MTZ CLINICAL RESEARCH

Quality is a member of our team

Statement of audit performed by MTZ Clinical Research Sp. z o.o. in LLC «CDC «PHARMBIOTEST» , Rubezhnoye, Ukraine

Purpose of the audit	The purpose of the audit was to assess the compliance of clinical research practice with the appropriate ICH/GCP requirements and Ethical Principles.
Date of audits	10 - 11 October 2018
Auditors	Malgorzata Drop, MTZ Director of Quality Management, Quality Management System Representative Teresa Brodniewicz – Proba MTZ President/Scientific & Business Development Director
Pharmbiotest representatives	Igor Kuznetsov, Director Grygorii Tsapko, Head Physician Nataliia Reznichenko, Head of QAU Ekaterina Kovalyova, Head of Research Planning and Biostatistics Olga Berezhnaya, Head Nurse
Place of audit	LLC «CDC «PHARMBIOTEST» 9 Pochayevskaya Street; 93000 Rubezhnoye, Ukraine
Scope	1. General Company organization 2. Clinical Research Site 3. Systems Security 4. Access Control Systems 5. Security 6. Laboratory: blood and urine sampling for PK biological samples processing 7. Pharmacy (IMP storage, setup, dispensing and accountability) 8. Equipment: records/calibration/validation/maintenance 9. Quality Assurance System 10. SOPs review 11. Vendor management 12. Organizational Risk Management 13. Quality Control 14. IT systems & validation 15. Computer Server Room 16. Storage areas and archiving
Methods of audit	1. Documentation review 2. Tour of facility, observations 3. Personnel interview
The audit performed in Pharmbiotest confirmed compliance of clinical research practice with the appropriate ICH GCP E6 (R2) requirements and Ethical Principles for Medical Research Involving Human Subjects - WMA Declaration of Helsinki.	
Auditor name and signature	MAŁGORZATA DROP
Auditor name and signature	TERESA BRODNIEWICZ - PROBA

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