

RPACT Personnel Qualification and Training Policy

RPACT GbR

POL-RPACT-005

Version 1.0.0

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RPACT GbR

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Policy ID	POL-RPACT-005
Title	RPACT Personnel Qualification and Training Policy
Description	This policy defines the principles and procedures followed by RPACT GbR to ensure that all team members and future employees are appropriately qualified and trained to perform their assigned responsibilities, in alignment with regulatory and client expectations.
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1 Purpose

This policy defines the principles and procedures followed by RPACT GbR to ensure that all team members and future employees are appropriately qualified and trained to perform their assigned responsibilities, in alignment with regulatory and client expectations.

2 Scope

This policy applies to all current partners, independent collaborators, and any future employees or contingent workers of RPACT GbR. It includes onboarding, training, documentation of qualifications, and continuing education.

3 Company Context

RPACT GbR is currently structured as a partnership of highly specialized professionals. As of the effective date of this policy, there are no employed staff. All core tasks are performed by the partners and a trusted external expert (under NDA), all of whom have long-standing academic and industry experience in software development, biostatistics, and GxP-compliant systems.

This policy also anticipates future growth, including the potential hiring of employees or onboarding of additional collaborators.

4 Qualification Requirements

4.1 Baseline Qualifications

- All personnel must demonstrate suitable education, experience, or training in their respective area of responsibility.
- For developers and validators, this includes knowledge in R programming, statistical software engineering, and validation standards in regulated environments.
- For administrative or infrastructure tasks, relevant IT security and data privacy awareness are expected.

4.2 Documentation

- For partners and collaborators, CVs and professional profiles (e.g., LinkedIn, ORCID) are maintained and reviewed.
- For future employees, formal documentation of education, experience, and any required certifications will be stored in individual personnel files.

4.3 Training

- All team members must be familiar with RPACT's Standard Operating Procedures (SOPs) relevant to their role.
- Security awareness training will be part of onboarding for any new collaborators or employees.
- Project- or client-specific training will be conducted as required and documented accordingly.

5 Training History and Tracking

- For collaborators and employees with significant roles (e.g., developer or admin), training assignments will be tracked and recorded.
- Completion status and dates will be documented either via electronic log or signed training confirmation.
- As of now, training history is tracked informally, but structured documentation will be introduced as the company scales.

6 Review and Updates

This policy is reviewed annually or whenever significant changes occur in team composition or regulatory expectations.

Approved by:

Dr. Friedrich Pahlke
Prof. Dr. Gernot Wassmer

Date: *2025-03-31*

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