



MALTA

MEDICINES  
AUTHORITY

**P-LG01/04 Appendix 2 Version 1**

**Experts Form**

Please note that ♦ indicates a mandatory field

**Title**

1. ♦ **Family Name**
2. ♦ **First Name**
3. ♦ **Nationality**
4. ♦ **Organisation/ Company Name and Professional Address**
5. ♦ **Home address**
6. ♦ **Business Phone No (including International Code)**
7. ♦ **Business email address**
8. ♦ **Passport number**
9. ♦ **Qualifications - Degrees, Diplomas and Professional Affiliations<sup>i</sup>**
10. ♦ **Present position and time spent in current assignment<sup>ii</sup>**
11. ♦ **General Category of Activities**

	<b>H<sup>iii</sup></b>	<b>V<sup>iv</sup></b>
MEDICINES EVALUATION		
Biologicals/Biotechnology products	<input type="checkbox"/>	<input type="checkbox"/>
Chemicals	<input type="checkbox"/>	<input type="checkbox"/>
Herbal/Traditional Products	<input type="checkbox"/>	<input type="checkbox"/>
Inspections	<input type="checkbox"/>	<input type="checkbox"/>
Pharmacovigilance	<input type="checkbox"/>	<input type="checkbox"/>
Regulatory affairs	<input type="checkbox"/>	<input type="checkbox"/>

Other activity (please specify):

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♦ **Are you a member of staff of a competent authority?**

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

♦ **Are you an external expert?**  
(e.g., University, hospital, member of staff of another organisation, or a pharmaceutical company, etc)?

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

**12. Specific Functional Expertise**

	<b>H<sup>iii</sup></b>	<b>V<sup>iv</sup></b>
QUALITY		
Immunological/Biotechnology products	<input type="checkbox"/>	<input type="checkbox"/>
Vaccines	<input type="checkbox"/>	<input type="checkbox"/>
Blood products	<input type="checkbox"/>	<input type="checkbox"/>
Chemicals	<input type="checkbox"/>	<input type="checkbox"/>
SAFETY		
Immunological/Biologicals	<input type="checkbox"/>	<input type="checkbox"/>
Chemicals	<input type="checkbox"/>	<input type="checkbox"/>
ENVIRONMENTAL RISK ASSESSMENT		
Genetically Modified Organisms	<input type="checkbox"/>	<input type="checkbox"/>
CLINICAL		
Immunologicals/Biologicals	<input type="checkbox"/>	<input type="checkbox"/>
Chemicals	<input type="checkbox"/>	<input type="checkbox"/>
Pharmacovigilance and		
Risk management	<input type="checkbox"/>	<input type="checkbox"/>
INSPECTIONS		
Laboratory Procedures	<input type="checkbox"/>	<input type="checkbox"/>
GMP	<input type="checkbox"/>	<input type="checkbox"/>
GCP	<input type="checkbox"/>	<input type="checkbox"/>
GLP	<input type="checkbox"/>	<input type="checkbox"/>

**13. Availability**

- Dossier Evaluation**  
 **Scientific Advice**  
 **Guidelines**  
 **Other**

**14. Languages known:**

please specify level, including your mothertongue	<b>R</b>	<b>W</b>	<b>S</b>
<b>R: Read, W: Written, S: Spoken, P: Poor, A: Average, G: Good, E: Excellent</b>			

**14. Areas of Expertise**

(Please select main areas of expertise)

<b>14.a Quality</b>				<b>14.b Pre-Clinical</b>
<b>Chemistry:</b> <input type="checkbox"/> Analytical chemistry <input type="checkbox"/> Synthetic chemistry <input type="checkbox"/> Development pharmaceuticals <input type="checkbox"/> Stability <input type="checkbox"/> Phytochemistry <input type="checkbox"/> Radiopharmaceuticals <input type="checkbox"/> Premixes for medicated Feed production <input type="checkbox"/> Drug/Device combinations <input type="checkbox"/> Packaging <input type="checkbox"/> Manufacture of medicines <input type="checkbox"/> Peptide chemistry <input type="checkbox"/> Medicinal gasses <input type="checkbox"/> Structural similarity	<b>Biology:</b> <input type="checkbox"/> Development genetics <input type="checkbox"/> Genetic engineering: expression factor <input type="checkbox"/> Cell culture Fermentation <input type="checkbox"/> Protein purification <input type="checkbox"/> Protein analysis - characterisation; purity testing; biological assay <input type="checkbox"/> Virology: validation of inactivation/removal steps; cell bank qualification; choice of viruses <input type="checkbox"/> Microbiological testing <input type="checkbox"/> Monoclonal antibodies <input type="checkbox"/> Blood products <input type="checkbox"/> Allergens <input type="checkbox"/> Vaccines <input type="checkbox"/> Gene therapy <input type="checkbox"/> Cell therapy <input type="checkbox"/> Tissue engineering <input type="checkbox"/> Plant biotechnology <input type="checkbox"/> Nanobiotechnology	<b>Risk Assessment of GMOs:</b> <input type="checkbox"/> Vaccines <input type="checkbox"/> Gene therapy/biotechnology <input type="checkbox"/> Transgenic plant	<b>Manufacturing Process, Development and Validations:</b> <input type="checkbox"/> Blood products <input type="checkbox"/> Biological products <input type="checkbox"/> Biotechnology products <input type="checkbox"/> Vaccines <input type="checkbox"/> Cell therapy	<input type="checkbox"/> Toxicology <input type="checkbox"/> General toxicology: Acute/chronic toxicity, etc. <input type="checkbox"/> <input type="checkbox"/> Special toxicology: In vitro toxicology <input type="checkbox"/> Immunotoxicity <input type="checkbox"/> Reproduction toxicity <input type="checkbox"/> Genetic toxicity <input type="checkbox"/> Carcinogenicity <input type="checkbox"/> Toxicokinetics <input type="checkbox"/> <input type="checkbox"/> Pharmacology in laboratory and target animals <input type="checkbox"/> Pharmacodynamics <input type="checkbox"/> Pharmacokinetics Pathology <input type="checkbox"/> Environmental Risk Assessment <input type="checkbox"/> Residue safety assessment <input type="checkbox"/> Behavioural toxicology <input type="checkbox"/> Occupational toxicology <input type="checkbox"/> Microbiology Bacteriology <input type="checkbox"/> Parasitology <input type="checkbox"/> Mycology <input type="checkbox"/> Virology <input type="checkbox"/> <input type="checkbox"/> Safety Pharmacology

**14.c Clinical**

(Please select 2 or 3 main areas only)

<input type="checkbox"/> AIDS  <input type="checkbox"/> Anaesthesiology  <input type="checkbox"/> Biostatistics  <input type="checkbox"/> Cardiology  <input type="checkbox"/> Dermatology  <input type="checkbox"/> Endocrinology  <input type="checkbox"/> Gastroenterology  <input type="checkbox"/> Genetics: Pharmacogenetics <input type="checkbox"/> Clinical Genetics <input type="checkbox"/>  <input type="checkbox"/> Geriatrics  <input type="checkbox"/> Gynaecology/obstetrics  <input type="checkbox"/> Haematology  <input type="checkbox"/> Hepatology  <input type="checkbox"/> Immunology: Biological <input type="checkbox"/> Clinical <input type="checkbox"/>  <input type="checkbox"/> Infectious diseases: Microbiology <input type="checkbox"/>  Bacteriology <input type="checkbox"/>  Parasitology <input type="checkbox"/>  Mycology <input type="checkbox"/>  Virology <input type="checkbox"/>	<input type="checkbox"/> Intensive care  <input type="checkbox"/> Internal medicine  <input type="checkbox"/> Metabolic medicine  <input type="checkbox"/> Nephrology Neurology  <input type="checkbox"/> Nuclear medicine  <input type="checkbox"/> Oncology: Blood <input type="checkbox"/>  Breast <input type="checkbox"/>  CNS <input type="checkbox"/>  Gastro-intestinal <input type="checkbox"/>  Gynaecological <input type="checkbox"/>  Head & Neck <input type="checkbox"/>  Lung <input type="checkbox"/>  Renal <input type="checkbox"/>  Other (please specify) <input type="checkbox"/> _____	<input type="checkbox"/> Ophthalmology  <input type="checkbox"/> Organ transplantation  <input type="checkbox"/> Orthopaedic Surgery  <input type="checkbox"/> Otorhinolaryngology  <input type="checkbox"/> Other (e.g. rare disease), Please specify: _____	<input type="checkbox"/> Plastic Surgery  <input type="checkbox"/> Pneumology/Respiratory  <input type="checkbox"/> Proctology  <input type="checkbox"/> Psychiatry  <input type="checkbox"/> Public Health  <input type="checkbox"/> Radiology  <input type="checkbox"/> Rheumatology  <input type="checkbox"/> Stomatology  <input type="checkbox"/> Urology  <input type="checkbox"/> Vaccines: Microbiology <input type="checkbox"/> Mycology <input type="checkbox"/> Parasitology <input type="checkbox"/> Virology <input type="checkbox"/>
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14.d Target Species	14.e Pharmacovigilance and Risk Management
<input type="checkbox"/> Food producing animals: horses <input type="checkbox"/> cattle <input type="checkbox"/> goats & sheep <input type="checkbox"/> pigs <input type="checkbox"/> poultry <input type="checkbox"/> fish <input type="checkbox"/> bees <input type="checkbox"/> rabbits <input type="checkbox"/> <input type="checkbox"/> (Other) minor species <input type="checkbox"/> Pet animals <input type="checkbox"/> Wild (zoo) animals	<input type="checkbox"/> Epidemiology <input type="checkbox"/> Pharmacoepidemiology <input type="checkbox"/> Phase I-III Safety <input type="checkbox"/> Surveillance <input type="checkbox"/> Phase IV and PMS Surveillance <input type="checkbox"/> Spontaneous reporting systems and databases <input type="checkbox"/> Drug utilisation <input type="checkbox"/> Statistics <input type="checkbox"/> Terminology & coding <input type="checkbox"/> Risk Communication <input type="checkbox"/> Safety of Viral Vectors <input type="checkbox"/> Atypical Infections/Zoonoses <input type="checkbox"/> Vaccine Safety <input type="checkbox"/> Risk Management

<b>14.f Control/Inspections GMP/GLP/GCP</b>			
<b>Products: Laboratory/Procedure Activities:</b>	<b>GMP:</b>	<b>GLP:</b>	<b>GCP:</b>
<input type="checkbox"/> Chemical <input type="checkbox"/> Biological <input type="checkbox"/> Biotechnology <input type="checkbox"/> Immunologicals – Vaccines <input type="checkbox"/> Immunologicals – Others <input type="checkbox"/> Radiopharmaceuticals <input type="checkbox"/> Other (please specify)  <input type="checkbox"/> Active Substances <input type="checkbox"/> Other Starting Materials <input type="checkbox"/> Finished Product <input type="checkbox"/> Market Surveillance <input type="checkbox"/> Official Batch	<input type="checkbox"/> Active Substances <input type="checkbox"/> Other Starting Materials <input type="checkbox"/> Finished Product <input type="checkbox"/> Control Laboratories <input type="checkbox"/> Distributors <input type="checkbox"/> Other (please specify)	<input type="checkbox"/> Quality Systems/Assurance Documentation <input type="checkbox"/> Joint Visits/Self Auditing <input type="checkbox"/> Other (please specify)	<input type="checkbox"/> Quality Systems - (sponsor) <input type="checkbox"/> Trial Site Statistics <input type="checkbox"/> Computer Systems <input type="checkbox"/> Documentation <input type="checkbox"/> Other (please specify) <hr/>