



## Markus Veit

**Nationality:** German

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Date of birth: 04/07/1959

**Gender:** Male

 **Email address:** [m.veit@alphetopics.de](mailto:m.veit@alphetopics.de)

 **Address:** Iglingerstrasse 27, 86916 Kaufering (Germany)

### WORK EXPERIENCE

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#### Managing Director

**Alphetopics GmbH** [ 14/01/2011 – Current ]

City: Kaufering

Country: Germany

#### Managing Director and Founder (6 Employees)

GxP Training and Consulting

- GMP
- GDP
- GLP
- Regulatory Affairs (Pharmaceuticals, Medical Devices, Food Supplements)
- Herbal Medicinal Products
- Medicinal Cannabis
- Setting of Specifications
- Pharmaceutical Stability Studies
- Pharmaceutical Reference Standards
- Dissolution Testing
- Impurities in APIs and Finished Products
- Genotoxic Impurities
- Quality Requirements for Packaging Materials
- Analytical Method Validation
- Analytical Method Development
- Quality of Herbal Medicinal Products
- Bioavailability of Herbal Medicinal Products
- Spectroscopic Methods in Pharmaceutical Analysis
- Quantitative NMR in Pharmaceutical Analysis
- Reference Substances in Pharmaceutical Quality Control
- European Pharmacopeia
- Separation Techniques in Natural Product Chemistry
- Contaminants in Herbal Medicinal Products
- In-vitro Dissolution Testing
- Scientific Writing
- Instrument Qualification and Calibration
- Process Validation

## **Managing Director**

*i.DRAS GmbH* [ 01/10/2005 – 01/11/2018 ]

City: Munich

Country: Germany

### **Founder & Managing Director (50 employees)**

Service Provider for Regulatory Affairs (Pharmaceuticals, Medical Devices, Food Supplements)

- GxP: (Mock)Audits
- GxP: Filing of documents and SOPs
- GxP: Training
- DRA: Filing strategy EU (National, MRP, DCP, Centralised, Abridged applications)
- DRA: Filing of all kinds of (CTD) documents
- DRA: Expert reports & Response to agency questions
- DRA: Detailed and professional support with presubmission meetings
- DRA: Due diligence for dossiers
- DRA: Regulatory Compliance
- DRA: Drug Device Combination Products
- DRA: Change Management & Variations
- DRA: Quality:
  - (Bio)analytical development and validation
  - Quality testing of medicinal products
  - Stability testing
  - Impurities
  - Dissolution testing
  - Pharmacokinetics and Bioavailability
  - Reference compounds
  - Pharmaceutical Development

## **Managing & Scientific Director**

*Zentralinstitut Arzneimittelforschung* [ 01/10/1999 – 01/10/2002 ]

City: Sinzig

Country: Germany

### **Managing & Scientific Director (14 Employees)**

Quality Control of pharmaceutical APIs and Finished Products

Establishment and Characterisation of Pharmaceutical Reference Standards

Drug Regulatory Affairs

## **Managing Director**

*HWI Analytik GmbH* [ 01/01/2010 – 31/12/2013 ]

City: Rülzheim

Country: Germany

### **Managing Director (80 Employees)**

**Service Provider for Pharma, Biotec, Medical Devices**

All kind of analytical testing for Pharmaceutical Quality Control and Stability testing

Batch release testing

Establishment of Reference Substance

Evaluation and isolation of impurities

Review specifications, analytical methods and validation reports according to the latest scientific knowledge and regulatory requirements

Planning and implementation of analytical method transfers and production validations

Gap analysis of CTD modules 2.3/3

GACP/GMP Audits

## **Managing Director**

**LAT GmbH Dr. Tittel** [ 01/10/2002 – 01/06/2006 ]

City: Munich

Country: Germany

## **Managing Director (65 Employees)**

### **Service Provider for Pharma, Biotec, Medical Devices**

All kind of analytical testing for Pharmaceutical Quality Control and Stability testing

Batch release testing

Review specifications, analytical methods and validation reports according to the latest scientific knowledge and regulatory requirements

Planning and implementation of analytical method transfers and production validations

Gap analysis of CTD modules 2.3/3

GACP/GMP Audits

## **PostDoc and Assistant Professor**

**University of Würzburg** [ 01/01/1991 – 01/10/1999 ]

City: Würzburg

Country: Germany

Teaching & Research Pharmaceutical Biology

## **Adjunct Associate Professor**

**University of Frankfurt - School of Pharmacy** [ 01/01/2003 – Current ]

City: Frankfurt

Country: Germany

Academic Teaching

## **Adjunct Associate Professor**

**University of Florida** [ 01/01/1999 – Current ]

City: Gainesville

Country: United States

Academic Teaching

## **EDUCATION AND TRAINING**

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### **Pharmacist**

**University Frankfurt - School of Pharmacy** [ 01/10/1978 – 01/10/1985 ]

Address: (Germany)

<https://www.uni-frankfurt.de/53547105/Pharmazie>

### **PhD (Dr. rer. nat)**

**University Würzburg - School of Pharmacy** [ 01/10/1986 – 01/10/1990 ]

<https://www.biozentrum.uni-wuerzburg.de/pbio/startseite/>

### **Professor (Habilitation, Dr. habil.)**

**University of Würzburg** [ 01/01/1997 – 01/10/1999 ]

<https://www.biozentrum.uni-wuerzburg.de/pbio/startseite/>

## **LANGUAGE SKILLS**

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Mother tongue(s): **German**

Other language(s):

**Englisch**

**LISTENING B2 READING B2 WRITING C1**

**SPOKEN PRODUCTION C1 SPOKEN INTERACTION C1**

## **DIGITAL SKILLS**

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Microsoft Word / Microsoft Excel