MALTA
MEDICINES AUTHORITY

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**[i]

10. ♦ **Present position and time spent in current assignment** [ii]

11. ♦ **General Category of Activities**

	H [iii]	V [iv]
MEDICINES EVALUATION		
Biologicals/Biotechnology products	☐	☐
Chemicals	☐	☐
Herbal/Traditional Products	☐	☐
Inspections	☐	☐
Pharmacovigilance	☐	☐
Regulatory affairs	☐	☐

Other activity (please specify):

_____

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

YES ☐ NO ☐

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

YES ☐ NO ☐

12. Specific Functional Expertise

	H [iii]	V [iv]
QUALITY		
Immunological/Biotechnology products	☐	☐
Vaccines	☐	☐
Blood products	☐	☐
Chemicals	☐	☐
SAFETY		
Immunological/Biologicals	☐	☐
Chemicals	☐	☐
ENVIRONMENTAL RISK ASSESSMENT		
Genetically Modified Organisms	☐	☐
CLINICAL		
Immunoloigcals/Biologicals	☐	☐
Chemicals	☐	☐
Pharmacovigilance and Risk management	☐	☐
INSPECTIONS		
Laboratory Procedures	☐	☐
GMP	☐	☐
GCP	☐	☐
GLP	☐	☐

13. Availability

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

14. Languages known:

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

14. Areas of Expertise
(Please select main areas of expertise)

14.a Quality

Chemistry:

- ☐ Analytical chemistry
- ☐ Synthetic chemistry
- ☐ Development pharmaceutics
- ☐ Stability
- ☐ Phytochemistry
- ☐ Radiopharmaceuticals
- ☐ Premixes for medicated Feed production
- ☐ Drug/Device combinations
- ☐ Packaging
- ☐ Manufacture of medicines
- ☐ Peptide chemistry
- ☐ Medicinal gasses
- ☐ Structural similarity

Biology:

- ☐ Development genetics
- ☐ Genetic engineering: expression factor
- ☐ Cell culture Fermentation
- ☐ Protein purification
- ☐ Protein analysis - characterisation; purity testing; biological assay
- ☐ Virology: validation of inactivation/ removal steps; cell bank qualification; choice ofviruses
- ☐ Microbiological testing
- ☐ Monoclonal antibodies
- ☐ Blood products
- ☐ Allergens
- ☐ Vaccines
- ☐ Gene therapy
- ☐ Cell therapy
- ☐ Tissue engineering
- ☐ Plant biotechnology
- ☐ Nanobiotechnology

Risk Assessment of GMOs:

- ☐ Vaccines
- ☐ Gene therapy/biotechnology
- ☐ Transgenic plant

Manufacturing Process, Development and Validations:

- ☐ Blood products
- ☐ Biological products
- ☐ Biotechnology products
- ☐ Vaccines
- ☐ Cell therapy

14.b Pre-Clinical

- ☐ Toxicology
- ☐ General toxicology:
  - Acute/chronic toxicity, etc. ☐
- ☐ Special toxicology:
  - In vitro toxicology ☐
  - Immunotoxicity ☐
  - Reproduction toxicity ☐
  - Genetic toxicity ☐
  - Carcinogenicity ☐
  - Toxicokinetics ☐
- ☐ Pharmacology in laboratory and target animals
- ☐ Pharmacodynamics
- ☐ Pharmacokinetics Pathology
- ☐ Environmental RiskAssessment
- ☐ Residue safety assessment
- ☐ Behavioural toxicology
- ☐ Occupational toxicology
- ☐ Microbiology
  - Bacteriology ☐
  - Parasitology ☐
  - Mycology ☐
  - Virology ☐
- ☐ Safety Pharmacology

14.c Clinical

(Please select 2 or 3 main areas only)

☐AIDS

☐Anaesthesiology

☐Biostatistics

☐Cardiology

☐Dermatology

☐Endocrinology

☐Gastroenterology

☐Genetics:

Pharmacogenetics ☐

Clinical Genetics ☐

☐Geriatrics

☐Gynaecology/obstetrics

☐Haematology

☐Hepatology

☐Immunology:

Biological ☐

Clinical ☐

☐Infectious diseases:

Microbiology ☐

Bacteriology ☐

Parasitology ☐

Mycology ☐

Virology ☐

☐Intensive care

☐Internal medicine

☐Metabolic medicine

☐Nephrology

Neurology

☐Nuclear medicine

☐Oncology:

Blood ☐

Breast ☐

CNS ☐

Gastro-intestinal ☐

Gynaecological ☐

Head & Neck ☐

Lung ☐

Renal ☐

Other (please specify) ☐

_____

☐Ophthalmology

☐Organ transplantation

☐Orthopaedic Surgery

☐Otorhinolaryngology

☐Other (e.g. rare disease),

Please specify:

_____

☐ Pain Paediatrics

☐Pharmaceutical Medicine

☐Pharmacology

☐Pharmacokinetics

☐Pathology

General pathology ☐

Chemical pathology ☐

Haematology ☐

Histopathology ☐

☐Plastic Surgery

☐Pneumology/Respiratory

☐Proctology

☐Psychiatry

☐Public Health

☐Radiology

☐Rheumatology

☐Stomatology

☐Urology

☐Vaccines:

Microbiology ☐

Mycology ☐

Parasitology ☐

Virology ☐

14.d Target Species	14.e Pharmacovigilance and Risk Management
☐Food producing animals: horses☐ cattle ☐ goats & sheep ☐ pigs ☐ poultry ☐ fish ☐ bees ☐ rabbits ☐ ☐ (Other) minor species ☐Pet animals ☐Wild (zoo) animals	☐Epidemiology ☐Pharmacoepidemiology ☐Phase I-III Safety ☐Surveillance ☐Phase IV and PMS Surveillance ☐Spontaneous reporting systems and databases ☐Drug utilisation ☐Statistics ☐Terminology & coding ☐Risk Communication ☐Safety of Viral Vectors ☐Atypical Infections/Zoonoses ☐Vaccine Safety ☐Risk Management

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