EXECUTIVE SUMMARY FOR INTERNATIONAL CONFERENCE FOR HARMONIZATION (ICH) Q1 STABILITY GUIDELINE WORKSHOP

Overview:
The International Conference for Harmonization (ICH) Q1 workshop was organized by the National Agency for Food and Drug Administration and Control (NAFDAC) supported by Northeastern University Boston USA and ICH, was held from 22nd-24th July 2024 at the Marriot Hotels Ikeja Lagos. The workshop focused on advancing the technical competence of regulators and industry professionals in drug stability program design, testing and quality control. The training was designed to align with the latest ICH Q1 guidelines, emphasizing stability testing requirements which are critical for the registration of pharmaceuticals.

Objectives:

- Enhance understanding of the ICH Q1 guidelines on stability: program design, determination of shelf-life and testing.
- Equip participants with practical skills for implementing stability protocols.
- Promote collaboration between regulators and industry stakeholders to improve compliance with global standards.

Participants:
The training attracted 104 participants, which comprised of regulators, industry professionals, and representatives from National Regulatory Authorities (NRAs) in the West African region. This diverse group contributed to rich discussions and knowledge exchange across the pharmaceutical sector.

Effectiveness:

- **Participant Feedback:** Evaluation responses were received from 93 participants, representing an 89% response rate. The feedback highlighted the effectiveness of the training in achieving the intended objectives:
    - **Knowledge Gain:** 97% of respondents reported significant improvement in their understanding of ICH Q1 guidelines.
    - **Practical Application:** 99% felt confident in applying the knowledge gained to their work in regulatory and industry settings.
    - **Quality of Training:** 96% rated the content and delivery as highly satisfactory, with praise for the expertise of the facilitators.

Impact:
The training contributed to the enhanced capacity of regulatory bodies and pharmaceutical companies to ensure the stability and quality of medicines. Participants expressed readiness to

implement improved practices in their respective roles, which is expected to lead to better compliance with international standards and ultimately to improved public health outcomes.

Next Steps:
Building on the success of this training, the Agency proposes follow-up sessions focusing on more advanced aspects of ICH guidelines and real-world case studies. Additionally, survey will be deployed to collect how the knowledge gained impacted their regulatory functions. Also, relevant ICH guidelines have been adopted in our document systems as shown in the implementation of ICH Q1

Implementation

1. **Implementation of stability requirement are as shown in the documents below.**
    a. Quality Guidelines for the Registration of Pharmaceutical Products for Human Use in Nigeria: 2.3S 7, 3.2.S.7, S7.1-S 7.3 and 2.3 P.8
    b. NAFDAC GMP for Pharmaceutical Product Guidelines 2021: Stability Section: 8.55 to 8.80

Conclusion:
The ICH Q1 Training successfully met its objectives of improving technical competence in drug stability testing among key stakeholders. With strong participation and positive feedback, this initiative has laid the foundation for continuous improvement in pharmaceutical quality assurance in the region.