

Hans-Joachim Kremer

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

Professional experience

- Since July 2003 Freelance medical writer and consultant for pharmaceutical medicine
- Jan 2001 Director Medical Writing within the department Clinical Development, Drug Development Centre, 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, clinical summaries and clinical overviews
- 1996 Head clinical research phase II-IV at Focus Clinical Drug Development GmbH, Neuss, Germany
- 1995 Writing of clinical study reports as consultant
- 1988 - 1995 Working in the Department Clinical Research - Cardiovascular Diseases, of the Sandoz Pharma AG, Basel, Switzerland, 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
- 1986 Work with the Drugs' Commission of the German Medical Association
- 1981 - 1988 Pharmacist in several German pharmacies

Postgraduate education

- Continuously Participation in congresses, workshops, seminars etc. of the European Medical Writers Association (EMWA), Swiss Association of Pharmaceutical Professionals (SwAPP), Deutsche Gesellschaft für Pharmazeutische Medizin (DGPharMed), German Cochrane Society, and Centre of Clinical Research of the University Freiburg.
- 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

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

CV of Hans-Joachim Kremer, continued

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:

- Macimorelin for diagnosis of growth hormone deficiency
- Flunisolide HFA aerosol for asthma
- Fluticasone-azelastine nasal spray for allergic rhinitis
- Imiquimod 3.75% cream for actinic keratoses
- Imiquimod 5% cream, various expert statements
- Imiquimod for various forms of non-melanoma skin cancer
- Azelastine nasal spray (new formulations, higher dosage, and long-term treatment)
- Azelastine + fluticasone nasal spray for allergic rhinitis
- Fentanyl buccal film for breakthrough pain
- Nabumetone (NSAID)
- Chamomille ointment and cream for dermatitis
- 3,4-diaminopyridine for Lambert-Eaton syndrome
- Intoxications with propylene oxide and osmium tetroxide
- Buprenorphine patch for severe pain
- Nebivolol for hypertension and heart failure
- Sibutramine for weight reduction
- Simethicone for gastric pain
- Bisacodyl for constipation
- Butylscopolamin for spasmodic pain
- Prothipendyl for sleep disorders and psychiatric and neurologic disorders
- Salbutamol, formoterol, and budesonide powder inhalers for asthma and COPD
- Appraisal on ECG findings of retigabine
- Retigabine for epilepsy
- Hydrocortisone for dermatitis
- Alpha-lipoic acid for diabetic neuropathy
- Dexlipotam in type 2 diabetes mellitus
- Tramadol sustained release capsules
- Azelastine tablets and nasal spray (allergic rhinitis, idiopathic urticaria)
- Ciclosporine as immunosuppressive agent following kidney transplantation
- Spirapril in congestive heart failure

Relevant 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 castus (premenstrual syndrome); fluticasone/salmeterol (asthma), flupirtin (fibromyalgia, Creutzfeldt-Jakob disease), galantamine (dementia), risperidone (bipolar disorders / dementia), somatotropin (growth retardation), tiotropiumbromide (COPD), various antibiotics for nosocomial infections, various investigational products, hydromorphone (severe pain), lenalidomide (bone marrow cancer), immune response modifier for actinic keratoses, irinotecan, valsartan plus aliskiren for hypertension, erythropoietin in patients on dialysis, iclaprim (antibiotic), leuprorelin, quetiapine, fractionated photothermolysis for facial wrinkles, treatments of anal dysplasias, guideline on differential diagnostics of vulva carcinoma and the respective WHO nomenclature, after-care after vaginal carcinoma, treatment guideline for actinic keratoses, treatment guideline for basal cell carcinoma.

CV of Hans-Joachim Kremer, continued

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 basal cell carcinoma
- Placebo: Myths and facts

...and contributions to publications on various products and indications.

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).

Member of a GCP-SOP teams in pharmaceutical companies since 1992.

Peer reviewer for some scientific journals.

Services

Writing/editing of

- Clinical trial protocols
- Observational plans (for noninterventional studies)
- Case report forms
- Informed consents
- Clinical study reports (interventional and noninterventional studies, PASS)
- Assessments and narratives of serious adverse events and similar issues
- Publication manuscripts (originals and reviews)
- Clinical summaries
- Clinical overviews
- Addendum clinical overviews
- IND annual reports and periodic safety update reports
- Response documents on regulatory deficiency letters
- Pharmacovigilance: Medical assessment of individual case safety reports. Risk management plans, DSUR, PSUR
- Literature research and assessments
- Product training materials
- Standard operating procedures concerning clinical research and development, pharmacovigilance, and related areas.
- Templates for the above mentioned items

Memberships

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

Family

Married, two children.

CV of Hans-Joachim Kremer, continued



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