

Appendix 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. ♦ Business Phone No (incl Int Code)
6. ♦ Business email address
7. ♦ Passport number
8. ♦ Qualifications - Degrees, Diplomas and Professional Affiliationsⁱ
9. ♦ Present position and time spent in current assignmentⁱⁱ

10. ♦ General Category of Activities

Hⁱⁱⁱ V^{iv}

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): _____

YES NO

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

♦ Are you an external expert (e.g. University, hospital, member of staff

of another organisation, or a pharmaceutical company, etc)?

11. Specific Functional Expertise

Hⁱⁱⁱ V^{iv}

QUALITY

Immunologicals/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

Immunologicals/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"/>
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CLINICAL

Immunologicals/Biologicals	<input type="checkbox"/>	<input type="checkbox"/>
Chemicals	<input type="checkbox"/>	<input type="checkbox"/>

Pharmacovigilance and Risk Management

☐ ☐

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"/>

12. Availability

- ☐ Dossier Evaluation
☐ Scientific Advice
☐ Guidelines
☐ Other

13. 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			

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

14.a Quality				14.b Pre-Clinical
Chemistry: <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	Biology: <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	Risk Assessment of GMOs: <input type="checkbox"/> Vaccines <input type="checkbox"/> Gene therapy/biotechnology <input type="checkbox"/> Transgenic plant	Manufacturing Process, Development and Validations: <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"/> Pharmacology in laboratory and target animals <input type="checkbox"/> Pharmacodynamics <input type="checkbox"/> Pharmacokinetics <input type="checkbox"/> 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: <div style="margin-left: 20px;"> <input type="checkbox"/> Pharmacogenetics <input type="checkbox"/> <input type="checkbox"/> Clinical Genetics <input type="checkbox"/> </div> <input type="checkbox"/> Geriatrics <input type="checkbox"/> Gynaecology/obstetrics <input type="checkbox"/> Haematology <input type="checkbox"/> Hepatology <input type="checkbox"/> Immunology: <div style="margin-left: 20px;"> <input type="checkbox"/> Biological <input type="checkbox"/> <input type="checkbox"/> Clinical <input type="checkbox"/> </div> <input type="checkbox"/> Infectious diseases: <div style="margin-left: 20px;"> <input type="checkbox"/> Microbiology <input type="checkbox"/> <input type="checkbox"/> Bacteriology <input type="checkbox"/> <input type="checkbox"/> Parasitology <input type="checkbox"/> <input type="checkbox"/> Mycology <input type="checkbox"/> <input type="checkbox"/> Virology <input type="checkbox"/> </div>	<input type="checkbox"/> Intensive care <input type="checkbox"/> Internal medicine <input type="checkbox"/> Metabolic medicine <input type="checkbox"/> Nephrology <input type="checkbox"/> Neurology <input type="checkbox"/> Nuclear medicine <input type="checkbox"/> Oncology: <div style="margin-left: 20px;"> <input type="checkbox"/> Blood <input type="checkbox"/> <input type="checkbox"/> Breast <input type="checkbox"/> <input type="checkbox"/> CNS <input type="checkbox"/> <input type="checkbox"/> Gastro-intestinal <input type="checkbox"/> <input type="checkbox"/> Gynaecological <input type="checkbox"/> <input type="checkbox"/> Head & Neck <input type="checkbox"/> <input type="checkbox"/> Lung <input type="checkbox"/> <input type="checkbox"/> Renal <input type="checkbox"/> <input type="checkbox"/> Other (please specify) </div>	<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), <div style="margin-left: 20px;">please specify:</div> <input type="checkbox"/> Pain Paediatrics <input type="checkbox"/> Pharmaceutical Medicine <input type="checkbox"/> Pharmacology <input type="checkbox"/> Pharmacokinetics <input type="checkbox"/> Pathology <input type="checkbox"/> <div style="margin-left: 20px;"> <input type="checkbox"/> General pathology <input type="checkbox"/> <input type="checkbox"/> Chemical pathology <input type="checkbox"/> <input type="checkbox"/> Haematology <input type="checkbox"/> <input type="checkbox"/> Histopathology <input type="checkbox"/> </div>	<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: <div style="margin-left: 20px;"> <input type="checkbox"/> Microbiology <input type="checkbox"/> <input type="checkbox"/> Mycology <input type="checkbox"/> <input type="checkbox"/> Parasitology <input type="checkbox"/> <input type="checkbox"/> Virology <input type="checkbox"/> </div>

14.d Target Species	14.e Pharmacovigilance and Risk Management
<input type="checkbox"/> Food producing animals: <div style="margin-left: 20px;"> <input type="checkbox"/> horses <input type="checkbox"/> <input type="checkbox"/> cattle <input type="checkbox"/> <input type="checkbox"/> goats & sheep <input type="checkbox"/> <input type="checkbox"/> pigs <input type="checkbox"/> <input type="checkbox"/> poultry <input type="checkbox"/> <input type="checkbox"/> fish <input type="checkbox"/> <input type="checkbox"/> bees <input type="checkbox"/> <input type="checkbox"/> rabbits <input type="checkbox"/> </div> <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 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

14.f Control/Inspections GMP/GLP/GCP			
Products: <input type="checkbox"/> Laboratory/Procedure <input type="checkbox"/> Activities: <input type="checkbox"/> <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"/>	GMP: <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"/>	GLP: <input type="checkbox"/> Quality Systems/Assurance <input type="checkbox"/> Documentation <input type="checkbox"/> Joint Visits/Self Auditing <input type="checkbox"/> Other (please specify) <input type="checkbox"/>	GCP: <input type="checkbox"/> Quality Systems - <input type="checkbox"/> (sponsor) Trial Site <input type="checkbox"/> Statistics <input type="checkbox"/> Computer Systems <input type="checkbox"/> Documentation <input type="checkbox"/> Other (please specify) <input type="checkbox"/>

ⁱ 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.

ⁱⁱ Please give a brief description of your current job position and indicate the year that you started your current assignment.

ⁱⁱⁱ Human domain.

^{iv} Veterinary domain.