Executive Summary of the ICH Q7 (Good Manufacturing Practice Guidiance for Active Pharmaceutical Ingredient)Training for Regulators and Industry

The recently concluded ICH Q7 training program, organized by NAFDAC and the Northeastern University Boston USA which was held from the 25th-26th July 2024, it successfully brought together regulators, industry professionals, academia and regulators from the west African region. The training aimed to enhance the understanding and implementation of the ICH Q7 guidelines, which cover Good Manufacturing Practice (GMP) for Active Pharmaceutical Ingredients (APIs).

Key Highlights:

- **Participants:** A total of 95 participants were in attendance, including representatives from National Regulatory Authorities (NRAs), pharmaceutical manufacturers, academia and NRA's across the region.
- **Content Focus:** The training delved into the critical aspects of the ICH Q7 guidelines, emphasizing compliance with GMP in the production of APIs. Topics included API supply chain management, quality systems, contamination control, and inspections.
- **Engagement:** Participants actively engaged in discussions and interactive workshops, which enabled them to apply the principles learned to real-world situations.
- **Outcomes:** The training successfully reinforced the importance of harmonized GMP practices across the industry, leading to improved regulatory oversight and enhanced product quality in the pharmaceutical sector.

Effectiveness:

- **Participant Feedback:** Evaluation responses were received from 81 participants, representing an 83.95% response rate. The feedback highlighted the effectiveness of the training in achieving the intended objectives:
    - **Knowledge Gain:** 92.6% of respondents reported significant improvement in their understanding of ICH Q7 guidelines.
    - **Practical Application:** 100% felt confident in applying the knowledge gained to their work in regulatory and industry settings.
    - **Quality of Training:** 99% rated the content and delivery as highly satisfactory, with praise for the expertise of the facilitators.

Implementation

- ICH Q7 is being deployed in our system through development of regulations for API using the ICHQ7 guideline.

- Development of a NAFDAC GMP for Active Pharmaceutical Ingredient guideline

Conclusion

The ICH Q7 training has set a strong foundational knowledge base for the manufacturing of API and regulation of the same. This is a good footing for future capacity-building efforts in the region with respect to GMP for APIs, fostering continuous improvement in regulatory practices and industry standards for pharmaceutical manufacturing.