**STATEMENT**

**REQUIREMENTS FOR THE TENDERER**

**RFP 024461 /** **CONSULTANCY IN TOXICOLOGY INCLUDING PREPARATION OF IMPD/IB REGULATORY DOCUMENTATION**

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| **REQUIREMENTS** | **CONFIRMATION [YES/NO]** |
| Toxicologist certification awarded by professional organizations such as the American Board of Toxicology (ABT) or The Academy of Applied Environmental Studies (AAES) or other equally important. Completed medical studies with a specialization. Higher medical education, PhD, Experience in oncology. |  |
| Preparation/consultation of IND/ IMPD/IB documentation for oncological products for FIH applications – at least 3 submissions |  |
| Experience in medical writing – at lease 2 years |  |
| Experience in consulting toxicology of biologics, especially in immunotoxicity, hepatotoxicity, and translation of preclinical results to patient risk- at least 3 years of experience.  |  |
| Experience in supporting regulatory submissions writing, reviewing and supplementing regulatory documentation for IND/IMPD and/or contact with a regulatory Agency – at least 3 years |  |
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 *(date and signature of Tenderer's authorized representative)*