

Curriculum Vitae

Personal information **Stefan Strasser**

Work experience

1. Employer: BASG – Federal Office for Safety in Health Care, AGES – Austrian Agency for Health and Food Safety
 - Start date: 012019
 - End date:
 - Position: Head of department
 - Activities: _ process management of clinical trial applications and inspections (Austrian Medicinal Products Act and Austrian Medical Devices Act) _ preparation for the new regulations for clinical trials (536/2017), medical devices (2017/745) and IVDs (2017/746) _ oversight over the business aspects of process and IT development (National systems and EU) quality management stakeholder engagement and information (meetings, publications, website) _ preparation of management reviews and reports _ human resources (performance reviews, development and motivation of employees)
 - Country: Austria
2. Employer: BASG – Federal Office for Safety in Health Care, AGES – Austrian Agency for Health and Food Safety
 - Start date: 072014
 - End date: 122018
 - Position: Deputy head of department
 - Activities: _ process management of clinical trial applications _ contribution to process and IT development _ contribution to quality management _ contribution to management reviews and reports _ organisation of stakeholder and information meetings
 - Country: Austria
3. Employer: BASG – Federal Office for Safety in Health Care, AGES – Austrian Agency for Health and Food Safety
 - Start date: 042009
 - End date:
 - Position: Clinical assessor
 - Activities: _ AGES senior expert and EMA expert _ assessment of clinical trial applications _ national and EMA scientific advice _ assessment of centralized marketing authorization procedures _ member of the Clinical Trials Expert Group _ member of the CTFG (Clinical Trials Facilitation Group) _ member of the Clinical Information System Experts Group _ member of the EUDAMED CI/PS Module Experts Group
 - Country: Austria
4. Employer: Medical University Innsbruck, Department of Surgery
 - Start date: 042007
 - End date: 042009
 - Position: Research assistant
 - Activities: _ conduct of commercial and non-commercial clinical trials _ planning of non-commercial clinical trials _ statistical evaluation of trial data _ ICH GCP _ teaching (clinical trial basics, small group)
 - Country: Austria

Education and training

1. Subject: BASG – Federal Office for Safety in Health Care, AGES – Austrian Agency for Health and Food Safety
 - Start date: 042009
 - End date: 062011
 - Qualification: Certified Assessor for Clinical Trials
 - Organisation: _ basics of drug regulatory affairs _ national and international regulatory framework _ Austrian Medicinal Products Act _ European Medicines Agency (EMA) _ ICH (International conference on harmonization) guidelines _ regulatory and clinical guidelines _ clinical assessment (general) _ assessment of clinical trials _ National and EMA Scientific Advice Procedure
 - Country: Austria
2. Subject: Medical University Innsbruck
 - Start date: 101996
 - End date: 102006
 - Qualification: Doctor of medicine (MD)
 - Organisation: _ medical training
 - Country: Austria

Additional information

Publications

1: Lanthaler M, Biebl M, Strasser S, Weissenbacher A, Falkeis C, Margreiter R, Nehoda H. Surgical treatment of intrahepatic cholangiocarcinoma: single center experience. Am Surg. 2010 Apr;76(4):411-7. PubMed PMID: 20420253. 2: Lanthaler M, Strasser S, Aigner F, Margreiter R, Nehoda H. Weight loss and quality of life after gastric band removal or deflation. Obes Surg. 2009 Oct;19(10):1401-8. Epub 2009 Aug 13. PubMed PMID: 19680730. 3: Lanthaler M, Sieb M, Strasser S, Weiss H, Aigner F, Nehoda H. Disappointing mid-term results after laparoscopic gastric banding in young patients. Surg Obes Relat Dis. 2009 Mar-Apr;5(2):218-23. Epub 2008 Aug 19. PubMed PMID: 18849198.

Projects

Memberships

Clinical Trials Advisory Group (CTAG)
Clinical Trials Experts Group (CTEG)
Clinical Trial Coordination Group (CTCG)

Other Relevant Information