Quality Policy

The management of the BB – NCIPD EAD gives a primary importance to quality of the products manufactured by the company. The implementation of the quality policy is based on the following principles:

1. Quality is the responsibility of all persons involved in manufacturing.

2. The company establishes, documents, and implements an effective system for managing quality that involves the active participation of management and appropriate manufacturing personnel.

3. The system for managing quality encompasses the organizational structure, procedures, processes and resources, as well as activities necessary to ensure confidence that the APIs meet the specifications for quality and purity. All quality related activities are defined and documented.

4. There is separated quality assurance (QA) and quality control (QC) units that are independent of production.

5. The persons authorized to release intermediates and APIs are specified.

6. All quality related activities are recorded at the time they are performed.

7. Any deviation from established procedures are documented and explained. Critical deviations are investigated, and the investigation and its conclusions are documented.

8. No materials are released or used before the satisfactory completion of evaluation by the quality units

9. Procedures exist for notifying responsible management in a timely manner of regulatory inspections, serious GMP deficiencies, product defects and related actions (e.g. quality related complaints, recalls, regulatory actions, etc.).

10. The quality system incorporates Good Manufacturing Practice, Quality Control and Quality Risk Management.

Organizational Context

1. The management of the BB – NCIPD EAD has developed a procedure and methodology for analysis of the organizational context in terms of the interests and requirements of the interested parties.

2. The general context of the organization has been analysed via the PESTEL instrument.

3. The company has identified the major interested parties and each of them is reviewed separately using SWOT analysis.

4. The opportunities and threat sections of the SWOT analysis of the interested parties have been used as starting points for risk analysis.

Quality Risk Management

✉ BULGARIA, 1504 Sofia, 26 Yanko Sakazov blvd. ☎ Telephone. ++359 2 944 61 91 🖷 Fax ++359 2 943 34 55
🖃 E-mail:bulbio@bulbio.com

1. Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the active substance. It is applied both proactively and retrospectively.

2. The quality risk management system ensures that:

- the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient through communication with the user of the active substance

- the level of effort, formality and documentation of the quality risk management process is commensurate with the level of risk

Responsibilities of the Quality Units (QA and QC)

1. The quality units should be involved in all quality-related matters.

2. The QA review and approve all appropriate quality-related documents.

3. The main responsibilities of the independent quality units are described in writing and include but not necessarily be limited to:

3.1. QC approves all specifications; QC is responsible for releasing or rejecting all APIs; releasing or rejecting intermediates for use outside the control of the manufacturing company;

3.2. QC has a system to release or reject raw materials, intermediates, packaging and labelling materials;

3.3. QC ensures that materials are appropriately tested and the results are reported;

3.4. QC ensures that there is stability data to support retest or expiry dates and storage conditions on APIs and/or intermediates

3.5. QA reviews completed batch production and laboratory control records of process steps before release of the API for distribution;

3.6. QA makes sure that critical deviations are registered, investigated and resolved;

3.7. QA approves the master production instructions

3.8. QA approves all procedures impacting the quality of intermediates or APIs;

3.9. QA makes sure that internal audits (self-inspections) are performed;

3.10. QA approves changes that potentially impact intermediate or API quality;

3.11. QA reviews and approves validation protocols and reports;

3.12. QA makes sure that quality related complaints are investigated and resolved;

3.13. QA makes sure that effective systems are used for maintaining and calibrating the equipment;

3.14. QA and QC perform product quality reviews

Responsibility for Production Activities

The responsibility for production activities is described in writing, and includes but not necessarily be limited to:

1. Preparing, reviewing and following the instructions for the production of intermediates or APIs according to written procedures;

2. Producing APIs and, intermediates according to pre-approved instructions;

3. Reviewing all production batch records and ensuring that these are completed and signed;

4. Making sure that all production deviations are reported and evaluated and that critical deviations are investigated and the conclusions are recorded;

5. Making sure that production facilities are clean and when appropriate disinfected;

6. Making sure that the necessary calibrations are performed and records kept;

7. Making sure that the premises and equipment are maintained and records kept;

8. Making sure that validation protocols and reports are reviewed and approved by QA;

9. Evaluating proposed changes in process or equipment;

10. Making sure that new and/or modified facilities and equipment are qualified.

Internal Audits (Self Inspection)

1. In order to verify compliance with the principles of GMP for APIs, regular internal audits are performed in accordance with an approved schedule.

2. Audit findings and corrective actions are documented and brought to the attention of responsible management of the firm. Agreed corrective actions should be completed in a timely and effective manner.

Product Quality Review

1. Regular quality reviews of APIs should be conducted with the objective of

verifying the consistency of the process. Such reviews are normally conducted and

documented periodically and include at least:

- A review of in-process control and API test results;
- A review of all batches that failed to meet established specification(s);
- A review of all critical deviations or non-conformances and related investigations;
- A review of any changes carried out to the processes or analytical methods;
- A review of results of the stability monitoring program;
- A review of all quality-related returns, complaints and recalls;
- A review of adequacy of corrective actions.

2. The results of this review should be evaluated and an assessment made of whether corrective action or any revalidation should be undertaken. Reasons for such corrective action should be documented. Agreed corrective actions should be completed in a timely and effective manner.

Head of QA Department:: ……..

Executive Director: ……..

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