

## Hans-Joachim Kremer

Pharmacist, Dr. rer. nat., ECPM certified, SwAPP Diploma of Pharmaceutical Medicine

### Professional experience

- Jul 2003 Freelance medical writer and consultant for pharmaceutical medicine
- Jan 2001 Director Medical Writing within the department Clinical Development, Drug Development Center, ASTA Medica AG (as of January 2002 the company was renamed to VIATRIS GmbH & Co. KG)
- Oct 1996 Medical Writer with ASTA Medica AG, Frankfurt, Germany.  
General tasks: revision and maintenance of the Clinical R&D SOP as well as respective templates (clinical trial protocols, clinical trial reports, periodic safety update reports, clinical expert reports, investigator's brochures, design of standard CRFs, standard CRF manuals, GCP forms.  
Specific tasks: writing, reviewing, editing of protocols, reports, summaries on: ciclosporine as immunosuppressive agent; a betablocker in hypertension; diclofenac; tramadol; an antiepileptics drug; an antihistaminic with different formulations (tablets, nasal spray, eye drops) for allergic rhinitis and urticaria; disodium cromoglycate + reproterol, salbutamol, formoterol, and budesonide for asthma; a soft-corticosteroid for allergic rhinitis; a PDE-4-inhibitor for allergic rhinitis; lipoic acid and its enantiomer for diabetes mellitus, neuropathy, and Alzheimer's disease; an LHRH antagonist (cetorelix) for steering female hormone stimulation, a neuroleptic drug for sleep disorders and psychiatric disturbances, a analgesic against Creutzfeld-Jacob-Disease, a potassium channel opener for epilepsy, an ACEI/HCTH combination for hypertension, low-dose topical hydrocortisone, various human pharmacological protocols.
- 1996 Head clinical research phase II-IV at Focus Clinical Drug Development GmbH, Neuss, D. Projects: betablocker in hypertension and angina pectoris, antibacterial eye drops, a lipid lowering drug and its effects on male fertility, antihistaminic for urticaria, nitroglycerine for male infertility, potassium/magnesium supplement as antiarrhythmic, sulfonylurea/insulin in diabetes. Calcium-channel-blocker for hypertension.
- 1995 Writing of clinical study reports as consultant
- 1988 - 1995 Working in the Department Clinical Research - Cardiovascular Diseases, of the Sandoz Pharma AG, Basel, CH, as Project Assistant, GCP-officer and finally Clinical Research Manager. Tasks: clinical trials with an ACE-inhibitor in congestive heart failure and a lipid-lowering drug. Significant contribution to data analysis plans, standard CRFs, statistical and medical evaluation of the studies; planning and evaluation of integrated summaries for efficacy and safety; expert report for spirapril in congestive heart failure.
- 1986 Work with the Drugs' Commission of the German Medical Association
- 1981 - 1988 Pharmacist in several German pharmacies

### Postgraduate education

- 2000 SwAPP Diploma of Pharmaceutical Medicine (Swiss Association of Pharmaceutical Professionals)
- 1995 EUCOR/ECPM Certificate in Pharmaceutical Medicine (issued by the Universities of Basel, CH, Freiburg, D, Strasburg, F)
- 1993 - 1995 Participant of the European Course in Pharmaceutical Medicine (ECPM)
- 1988 - 1993 Various educational courses in pharmacokinetics, clinical trials methodology and statistics

## CV of Hans-Joachim Kremer, continued

### University education

- 1987           Dissertation: *Dr. rer. nat.* (PhD), University of Bonn
- 1983 - 1988    Research at the Institute of Pharmacology, University of Cologne  
Tutors: Prof. W. Klaus and Prof. U. Fricke  
Subject: Investigations on the cardiac toxicity of cardiac glycosides infused to Guinea Pigs, receptor-binding studies, ECG-evaluation, assessment of tissue concentrations of cardiac glycosides in various organs using HPLC. (external dissertation)
- 1981 - 1983    Study of economics, University of Cologne
- 1981           Pharmacist
- 1976 - 1980    Study of pharmacy, University of Bonn

### Memberships

- SwAPP: Swiss Association of Pharmaceutical Professionals
- DGPharMed: Deutsche Gesellschaft für Pharmazeutische Medizin
- ECPM alumni
- EMWA: European Medical Writers Association

### Leading authorship of meta-documents

Namely clinical expert reports, investigator's brochures, IND annual reports, integrated summaries of safety / efficacy, clinical overviews and clinical summaries acc. ICH-CTD, including contribution to summary of product characteristics; these were on:

- Spirapril in congestive heart failure
- Azelastine tablets for allergic rhinitis and idiopathic urticaria
- Ciclosporine as immunosuppressive agent following kidney transplantation
- Prothipendyl for sleep disorders and psychiatric and neurologic disorders
- Tramadol sustained release capsules
- Alpha-lipoic acid for diabetic neuropathy
- Dexlipotam in type 2 diabetes mellitus
- Salbutamol, formoterol and budesonide multidose dry powder inhalers (MDPI)
- Hydrocortisone for dermatitis
- Appraisal on ECG findings of retigabine
- Retigabine for epilepsy
- Bisacodyl for constipation
- Budesonide/formoterol combination
- Butylscopolamin for spasmodic pain
- Simethicone for gastric pain
- Buprenorphine patch for severe pain
- Nebivolol for hypertension and heart failure
- Sibutramine for weight reduction
- 3,4-diaminopyridine for Lambert-Eaton syndrome
- Imiquimod for nonmelanoma skin cancer
- Nabumetone (NSAID)

### Other contributions to clinical study protocols, reports, or publications

Cetrorelix (benign prostate hyperplasia), insulin (diabetes), DNCG/reproterol (asthma), eprosartan/HCTH (hypertension), extract of pelargonium sidoides (tonsillitis), extract of vitex agnus

## CV of Hans-Joachim Kremer, continued

castus (premenstrual syndrome); fluticasone/salmeterol (asthma), flupirtin (fibromyalgia, Creutzfeldt-Jakob disease), galantamine (dementia), risperidone (bipolar disorders / dementia), somatopropin (growth retardation), tiotropiumbromide (COPD), various antibiotics for nosocomial infections, various investigational products, hydromorphone (severe pain), reflimid (bone marrow cancer).

### Publications and lectures

Own publications on:

- Cardiac glycosides
- ACE-inhibitors in congestive heart failure
- Budesonide MDPI in asthmatic patients
- Retigabine for epilepsy
- PK/PD of inhaled formoterol
- Exercise-induced asthma
- Peak inspiratory flow rates in various patient groups
- Imiquimod for actinic keratoses

...and miscellaneous publications on various products as ghost writer.

Lectures on methodology of meta-analyses, GCP, SOPs, fraud, CRF standards, several medical writing issues (protocols, reports, IBs, Clinical Overviews according to ICH-CTD, technical aspects).

(Former and current) member of a GCP-SOP team.

### Services

Writing/editing of

- Clinical trial protocols
- Case report forms
- Informed consents
- Clinical study reports
- Publication manuscripts
- Clinical summaries
- Clinical overviews
- IND annual reports
- Periodic safety update reports
- Regulatory response documents (MRP)
- Product training materials
- Standard operating procedures
- Templates for the above mentioned items

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