

**Experts Form**

# Please note that ♦ indicates a mandatory field

**Title**

# ♦ Family Name

1. **♦ First Name**

# ♦ Nationality

1. **♦ Organisation/ Company Name and Professional Address**

# ♦ Home address

1. **♦ Business Phone No (including International Code)**

# ♦ Business email address

1. **♦ Passport number**

# ♦ Qualifications - Degrees, Diplomas and Professional Affiliationsi

1. **♦ Present position and time spent in current assignment** ii

# ♦ 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 of staff of another organisation,

or a pharmaceutical company, etc)?

 YES NO

# 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

1. **Availability 14. Languages known:**

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

 **Dossier Evaluation**

 **Scientific Advice**

 **Guidelines**

 **Other**

|  |
| --- |
| **14. Areas of Expertise**(Please select main areas of expertise) |
| **14.a Quality** | **14.b Pre-Clinical** |
| **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 of viruses🗆 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 | 🗆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 Risk Assessment🗆 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🗆PathologyGeneral 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)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. Please give a brief description of your qualification (e.g. MD, PhD and your specialisation). A Curriculum Vitae (CV) must be attached.

 Do not refer to your CV in this box. Your main areas of expertise are to be addressed in section 14.

1. Please give a brief description of your current job position and indicate the year that you started your current assignment.
2. Human domain.
3. Veterinary domain.