
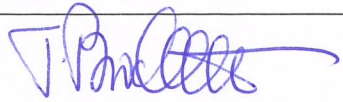


**Statement of audit performed by MTZ Clinical Research Sp. z o.o.  
in LLC «CDC «PHARMBIOTEST» , Rubezhnoye, Ukraine**

<b>Purpose of the audit</b>	The purpose of the audit was to assess the compliance of clinical research practice with the appropriate ICH/GCP requirements and Ethical Principles.
<b>Date of audits</b>	10 - 11 October 2018
<b>Auditors</b>	Malgorzata Drop, MTZ Director of Quality Management, Quality Management System Representative Teresa Brodniewicz – Proba MTZ President/Scientific & Business Development Director
<b>Pharmbiotest representatives</b>	Igor Kuznetsov, Director Grygorii Tsapko, Head Physician Nataliia Reznichenko, Head of QAU Ekaterina Kovalyova, Head of Research Planning and Biostatistics Olga Berezhnaya, Head Nurse
<b>Place of audit</b>	LLC «CDC «PHARMBIOTEST» 9 Pochayevskaya Street; 93000 Rubezhnoye, Ukraine
<b>Scope</b>	<ol style="list-style-type: none"> <li>1. General Company organization</li> <li>2. Clinical Research Site</li> <li>3. Systems Security</li> <li>4. Access Control Systems</li> <li>5. Security</li> <li>6. Laboratory: blood and urine sampling for PK biological samples processing</li> <li>7. Pharmacy (IMP storage, setup, dispensing and accountability)</li> <li>8. Equipment: records/calibration/validation/maintenance</li> <li>9. Quality Assurance System</li> <li>10. SOPs review</li> <li>11. Vendor management</li> <li>12. Organizational Risk Management</li> <li>13. Quality Control</li> <li>14. IT systems &amp; validation</li> <li>15. Computer Server Room</li> <li>16. Storage areas and archiving</li> </ol>
<b>Methods of audit</b>	<ol style="list-style-type: none"> <li>1. Documentation review</li> <li>2. Tour of facility, observations</li> <li>3. Personnel interview</li> </ol>
<b>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.</b>	
<b>Auditor name and signature</b>	MALGORZATA DROP 
<b>Auditor name and signature</b>	TERESA BRODNIWICZ - PROBA 

**MTZ Clinical Research Sp. z o.o.**

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