8.3.1. General

BAI has established, implemented and maintains a design and development process that is appropriate to ensure the subsequent provision of products. All designs on technical specifications are in discussion with division chief from planning, inputs, control, outputs and changes as applicable.

For new designs and for significant design changes, BAI ensures the translation of customer needs and requirements into detailed design outputs. These address performance, reliability, maintainability, testability, and safety issues, as well as regulatory and statutory requirements.

This process ensures:

a. Design planning is conducted
b. Design inputs (requirements) are captured
c. Design outputs are created under controlled conditions
d. Design reviews, verification and validation are conducted
e. Design changes are made in a controlled manner.

These activities are further defined in the document GP BAI-12 Design and Development.

8.3.2. Design and Development Planning

The staff of the LRDD and heads of the vaccine and pharmaceutical production laboratories of the BAI are encouraged to develop new products. The need for the new product/technology is established through consultation/dialogue with stakeholders. The proponent or study leader shall submit the complete research proposal indicating the personnel involve methodology and testing procedures. Supplies and material expenses for the conduct of the research are drawn and the source of fund indicated. Indicated as well are the phases of the study in order to monitor percentage completion. The Deputy QMR (Division Chief) approves the research design.

8.3.3. Design and Development Inputs

The DQMR ensures that inputs to the researches are met. Copies of literature used in the conduct of the study are kept. The guideline in the testing for the new product shall follow international standards set and shall be applied. Procedures used shall be in accordance with Good Manufacturing Practices/Agricultural Standards.

BAI determines the requirements essential for the specific types of products and services to be designed and developed. BAI considers:

a. Functional and performance requirements;
b. Information derived from previous similar design and development activities;
c. Statutory and regulatory requirements;
d. Standards or codes of practice that BAI has committed to implement; and

e. Potential consequences of failure due to the nature of the products.

Inputs are adequate for design and development purposes, complete, and unambiguous. Conflicting design and development inputs are resolved.

BAI retains documented information on design and development inputs.

8.3.4. Design and Development Controls

BAI applies controls to the design and development process to ensure that:

a. The results achieved are defined,

b. Reviews are conducted to evaluate the ability of the results of design and development meet requirements;

c. Verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d. Validation activities are conducted to ensure that the resulting products and service meet the requirements for the specified application or intended use;

e. Any necessary actions are taken on problems determined during the reviews, or verification and validation activities; and

f. Documented information of these activities is retained.

8.3.5. Design and Development Outputs

BAI ensures that design and development outputs:

a. meet the input requirements;

b. are adequate for the subsequent processes for the provision of products and services include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

c. specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The BAI retains documented information on design and development outputs.

Experimental batches are produced following the methodology described. The final product is tested according to the existing appropriate test procedure adopted by the proponent.

For new biological products, field trials are done to determine its field efficacy and safety. A field trial protocol is developed and is approved by the Deputy QMR(Division Chief). Field trial shall commence upon approval of protocol.

Field trial results are recorded and shall form part of the product document. Samples of the product together with the product documents are submitted to the VBAS for evaluation and testing.

After the evaluation and testing by the VBAS, large scale production shall commence.

8.3.6. Design and Development Changes

BAI identifies, reviews, and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

BAI retains documented information on:

a. Design and development changes;

b. The results of reviews;

c. The authorization of the changes; and

d. The actions taken to prevent adverse impacts

Base on the phases of research indicated, a periodic review is conducted with the Deputy QMR (Division Chief). Problems or any modifications are recorded and reported. Result of the review is recorded.

Draft report of the research conducted is submitted for verification to the Deputy QMR (Division Chief). The DQMR shall focus on the results and discussion prepared by the proponent. Comments on the draft report are recorded.