



## Curriculum Vitae

Personal information **Stefan Strasser**

### Work experience

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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

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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

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#### Publications

1: Lanthaler M, Biebl M, Strasser S, Weissenbacher A, Falkeis C, Margreiter R, Nehoda H. Surgical treatment of intrahepatic cholangiocarcinoma: a 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 Experts Group Clinical Trial Facilitation Group (CTFG) Clinical Informations System Experts Group  
EUDAMED CI/PS Module Experts Group

Other Relevant Information