1.0 Objectives

- To establish the procedure in the development of new veterinary biological products.
- To produce experimental batches of developed products to be able to test its quality, stability, shelf life and in the conduct of field trials prior to actual production.

2.0 Scope

- This procedure covers all activities pertaining to the development of a new product line up to the validation of the new product as to its purity, sterility, potency and efficacy in the field for vaccines or its specificity and sensitivity for diagnostic antigens.

3.0 Definition of Terms

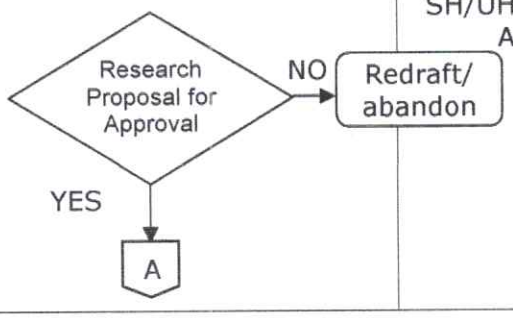
- AFVDBCD refers to Animal Feed, Veterinary Drugs & Biologics Control Division
- VLD refers to the Veterinary Laboratory Division
- VBAS refers to the Veterinary Biologics Assay Section

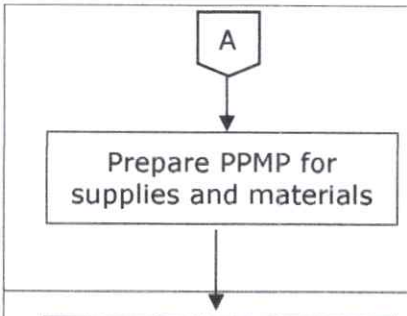
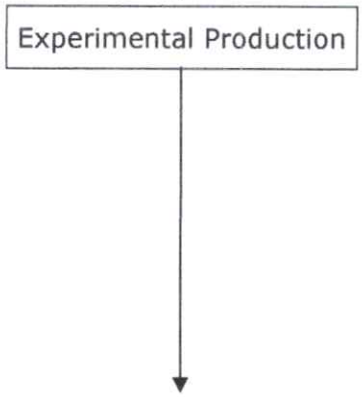
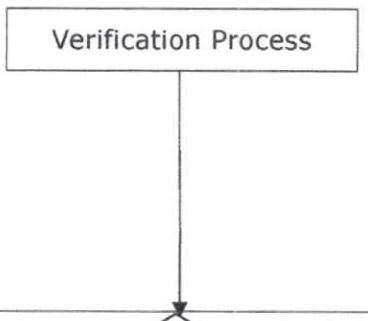
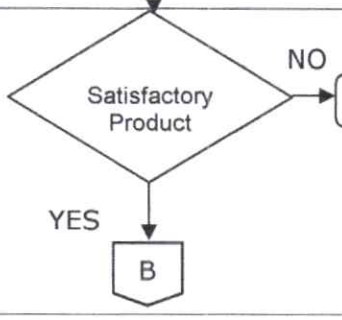
4.0 Records

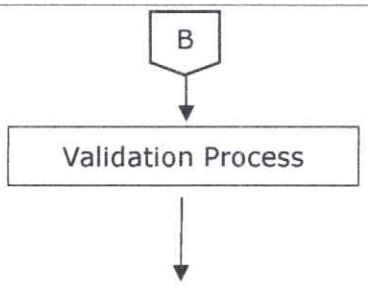
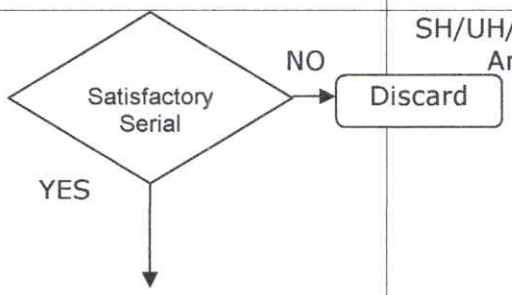
- R-BAI-61 Research/Project Proposal File
- R-BAI-100Research Journal
- R-BAI-101Research Report File
- R-BAI-102Financial Status Report File
- R-BAI-103 Monitoring Accomplishment Report File

5.0 References

6.0 Process Flow

PROCESS	RESPONSIBILITY	DETAILS
Initiation/ Conceptualization	SH/UH/Specialist/ Analyst	• Research proposal is initiated by the SH/UH/ Specialist from the VBPS from the need/query of diagnosticians from the Animal Disease Diagnostic & Reference Lab. (ADDRL), 16 Regional Animal Disease Diagnostic Labs or from livestock producers/ practitioners
Gather data/ information for the proposed product	SH/UH/Specialist/ Analyst	• Download current information on the proposed new product • Any relevant local information from formal literature, personal communications or verbally should be included in the bibliography
Prepare Project/ Research Proposal	SH/UH/Specialist/ Analyst	• Use GF BAI-144Research Project Proposal Format • Indicate phases of the research when necessary • Include in the proposal the verification and validation methods/procedures used in the quality assay of the new product base on recommended international/harmonized standards of testing
	SH/UH/Specialist/ Analyst	• Proposal is submitted to the Division Chief for approval

	SH/UH/Specialist/ Analyst	• If supplies and materials are available, initial steps of the research shall commence
	SH/UH/Specialist/ Analyst	• Biological media for optimum growth of pathogen is prepared • Attenuation procedures indicated in the methodology is followed • Activities done are logged/ written with observations/ remarks for every procedure done in the journal (R-BAI-100 Research Journal) • The journal is updated regularly for reporting purposes • Stabilizer/adjuvant is incorporated for product stability.
	SH/UH/Specialist/ Analyst	• Verification procedure stated in the research proposal is used such as testing for purity, safety, sterility, potency for vaccines or sensitivity and specificity for diagnostic antigens. • Use international/ASEAN standards for testing vet. biologics
	SH/UH/Specialist/ Analyst	• Use GF BAI-167 Waste Disposal Slip for discards. • Experimental batches are produced until the product is satisfactory.

	SH/UH/Specialist/ Analyst	• Developed vaccines are validated against existing commercial products of the same type (Relative Potency) if applicable; or • Samples of the product developed are submitted to the Vet. Biologics Assay Section (VBAS) to validate claims of the product.
	SH/UH/Specialist/ Analyst	• Use GF BAI-167 Waste Disposal Slip for discards. • Serial of the biological product that passed the validation process is tested for field efficacy. • Other tests necessary to comply with product registration are done.
Register Product with AFVDBCD	SH/UH/Specialist/ Analyst	• Secure application form for product registration and comply with requirements stated such as production outline, testing protocol, label, etc.
Certificate of Product Registration Released	SH/UH/Specialist/ Analyst	• Submit copies of requirements for evaluation of AFVDBCD
Mass Production	SH/UH/Specialist/ Analyst	• Samples are submitted to the national testing lab. (VBAS) • Use GF BAI-109Vaccine Release Transmittal Form • Store products at required temperature • Label products after passing VBAS testing

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