

## Curriculum Vitae

Personal information **Svenja Werner**

### Work experience

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- 08/2025 - present    Quality Assessor, Federal Institute for Drugs and Medical Devices, Bonn, Germany
- Scientific evaluation of marketing authorisation applications and change notifications (Quality part, Module 3 of eCTD)
- 08/2023 - 07/2025    Regulatory Affairs Project Manager, Miltenyi Biotec B.V. & Co. KG, Bergisch Gladbach, Germany
- Project lead of a regulatory projects to streamline different regulatory statuses which follow national and international regulatory requirements and harmonization of product portfolio (raw materials for ATMPs)
  - Leading of a multifunctional project team, including R&D, manufacturing, quality control, quality assurance, regulatory affairs and marketing
  - Regular communication with management and internal partners about the progress of the project
- 06/2020 - 07/2023    Project Manager CMC (Chemistry, Manufacturing and Controls), Heidelberg Pharma Research GmbH, Ladenburg, Germany
- Planning, monitoring and supervision of the manufacture of investigational medicinal products (antibody-drug conjugates) at external Contract Development and Manufacturing Organizations (CDMOs)
  - Coordination of communication between internal Subject Matter Expert and external CDMOs and customers
  - Technology transfer to contract manufacturers and process optimization
  - Creation of SOPs and QA and regulatory relevant documentation (e.g. IND, IMPD)
- 03/2020 - 05/2020    Consultant and Research Associate Strategic Consulting Health-Care, SKC Beratungsgesellschaft mbH, Hannover, Germany
- Strategy development for market access in the field of oncology and gene therapy
  - Participation in the creation of an AMNOG (Arzneimittelmarktneuordnungs-Gesetz) database
- 07/2018 - 12/2019    Postdoctoral Researcher, University of Bonn, Pharmaceutical Institute, Bonn, Germany
- Project work in cooperation with pharmaceutical industry
  - Optimization of lead structure and synthesis of potential drug candidates against diseases of the central nervous system
  - Determination of structure-activity relationship and optimization of the physicochemical properties
- 05/2015 - 07/2018    Research Associate, University of Wuppertal, Wuppertal, Germany
- Supervision of (international) students during their thesis or internships
  - Teaching of bachelor and master students in practical laboratory course and seminars
  - Presentation of research results on conferences and writing of publications

### Education and training

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- 03/2015 - 07/2018    PhD, University of Wuppertal, organometallic and bioinorganic Chemistry, Wuppertal, Germany
- Synthesis of biological active compounds against malaria and cancer
  - Characterization of metal complexes via NMR, mass, IR and UV/VIS spectroscopy as well as chromatography and crystal-structure analysis
  - Implementation of biological assays and working with cell cultures at the clinic and polyclinic for nuclear medicine, University Hospital of Cologne
- Doctoral Thesis: Transition metal complexes against malaria and cancer: Chloroquine based ligands and their gold complexes as well as cytotoxic platinum(II) dithiocarbamates and their bioconjugates  
Degree: Dr. rer. nat. (summa cum laude)
- 04/2013 - 02/2015    Chemistry studies, University of Wuppertal, Wuppertal, Germany  
Main focus: Synthetic chemistry  
Master thesis: Platinum(II) and palladium(II) dithiocarbamates with water-soluble phosphine ligands (1.1)  
Degree: Master of Science (1.5)
- 10/2010 - 03/2013    Chemistry studies, University of Wuppertal, Wuppertal, Germany  
Bachelor thesis: Reactions of gold(I) and gold(III) azides  
Degree: Bachelor of Science
- 10/2009 - 09/2010    Chemistry studies, University of Göttingen, Göttingen, Germany

### Additional information

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#### Publications

- Esther Schuh, Svenja Werner, Daniela Otte, Uwe Monkowius, and Fabian Mohr

Organometallics, 2016, 35 (20), 3448-3451  
DOI: 10.1021/acs.organomet.6b00714

- Sivatharushan Sivanathan, Florian Körber, Jannis Aron Tent, Svenja Werner, and Jürgen Scherkenbeck  
The Journal of Organic Chemistry 2015 80 (5), 2554-2561  
DOI: 10.1021/jo502529g
- Karsten Klauke, Svenja Werner, Fabian Mohr;  
European Journal of Inorganic Chemistry, 2017, 8, 1053 - 1056  
DOI: 10.1002/ejic.201701321
- Svenja Werner, 2018, **Ü**bergangsmetallkomplexe gegen Malaria und Krebs: Chloroquin-basierte Liganden und deren Gold-Komplexe sowie zytotoxische Platin (II)-dithiocarbamate und deren Biokonjugate, Doctoral dissertation, Bergische Universität, Wuppertal, 2018

[Projects](#)

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