National Agency for Food and Drug Administration and Control
Laboratory Services Drugs – Central Drug Control Laboratory
8-10 Merret Road, Medical Compound Yaba, Lagos State.

HIGHLIGHT OF QUALITY MANAGEMENT SYSTEM (QMS) ACTIVITIES IN CDCL 2021, 2022 & 2023

a. 2021

1. **NAFDAC Laboratory Harmonization Project;** in continuation of the harmonization project, CDCL alongside other NAFDAC Laboratories, participated in the ongoing Harmonization project. This involved development and review of SOPs, and other quality documents as well as trainings.
2. **Laboratory Annual Internal Audit;** Two (2) phases of Internal Audit were implemented in the year under review namely; the Audit for non-technical processes held in March and the technical processes held in August.
3. **External Audits;** The Laboratory participated in the following external audits and assessments;
    a. WHO GBT Follow-up Assessment held virtually 5th – 9th July 2021
    b. ISO 9001:2015 Surveillance Assessment Audit. The Agency wide assessment was undertaken on 5th November 2021.
    c. ISO 17025:2017 Surveillance Assessment Audit: This audit took place 15th – 19th November 2021.
4. **Intra-Laboratory Audit** – In line with the NAFDAC Laboratory Harmonization Project, the Laboratory participated in Intra-Lab Audit in July 2021. Follow-up to this assessment was undertaken in September 2021.
5. **Training:** The Laboratory implemented several training activities all of which is captured in the Laboratory's Training Inventory. Some key trainings undertaken in the year under review include;
    a. QMS Internal Audit Training for Laboratory Auditors held 8th – 12th March 2021
    b. Trainings on NAFDAC Laboratory Harmonized SOPs.
6. **Visitation;** Educational Visit by students of Medical Intermediate Officer Course 4/21 of the Nigerian Army in the month of October and November.
7. **Management Review Meeting (MRM)**; The Directorate had a one-day MRM which is mandatory for an ISO: 17025:2017 accredited laboratory. The

meeting was done alongside with other NAFDAC Laboratories and it held virtually on 24th September 2021.

b. 2022

1. **Laboratory Annual Internal Audit Plan;** Two (2) phases of Internal Audit were implemented in the year under review namely; the Audit for non-technical processes held in March and the technical processes held in August.
2. **Laboratory Intra-Laboratory Audit;** In line with the NAFDAC Laboratory Harmonization Project, the Laboratory participated in Intra-Lab Audit in July 2021. Follow-up to this assessment was undertaken in August 2022
3. **External Audits**
    a. **WHO-GBT Reassessment**; this assessment took place 21st- 25th February 2022. and culminated in Nigeria's attainment of the WHO Maturity Level 3 Status which was announced by WHO in 22nd March 2022.
    b. **ISO 9001:2015 Recertification Audit** for NAFDAC started on Tuesday Nov 1st 2022. According to the audit plan, the assessment was on-site, conducted by AFNOR external auditor who visited CDCL on Thursday Nov 3rd 2022. The outcome was satisfactory with no non-conformities identified.
    c. **ISO 17025:2017 Reaccreditation Audit** held virtually from 21st - 24th November 2022 by ANAB Auditor. Also, the outcome was commendable with CDCL retaining all accredited scopes and no non-conformance were identified.

4. **RCORE Capacity Building Activities:**
    a. **Uganda FDA Knowledge sharing visit** to Central Drug Control Laboratory, Yaba took place 9th - 12th May 2022.
    b. Educational visit by Staff of **Burkina Faso National Regulatory Authority** Laboratory 30th September -7 October 2022

c. **NIPRID/USP Capacity Building**: staff of National Institute of Pharmaceutical Research and Development visited the laboratory from 14th – 17th June 2022 to build capacity in microbiology processes.
d. **Intra-Laboratory Training on LIMS**; In the month of August, a team of officers from CDCL to Area Laboratory, Maiduguri, Port-Harcourt Laboratory, Kaduna Area Laboratory to train officers on **Laboratory Information Management System**

5. **Training:** The Laboratory implemented several training activities all of which is captured in the Laboratory's Training Inventory.
6. **Management Review Meeting (MRM)**; The Directorate MRM held virtually on 5th October 2022.

c. 2023

1. **Laboratory Annual Internal Audit Plan:** Two (2) phases of Internal Audit were implemented in the year under review namely: the Audit for non-technical processes held in March and the technical processes held in June.

2. **External Audits:**
   a. **Second Audit towards attaining WHO Pre-Qualification;** the audit held 15th – 19th February 2023, with the Laboratory attaining **WHO PQ status** on 30th October, 2023.
   b. **ISO 17025:2017 Surveillance Audit** held virtually on 17th October 2023 by the ANAB Auditor. The outcome was satisfactory with no identified non-conformities.
   c. **WHO Institutional Development Plan (IDP) Follow-Up and GMP Observed Audit Visit**; which held 23rd – 27th October 2023. The outcome was successful.
   d. **ISO 9001:2015 Surveillance Audit held in November 2023 –** Laboratory was found to be in compliance with ISO standards and no non-conformities were identified.

3. **Laboratory Intra-Laboratory Audit;** In line with the NAFDAC Laboratory Harmonization Program, the Laboratory participated in Intra-Lab Audit from **3rd to 6th July 2023.** Follow-up to this assessment took place in September.

4. **RCORE Training/ Information-Sharing Activities:**
    a. **Liberia Medicine Health Regulatory Authority (LMHRA) visited** Central Drug Control Laboratory, Yaba for a two-week training program from 17th - 28th April 2023. The training focused on Laboratory Quality Management, and hands-on training in key technical Processes, SHE activities etc.

5. **Trainings:** The Laboratory implemented several training activities all of which is captured in the Laboratory's Training Inventory. Some key trainings undertaken in the year under review include;
    a. USP PQM+ Sponsored Capacity Building **One-Week Retreat Towards WHO Prequalification** held 16th – 20th January 2023.

6. **Management Review Meeting (MRM)**; The Directorate MRM held virtually on 9th October 2023.

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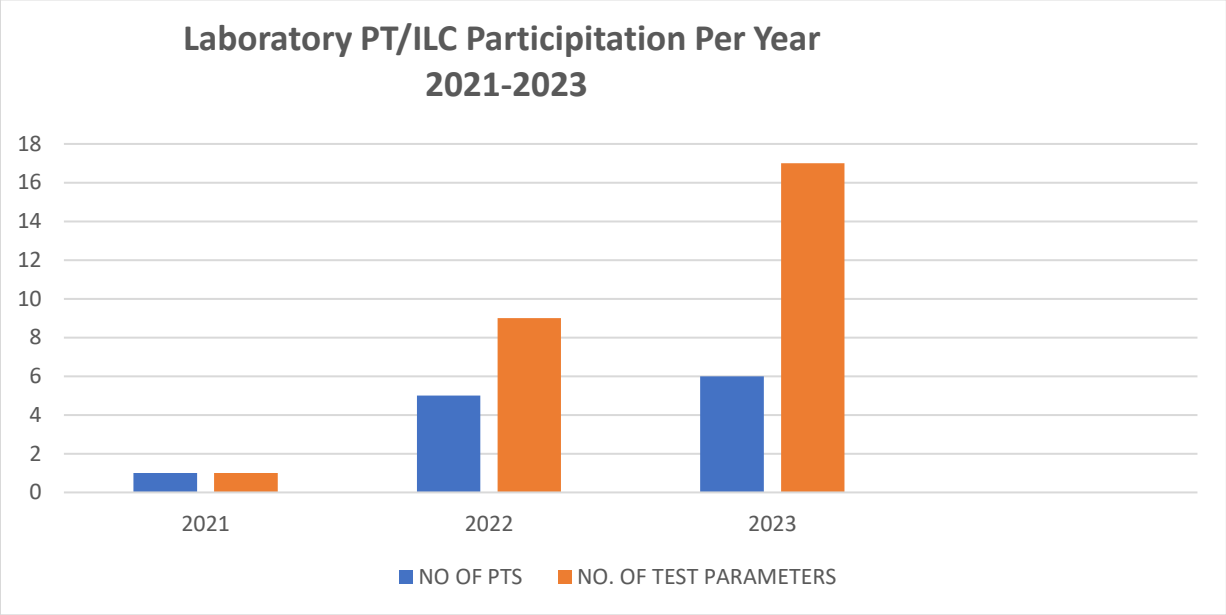
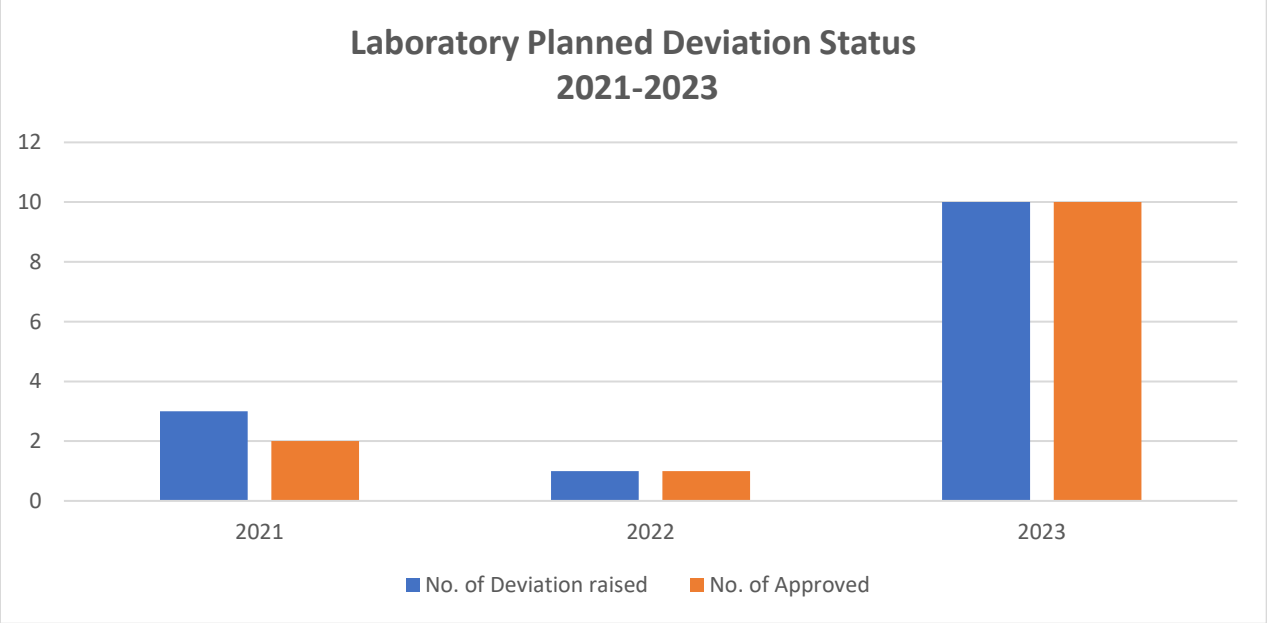
Summary of Laboratory Proficiency Testing Participation, Out of Specification (OOS) and Planned Deviations 2021 – 2023



Graph 1: Proficiency Testing /Inter Laboratory Comparison Participation 2021 - 2023



Graph 2: Laboratory Planned Deviation Status - Number Raised and Approved 2021 - 2023

Table 1: Laboratory Out of Specifications (OOS) Investigations Undertaken with Parameters 2021 - 2023

	NO. OF OOS Investigated per year		
Parameters	**2021**	**2022**	**2023**
Disintegration Testing	2	0	0
Microbial Limit Test	169	115	82
Physical parameter	19	1	3
Hydroquinone	4	0	0
Uniformity of weight	3	4	4
Antimicrobial	0	4	9
Sterility	0	1	0
Friability	0	18	0
Dissolution	0	1	0
Microbial Assay	0	1	1
Hardness	0	2	0
PH	0	0	1
Assay and Identification	6	14	18
Total	**203**	**161**	**118**