

**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:**

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

**Dossier Evaluation**

**Scientific Advice**

**Guidelines**

**Other**

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| **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 |

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| **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 🗆 |

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| **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 |

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| **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.