and taught at the course "Introduction to clinical drug research. Handling of trial medication". Nomeco.A/S
2006 – 2012 (repeated once yearly)	Course director and teacher at the new Ph.D. course "GCP and investigator-initiated Clinical Trials". The GCP-unit in Copenhagen. Faculty of Health Science, Copenhagen University. <i>1,5 ECTS – Please se attachment 2 for the program</i>
2005-2006	Developed an e-learning course in GCP in collaboration with AstraZeneca and the GCP-unit in Århus
2004 – 2007, (repeated once or twice yearly)	Established and taught at the course "Introduction to clinical research for nurses". Arranged by the GCP-Unit Copenhagen
2004 (repeated twice)	Co-organizer of the course "GCP Course for Medical Doctors" in collaboration with Eli Lilly Danmark A/S.
2004 (repeated five times)	Organizer of the course/information meeting: "GCP in academic research. Course for Investigators". Has been repeated on different hospitals in Copenhagen (Rigshospitalet, Gentofte, Hvidovre, Bispebjerg og Herlev hospital).



## Planning and describing new educational activities

- Jan 2011 – Dec. 2011 Member of the coordination group describing a new combined course at the Faculty of Health offering the medical student to stay at a researching department while preparing the thesis. Faculty of Health Sciences, University of Copenhagen.
- Jan. 2004 – May 2005 Member of the board for the Specialist Education in Hospital Pharmacy, Faculty of Pharmacy, University of Copenhagen
- Feb. 2002 – May 2005 Member of the Education Committee for courses on postgraduate clinical training of pharmacist ( Klinisk Videreuddannelse for Farmaceuter)

## Supervising responsibilities

- 2006 – 2007 Master Thesis of Louise Berendt and Cecilia Håkansson: "Development of investigator initiated clinical drug research in Denmark in the period 1993 – 2005". Dept. of social pharmacy, Faculty of Pharmacy, University of Copenhagen.
- 2009 - 2014 Ph.D. Thesis of MSc.Pharm. Louise Berendt: "Conductance and Publication of academic research on medicinal products". Faculty of Health Science, University of Copenhagen.
- 2011 Master Thesis of Rolf Munkholm Jensen: "What characterizes variations between the primary endpoint in protocols and primary endpoints in the corresponding publications?", Faculty of Health Science, University of Copenhagen
- 2011- 2012 Master Thesis of Lise Hjermand: "The influence of academic research on treatment practice". Faculty of Health Science, University of Copenhagen.
- 2012 Master Thesis of Mona Utoft and Angelica Eeg Justesen: "Quality assurance and quality control in relation to a clinical cancer study, MRI-FLT-GBM". Faculty of Pharmacy, University of Copenhagen

## Puplication of educational material

Book Chapters :

**KF Bach:** Chapter 10: Good Clinical Practice – GCP. Clinical Research Methodology. 2. edit. Munksgaard. 2005. ISBN 87-628-0513-4 and 3. edit. Munksgaard. 2011. ISBN 978-87-628-1061-7

# LIST OF PUBLICATIONS

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## Original Contributions

1. SE Andersen, AB Pedersen, **KF Bach**: Medication History on Internal Medicine Wards: Assessment of extra Information Collected from Second Drug Interviews and GP Lists. *Pharmacoepidemiology & Drug Safety* 2003; 12: 491-8. *Impact factor: 2.342*
2. Berendt L, Håkansson C, **Bach KF**, Dalhoff K, Andreasen PB, Petersen LG, Andersen E, Poulsen HE. Effect of European Clinical Trials Directive on academic drug trials in Denmark: retrospective study of applications to the Danish Medicines Agency 1993-2006. *BMJ* 2008;336:33-35 *Impact factor: 13.471 (>2.000 accesses of full article since dec. 2007)*
3. Berendt L, Håkansson C, **Bach KF**, Andreasen PB, Petersen LG, Andersen E, Poulsen HE, Dalhoff K. Methodological characteristics of academic clinical drug trials - a retrospective cohort study of applications to the Danish Medicines Agency 1993-2005. *Br J Clin Pharmacol* 2010;70:729-35. doi: 10.1111/j.1365-2125.2010.03755.x *Impact factor: 3.063*
4. Berendt L, Callréus T, Petersen LG, Bach KF, Poulsen HE, Dalhoff K. From protocol to published report: a study of consistency in the reporting of academic drug trials. *Trials*. 2016 Feb 19;17:100. doi: 10.1186/s13063-016-1189-4
5. Berendt L, Petersen LG, **Bach KF**, Poulsen HE, Dalhoff K. Barriers towards the publication of academic drug trials. Follow-up of trials approved by the Danish Medicines Agency. *PLoS One*. 2017 May 9;12(5):e0172581. doi: 10.1371/journal.pone.0172581. eCollection 2017.

## Abstracts

6. **KF Bach**: Drug Information Centers - the role of the pharmacist. Abstract Book. 3<sup>rd</sup> Congress of the European Association of Hospital Pharmacists, Edinburgh, Scotland UK, 12-14 March 1998
7. **KF Bach**: Drug information at the hospitals – the role of the pharmacist. Abstracts. Nordic Pharmacy Congress, Copenhagen, 7-10. juni 1998.
8. **KF Bach** and A Arnberg: Drug Information Centres in Denmark. Abstracts. ESCP 27<sup>th</sup> European Symposium on Clinical Pharmacy, Jerusalem, Israel, 26-28 October 1998.
9. G Jürgens, **KF Bach**, NE Knudsen, HR Christensen, JP Kampmann: Strategies for implementation of rational pharmacotherapy. Abstracts. ESCP 27<sup>th</sup> European Symposium on Clinical Pharmacy, Jerusalem, Israel, 26-28 October 1998.

10. **KF Bach**, K Friis, A Jørgensen: Public GCP-units in Denmark. Abstracts. 2<sup>nd</sup> ACCP-ESCP International Congress on Clinical Pharmacy. 28-30 April 2004, Paris, France.
11. Berendt L, Callréus T, Petersen LG, **Bach KF**, Poulsen HE, Dalhoff K: From protocol to publication. A study of consistency in the reporting of Danish academic clinical drug trials. Symposium, EQUATOR network 11-12 oktober 2012: "ACT – accuracy, completeness and transparency in health research reporting"

#### Letter to the Editor

12. A Jørgensen, **KF Bach**, K Friis: Good Clinical Practice is now Obligatory in Academic Clinical Drug Research in the European Union. Letter to the Editor. Basic Clin Pharmacol Toxicol 2004; 94: 57-8. *Impact factor: 2.371*

#### Articles in Danish ( reviewed)

13. Hemmingsen B, Støy L, Wetterslev J, Tarnow L, **Friis KB**, Christensen LL, Sales N, Gluud C: Reporting adverse reactions and events in randomised clinical trials. Ugeskr Laeger. 2010 Aug 30; 172 (35): 2381-4.
14. **KF Bach**, J Kjærgaard, HR Christensen: Can drugs reduce the need for blood transfusion in the course of surgery? Ugeskr Laeger, 1999; 161 (4): 457-8.
15. **KF Bach**, K Friis og A. Jørgensen: New regulations on drug research. Ugeskr læger 2004; 166 (18): 1657-9

#### Duplicate publications

16. Berendt L, Håkansson C, **Bach KF**, Dalhoff K, Andreasen PB, Petersen LG, Andersen E, Poulsen HE. Effect of the GCP Directive on academic drug trials. Republication. Ugeskr Læger. 2008; 170 (33): 2437-9

#### Articles in Danish (not reviewed)

17. **KF Bach**: The qualities of the pharmacist are being recognized at the wards. Farmaceuten (monthly journal for Pharmadanmark, the association of professionals in Pharmaceutical Sciences), 1999; 7: 190-1.
18. J Agnholt og **KF Bach**: TNF alpha inhibiting drugs. Rationel Farmakoterapi (monthly journal from the Institute of Rational Farmacotherapi, Danish Medicines Agency). 2000; 8: 1-4

19. J Unkerskov, **KF Bach**, JP Kampmann: Trough/peak-ratio – what is the implication for ACE-inhibitors? *Rationel Farmakoterapi* (monthly journal from the Institute of Rational Pharmacotherapy, Danish Medicines Agency). 2001; 10: 1-3.
20. S Thirstrup og **KF Bach**: ATC and DDD. What is it and how can it be used? *Månedsskrift for Praktisk Lægegering* (monthly journal for General Practitioners), 2001; 12: 1497-1503.
21. **KF Bach**, J Hallas: Paracetamol – risk for adverse reactions in the gastro-intestinal system? *Rationel Farmakoterapi* (monthly journal from the Institute of Rational Pharmacotherapy, Danish Medicines Agency). 2002; 1: 3-4
22. D Glintborg, J Unkerskov, **KF Bach**, H Rasmussen, JP Kampmann: NSAID – sore points. *Rationel Farmakoterapi* (monthly journal from the Institute of Rational Pharmacotherapy, Danish Medicines Agency). 2002, 8: 1-4.
23. **KF Bach**, S Thirstrup, B Toft: Rational pharmacotherapy in general practice. *Practicus* (journal of The Danish College of General Practitioners), 2002; 153: 135-40.
24. D Glintborg, **KF Bach**: Evidencebased Medicine. Critical evaluation of the literature. *Farmaci* (journal of the Association of Danish Pharmacies). Januar 2003.

#### Editorials, letters and comments

25. Unkerskov J, Glintborg D, **Bach KF**, Kampmann JP: Osteoarthritis. Comment. *Ugeskr Læger*. 2002 Aug 12;164(33): 3875
26. **KF Bach**, K Friis og A. Jørgensen: Is good clinical practice a problem? Editorial. *Ugeskr læger* 2004; 166 (18): 1649
27. NH Bjarnason og **KF Bach**: What is necessary to archive when one writes a case report? Letter. *Ugeskr læger* 2006; 168 (1): 78-79
28. **KF Bach**: How to achieve an easier way to clinical research? Letter. *Ugeskr Læger* 2010; 172 (15): 1154
29. **KF Bach**: Empty boxes and lobbyism. Editorial. *Ugeskr Læger* 2011; 173 (2): 105.
30. Spindler P, **Bach KF**, Schmiegelow M, Bedlington N, Eichler HG (2015) Innovation of medical products: the evolution of regulatory science, research and education. *Therapeutic Innovation & Regulatory Science* 2016, Vol. 50(1) 44-48