**GUIDELINES FOR APPLICATION FOR REGISTRATION OF BIOLOGICAL/ BIOTECHNOLOGY PRODUCT**

Follow the requirements for Registration of Pharmaceutical Product – as laid down in the Guidelines For Application For Registration of Pharmaceutical Products (Containing Scheduled Poisons and Non-Scheduled Products) **BPFK/P/GP/01**

Where appropriate the relevant EC guidelines should be consulted for products produced by recombinant DNA technology, and for monoclonal antibodies intended for therapeutic use.

**The additional requirements for registration of Biotechnology Products, Vaccines and Blood Products**

1. Comply with WHO requirements for the product as can be found in the WHO Technical Report Series
   Including:
   - Control of starting materials, including baseline data both on the host cell and on the source, nature and sequence of the gene used in the production. A well-characterized, clean starting materials.
   - Control of the manufacturing process.
   - Control of the final product.
   - Stabilisation and storage.
   - Viral Safety Evaluation.

2. Product formulation containing ingredients from human origin/plasma (eg. Albumin) also require supporting documents regarding the quality of the ingredient and obtained from a safe source of plasma. (eg. Statement on accreditation/GMP status of the plasma collection centres by the relevant authority and viral safety).

3. Product formulation containing materials from bovine, ovine or caprine, used in pharmaceuticals as raw materials, active principles, reagents or excipients, a certificate of suitability concerning transmissible spongiform encephhalopathy (TSE) risk.

4. Summary Lot Protocol as WHO model (for vaccines only)

5. Certification of the product: Certificate of approval of a biological product and Certificate for release of a lot or lots of biological product/ Batch Release Certificate issued by the relevant authority in the country of manufacture

6. Plasma Master Files of the collection establishments/centres.

7. Certificate of Fitness for Purpose/Compliance Certificate confirming that the blood or plasma used in the production of the lot is tested and found to be negative for HIV antibody and HBsAg, and that high-risk donors are excluded

8. Summary of scientific and medical basis of claims for safety and efficacy.

9. Published Clinical Trials Studies/Data.

10. Periodic Safety Update Reports (PSUR)

11. Analytical Validation, Process Validation and Viral Validation Studies Documents

12. Worldwide product registration status