

The Paul-Ehrlich-Institut – a Competent Partner in Research & Development

The Paul-Ehrlich-Institut (PEI) is the Federal Institute for Vaccines and Biomedicines and reports to the Federal Ministry of Health. In its role as a medicines authority, it is responsible for vaccines for human and veterinary use, immunological veterinary medicines, and all biomedicines for the use in humans¹. In these areas, the institute has the following regulatory duties:

- scientific and procedural advice to applicants in the preparation of the clinical development of new vaccines and medicines
- authorisation of clinical trials and field trials
- evaluation of applications for marketing authorisation (nationally as well as in decentralised procedures, mutual recognition procedures, and centralised procedures for the European Medicines Agency), national approvals and authorisations
- experimental batch release testing and official batch release before the marketing of vaccines for human and veterinary use, sera, allergens, blood products, and immunoglobulins
- pharmacovigilance (monitoring of the safety of authorised medicines, monitoring of adverse effects, taking pre- and post-marketing authorisation action, and the coordination of such measures)
- GCP and GMP inspections
- scientific advice for politics, the science community and the general public within the area of competence of the institute.

The testing laboratory for *in-vitro* diagnostic medical devices (IVDs) at the PEI controls the quality of high risk IVDs used to ensure the safety of stem cell preparations and blood components for transfusion. Furthermore, the institute hosts a collaboration centre of the World Health Organisation (WHO) for the quality assurance of blood products and *in-vitro* diagnostic devices as well as a WHO collaboration centre for the standardisation and evaluation of vaccines.

The regulatory tasks of the PEI are complemented by research duties within the limits of three programmatic foci, i.e. “regulatory research & innovative product testing”, “pathogen-host & biomedicine-organism interactions” and “experimental vaccines, therapies & diagnostics”. Research topics of the institute are related to the fields of immunology, microbiology, virology, allergology, haematology and cell & gene therapy.

Based on its regulatory research expertise, the PEI essentially contributes to ensuring the quality, safety, and efficacy of vaccines and biomedicines and to advancing the further development of these products. In addition, the institute also performs research on entirely new medicinal concepts and model therapeutics for the prevention and treatment of diseases, thus supporting the future supply with innovative vaccines and biomedicines. Thanks to the institute’s combination of regulatory duties and research, the PEI has a long-standing expertise in the regulatory assistance of the development of vaccines and biomedicines². This includes the translation of pre-clinical research results and the assessment of adverse drug reactions as well as the clarification of the respective causes.

¹ Sera and (monoclonal) antibodies, immune therapeutics, allergens, gene & cell therapeutics, tissue engineering medicines, tissue preparations, blood products for haematology and transfusion medicine, as well as medicines derived from blood plasma

² Innovation Office/Scientific Advice for Pharmaceutical Enterprises: innovation@pei.de

Important research technologies have been grouped at the institute into platforms (proteomics, mass spectroscopy, raman spectroscopy, flow cytometry, microscopy including LSM, apotome, axiophot and EM, RNAseq and microbiome sequencing, media laboratory). The PEI also runs a central animal facility with laboratories and animal containments of biosafety levels I to III.

A prerequisite for the institute's success is the cooperation with various national and international research institutions as well as regulatory authorities and public health organisations. In many areas, the cooperation with pharmaceutical companies is also imperative and desirable from a health perspective's point of view. Since the PEI is a medicines authority, such cooperation is, however, only acceptable if it is assured that any appearance of a conflict of interest can be avoided.

For this reason, the institute and its scientific staff do in principle not make use of research grants, awards, and prizes sponsored by pharmaceutical companies or by funding organisations with close contact to such companies. Staff members of the PEI do not participate in projects for the non-clinical and clinical development of medicines with the particular aim of marketing authorisation and commercial launch. Moreover, the PEI is not entitled to participate in the preparation of applications for (i) the marketing authorisation of a medicine, (ii) the manufacturing authorisation, or (iii) the authorisation of clinical trials. Original research data of the institute are therefore never part of such application documents (dossier) for regulatory approval by a medicines authority. In line with good scientific practice, however, a reference made by the applicant to research results published by the PEI in such dossiers is, as a matter of course, possible.

With the aim of advancing the cooperation with regional research institutions, PEI has concluded a cooperation framework agreement with the University Medical Center of the Johannes Gutenberg University Mainz and the Johann Wolfgang Goethe University Frankfurt/Main. In addition, the institute cooperates with national and international research organisations, also through a temporary exchange of professionals (clinician scientists, guest scientists, young scientists, etc.).

As a federal authority, the PEI does not have a teaching mandate and does not possess the right to confer PhD degrees. In spite of this, many scientists of the institute assume teaching duties at various German universities and feel obliged to contribute to the qualification of young scientists. The institute regularly gives bachelor, master, PhD, and medical students the opportunity to work on an appropriate research project and to use the respective results for preparing a thesis at a university with the aim to graduate. Besides, the PEI continuously provides employment for a large number of young scientists (PhD students, post docs, or heads of junior research groups) within the framework of temporary research undertakings. To advance the success of PhD projects and the career development of the respective young scientists, the institute has established a Postgraduate Training & Education Programme in Biomedical Research (PEP-BIOMED). In addition to various offers for courses of further education, this programme also comprises targeted support by an individualised "Thesis Committee" and defines particular rules and duties for the supervisors of PhD projects at the institute.