

## Curriculum Vitae

Personal information Regina Wolf

### Work experience

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1. Employer: Paul Ehrlich Institut
  - Start date: 012021
  - End date:
  - Position: Head of unit Safety of immunological veterinary products
  - Activities: For for veterinary immunological products: Assessment PSURs, Signal Management, DDPS/PSMF, Pharmacovigilance notifications, Group strategic development, Group representation to internal and external stakeholders, budget and staff responsibility
  - Expert at the CVMP Pharmacovigilance Working Party since 092021
  - Country: Germany
2. Employer: Klifovet AG
  - Start date: 082017
  - End date: 122020
  - Position: Head of Regulatory Affairs
  - Activities: Budget and staff responsibility for the Regulatory Affairs division Responsible for financial results of the regulatory affairs division for the company Management for the regulatory affairs division of the company Responsible for the strategy of the regulatory affairs division of the company Responsible for sales activities for the regulatory affairs division of the company Scientific and strategic consultancy for development and regulatory requirements for veterinary products with focus on European registrations (national and centralised procedures) for national and international clients (start\_up and small and medium size companies as well as major players) and during innovation task force meetings, scientific advice, procedures and oral hearings Regulatory due diligence evaluations of veterinary vaccine portfolios for clients Deputy Qualified Person (QP) for veterinary vaccines (test material and commercial product) Presentations on regulatory affairs at national and international conferences Expert reports for dossiers Life\_cycle consultancy for various national and international clients
  - Country: Germany
3. Employer: Klifovet AG
  - Start date: 032012
  - End date: 072017
  - Position: Head of Product Development
  - Activities: Budget and staff responsibility for the division within the company Regulatory and strategic due diligence on veterinary vaccine portfolios Scientific and strategic consultancy for veterinary development programmes Bid\_defence meetings for projects GMP site evaluation and audits for vaccines in Europe Support in tech\_transfer of non\_EU production to EU GMP production site Implementation of development plans (study placement GLP and GCP) and co\_ordinate activities for developmen Project management for veterinary products also during their life\_cycle (e.g. for variations, claim extensions) Act as primary contact for projects for the sponsor and partners Expert reports for veterinary vaccines Supply chain management for client for launch
  - Country: Germany
4. Employer: Veterinary Medicines Directorate (VMD)
  - Start date: 062008
  - End date: 022012
  - Position: Assessor Immunologicals
  - Activities: Scientific assessment of dossiers and variations for national and centralised procedures. Acting as expert for RMS, CMS or Rapporteur for veterinary immunological products (vaccines). During that phase also setting up first SOPs for the department for obtaining ISO certification of the Directorate. Representing the VMD on the DARC (DEFRA Antimicrobial Resistance Committee).
  - Country: United Kingdom
5. Employer: Pfizer Animal Health
  - Start date: 102003
  - End date: 052008
  - Position: Senior Clinical Research Investigator and Manager Clinical Trials
  - Activities: Monitoring of veterinary clinical trials to GCP and GLP, protocol and report writing. Leading clinical trial programmes as sponsor representative for veterinary pharmaceuticals with focus on antimicrobials for small and large animals (write/review protocols and reports, monitor studies). Representative on European development for pharmaceuticals for global development teams. Selection of suppliers for studies (CRO) where necessary, training of new sponsor study monitors. Staff responsibility for one new clinical trial monitor during on\_boarding phase.
  - Country: United Kingdom
6. Employer: Icon Clinical Research GmbH
  - Start date: 012001
  - End date: 102003
  - Position: Clinical Research Associate
  - Activities: Monitoring of clinical trials for human medicines phase IIIa in Germany, Hungary, Poland, Croatia, Austria. Mentoring and medical advice support for new clinical research associates on the projects for France, Germany, Austria and Eastern Europe.
  - Country: Germany
7. Employer: Royal CaninTiernahrung GmbH
  - Start date: 091995
  - End date: 122000
  - Position: Nutritional Advisor and Junior Manager Distribution and Marketing Veterinary + Key

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- Account Manager Veterinary
  - Activities: Nutritional advice for pet diets and pet food to veterinarians and breeders, Staff and Budget responsibility for the direct veterinary distribution channel, representation to internal and external Stakeholders, handling of pet food reclamations
  - Country: Germany
- 8. Employer: Institute of Veterinary Pathology, Munich
  - Start date: 10/1994
  - End date: 08/1995
  - Position: Scientific Assistant
  - Activities: Scientific studies with transgenic mice
  - Country: Germany

## Education and training

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- Subject: Open University
  - Start date:
  - End date: 2004
  - Qualification: Master of Business Administration
  - Organisation: Strategy, Knowledge and Change Management, Finance, Business Administration
  - Country: United Kingdom
- Subject: Ludwig\_Maximilian\_University Munich
  - Start date:
  - End date: 1994
  - Qualification: Doctorate of Veterinary medicine (Dr.med.vet)
  - Organisation: "Detection and quantification of mRNA of Natriuretic Peptides and their receptors in the Thymus of the rat via RT-PCR Quantitative RT-PCR,
  - Country: Germany
- Subject: Ludwig\_Maximilian\_University Munich
  - Start date:
  - End date: 1992
  - Qualification: Diploma in Veterinary Medicine (Staatsexamen)
  - Organisation: Professional skills of veterinarian (including small and large animals, poultry, Food Hygiene, microbiology, pharmacology)
  - Country:

## Additional information

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Publications

Projects

Memberships

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Other Relevant Information