

## // MAJOR EMPLOYER IN THE RHINE-MAIN REGION //

The Paul-Ehrlich-Institut currently employs almost 800 members of staff. About a third of them are scientists, in particular in the area of life science. Among these, there are about 50 medical doctors, plus 35 PhD students preparing their PhD theses in research on biomedicines. The institute is very committed to integrating work and family, as well as to the inclusion of people with disabilities.

>> [www.pei.de/directions](http://www.pei.de/directions)

### RESEARCH

The PEI combines the marketing authorisation and assessment of biological medicinal products with internationally renowned research. This means that doctors also have the opportunity of being involved in research associated with testing.

>> [www.pei.de/research](http://www.pei.de/research)

### ARRANGEMENT OF FLEXIBLE WORKING HOURS

The Paul-Ehrlich-Institut promotes the availability of safe and effective medicinal products. The institute's demanding regulatory duties require highly qualified and motivated members of staff. Flexible working hours schemes are possible.



Pia Tkotz  
Head of the Personnel unit

"Being a scientific institute, the PEI offers interesting jobs for medical doctors who intend to work in the diverse sector of marketing authorisations and medicines testing. As the PEI is a senior federal authority, it provides all the benefits of an institute in the public service. With its policy of flexible working hours, it facilitates the integration of work and family."



## // DOCTORS AT THE PAUL-EHRlich-INSTITUT //

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Dr med Uta Buckpesch-Heberer  
Neurologist, Monoclonal and Polyclonal Antibodies section

"I appreciate two aspects of my work in particular: Marketing authorisations and assessment of innovative medicinal products, such as monoclonal antibodies, present an interesting challenge. I can use my clinical experience as a neurologist and, at the same time, continue my scientific training."

### CONTACT



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The Paul-Ehrlich-Institut is an Agency of the German Federal Ministry of Health.



## // FOCUS ON HEALTH //

As the Federal Institute for Vaccines and Biomedicines, the Paul-Ehrlich-Institut (PEI) sets high standards on the quality, efficacy and safety of biomedicines for people and animals. The PEI monitors biomedicines from their development to their application:

- Scientific advice at national and international level
- Approval of clinical trials and marketing authorisation-related field trials
- Marketing authorisation and official batch testing
- Recording and evaluation of adverse reactions

### BIOMEDICINES FOR HUMAN USE

- Vaccines
- Biotechnological medicinal products and medicines containing antibodies
- Allergens for therapy and diagnostics
- Advanced therapy medicinal products (ATMP):  
Cell and gene therapeutics and tissue engineering products
- Blood and blood products
- Tissue preparations

### BIOMEDICINES FOR VETERINARY USE

- Vaccines and sera

>> [www.pei.de/medicinalproducts](http://www.pei.de/medicinalproducts)

## // DOCTORS AT THE PAUL-EHRLICH-INSTITUT //

### CLINICAL ASSESSMENT

Doctors from various fields are essential for the testing and evaluation of clinical parameters in the marketing authorisation procedure. They carry out assessments on a scientific basis and help to determine which biological medicinal products will be available for which indications in the future. Innovative developments such as monoclonal antibodies and advanced therapy medicinal products (ATMP) are a new challenge – from both a medical and a regulatory perspective. The expertise of doctors is also required for the approval of clinical trials.

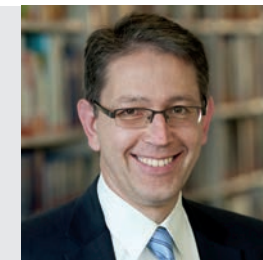


Dr med Karen Brigitta Götz  
Deputy Head of the Microbial  
Vaccine section

"For the marketing authorisation of microbial vaccines, I bring in my expertise as a medical doctor. My work offers a look behind the scenes of drug development and lets me support the development and improvement of vaccines scientifically and strategically – both at national and European level, but also worldwide."

### SAFETY OF MEDICINAL PRODUCTS

An important element of the monitoring of medicinal product safety is to record and evaluate suspected adverse effects, both before and after marketing authorisation. It is only in this way that very rare adverse reactions can be detected. Doctors are essential for this work: they assess the reported suspected cases with regard to clinical information, check whether measures are required and, if so, they initiate these measures.



Dr med Dirk Mentzer  
Pediatrician and Head of  
Pharmacovigilance I unit

"As a medical doctor, I contribute to the safety and compatibility of medicines. The work at the PEI gave me the chance to become chair of the Paediatric Committee of the European Medicines Agency. That way I could contribute to the implementation of the European Paediatric Medicines Regulation. New medicines must now receive a marketing authorisation for children and adolescents as well."

### INFLUENTIAL IN EUROPE

The PEI contributes, in the context of international collaboration, to draft legislation and guidelines that enable the development and marketing authorisation of important new medicinal products, while at the same time guaranteeing the highest level of safety. In the area of marketing authorisation and testing, the Institute is also increasingly operating on an international level: more and more medicinal products are being authorised by the EU Commission in a centralized procedure for the whole European Economic Area. In this case, the European Medicines Agency EMA coordinates the scientific assessment. PEI experts are represented on important working parties of the EMA and the Council of Europe – the expertise of the institute is widely recognized in Europe as well as worldwide.



Prof. Dr med Rainer Seitz  
Head of the Haematology/  
Transfusion Medicine division

"I have been working for the PEI for over 20 years now and had the chance to establish the Division Haematology/Transfusion Medicine. Challenges included HIV and prions. Thanks to our active cooperation within the European network, we were able to contribute to ensuring that blood products are and remain highly safe medicinal products, both in Germany and in Europe."