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Retrospective Study of Inspectors Competency in the Act of Writing GMP Inspection Report

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Retrospective Study of Inspectors Competency in the Act of Writing GMP Inspection Report

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ABSTRACT

The research was a retrospective study of twenty-five Good Manufacturing Practice (GMP) inspection reports (from March 2017 through to December 2018) of a national medicine regulatory agency, drug Inspectorate, in West Africa, designed to assess the inspectors' expertise in the act of inspection report writing.

The investigation examined a paper-based tool of thirteen pre-registration Inspection reports and twelve GMP reassessment reports written prior and following an intervention program by external GMP trainers to enhance inspectors' skill in pharmaceutical cGMP inspection.

The study made use of quantitative analysis to investigate each team's expertise in the act of writing GMP inspection report. Likewise, each report's compliance with the requirements of three regulatory standards on GMP inspection report writing was ascertained. Impact of intervention program on lead inspectors' competence was assessed. Lastly, gap in each team writing effectiveness, and lead inspectors' abilities to deliver an effective report were determined.

The results showed one of the inspection team (4.0%) wrote an *excellent* report. Two (8.0%) of the twenty-five inspection teams penned *good* inspection reports. Eleven (44.0%) teams drafted *needs improvement* reports and the remaining eleven teams (44.0%) prepared *unacceptable* reports.

The *excellent* report and the two *good* reports had report format that *meet expectation*. One (50.0%) of the *good* reports showed the authors possess *excellent knowledge* of cGMP technical areas. The remain *good* report (50.0%) revealed the writers' *knowledge*.as *good*. The excellent report showed the authors displayed *partial mastery* in the use of objective evidence while the two *good* reports disclosed theirs as having partial and evolving abilities. One of the teams (50.0%) that wrote good reports displayed good use of third person narrative past tense in report writing whereas the other team used the same tense and voice excellently.

Generally, a sort of marginal level of performance was prominent among the inspection teams. A gap, if not tackled, will slow down regulatory process through increase report review, litigations that query report factual accuracy (AIHO, 2017) and delay in issuance of marketing authorization.

In conclusion, trainings on quality attributes, such as technical content (Quality Management System (QMS) and Site), the use of objective evidence, assignment of risk levels to GMP violations and citing of applicable laws, regulation and guidelines that substantiate GMP observations, were recommended, to enhance knowledge sharing and regulators' performance in the act of writing inspection report.

KEYWORDS: Regulatory System, Good Manufacturing Practice, Pharmaceutical Inspectors, Inspectional observation., Inspection report, compliance letter.

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Introduction

Knowledge and skill to write competently and in a way which suits one's goal and audience is a task which many individuals never acquire in their first language, even with the fact that significant part of the educational process is devoted to developing of such skills (May, 2015). Information sharing in a diversity of written formats and for array of reasons is an act that leads to analytical, critical, and logical thinking (Fasset, 2019).The old saying that, "A job is not complete until the paperwork is over," is partially correct (Fasset, 2019).Invariably, it should `be understood that an effective report, is one which the author need to articulate his or her point and relay the information in such a manner that the reader will understand exactly what he or she means (Your dictionary, 2002).This means that reports have to be presented as organised information based on sound evidence that would unavoidably, lead to a logical conclusion (Smyth, 2012). This educational skill is highly valued by employers and should be assessed from time to time, especially where what one writes and how well he or she writes it, can affect people's lives (Smyth, 2012).

Writing competence" is defined as possessing the required writing abilities to produce an orderly use of words. With the support of written statement, it is likely to communicate with individuals who are not with us. The act of writing can be used to discern our thoughts, and to visualize the realities of existence as well as things that are yet to happen. Basic writing competence was defined as the ability to make effective use of basic writing functions such as purposeful, in written art and handicraft. Through purpose writing we share information for different reasons in different situations. It could be through text, words, spelling, sentences, composition and drawing as well as other signs in written art and handicraft we engage the intellectual, psychological, and physical parts of skills to provide us with a well-written document for a brilliant presentation (Kjell Lars Berge, 2009).

The aim of writing is often associated with the nature of activity that goes on in a particular area. Therefore, the way of writing in particular discipline reflect their specific ideology, internal reason, and work ethics (Kjell Lars Berge, 2009). FDA employees across the globe write a range of documents, which include but are not limited to letters and web content for a variety of audiences, guidance documents, regulations, compliance directives, consumer safety notices and updates, recall notices, warning letters, press releases, policies and procedures and GMP reports in some climes(FDA, 2019).The high volume and wide range of documents these employees handle, made it essential that the competence of the regulators involved in this task be assessed periodically, to assure adherence to good documentation procedures and good report writing practice. This would not only foster accountability and transparency in drug regulatory process but would assure the consistency of information and associated GXP (Good Whatever Practice) (WHO, Guidance on good data and record management practices, 2016).

Internationally, the World Health Organization (WHO) guesses that minimum of 30% of National Medicine Regulatory Authorities (NMRAs) have partial capacity to carry out their core regulatory functions. In Africa, there are 54 NMRAs with different capabilities to perform regulatory tasks (Ndomondo-Sigonda, Miot, Naidoo, Dodoo, & Kaale, 2017). Most of these had fragmented regulatory systems which on several occasions had been linked to weak legal and regulatory framework. Gaps and overlaps of responsibilities were common, especially in licensing (involving the Ministry of Public Health or Ministry of Trade) and inspection (involving pharmaceutical councils, regional authorities, or public health inspectorates). Organizations of this type have limited autonomy (WHO, Regulatory Harmonization:, 2010). An assessment of 26 regulatory systems in sub Saharan Africa revealed that all of them had critical weaknesses, including a lack of sustainable funding and a severe lack of human resources (USAID, 2018).

Most of these NMRAs lack sufficient competent staffs to realise their mandate. Competency is missing in core regulatory functions, such as clinical trials monitoring, inspection of facilities Inspection report writing, dossier review, bioequivalence data evaluation, quality management systems pharmacovigilance and post-marketing surveillance (Ekeigwe, 2019). In some cases, an unqualified individual without professional expertise and hands-on knowledge of regulatory science due to his/her background or political connection, becomes employed into an NMRA. Some of these individuals with minimal regulatory knowledge and experience, in a short space of time ascend to positions where sensitive regulatory decisions are taken.

Consequently, this creates bottlenecks because their lack of expertise often results in slow decision making in situations that should otherwise call for prompt action in the interest of public health. Also, the inability of most regulators to get expose to regulatory sciences and medicine regulation courses during their early career days in pharmacy schools, science departments, and other academic institution, explains their poor performance in execution of their assigned tasks. Occasionally, these employees may or may not have the privilege to be trained by their employers. On the job training becomes the only available option through which fresh employees struggled their way to learn (Ekeigwe, 2019).

Strong regulatory systems are required to guarantee the quality, safety, and efficacy of medical products and advancement of trade and socioeconomic development. The strictness in regulation activities should be guided by the type of the drug formulation, questions asked during product safety, quality, and usefulness evaluation, and by complexities of the pharmaceutical supply chain. All nations then need to have functional and competent national medicines regulatory authorities (NMRAs) (Ndomondo-Sigonda, Miot, Naidoo, Dodoo, & Kaale, 2017) or else make it would make regulatory processes excessively complicated, lengthy, and lacking in transparency (USAID, 2018).

Inspection of manufacturing facilities to assess their compliance with current good manufacturing practice (cGMP) regulations is one of the core functions of National Medicine Regulatory Agency (IAuditor, 2020). Health risks due to factors like poor hygiene, inadequate temperature-control, cross-contamination, adulteration etc in any step of the manufacturing process, could lead to fatal consequences to consumers. As such, Good Manufacturing Practice (GMP) is implemented by many manufacturers around the world. It is mandated by individual countries government to regulate production, verification, and validation of manufactured products to ensure that they are of good quality, effective and safe for market distribution. For instance, in the United States of America, GMP is enforced by the US FDA through Current Good Manufacturing Practices (CGMP) which covers a broader range of industries such as cosmetics, food, medical devices, and prescription drugs (IAuditor, 2020). When a manufacturing site for pharmaceutical products is assessed, the inspection team that carried out the audit normally draw up a report which detail the outcome of observations made during the exercise. The ability of inspectors to write clearly for a general audience, as well as the ability to adapt their mode of writing to different audiences and purposes, are important competencies they should possess (Cyn et al, 2014). Success in this area depends much on the level of the inspector's proficiency, his readiness to learn and the open-mindedness to have the report reviewed to get more constructive feedbacks on his or her performance. This is not the case with many regulatory inspectors in West Africa. Issues on deficiencies in inspection report writing practice have been areas of great concern which require attention. These areas of concern include.

Non-uniform application of common standards or principles (Requirement, Evidence and Deficiency) that guide GMP inspection report writing. (WHO 2016a). Incomplete capturing of some sections or sub sections stipulated in the inspection report format of the NMRA. Non-usage of third person narrative past tense writing style (WHO 2016a). Listing of observed deficiencies under a wrong GMP system or sub-system. Inspectional observation(s) not made clear and specific. Repeat of observations and non-ranking of the violations in order of significance. Wrong citation or non-citing of applicable sections of the laws and regulations administered by the FDA (Gutting, 2013).that validate inspector's opinion on violation. Capturing of violations under wrong risk-based classification status. Non-reporting of GMP systems or sub-systems "NOT INSPECTED" or VERIFIED. Conflicting information in the report or subtle addition of non-existent observation in the report. Evasiveness in making categorical statement on GMP status of the auditee (whether it is satisfactory. marginal or unsatisfactory). Non-endorsement of report by one or two members of the inspection team. At the end, timely submission of Inspection report.(WHO 2016a)

Resources and Guidance Documents for Compliance Monitoring

WHO TRS No. 996 2016, Annex 4 provided a reviewed guidance on good manufacturing practice for National Medicine Regulatory Authorities. The document described the common principles and suggested standardized report format to be used by regulatory authorities and other establishments that perform pharmaceutical Inspections. In line with the provision of this document, writing inspection reports must produce a accurate and unbiased information on activities carried out. Inspection rating comments (both compliant statement and non-compliant statement) on each GMP system and sub-systems

are discussed with the firm's management during the close out meetings and conclusion is reached at the time the report is written(WHO, 2016). The second reference document on GMP inspection report writing is WHO Technical Report Series, No. 902, 2002 Annex 8, section 7.4 p 108 on Quality Systems Requirements for National Good Manufacturing Practice Inspectorates. This particular document discussed the need for reports to be signed and dated by inspectors,(WHO 1992). The third document is Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme guidance document (PIC/S PI 013-3 1 Annex 25 September 2007) on Standard Operation Procedure for PIC/S Inspection report format which provided guidance on the format to be used for preparation of PIC/S inspection reports(PIC/S 2007). All these regulatory standards emphasized the need for the report to be clear, accurate and evidence-based, with explanation of activities, systems, procedures, processes, and other observations made during the audit. Based on this, conclusion can be reached that GMP inspection report should be such a write up that can easily assist the target audience, to address observations made during their facility audit, without any dispute over observation. (Pharmalex, 2019).

Background Information About the Research Problem

In one West Africa nation, the National Medicine Regulatory Agency (NMRA) is the Health Regulatory Agency (HRA) identified as overseeing pharmaceutical products regulation. This is an agency under the ministry of health established by the provisions of the food, drug and cosmetic act in sub-section xi a and b, section 42 of the country's 1952 drug law. The primary goal of the organization is to ensure the safe use of food, medicines and cosmetics products for beneficial health purposes while protecting people against harmful effects of counterfeit and substandard medicines and unwholesome processed food (Geno & Kim, 2019).

The Inspectorate of the NMRA is an independent arm that is charged with the responsibility of assessing pharmaceutical manufacturers compliance with good manufacturing practice regulations for medicinal products. Though the department had been established many years ago, yet the issue of low expertise in the act of writing GMP inspection report, was found to be common among her inspectors. (Please see Figure 1 for more information). The challenge which manifested in the form of non-uniform usage of approved report format, poor knowledge of technical requirements of GMP, ineffective use of objective evidence to support observations, providing evasive answers to inspected facility GMP status etc., had over time affected the quality of reports written by their inspectors (WHO, Guideline on Implementation of Quality Management System for National Regulatory Authorities, 2019).

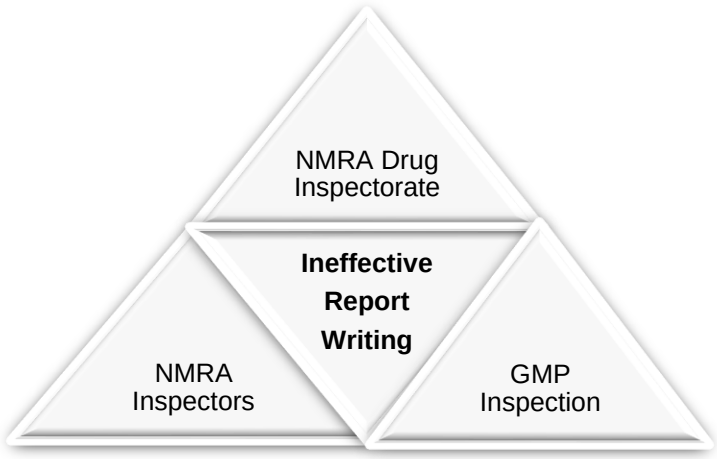

Figure 1.

Tackling Ineffective GMP Inspection report writing in National Medicine Regulatory Agency

The challenge was earlier blamed on the use of decentralized procedure which empowered the regional offices to handle inspection activities under their territory. Much later, it was found that subsequent adoption of a centralized approach which ceded the mantle of co-ordination to the inspectorate head office, did not reduce the anomalies. No data on how this deficiency impacted regulatory function of the organization was provided. As such, the level of the inspectors' competence in the act of inspection report writing and the bottlenecks which it had created so far were yet to be quantified. Secondly, the Agency's policy on sharing reports with auditees was another area of concern. This is because murky reporting has factual accuracy problems that can negatively affect company's response to inspectional observations. Thus, leading to re-observation of poorly captured violations during a re-inspection of the facility's corrective actions effectiveness. Thirdly, the organization's effort to become one of the

regulatory partners in regulatory reliance initiative would suffer a set-back. Reason being that poor report writing practice, would cast doubt on the Agency's capability to assure acceptable level of GMP compliance. Other setbacks include, accumulation of un-cleared drug products' registration applications, delay in issuance of marketing authorization (Ekeigwe, 2019) as revealed in Figure 2 below. Multiple cycles of report review, increase in process time for report evaluation, increase in regulatory burden for few proficient inspectors, failure of the inspectorate to meet the administrative process timelines. At last, delay in conveyance of observations to regulated subjects (both local and foreign clients).

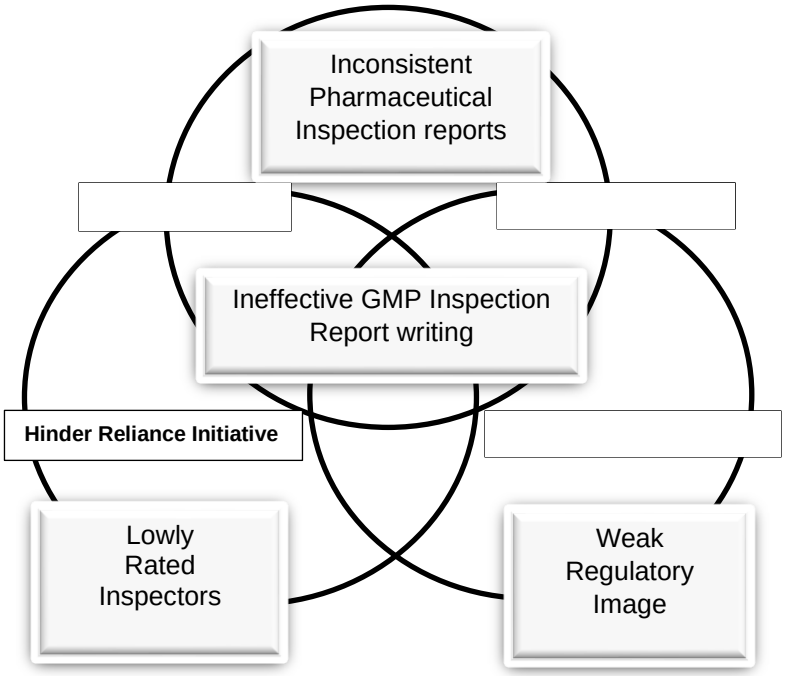

Figure 2

Venn diagram characteristics that illustrated the effects of Ineffective GMP Inspection Report writing.

Based on these findings, the research intended to identify the proficiency of the study NMRA inspectors in the act of GMP inspection report writing. The gaps that exist in the inspectors' writing practice and make recommendations on how the deficiencies could be overcome to meet the desired competence approved by internationally best practice.

Aim of the Study.

The purpose of the research was to conduct a retrospective study of a National Medicine Regulatory Agency (NMRA) inspectors' competence in the act of writing GMP inspection report.

Objectives

a. To identify the appropriateness of the reports through evaluation of their coverage and practice attributes.
b. To find out the impact of intervention program on inspectors' writing performance.
c. To verify the individual reports' compliance status with regulatory standards for writing inspection report.
d. To demonstrate the competence of lead inspectors in the act of writing GMP inspection report.
e. To identify the gaps that need to be tackled to guarantee quality improvement of GMP inspection reports writing practice among NMRA drug Inspectors.

Research Questions

The subsequent opinions guided this research.

a. Does the review of NMRA establishment inspection reports reveal the capabilities of drug inspectors to effectively rate pharmaceutical industries compliance with cGMP requirements on medicinal products manufacture?

b. To what extent does a few days GMP training, by an aid agency impact the writing effectiveness of GMP inspectors in West Africa?

c. Does educational qualification and experience of lead inspectors affect their capability to organize an effective GMP inspection report?

Need for Pharmaceutical Regulation

Pharmaceutical manufacturing and management are a complex endeavor. It involves multiple companies and stakeholders, a myriad of sites, complex multi-level supply chains, and many national and international requirements and regulations that must be met to assure the quality of medicines being produced. This is further complicated by strong competition within the industry and shifting market forces, which drive frequent supply and demand fluctuations (Roth L, et al,, 2017). This litany of

systems, structures, processes, and practices which ensure that medicines are consistently produced in compliance with requirements, specifications, guidelines or characteristics appropriate to their intended use and as demanded by the product parameters are referred to as GMP (WHO, 2007). The question is what is GMP?

What is GMP?

According to WHO, Good Manufacturing Practices (GMP) is defined as that part of organizational resources which guarantees that products are constantly produced and controlled accordingly. This implies that there should be strict adherence to standard requirements, specifications, guidelines, or characteristics appropriate to the product's intended use and as required by the marketing authorization, clinical trial studies or product specification. The primary objective of GMP is to manage and reduce the intrinsic risks in pharmaceutical production to assure the highest standard of quality, safety, and efficacy of products and no harm in processes that involves the making of well-being products (Geyer , Varley , & Damaris, 2018).

This implies there should be definite manufacturing procedures, justified critical production steps, suitable sites, and warehouse management system. Other requirements include transport, trained and competent production and quality control staffs, adequate quality control laboratory facilities, and officially approved written procedures and instructions. Documentary evidence of compliance to all steps in the approved procedures, effective batch traceability system, complaints investigation and product recall system are equally important. Conclusively, the effective implementation of GMPs not only supports but equally help to guarantee the safety, efficacy, and quality of medicines (Roth L, et al,, 2017).

Who is a GMP Inspector?

According to Neil Gunning ham (2012), "being a good inspector is a job that requires great effort and determination to carry out his job in the face of daunting challenges that confront him. GMP Inspection is an activity which can impact a company's viability and may lead to regulatory actions such as product recalls, loss of sales, placing of manufacturing lines or entire facilities. on "HOLD" where gross violations are uncovered and a negative corporate image for the firm (Woodcock, 2012.). Consequently, an inspector should be an individual, who is skillful at objectionable condition identification and assessment; an expert at systems engineering; competent at regulatory requirements interpretation; and have good intermediary skill. Bearing in mind, that manufacturing site inspections are often a disliked event with regulated entities, the inspector needs to be firm in execution out his or her duty.

Role of GMP Inspector

Regulatory compliance assessment of inspected manufacturing sites against the requirements of national legislation is identified as the key role of an inspector. Here, the suitability of a site for the activities which it sought permit or the one it has already gotten authorization was evaluated. The inspector was expected to give technical advice and guidance to both internal and external customers of the FDA. He offered support to the implementation and execution of national regulations in relation to matters that concern medicinal products (Health Product Regulatory Authority, 2018).

Competence of GMP Inspector

To assure a universally appropriate and flexible competency framework which support systematic strengthening of regulatory professionals. was developed by WHO. Based on this, the word "competency" was defined as the knowledge, skills, attitudes, and behaviors developed through education, training, and experience (Bruno, Ian, Tina, & Claire, 2019).

Criteria for Rating Competency of GMP Inspectors.

Since verification of the licensee's compliance with statutory requirements in the authorization is the main goal of GMP inspection, the criteria for assessing the performance of an inspector were listed as follows.

- His or her ability to comprehend the regulatory body's requirements for conducting inspection.
- The inspector's capacity to consider other regulatory entities' remarks during the inspection process.
- Aptitude to come up with an action plan for specific facility inspection.
- Capability to identify safety concerns and likely deficiencies by observation. Ability to

make assessment on the safety of a manufacturing site and its regulatory compliance status.

- Ability to recognize when immediate actions were required to rectify non-compliance if there was imminent likelihood of a safety significant event.
- His or her ability to guide on how to unravel the root cause analysis of an objectionable condition.
- Good understanding of how to use risk-based approach at carrying out an inspection exercise (IAEA, 2013).

These recommendations were corroborated by WHO guidance on quality systems requirements for national good manufacturing practice inspectorates which proposed specified competency requirement of GMP inspector which are,

- GMP inspectors should have the requisite self traits of tact, integrity, courage, and character to carry out his obligations.
- He or she should be educationally skilled in a recognized scientific/technological field that relate to pharmaceutical sciences. (Relevant knowledge in pharmaceutical manufacture could be considered an added advantage).
- Having participated in a cross functional training course on inspecting GMP systems.
- Possessing sufficient working knowledge of several regulatory guidelines on GMP for pharmaceutical products and/or relevant national regulatory authority GMP inspection procedures.
- Having undergone appropriate training in the current procedures and techniques of GMP inspections before conducting an inspection (WHO, 2002).

Competency Measurement Model

The flow chart of competency analysis model in figure 3 summarized the need for management of a regulatory authority to evaluate prevailing competences of their staff, by relating the current with Ideal competences, execution of gap analysis study and priority areas selection for necessary action.

GMP Inspection Writing

According to Association of Southeast Asian Nations (ASEAN) Guideline on GMP for Traditional Medicine/Health Supplement. the term "GMP inspection report writing" was defined as that type of writing where inspectors of an audited facility compiled facts of inspectional observations in a simple manner, using standard GMP inspection report format, followed by conclusions at the end of the

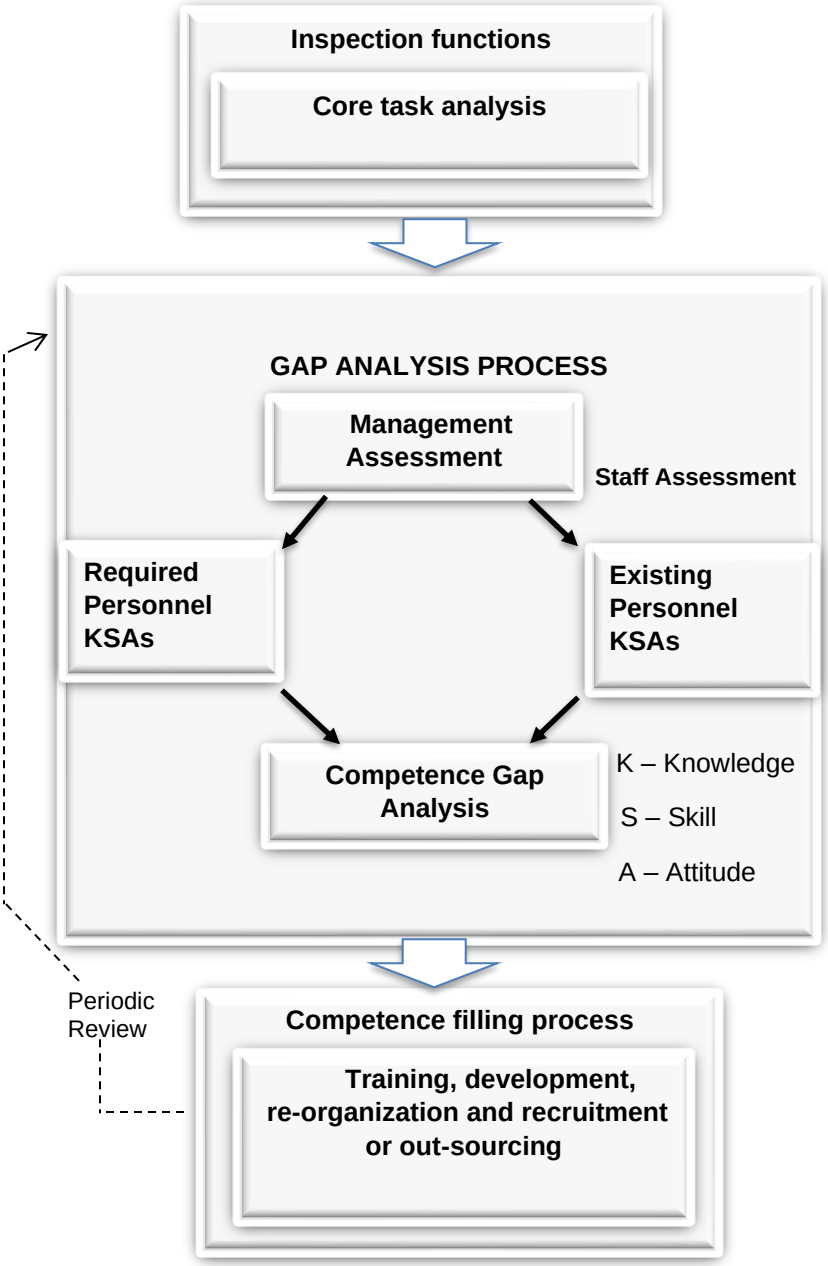

Figure 3

Competence Analysis flow Chart (IAEA, 2013)

report at the end of the report and signature of the inspectors (ASEAN, 2017). This agreed with the provisions of WHO guidance on Inspection reports which stated the aim of writing an inspection report is to produce accurate and unbiased information on activities carried out, findings made whether positive and negative for each inspected area, as made known to the company during the close out meetings and a conclusion that was reached at the time the report was written.

By this, the above statement supported the fact that.

If it is not documented, then it never happened.
However, in the case of ineffective GMP Inspection report writing, I would rather state that.

If it was "not documented correctly", it happened, but in "deplorable style.

Procedure for NMRA GMP Inspection Report Writing

Upon completion of an inspection, the report is prepared by the designated member of the inspection team using a list of discrepancies written during the inspection as noted in the NMRA inspector's notebook. The team provides in the report facts of observations (both compliant statement and non-compliant remarks) made during the audit as outlined in the applicable Inspection report format. The inspector will ensure that the report captures the objectionable conditions sighted during the inspection. The deficiencies are written clearly without ambiguity and classified as critical, major and others using the risk-based classification approach described in Annexure 4 of the study NMRA Inspector's guide to GMP Assessment.

The relevant sections of the applicable NMRA GMP guidelines and regulations where observed violations are of regulatory significance are cited in the report.
The recommendations of the team are based on the audit findings on the inspected site with a clear statement on the status of the auditee's operations. The inspection report is compiled, endorsed by the inspection team, and forwarded to the divisional head or state manager for review within ten workdays of completion of the facility audit (NMRA, 2019.).Upon conclusion that the report complied with standard practice, it is further processed for issuance of marketing authorization where the inspected facility GMP outcome was found satisfactory. Otherwise, NMRA will provide guidance and timeline for the regulated entity to develop a plan to effect corrective actions and revert to the Agency for necessary review (Bablani & Manthan, 2019).

Characteristics of GMP Inspection Report

The characteristics of an inspection report include aspects such as the importance and correctness of the information it contains, the reliability of its arguments, its legibility, and the relevance of the matters it covers. Such features are mostly covered in inspection reporting standards like (WHO, Quality Systems Requirements for National Good Manufacturing Practice Inspectorates, 2002). Detailed description from another guideline shows that report template should comprise a title that aid the reader easily understand its contents. It must visibly spell out the objective and scope of the assessment task to establish its purpose and limits. The inspection processes that were carried out should be well articulated, the evidence collected, and the analysis undertaken. The report should also be dated to provide a timeframe and context to the reader about the observations made during the exercise. Other useful "reader aids" to be included in the report are a list of report rubrics, a keyword index, a glossary (an alphabetical list explaining terms and abbreviations used in the report (PASAL, 2020). Once these actions are accomplished, report's sharing with concerned parties should not be a challenge to the inspectorate. In the instance of this research, the report structure was categorized into two key features namely the coverage attribute and the practice attribute of an inspection report.

Coverage attributes – Those attributes of inspection report that bordered mainly on the reporting template, findings made during audit and the objectivity of evidence that described those findings. The attributes include.

a. Use of the right inspection report format.
b. Demonstration of good knowledge of report technical content (Quality Management System (QMS) and site) or elements of good manufacturing practice,
c. Provision of objective evidence for Inspectional observations.
d. Use of third person narrative past tense (WHO, 2016)

Practice Attributes – Convergence of practices that; determine the strength of the report, provide information on the compliance status of the auditee,

and finally qualify the outcome of the inspection. The attributes are.

e. Risk-based classification of GMP deficiencies.
f. Reference of deficiencies to applicable sections of the guidelines, laws and regulations administered by the NMRA and other relevant bodies.
g. Signing off on an inspection report by members of inspection team.
h. Writing and submission of the report in a timely manner (Gutting, 2013). (Please Appendix 2 and 5 for details on assessment rubrics for GMP inspection report)

Implication of the Study

The study was relevant because, facts and findings gathered will built on the limited data available on inspectors' competence, in the act of writing GMP inspection report. The research findings on various inspection teams writing competency would help the agency address issues of low expertise among her regulators. Facts obtained from the study could be used as baseline for future review of inspector's report writing abilities within the organization. The study may serve as a guide to other regulatory authorities (FDA and non-FDA) on how to assess the capabilities of their regulators in inspection report writing. Observations made may be of relevance to study NMRA regional offices because it would help to instill uniformity in their report writing abilities. Other possible gains in the study include reduction in the number of report review cycles, reduced burden for experienced lead inspectors, removal of bottlenecks in administrative functions that relate to issuance of marketing authorization. Potential barriers murky reporting will create against study NMRA effort to partner with other national competent authorities on reliance initiative would be averted. The investigation may assist other NRAs to reduce the number of report queries they received from auditees The goal of safeguarding public health which ensure that auditees comply with good manufacturing practice and assure consumers' access to quality, safe and efficacious medicinal products would be achieved (Daniel , 2011).

Definition of Terms and Concepts

Current Good Manufacturing Practices (cGMP), GMP is also sometimes referred to as "**cGMP**". The "c" stands for "current," reminding manufacturers that they must employ technologies and systems which are up to date to comply with required quality approach to manufacturing (ISPE, 2021). As a result, strict adherence to relevant requirements, appropriate to their intended use and as required by the marketing authorization, clinical trial studies or product specification is important.(WHO 2007).

Pharmaceutical Inspection: It is an aspect of universal drug quality assurance system which aimed at enforcing Good Manufacturing Practice (GMP) compliance or providing license for the manufacture of pharmaceutical products. This focuses mainly on request made by applicants of drug product registration for marketing authorization (WHO, Provisional Guidelines on the Inspection of Pharmaceutical Manufacturers. , 1992).

Inspection report In GMP Context: is a documentary evidence used to provide accurate and unbiased information on activities carried out. Findings made whether compliant statement or not for each inspected area. Both of which are made known to the company during the close out meetings and a conclusion that was reached at the time the report was written (WHO, Guidance on Good Manufacturing Practices: Inspection Report. , 2016).

Report writing in GMP context is the type of writing where inspectors of an audited facility are writing and compiling the facts of inspection observations in a simple manner using standard GMP report format with their conclusion at the end of the report and signature of the inspector (ASEAN, 2017)**.**

Inspectors in GMP context is a staff of a National Regulatory Authority whose principal duty is to present a comprehensive and accurate information on standards of production activities, and control steps relevant for the manufacture of any product. The inspector advises on ways to improve the in-process test procedure, or any other regulatory service which in his or her own view promotes the quality, safety, and efficacy of pharmaceutical products. (WHO, Provisional Guidelines on the Inspection of Pharmaceutical Manufacturers. , 1992).

An inspectional observation: is a finding or remarks made during an inspection and authenticated by objective evidence (WHO, Guidance on Good Manufacturing Practices: Inspection Report. , 2016).

Regulatory System: Regulatory System means a framework of legal provisions on Good Manufacturing Practices, inspections, and enforcements that safeguard the public health and provide the authority to assure compliance with its requirements (Day, 2017)

Competent Inspection team: A team of inspectors with requisite educational background, auditing expertise and experience in regulatory mandate that is required for successful accomplishment of assigned inspection duty. (World Health Organization 2019).

Regulatory Convergence and Harmonization was described as joint activities that was based on reliance and collaboration by various NMRAs to develop acceptable documentation that supports to a large extent common approach to regulatory issues among themselves. (Ball et al, April 2016)

2. METHODS

Design and Setting

In undertaking this study, we used purposive sampling technique to collect (25) paper based GMP inspection reports which comprised (13) pre-registration Inspection reports and ten (12) GMP reassessment reports for a period of one year and nine months, starting from March 2017 through December, 2018 (Conroy, 2010)**.**

Data Collection

Retrospective data were collected from paper -based inspection reports available on NMRA's drug inspectorate database. The activity took place from 8th December 2018 to 15th February 2020 which depicted a two or more days collection interval for a single report. Review of these reports was accomplished using tools like NMRA drug Inspectorate inspection format, NMRA drug Inspectorate SOP for inspection report writing, NMRA drug Inspectorate guidelines and regulations on GMP Inspection, the drug inspectors' handbook, the national drug inspectorate nominal roll, PIC/S inspection report format and WHO TRS No. 996 2016, Annex 4 guidance on GMP inspection report writing.
The data were segregated and analyzed based on the following variables which are.

a. Information on demographic data of lead inspectors of the twenty-five inspection teams.
    a. Educational qualification
    b. Field of study
    c. Years of cognate experience as inspectors
b. Quality characteristics of the inspection reports
    Coverage attributes
    a. Format
    b. Technical content (QMS and Site)
    c. Objective Evidence for non-compliance statement
    d. Use of third person narrative past tense.
    Practice attributes
    a. Risk-based classification of GMP deficiencies.
    b. Reference of deficiencies to right applicable laws, regulations and GMP text
    c. Signing off on a report by members of inspection team.

    d Timely submission of inspection reports
c. Competence of the inspectors
    a. Knowledge competence
    b. Skill competence
    c. Attitude competence

Data Collation

The collected data was transcribed using the following steps.

Scoring System for data obtained from Inspection report.

The scoring pattern or marking guide for observation made in a particular section of inspected facility, involved upward and sequential validation of each rubric. {*the components or the sub-components or criteria*} by use of assessment criteria stated in Figure 4. Using this approach, the rubric of interest was described as "available in the facility" or "not available in the facility" or "not captured at all in the report". The number of rubrics involved in a particular depth of report evaluation directly reflect the strength of evidence inspectors used to support observations they made in a specific GMP system or sub-system.

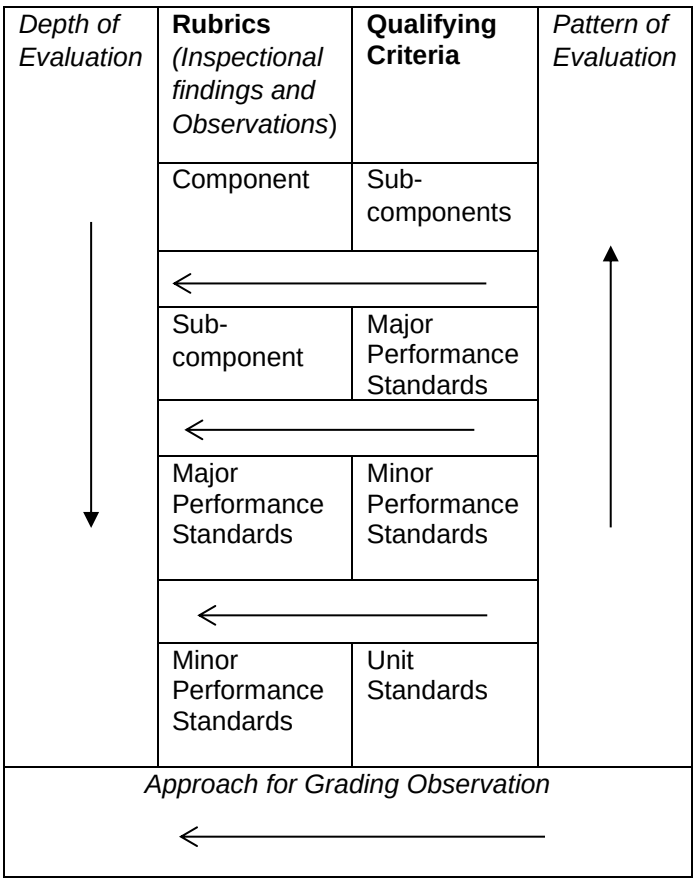

Figure 4

Pattern of Assessment and Grading of Inspectional Observations

The approach used in grading observations made by inspection teams is listed as follows,

Approach to Scoring Components of Inspection Report Attributes

The inspection report quality attributes components (format, technical content, objective evidence and use of third person narrative past tense) were scored based on a quality score range of ***zero (no correct answer) to maximum score of one (1.)*** The report component score was derived from the average sum up of all the sub-components quality scores that feed into a particular component of interest.

Approach to Scoring Sub-Components of Inspection Report Attributes

Here, the score range for a sub-component was also rated from ***zero (no correct answer) to maximum. score of one (1).*** The sub-component score was derived from average of sum up of major performance standards that validate or feed into sub-component of the report. The criteria used to score a report sub-component is captured in table 1 and listed as follows,

a. The sub-component that was ***not captured in the report*** and the inspection team is unaware of major performance standards that feed into it, will score zero (0). This is because it showed the inability of the team to identify the absence of the sub-component of a GMP system and the team's failure to report such uncovered area.
b. The sub-component that was ***captured in the report as not available*** in the facility, but the team talk about ***all*** (**not *some of)*** major performance standards that feed into the rubrics will score one (1). This is because it showed the ability of the inspectors to identify a gap that need to be corrected in the facility's GMP system.
c. Sub-component that was captured in the report as ***"Not Inspected"*** and the inspection team gives acceptable reason in writing for such action will score = 1. This is because the inspection team revealed an unresolved compliance issue, which the team for next inspection visit need to address during the exercise.
   Caution: Such action would be captured in the lead inspector's performance record for future reference if need be.
d. The sub-component that was ***captured in the report as available (****only as a sub-heading in the report without expounding its status****)***, but the team cannot identify ***any*** of the major performance standards will score zero (0). This is because the inspectors were not able to demonstrate knowledge of such important validation tools.
e. The sub-component that was not ***captured in the report as present***, but the team identify ***all*** the supporting major performance standards will scored one (1). This is because the Inspection team demonstrated their capability to identify a gap that need to be corrected in the facility's GMP system.

The same principle applies as the depth of evaluation goes down to assessment of the major performance standards, minor performance standards and unit standards as captured in Figure 4.

Table 1

Method of Scoring Quality Attributes of Inspection Report

S/N	Status of Quality Attributes	Knowledge of Qualifying Criteria that Feed the Attributes	Score
1	Not captured in the report	None	0
2	Captured in the Report	Good	1
3	Captured in the report as "Not Inspected"	Good	1
4	Capture in the Report as only heading or sub-heading	None	0
5	Not Capture in the Report	Good	1

Appropriateness of Inspection Reports

Since there is wide variability in audiences that view the inspection report, the tone of the report must be tactful, objective, and constructive. It must be clearly written with adequate description of all features of an inspection report. Some readers may want to know the technical matters as well as the exact regulatory citations and language. Others may be interested in a "broader" picture of the inspection to note trends. Regulatory agencies need to know precise details regarding violations noted and evidence obtained during the inspection. To achieve this, a great deal of appropriateness in the design and construction of the report is needed to paint complete picture of what transpired during the inspection task. In that wise, the research used the steps mentioned below to assess the extent each report complied to standards of inspection report writing practice.

a. Identification of all the report quality attributes, their components, sub-components, and other report's rubrics.
b. Risk-based classification of GMP deficiencies observed during an inspection visit was captured or not captured in the report.
c. Development of grading criteria for report quality attributes, their components, sub-components, and other assessment rubrics
d. Application of order of importance factor (OOI) to report components to reflect the relevance of each component and its impact on appropriateness of the report.
e. Calculation of each report's score through cross-multiplication of average of the sum of values of components that made up the coverage attribute with those of the practice attributes with the use of a risk matrix table.
f. Data generated was classified on the scale range of {0-3}, {4-6}, {7-9} and {10-12} to differentiate the reports into categories of; unacceptable, needs improvement, good, and excellent reports.

Impact of Intervention Program on Inspectors' Report Writing Effectiveness

The impact of intervention program was evaluated by comparing the reports that were written before and after the intervention program by external GMP trainers in the study organization. The method involved selecting two sets of twelve reports that were written before and after the intervention program which took place in a period of three days from 7-9 November 2018. A two-dimensional approach that involved; (a) investigating each team performance on different report quality attribute and (b) exploring various teams' performance on each quality attribute element was used. Five different numeric scale range were developed and use to assess program's effect on inspection teams' writing effectiveness as shown table 2A and 2B. These assessment tools include first a performance level descriptor that defined inspection team writing proficiency into four categories (Sender, 2015). The second tool was a four-point Likert scale that show the numerical change in the number of report components that occur at four performance levels of inspection team. The third one is also a four-point Likert scale the defined the change in number of teams at different performance levels during assessment of a particular quality attribute. The remaining tools are the impact factor ranking scale and the impact scale which were used in conjunction with other tools to generate program impact score on each inspection team.

Table 2A

Program Impact Evaluation Tools

Teams' Performance Level Descriptors		
S/N	Performance Level	Scale Score
1	Very under normal	0-25%
2	Under normal	26-50%
3	Normal	51-75%
4	Above normal	>75%
Change in Number of Team(s)		
S/N	Change in Number of Teams at Various Performance Levels	Scale Score
1	Insignificant change	1-3
2	Slight change	4-6
3	Significant change	7-9
4	Substantial change	10-12
Change in Number of Report Component(s)		
S/N	Change in Number of Components at Various Performance Levels	Scale Score
1	Insignificant change	1-2
2	Slight change	3-4
3	Significant change	5-6
4	Substantial change	7-8

Impact on Various Inspection Teams' Performance on each Quality Attribute Element

This pattern of evaluation involved examining how the various teams performed on a particular subcomponents/component of an inspection report. Changes were observed in the number of team(s) at different performance levels after the program. The change occurred as either an increase or a decrease in the number of team(s) at the four levels of performance used to assess each team's knowledge of a particular subcomponents/component. An increase in the number of teams on any performance level except very under normal, signifies the program made positive impact in relation to concerned quality attribute element under review. A decrease showed the opposite. No change in number of teams on a particular performance level signified no impact on concerned quality attribute element.

Impact on each Inspection Team Performance on various Report Quality Attribute

This approach involved reviewing the change in number of quality attribute elements at each performance level of an inspection team. In this case, investigation into changes in the number sub-components of technical content (the seventeen elements of GMP) at the four performance levels was carried out first. Then, the results generated from these changes were used to calculate changes in number of the report's components at the four performance levels. The change in the number of individual components were used to show how many components existed at the four performance levels after the training effort, and each team's performance rating on a particular component.

Moreover, a quadrant matrix of components' performance levels in each team's inspection report as column title and change in number of report components as row title was developed. (Please see Appendix entitled "Program Impact Analysis Matrix on Team's Ability to explain Status of Report Components"). The impact of the program on each team's descriptive ability on report components was assessed by relating changes in number of report components (increase or decrease) to components' performance level(s) in each team's inspection report. An increase in the number of components at above normal level of performance indicate that the concerned team possess best possible descriptive potentials over a wider coverage of report components. But in a situation where they skewed towards very under-normal level of performance, the reverse is the case. In any quadrant where change in number of components overlaps a performance level, that area defines the nature of impact on inspection team writing effectiveness. The formular used to compute the program's impact on overall performance of each team is described as follows. The values of change in number of report component at four performance levels were multiplied exclusively with their impact factor values. Then, individually

divided by the total number of performance levels and ultimately sum up to give program's impact score on each inspection team. The result obtained was measured on the impact scale to interpret the nature of impact the program had on the team's overall performance. See Appendix 8 for detailed result on Impact Score Calculation for each Inspection team.

Table 2B

Program Impact Evaluation Tools

Impact Factor Ranking		
S/N	Performance Level	Impact factor
1	Very under normal	1
2	Under normal	2
3	Normal	3
4	Above normal	4
Impact Scale		
S/N	Nature of Impact	Scale Score
1	Strong Impact	7.00-8.00
2	Moderate Impact	5.00-6.00
3	Weak Impact	3.00-4.00
4	No Impact	1.00-2.00

A Comparative Study of Reports' Compliance with International Standards and Regulatory Guideline on GMP Inspection Report Writing

Here, the assessment of each report compliance level with the requirements of the three regulatory standards for inspection report writing was carried out. The basic underlying principle in this analysis focused on content variation of quality attribute elements in the three guidance documents. **T**he difference in contents of report format and the submission timeline in the three documents served as the main indicator assessment tool for measuring each report level of compliance. The varying format sub-components include *introduction, scope of inspection*, *key personnel met during inspection, inspection findings and observations made, and product sample taken during inspection.* For submission timeline of an inspection report, ten calendar days was set aside by the study NMRA while the other two r organizations have theirs as thirty calendar days. The first step of data analysis process involved the calculation of compliance percentage of all the quality attributes elements. This include the compliance percentage of quality attribute elements that are content wise the same, and those that are content wise different in the three guidance documents. A scale score of 0 – 25 as very low, 26-50 as low, 51-75 for moderate and > 75 for high compliance was subsequently developed. The grading scale was used to measure the compliance percentage of each quality attribute element. (Inclusive of format subcomponents and submission timelines) with the requirements of the three standards. The relevance of each report component and their individual impact on report appropriateness was calculated by application of order of importance factor or weight factor (OOI). Then data gained from the later was multiplied with the compliance percentage of each report component to generate compliance score of each inspection report. Each report compliance score was rated on compliance Likert scale of {0-2}, {3-5}, {6-8} and {9-11} and used to determine their compliance levels.

Evaluation of the Lead Inspector's Competence

Following the general opinion that fresh inspectors cannot easily assess pharmaceutical GMP, the research assumed that the performance of an inspection team strictly lies on the proficiency of the team lead. This is because there is reasonable belief that he is experienced in conformity determination. He is a guidance counsellor on regulatory and organizational requirements that promote product quality. He supervises team of regulatory inspectors. Thus, a failure on his part, would have an overwhelming effect on the team's performance during inspection. In this instance, the research sought to know the impact of intervention program conducted by external GMP trainers on the proficiency of lead inspectors of twelve inspection teams selected from the study NMRA. The method of investigation used key three indicators namely,

Knowledge competence
This was defined as lead inspectors' knowledge of accepted report format, technical content (QMS and site) of the report, the use of objective evidence to substantiate observations made during inspection and the use of third person narrative past tense in their report.

Skill competence
This speaks to lead Inspectors' ability to assign risk level to GMP observations Next is their expertise to cite applicable laws or GMP text that substantiate observed violations.

Attitude competence
This points at the ability of the team lead to ensure the report is properly written, endorsed, and submitted within timeframe as stipulated by the study NMRA inspector's guide. The difference in values of lead inspectors' knowledge, skill, and attitude competence before and after intervention program was used to compute changes in their abilities to write effective report. A score range of one as maximum value (ideal value) and any value from 0 – 1 for current values was used as grading criteria for lead inspector's competence. This was further illustrated by use of a four-point bi-polar Likert scale captured in table 3. Competence score was computed by adding up the values of knowledge, skill and attitude competences and divide it by sum up of all report components' assigned weights.

Table 3

Scale Score for Inspectors' Competence

S/N	Likert Scale	Competence level
1	0.00-0.25	Novice or never meet expectation
2	0.26-0.50	Advanced beginner or far below expectation
3	0.51-0.75	Partly competent or near expectation
4	0.76 – 1.00	Competent or meet expectation

Gap Analysis of Inspection teams' Report Writing Ability

The study involved definition and comparative analysis of gaps in the inspection team's ability to describe observations made during inspection. The different teams' performance gaps were assessed and categorized based on their expertise in reporting the status of various technical components and subcomponent of a GMP system. Steps taken to accomplish the task is listed as follows.

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- Establishing a benchmark of not less than 75% as minimum score that depicts proficient performance of an inspection team. This was derived from cut score of not less than 75% which stood as proficiency grade in the study NMRA procedure on writing inspection report.
- Finding the key components of the report which are technical content, objective evidence, risk-based classification of deficiencies, reference of violations to the right GMP text etc.
- Establishment of the competence gap levels.
- Lastly, identification of gaps displayed by the various teams in the act of drafting their inspection reports. (Han van loon, 2004) (Please see table 4 for detailed information)

The different levels of competence gap exhibited by inspection teams in the act of writing inspection report were defined as follows:
Substantial gap: When more than 75% of the total inspection teams score less than 75% for any parameter of the report. The gap associated with the teams' performance is termed substantial gap.

Significant gap: When between 51% to 75% of inspection teams, score less than 75% for any quality attributes of the report. The gap associated with the teams' competencies is termed significant gap.

Slight gap: When between 26% to 50% of inspection teams, score less than 75%. The gap is termed Slight gap.

Insignificant gap: When between 0% to 25% of the total number of inspection teams, score less than 75%. The gap is termed Insignificant gap.

Table 4

Definition of Inspection Teams' Performance Gap

S/N	Performance rating of each Inspection team	Number of Teams	Performance Gap
1	>75% of total number of teams scored < 75% tor any quality attribute or sub-component.	>18	Substantial gap
2	Between 51% to 75% of total number of teams scored < 75% for any quality attribute or sub-component	13-18	Significant gap
3.	Between 26% to 50% of total number of the teams scored < 75% for any quality attribute or sub-component	6 -12	Slight gap
4.	Between 0% to 25% of total number of the teams scored < 75% for any quality attribute or sub-component	0 - 5	Insignificant gap

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Data Analysis

The collected data were entered and analyzed using SPSS software program frequency distribution tables. Chi-square tests were used to test association between categorized variables. The research used a sampling technique by which inference was drawn from values of analyzed sample and generalize to show proficiency of the Agency's inspector in the act of report writing.

Limitations of the study

The initial plan of using sample size of fifty inspection reports was not possible because of limited number of the types of inspection reports (pre-registration inspection report and GMP re-assessment inspection report) needed for the study. Consequently, the researcher resolved to use lesser sample size of twenty-five reports which was the quantity accessible on the inspectorate data base. The name of the organization was not disclosed due to its management policy (Birna et al, 2016). The study was not restricted to inspection report of a particular drug formulation report like oral solid dosage, oral liquid dosage, external preparations etc.

The research did not investigate the effectiveness of inspection teams' conclusive statement on audited facility GMP status. This statement was usually categorized as satisfactory, marginal, and unsatisfactory with granularity that provide information on whether the facility cGMP status is of high, medium, or low risk rating (TGA, 2016). The study did not investigate the establishment inspection reports based on actions taken because of observations. This implies categorizing the reports into *No Action Required, Needs Improvement and Official Action Required inspection* report. This is because such practice had not been initiated by the study NMRA as at the time of this research.

3. RESULTS AND DISCUSSION

The research was a retrospective study of twenty-five GMP inspection reports of a National Medicine Regulatory Authority somewhere in West Africa designed to assess the inspectors' proficiency in the act of inspection report writing.

Impact of Demographic Characteristics of Lead Inspectors on their Teams' Writing Effectiveness

In Appendix 1, the result indicated that of the twenty-five reports used in generation of research datasets, only one (4.0%) qualified as excellent report. Two (8.0%) were reported as good reports. Needs improvement reports and unacceptable reports were each eleven in number (44.0%). Of eleven (44.0%) unacceptable reports, seven (63.6%) were written by inspection teams whose team leads held bachelor's degree while the remaining four (36.4%) were drafted by teams whose lead inspectors possess MSc degree. The only team that had the lead inspector as

a PhD holder wrote a good report. None of the good reports was written by teams whose leaders were non-pharmacists. Rather, most non-pharmacist lead inspectors [3 of 4 (75%]] and their teams authored unacceptable reports. A review of lead inspectors' years of cognate experience, put the figure at five or more years. Hence, much expertise was anticipated in their ability to organize an effective report. But this was not so as most of the unacceptable reports [8 of 11(72.7%)] were written by teams whose lead inspectors had more than 15 years cognate experience. Only [1of 10 (10.0%)] lead inspectors with more than fifteen years of cognate experience wrote a good report with his team. As the remaining good report was drafted by a team whose lead inspectors' year of cognate experience, did not exceed ten years. (Please refer to Appendix 1)

Appropriateness of the Reports

a. Excellent Report

Coverage Status

The excellent report [1 of 25(4.0%)] (Report number 12) had a format that meet expectation. Review of the report show that the inspection team had excellent knowledge of the technical content. The writers of the excellent report demonstrated partial mastery in the use of objective evidence. The team also displayed good use of third person narrative past tense in their act of writing inspection report.

Practice Status

Analysis of the practice aspect of inspection report writing, shows that the authors of excellent report correctly assigned risk level to more than 75% of GMP deficiencies they saw during the inspection visit. Further review revealed that more than 75% of these deficiencies were appropriately alluded to the right GMP text. The excellent report was signed off by all members of the inspection team. Nevertheless, the report was not submitted in a timely manner.

b. Good Reports

Coverage status

All the good reports [2 of 25 (8.0%)], (Report number 17 and 25) had format that meet expectation. Findings in one of the two (50.0%) good reports showed the authors had excellent knowledge of the technical content. All the same, the authors of the remaining good report (50.0%) possess just good knowledge of it. One of the two teams (50.0%) that wrote good reports displayed partial mastery in the use of objective evidence. As the remaining one (50.0%) showed emerging mastery in its use. One of the two teams (50.0%) that drafted the good reports demonstrated good use of third person narrative past tense while the team that authored the remaining good report (50.0%) made excellent use of third person narrative past tense.

Practice Status

The two good reports demonstrated adequate assignment of risk levels to violations in the range of 51- 75%. In terms of referring observed violations to the right GMP text, One of the two good reports had 51- 75% of observed deficiencies adequately tied to the right regulatory text. The remaining good report had between 26-50% of the violations alluded to the applicable guidelines or regulations. Under signing off on an inspection report, one of the good reports was endorsed by all members of the inspection teams while the other one was not authorized. Lastly, the practice component of timely submission of report, revealed that only one (50.0%) of the two good reports (Report number 25) was submitted within the approved timeline.

c. Needs Improvement Reports

Coverage Status

Data analysis revealed that all needs improvement reports [11 of 25(44.0%) inspection reports], (Report number 7, 8, 9, 15, 16, 18, 19, 21, 22, 23 and 24) had format that meet expectation. Five of the eleven (45.5%) teams that wrote the needs improvement reports had good knowledge of the technical content as the teams that wrote the other six (54.5%) needs improvement reports had fair knowledge of the component. Two of the eleven (18.8%) teams that authored needs improvement reports demonstrated partial mastery in the use of objective evidence. Six of the eleven (54.5%) teams displayed emerging mastery while the remaining three (27.7%) showed no mastery in the use of objective evidence. Still on needs improvement reports, four of the eleven (36.4%) teams confirmed good use of third person narrative past tense, 6 of the eleven (54.5%) teams needs practice even as the remaining one (9.1%) made no use of it.

Practice Status

Eight of the eleven (72.7%) needs improvement reports, had adequate risk-based classification of more than 75% of GMP violations observed during inspection. Two of the eleven (18.2%) needs improvement reports had adequately classified deficiencies in the range of 51-75%. For the remaining report, the scale range of adequately classified violations lied between 0-25% of the total number of deficiencies. Four of the eleven (36.4%) needs improvement reports had more than 75% of observed deficiencies adequately referred to the right regulatory citation, Three out of eleven (27.3%) needs improvement reports had between 51-75% of their individual deficiencies properly cited. The remaining 4(36.4%) needs improvement reports had between 26-50% of the observed deficiencies properly referenced to the right regulatory standard. Eight of the eleven (72.7%) needs improvement reports were signed off by all members of the inspection team, 1(9.1%) of needs improvement reports was not signed off by all members of the team and remaining 2(18.2%) were not signed off at all. Lastly, all but two of the eleven (18.2%) needs improvement reports were not submitted in a timely manner.

d. Unacceptable Reports

Coverage Status

Eleven [11 of 25 (44.0%) Inspection reports] unacceptable reports (Report number 1, 2, 3, 4, 5, 6, 10, 11, 13, 14, and 20) had format that meet expectation. For other coverage components, only one of the eleven (9.1%) teams that authored unacceptable reports demonstrated excellent knowledge of the technical content. Five of the eleven (18.2%) teams possessed fair knowledge and poor knowledge of technical content was associated with the remaining eight (72.2%) teams that authored unacceptable reports. One of the eleven (9.1%) unacceptable reports confirmed that the authors had partial mastery in the use of objective evidence while the other ten (90.9%) teams had no mastery in the use of the component. Out of the eleven teams that wrote unacceptable reports, two (8.2%) made good use of third person narrative past tense. One (9.1%) needs practice, and the remaining eight (72,7%) teams made no use of it.

Practice Status

Outcome of eleven unacceptable reports revealed that two (18.2%) had adequate risk-based classification of more than 75% of observed GMP violations. One of the eleven (9.1%) unacceptable reports had correct assignment of risk level to an observation in the range of 51-75%. Another report had its own in the range of 26-50%. The remaining seven (63.6%) unacceptable reports revealed proper assignment of risk levels in the range of 0-25%. On issue of citing appropriate regulatory text, one of the eleven (9.1%) unacceptable reports had between 26-50% of observed deficiencies properly alluded to the right GMP text. Remaining ten (90.9%) unacceptable reports revealed that 0-25% of the GMP deficiencies was adequately referenced to right GMP text. Most unacceptable reports [9 of 11(81.8%)] were signed off by all the members of inspection team. One (9.1%) unacceptable report was not signed off by all members of the team just as the remaining one (9.1%) was not signed off at all. Four of the eleven (36.4%) unacceptable reports were submitted in a timely manner whereas the remaining seven (63.6%) were not received within the approved timeline. See Appendix 3 entitled as “Data on Quality Characteristics of Inspection reports.

Conclusively, among the twenty-five inspection reports that were selected for the study, one qualified as an excellent report, two (12%) were categorized as good reports. Needs Improvement reports were eleven (44%) in number, and the remaining eleven (44%) were unacceptable reports. (See Appendix 4 and Figure 5 for study NMRA Inspection Reports’ Classification and their Scores). Team 12 made the best performance in the act of writing inspection report in that they scored not less than 75% in four key components of inspection report. These components were technical content, third person narrative past tense, reference to right GMP text and signing off on a report by members of inspection team). The same result was recorded in seven of the seventeen (41%) sub-components of the technical content. On the contrary, the team’s weak point was in the practice of late submission of report which has the risk of causing delay in marketing authorization issue. Team 12 was followed by team number 25 and 17 which earned the second and the third place with the data measured during the study.

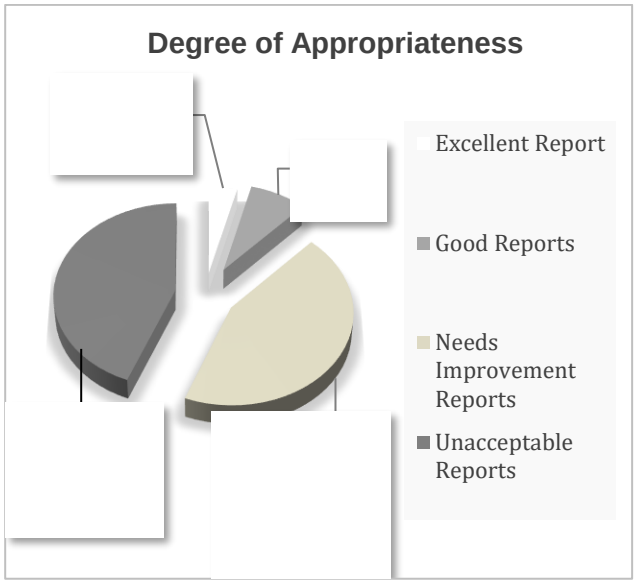

Figure 5

Summary on Inspection Teams Performance in relation to Appropriateness of the Reports

The report authored by team 11 was found to be the most unacceptable report. This is because it had a score of less than 25% in fifteen of the seventeen (88%) technical content sub-components. Also, the report scored less than 25% in other coverage attributes except in inspection report format. Lastly, team 11 report had less than 25% in each of the three components of report practice attributes except for signing off on an inspection report by members of inspection team. This was preceded by team 13 and 5 reports.

Impact of Intervention Program on Inspectors' Report Writing Effectiveness

Impact on Various Inspection Teams' Performance on each Quality Attribute Element

The analysis obtained from assessing impact of training program on inspectors' writing proficiency showed an increase in the number of teams performing at above normal level of performance. The increase was clearly observed from the difference in the values of report components like technical content {1of 12(8.3%)}, third person narrative past tense {1of 12(8.3%)}, risk-based classification of GMP deficiencies {3 of 12 (25%)}, Reference of deficiencies to applicable laws, guidelines etc., {3 of 12(25%)} and timely submission of report {1 of 12(8.3%) before and after the intervention program. A decrease in the number of teams by (16.7%) was noticeable on behalf of signing off on an inspection report, component. Besides, no change in number of teams was seen from the values of format component and the use of objective evidence component. Program impact on various teams' performance at very under normal level, showed a decrease in number of teams for values of all report components except format and timely submission of inspection report. More detailed description of how the various teams described the status of inspected facilities was captured in partly in Figure 6 and fully in Appendix 6, 7 and 8 as follows.

Technical content:
Inspectors' writing effectiveness of report technical content showed a significant change in the number of teams exhibiting very under normal level of performance. This was evident by the decrease in the number of teams on this level of performance from a figure of {8 of 12(66.7%)} before the capacity building program, to a value of {0 of 12(0.0%)} after the program. Also, an Insignificant change, and a slight change were observed in two group of teams displaying above normal and normal levels of performance. These changes manifested as an increase in the number of teams from values of {1of 12 (8.3%)} and {1of 12 (8.3%)} before the program, to {2 of 12(16.7%)} and {(5 of 12(41.7%) after the program. Teams exhibiting under normal level of performance on technical content witnessed an insignificant increase by {3 of 12(25%)} teams.

Among the seventeen elements of cGMP, pharmaceutical quality system, material management system, premises and documentation and procedure were identified as subcomponents of technical content, with slight change in the number of teams performing at above-normal level. Over this, the change was recognized as an increase from values of {2(16.7%)}, {2(16.7%)}, {1(8.3%)} and {1(8.3%)} before the program to {8(66.7%)}, {8(66.7%)}, {5(41.7%)}, and {5(41.7%)} after the training program. Insignificant changes in the number of teams exhibiting above-normal level of performance were noticeable in all other technical content subcomponents except for training, sanitation/personal hygiene, and good practice in quality control subcomponents. No change in the number of teams was witnessed among these subcomponents. At normal level of performance, the highest change in the number of teams played out in good practice in production (prevent contamination)

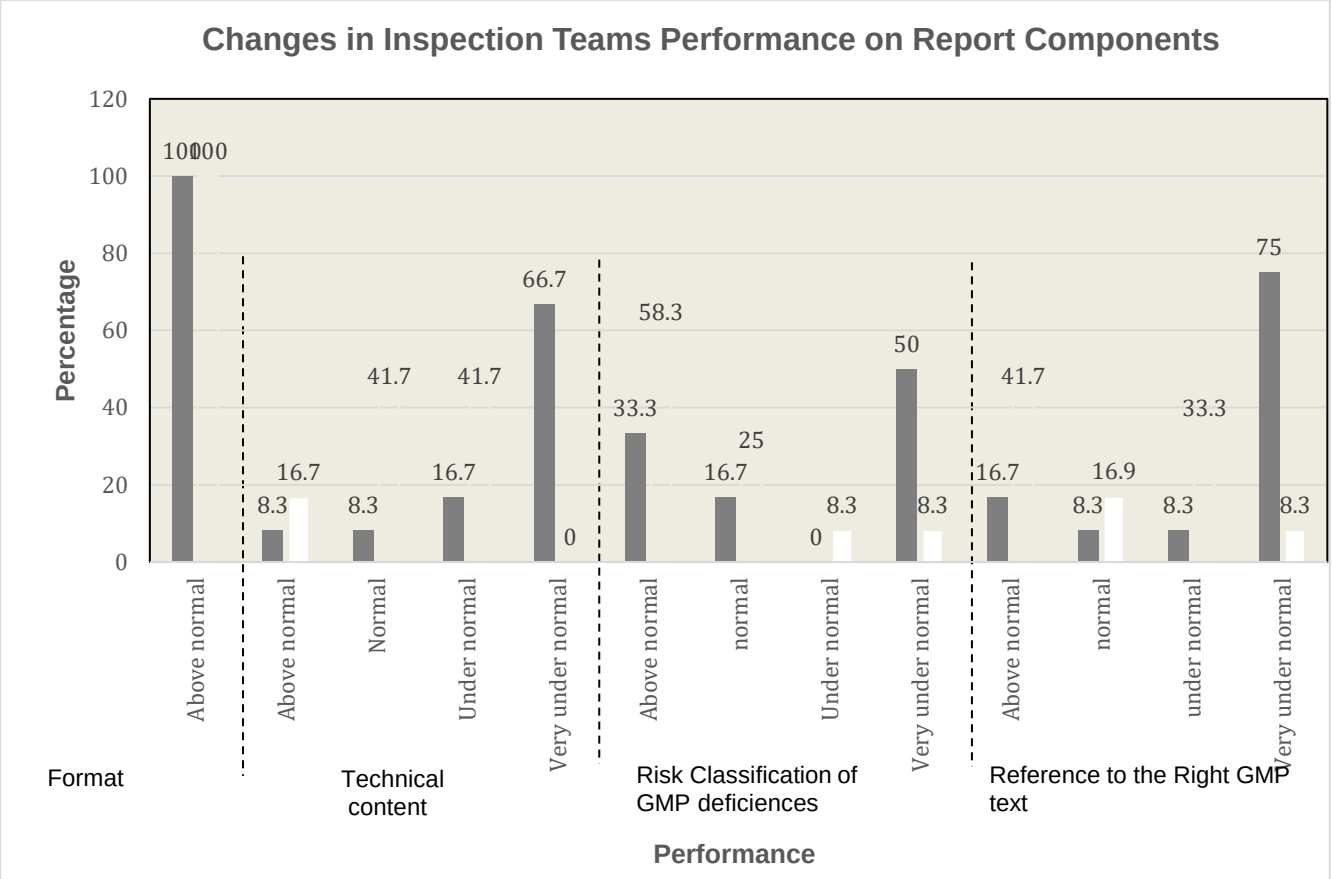

Figure 6

Sum changes of Inspectors' writing performance with respect to the various components of inspection report before and after the capacity building program

component. Last of all, decrease in number of teams on above-normal level of performance after the intervention program was associated with equipment component.

Objective Evidence

On behalf of this component, there was an insignificant increase in the number of teams at normal level of performance from a figure of {2 of 12(16.7%)} prior to the program to a value of {3 of 12(25.0%)} after the exercise. At above-normal level of performance, no change was observed before and after the program in the number of teams that used objective evidence in their report. Lastly, data available for under normal level of performance revealed a slight increase from a figure of {1 of 12(8.3%)} before the training activity to {5 of 12(41.7%)} after the exercise.

Third Person Narrative Past tense

An appraisal of this verb tense showed there was a significant decrease in the number of teams with very-under normal level of performance in the use of third person narrative past tense. This change was confirmed by a shift in value from {8 of 12(66.7%)}, prior to the intervention effort to {1 of 12(8.3%)}, after the activity. At above normal and normal levels of performance, an insignificant increase of 1(8.3%) and 2(16.7%) was equally observed in the teams' use of the right tense and voice. Lastly, data from under normal level of performance, showed a slight increase

of four (34.0%) after the training program.

Risk- Based Classification of GMP Deficiencies

The impact of the intervention program revealed an insignificant increase in number of teams properly assigning risk level to GMP violations. This was notable at above-normal, normal, and under-normal levels of performance where increase of not more than three (25.0%) teams occurred. Finally, a slight decrease was witnessed in the number of teams at under-normal level of performance from a value of 6(50.0%) prior to the training effort to one (8.3%) after the event.

Referring GMP Violations to the Right Regulatory Text

On issue of citing applicable laws, regulations and guidelines that substantiate observations made by inspectors, the number of teams at normal and under-normal levels of performance recorded a slight increase. This was proven by the change in value from two (16.7%) and zero (0.0%) before the program to five (41.7%) and 4 (33.3%) after the exercise. Moreover, improvement in the number of teams at normal level of performance recorded an insignificant increase of one (8.3%).

Signing Off on an Inspection Reports

A close look at signing off on an inspection report indicated a decrease in the number of teams at above normal and normal levels of performance. This was confirmed by the change in figures from nine (75.0%) and one (8.3%) prior to capacity building event to seven (58.3%) and 0(0.0%) after the exercise. Besides, no change in the number of teams performing at under-normal level of performance occurred. last of all, an increase in the number of teams at very under normal level moved from value of one (8.3%) before the training exercise to three (25%) after the coaching meeting.

Timely Submission of Inspection Reports

For this report component, there was an insignificant decrease in the number of teams that displayed very under normal level of performance. This downward trend was reflected in reduction from eight inspection teams (66.7%) in the pre-training phase to half (six) of the team (50.0%) in the post-training phase. This caused an increase at the above-normal level of performance though it was insignificant change {1(8.3%)} when compared with changes at other levels of performance.

Impact on each Inspection Team Performance

In this section, the impact analysis on inspection team's writing effectiveness were considered in two ways which are effect on components of each inspection report and overall effect on each inspection team performance.

Effect on each Inspection Team Performance on Report Quality Attribute Elements

The program impact at four levels of performance revealed that no substantial increase in the number of components was recorded at above-normal level by any of the twelve inspection teams. The strong impact felt by team four (T_4) at above-normal level of performance was occasioned by significant increase {5 of 8(62.5%)} in the components they effectively described during their report writing exercise.. Team twelve (T_{12}) recorded low impact in their writing abilities due to a slight-change {3 of 8(37.5%)} they experienced in the number of components at above-normal level of performance. Last of all, the program made no impact at above-normal performance levels of five teams which are team number three, five, six, nine and eleven (see Appendix 7 and 8)

Effect on each Inspection Team Overall Performance

The outcome of program impact evaluation on each inspection team writing effectiveness was not an outright success. This is because the impact felt by each inspection team was less than optimal. For instance, data on the best impact {Impact score ($I_{T)}$ = 6.25} the program produced, was recorded in two inspection teams. According to this result, it was quite clear that both teams (team four ($T_{4)}$ and team twelve ($T_{12)}$) experienced moderate impact in their writing ability. A weak impact on report writing effectiveness was evident in the performance of six other inspection teams which are; team (T_1), (T_5), ($T_{6)}$, (T_8), (T_9) and (T_{10}). Lastly, the training program had no impact on the

remaining four teams. (Please see Appendix 8 for more information).

A Comparative Study of Reports' Compliance with NMRA Guideline, WHO Model and PIC/S Requirements on GMP Inspection Report Writing

Components of inspection report like technical content, use of objective evidence, third person narrative past tense, risk-based classification of observed deficiencies and reference of violations to the applicable GMP text, which are content wise the same in the three guidance documents were not core indicators in the analysis of individual report's compliance. The reverse was the case for some report format subcomponents and submission timelines which are content wise different in the three guidance documents. Only those format sub-components (headings and sub-headings) which exhibit content variation in the

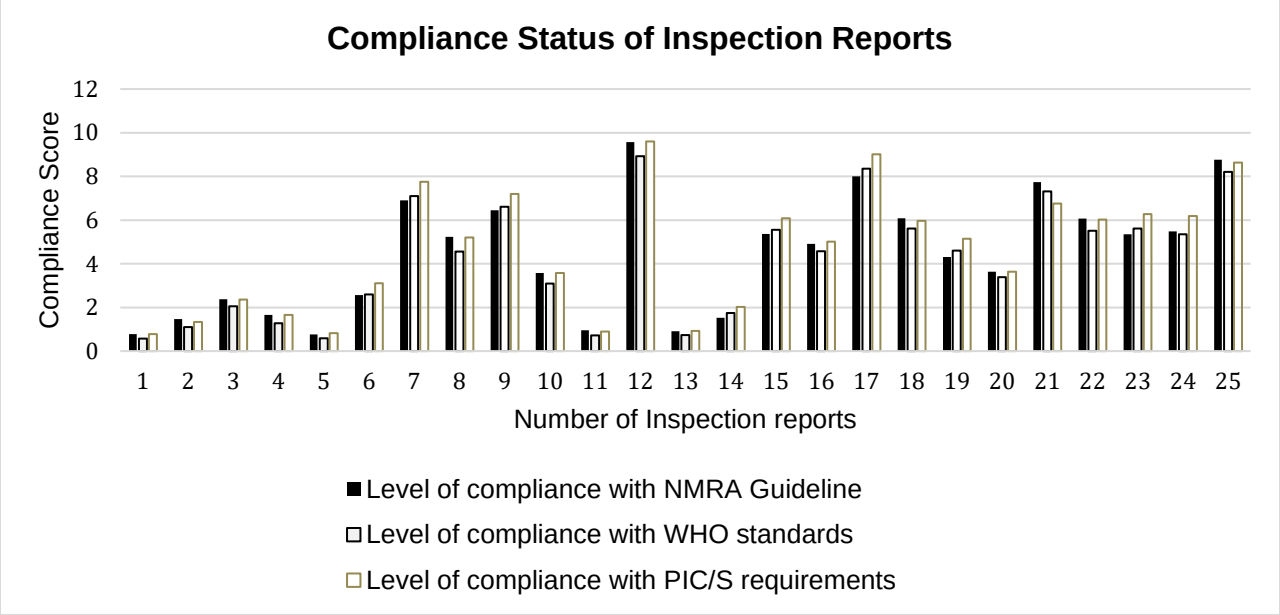

Figure 7

Comparative study of reports compliance level with NMRA guideline, WHO Model and PIC/S Requirement for Writing cGMP Inspection Report

three guidance documents and submission timelines, were used to assess each report's level of compliance. The five subcomponents and the submission timeline used in verifying this research goal are listed as follows.

Compliance Status of Quality Attribute Elements with the three Reference Standards

Determination of Percentage Compliance of Report Components that are Content Wise the Same in the Three Guidance Documents

The percentage compliance demonstrated by other report quality attribute elements except format subcomponents and submission timelines, were the same for the three reference standards. This is because unlike some format sub-components and submission timelines which showed content variation in the three guidance documents, these quality attributes elements remain content wise the same in the three regulatory standards.

Determination of Percentage Compliance of Report Components that are Content Wise Different in the Three Guidance Documents

Only those format subcomponents (headings and subheadings) which vary content wise across the three regulatory standards and the submission timelines were used during the study.

Format Subcomponents

Introduction

Of the twenty-five inspection reports, twenty-three (91%) showed high level of compliance to elements of introduction stipulated by study NMRA guideline on inspection report writing. Twenty-four (96.0%) reports had similar level of compliance with PIC/S perspective on what introductory part of GMP inspection report should. look like. Moderate level of compliance to WHO guidance on how to pen down introductory section were identified in twenty-one (84.0%) reports. Lastly, low compliance level to NMRA and WHO standards characterized the introductory section of report number. 18.

Scope and limitation of Inspection

High level of compliance with WHO requirement on *scope and limitation of inspection* was recorded in the content configuration of the twenty-five inspection reports captured it. Similar result was recorded in eighteen (72%) reports level of compliance with PIC/S position on what *scope and limitation of inspection should contain*. Finally, high level of adherence to NMRA opinion on should be the content of *scope and limitation of inspection* was confirmed in only seven (28%) inspection reports.

Key personnel met during Inspection.

In two separate instances, twenty-two (88.0%) reports showed high compliance levels with WHO and PIC/S requirements on *key personnel met during Inspection.* Similar level of compliance is apparent in the way the subcomponent was defined in twenty-five (100.0%) reports that conform to NMRA opinion. Report number 10 had very low compliance with the requirements of WHO and PIC/S guidelines on what should be the content of *key personnel met during inspection* in an inspection report.

Inspection team's findings and Observation

On separate occasions, twenty-one (84.0%) reports revealed high level of compliance with the three standards requirements on *inspection team's findings and observation*. The remaining four (16.0%) reports showed moderate level of compliance with all the three standards. Lastly, no report exhibited low compliance level with any of the reference standard need on Inspection team's findings and observation.

Product Sample taken during Inspection Task.

High level of compliance with the three reference standards of writing is obvious in twelve (48.0%) reports that comply to NMRA guideline. Similar result was recorded in thirteen (52.0%) reports that comply to WHO standard. Finally, thirteen (52.0%) reports that complied to PIC/S opinion on *product sample taken during inspection* showed a high level of compliance.

Submission timeline

The result analysis showed that fifteen (60%) reports independently showed high compliance level for WHO and PIC/S standards, Same compliance level was seen in only six (40%) reports' adherences to NMRA standard. In summary, the compliance percentage analysis of report format subcomponents and submission timelines, unveiled the following results. First, report number. 8 had the highest number of format subcomponents {(4 of 5(80.0%)} and submission timelines three (100.0%) that highly complied to the requirements of the three regulatory standards. This was followed by report number 14 and 19 which autonomously have three of the five (60.0%) format subcomponents and two of the three (66.6%)} submission timelines revealing high level of compliance to the reference standards' requirements. Report number 4 portrayed the least result with {(1 of 5(20,0%)} format subcomponent and three separate data on submission timeline that never complied to the requirements of the three reference standards. (Appendix 10. contains detail dataset on report components that are content wise different).

Compliance Status of each Inspection Report with the three Reference Standards

Compliance scale for scoring the different inspection reports showed that report number 12 displayed high level of compliance with NMRA and PIC/S requirements on inspection report writing. Report number 17 had high level of compliance with only the PIC/S model. None of the report showed high compliance with WHO requirement. Moreover, report number 1 and 5 had the lowest levels of compliance with the requirements of the three guidelines on inspection report writing. Lastly, only two reports had all round compliance with PIC/S requirements. One report had same with the NMRA standard and none recorded such with WHO Model (Please refer to figure 7 and Appendix 9).

Evaluation of Lead Inspectors' Competence

*Proficiency of Lead Inspectors after Intervention Program***.**

Knowledge Competence

Analysis showed that all the twelve (100%) lead inspectors were competent in the use of approved format. Two (16.7%) lead inspectors demonstrated competence in the act of drafting the technical aspect of the report. Five (41.7%) were partly competent in constructing technical section of the report, while the remaining three (25.0%) never meet expectation (novice). More in-depth analysis of the technical content), revealed that more than five lead inspectors (>41%) displayed competence in the way they assessed the companies' premises, pharmaceutical quality system (PQS) and material management system. In this case, eight (66.7%) lead inspectors meet expectation in their effort to describe the facilities' pharmaceutical quality system. Another eight (66.7%) achieved the same level of competence on material management system. Description of facility premises was carried out by five (41.7%) competent lead inspectors. Partial competence on production & process control and equipment subcomponents was visible in descriptive abilities of five (41.7%) lead inspectors. Basic understanding of sub-components like training and good practice in quality control were accomplished by another group of seven (58.3%) lead inspectors. In the end, ten (83.0%), eight (66.7%) and six (50%) lead alone never meet expectation on inspected companies' sanitation and hygiene, personnel hygiene, and complaint management. None of the lead inspectors meet expectation in their use of the objective evidence Rather, only three (25%) lead inspectors made effort to meet expectations (partly competent). Team No.25 had a team lead with the highest knowledge competence while the reverse was noticed with team No. 14 which had a gap value of 0.69. Only one (8.3%) lead inspector ensured a competent team that wrote their report in third person narrative past tense. Five (41.7%) lead inspectors were far below expectation in the use of the report component. Team 14 lead inspector was a complete novice in the use of the approved tense and voice.

Skill Competence

Here, seven (58.3%) lead inspectors demonstrated competence in risk-based classification of GMP deficiencies. On behalf of citing the right GMP text that substantiate observed deficiencies, only five (41.7%) lead inspectors meet expectation for the task. Overall, report number. 24 showed the least gap in skill competence with a gap value of 0.36. thereby making them team with the highest skill competence. The reverse was recorded with team 14 which displayed great deal of knowledge deficit (Ayu , 2009)

Attitude Competence

Careful review of this aspect of lead inspectors' competence disclosed that only team 19 and team 20 never meet expectation on signing off on an inspection report. Alike, ten (83%) lead inspectors never meet expectation on requirement for timely submission of report. In conclusion, the result of lead inspectors' assessment showed that after the intervention program, none of team leads progressed to the appropriate writing competency profile (>0.75). Eleven (91.6%) lead inspectors reached level of partial competence (0.51-0.75). Another lead inspector went on as advanced beginner (0,26-0.50). and not one remained a novice (0.00-0.25) after the training exercise

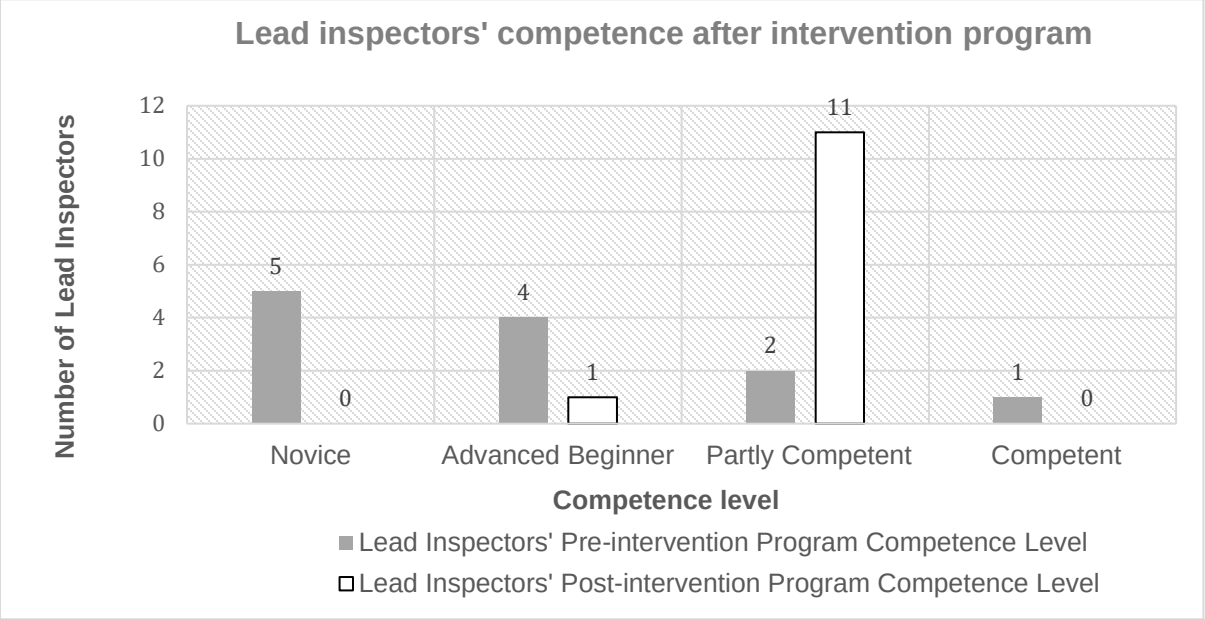

Figure 8

Sum changes of Inspectors 'writing competence before and after the capacity building program.

Overall, there were eleven partly competent inspection teams and one team at advanced beginner stage after training exercise. (Please refer to figure 8 and Appendix 11 for specifics).

Competence of Inspection teams' lead inspectors

Overall, the competence assessment of twenty-five inspection teams in Appendix 12, showed team 12 leader as the only lead inspector with appropriate writing competency profile. Fourteen (56.0%) lead inspectors were partly competent. Five (20.0%) displayed advanced beginners' skill. And the last five (20.0%) were novice team leads in the act of organizing effective GMP inspection report.

Performance Gaps in NMRA Inspection Report

Substantial Gap

Generally, there was a substantial gap in the way majority of the inspection teams described the technical aspect of facility GMP, the use of objective evidence to support statement of observation and the use of right tenses and voice in their report. This was so because more than 75% of Inspection teams (≥ 19) scored an equivalent value of 75% or less in an effort to air their view on quality status of the report technical content or construct report in required tenses and voice. (Please see appendix 13 for details).

Results in Figure 9 and Appendix 14 highlighted a substantial knowledge gap in almost all the teams' observations on fifteen (88.0%) elements of good manufacturing practice. These included sanitation/hygiene, complaint, product recall, contract production and analysis, self- inspection, training, personnel hygiene, quality control and good practice in production with six others. Sanitation/hygiene and training stood out as the sub-components (elements of GMP), all the inspection teams {25(100%)} displayed appropriate writing competency profile. The same result was recorded among 23(92.0%) teams in their use of third person narrative past tense. All the same, substantial gap was not observed among the components of skill competence.

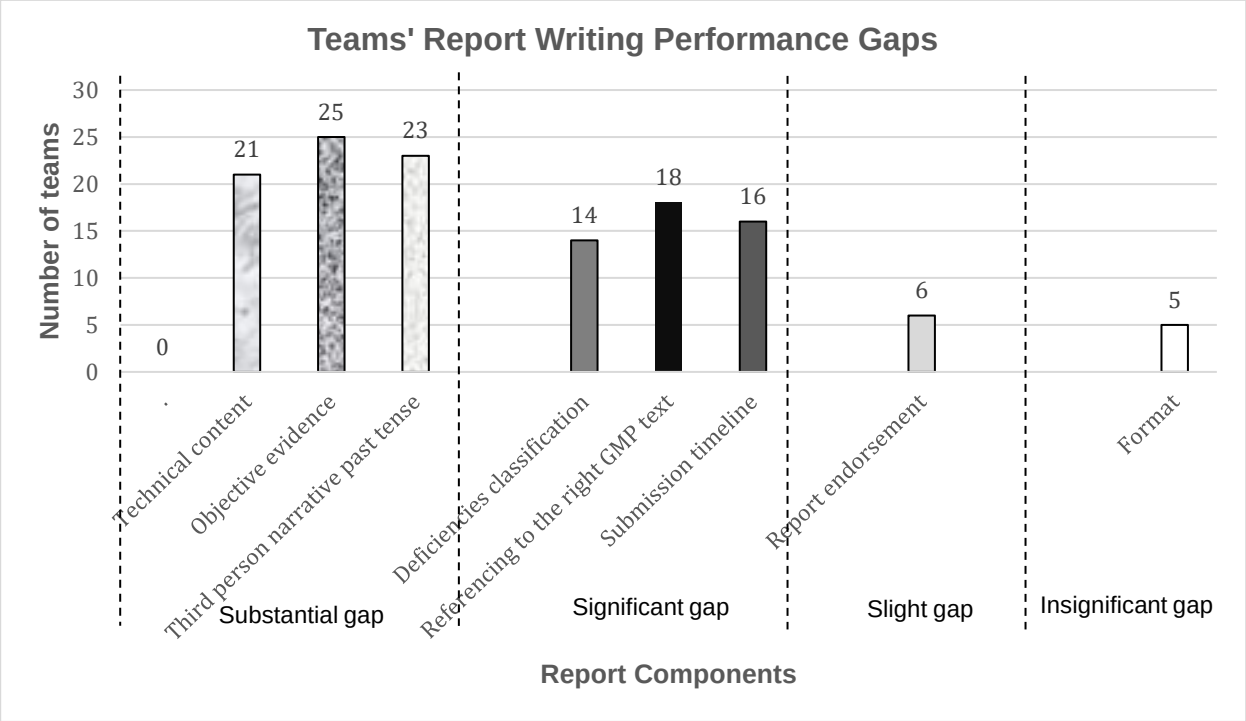

Figure 9

Performance gap demonstrated by the teams in the act of writing inspection report

Significant gap

Significant gap in different teams' performance rating was more evident in reports' components like technical content, use of objective evidence, use of third person narrative past tense, reference of violations to applicable laws and timely submission of inspection report. For example, in report components like technical content and use of objective evidence, two groups of inspection teams (fifteen (60%) and seventeen (68%) teams) autonomously displayed significant gap in their abilities to write on pharmaceutical quality system and material management system of inspected facilities. Furthermore, the same significant gap in assignment of risk levels to GMP deficiencies and citing of applicable law or GMP text was evident in writing abilities of two groups of Inspection teams (fourteen (56%) teams and eighteen (72%) teams).

Slight gap

The gap level labelled slight gap was not recorded in any team's descriptive effort on technical aspect of GMP and use of objective evidence. Nevertheless, six teams which could not sign off on their reports were identified.

Insignificant gap

Except for format component, none of the inspection teams demonstrated insignificant knowledge gap in their abilities to evaluate the status of the other seven components of inspection report. This implies that future training need should focused first on use of objective evidence, the right tenses and voice. (Please see figure 9 for more information)

4. CONCLUSION

The research was a retrospective study of twenty-five good manufacturing practice inspection reports (from March 2017 through December 2018) of National Medicine Regulatory Authority, Drug Inspectorate, somewhere in west Africa designed to assess the inspectors' capability and competence in the act of report writing. In the study, the attribute of effective inspection report writing was found to be lacking among a good number of regulatory inspectors in a National Medicine Regulatory Agencies in West Africa. The frequency of this problem was learned through review of selected inspection reports to make the following findings. The appropriateness of the reports, the impact of intervention program on inspectors' writing performance, individual reports compliance status with different models of inspection reports, inspection team leader inspectors' writing competence and gaps that exist in the act of GMP inspection report writing among the regulatory inspectors.

In view of the findings made in this study, the conclusions reached are as follows. The results show that of the twenty-five inspection teams, one team (4.0%) wrote an *excellent* report. Two (8.0%) penned *good* reports. Eleven (44.0%) team drafted *needs improvement* reports and the remaining eleven (44.0%) prepared an *unacceptable* report. Of eleven (44.0%) unacceptable reports, seven (63.6%) were written by inspection teams whose team leads held bachelor's degree while the remaining four (36.4%) were drafted by teams whose lead inspectors possess MSc degree. The only team that had the lead inspector as a PhD holder wrote a good report. None of the good reports was written by teams whose leaders were non-pharmacists. Rather, most non-pharmacist lead inspectors [3 of 4 (75%]] and their teams authored unacceptable reports. A review of lead inspectors' years of cognate experience, put the figure at five or more years. Hence, much expertise was anticipated in their ability to organize an effective report. But this was not so as most of the unacceptable reports [8 of 11(72.7%)] were written by teams whose lead inspectors had more than 15 years cognate experience. Only [1of 10 (10.0%)] lead inspectors with more than fifteen years of cognate experience wrote a good report with his team. As the remaining good report was drafted by a team whose lead inspectors' year of cognate experience, did not exceed ten years.

The outcome of program impact evaluation on each inspection team writing effectiveness was not an outright success. This is because the impact felt by each inspection team was less than optimal. For instance, the best impact {Impact score (I_T) = 6.25} the program produced was evident in two inspection teams. More distinctly, the teams (team four (T_4) and team twelve (T_{12})) individually experienced moderate impact in their report writing ability. Also, weak impact on report writing effectiveness was evident in the performance of six other inspection teams which are; team one (T_1), team five (T_5), team six (T_6), team eight (T_8), team nine (T_9) and team ten(T_{10}). Lastly, the training program had no impact on the remaining four teams.

In terms of compliance with NMRA guidelines and model inspection reports (PIC/S and WHO) the study made this observation. Compliance scale for scoring the different inspection reports showed that report number 12 displayed high level of compliance with NMRA and PIC/S requirements on inspection report writing. Report number 17 had high level of compliance with only the PIC/S model. None of the report showed high compliance to WHO requirement. Finally, report number 1 and 5 had the lowest levels of compliance with the requirements of the three guidelines on inspection report writing.

An assessment of lead-inspectors competence showed team 12 leader as the only lead inspector with appropriate writing competency profile. Fourteen (56.0%) lead inspectors were partly competent. Five (20.0%) displayed advanced beginners' skill. And the last five (20.0%) were novice team leads in the act of organizing effective GMP inspection report. Finally, substantial gap was notable among the sub-components of the reports' technical contents and their corresponding objective evidence except for the pharmaceutical quality system and the material management system. The same gap was recorded in almost all {twenty-three (92.0%)} the inspection teams' efforts to use third person narrative past tense in report writing. All the same, substantial gap was not observed among the components of skill and attitude competence.

5. RECOMMENDATIONS FOR NEXT STEPS

The study recommended the following:

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- Regulatory affairs professionals (NRAs and regulated entities) and the academia should collaborate on issue of reviewing pharmacy and related science school curricula to capture training on regulatory sciences. This will assist young graduates that wish to build their career in Food and Drug Authority organization or in drug manufacturing site to acquire basic knowledge on issues that border on medicine regulation (Gloria et al, 2019)..
- On occasional basis, The NMRA should expose their fresh inspectors and other cadres of inspectors to short-course intensive writing interventions that is jointly delivered by cGMP expert organizations and regulatory affairs writing specialists. Content components of such training program should focus on higher and lower approach of skill-building in effective writing. This includes developing the main message, arranging writing in a sensible way, listening to the pattern and flow of the sentences and paragraphs, choosing effective vocabulary to communicate meaning, and introducing the inspector's opinion in a way that his audience will understand him (Miller, Cynthia, An-Lin , & Anita , 2015).
- The Management of the NMRA drug inspectorate should carry out periodic reassessment of the inspectors' competence to improve their performance. This should include a mentorship program which will serve as means for closer monitoring and receiving of daily feedback on the progress of their performance.
- The study organization should leverage the opportunity provided by regulatory reliance pathway. or mutual recognition agreement to expose their staff to joint inspection programs where they will share their assessments with other National Regulatory Authorities' inspectors, gain from each other's expertise and deliberate on any deficiencies in the data being evaluated (WHO, Good reliance practices in regulatory decision-making: high-level principles and recommendations, 2020)
- While ensuring adherence to confidential agreement with reference regulatory authority, the NMRA should encourage the use of non-public regulatory reports to enhance learning and minimize the gaps that exist in their inspectors' writing abilities (Garg, S et al, 2013).
- The NMRA should release their staff to participate in WHO rotational fellowship which will provide them with a complete set of the WHO norms and standards that underpin prequalification. Moreover, opportunity to review and discuss inspection reports with high profile inspectors will help participants improve their inspectorate review process (WHO, Prequalification: WHO rotational fellowships: an update, 2016).
- Reviewers or more experienced inspectors should ensure that every claim and response an inspection team gives must be backed up with objective evidence. This is because unsupported or poorly explained assertions will confuse the auditee and cast doubts over the inspectors' ability to make accurate judgement (AIHO, 2017).
- To ensure precision and fairness, the inspectors should proofread, edit, and re-work where necessary their report before submission to ensure there is no issue factual inaccuracy that could result in dispute of observations (AIHO, 2017).
- The inspectorate should collaborate with one or two pharmaceutical manufacturing industries with unswerving history of compliance with cGMP on issue of short course internship programs for their fresh inspectors. This is because the step will provide them with practical requirements of what is expected of them as NMRA inspectors.

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Appendix 1

Impact of Lead Inspectors' Demographic Data on their Teams' Writing Effectiveness

Demographic Characteristics	Appropriateness of Inspection Reports				Frequency	X^2 Chi-square	p-value
	Excellently	Good	Needs Improvement	Unacceptable			
Educational level							
BSc/HND	0[0.0]	2[12.5]	7[43.8]	7[43.8]	16		
MSc	0[0.0]	0[0.0]	4[50.0]	4[50.0]	8		
PhD and above	0[0.0]	1[100.0]	0[0.0]	0[0.0]	1`	8.37	0.0770
Total	0	3	11	11	5		
Qualification							
Pharmacist	0[0.0]	3[14.3]	10[47.6]	8[38.1]	21		
Non-Pharmacist (Scientist)	0[0.0]	0[0.0]	1[25.0]	3[75.0]	4	0.57	0.1723
Total	1	3	11	11	25		
Years of experience							
5-10 years	0[0.0]	1[14.3]	3[68.0]	2[28.6]	6		
11-15years	0[0.0]	1[20.0]	6[66.6]	2[22.2]	9		
>15years	0[0.0]	1[10.0]	2[20.0]	7[70.0]	10	0.83	0.2656
Total	**0**	**3**	**11**	**11**	25		

Note: The values are in numerical form for those before the parenthesis and in percentage for those inside the parenthesis.

Appendix 2

Assessment Guide for Evaluating Quality Characteristics of Inspection Reports

Quality Characteristics	Components	Sub-components	Grading rubrics
Coverage Attributes	Format	Sections of the report • Sub-section(s)	Meets expectation. Near expectation Not near expectation Not acceptable
	Technical Content (QMS and Site)	Seventeen elements of WHO cGMP • Each element • Assessment criteria	Excellent knowledge Good knowledge Fair knowledge Poor knowledge
	Use of Objective evidence to support inspection rating comments or statements of observation	Compliant statement contained. • GMP requirements with high proficiency in command of evidence Non- compliant statement contained. • GMP requirements for manufacture of medicines • Deficiency • Compelling evidence of poor compliance level	Mastery Partial mastery, Emerging mastery No mastery
	Use of third person narrative past tense	Use of third person narrative past tense	Excellent use Good use Needs Practice No use
Practice Attributes	Risk-based classification of GMP deficiencies or non-compliance statement	Proper assignment of risk level to GMP violations Improper assignment of risk level to GMP violations Non-assignment of risk level to GMP violations	More than 75% of violations adequately assigned. Between 51-75% of violations adequately assigned Between 26-50% of violations adequately assigned Between 0- 25% of violations adequately assigned
	Reference of deficiencies to applicable laws, regulations and GMP text (Regulatory Citation)	Proper citing of applicable regulations Improper citing of applicable regulations Non citing of applicable regulations	More than 75% properly cited GMP violations Between 51-75% properly cited GMP violations Between 26- 50% properly cited GMP violations Between 0- 25% properly cited GMP violations
	Signing off on an inspection report	All members of the inspection team. Some members of the inspection team Not done by any member of the team	Completely signed off on an inspection report Partially signed off on an inspection report No signing off on an inspection report
	Timely submission of inspection reports	• Timely submission of report • late submission of report	Timely submitted. Not timely submitted

Appendix 3

Data on Quality Characteristics of Inspection reports

Quality characteristics	**Components percentage scale score** {Percentage}				**Number of teams**	**Entire team Components score**	**Percentage Score**
	>76	51-75	26-50	0-25			
Coverage Attribute							
Format	25	0	0	0	25.00	22.27	89.08
Technical Content	3	7	7	8	25.00	11.00	44.00
Objective Evidence	0	5	7	13	25.00	7.08	28.32
Third person narrative past tense	1	8	7	9	25.00	10.31	41.24
Practice Attribute							
Risk-based classification of GMP deficiencies	12	5	1	7	25.00	14.04	57.60
Reference to relevant GMP text	7	3	5	10	25.00	10.25	41.00
Signing off on an inspection report by Members of the Inspection team	19	1	2	3	25.00	20.12	80.84
Submission timeline	0	0	6	19	25.00	6.00	24.00

Appendix 4

NMRA Inspection Reports' Classification and their Scores

Report Code No	Company Location	Audit Date	Coverage Attributes Score	Practice Attributes Score	Report Scores (CA) X (PA)	Report grades	Gray Scale
RC1	L1	181217	0.75	1.04	0.78	UR	
RC2	L2	22-270317	1.20	1.22	1.46	UR	
RC3	L3	100818	1.98	1.20	2.38	UR	
RC4	L1	240817	1.18	1.40	1.65	UR	
RC5	L4	050218	0.74	1.04	0.77	UR	
RC6	L5	240718	1.25	2.05	2.56	UR	
RC7	L1	231018	2.38	2.90	6.90	NIR	
RC8	L2	29-301118	1.68	3.12	5.24	NIR	
RC9	L1	120718	2.21	2.92	6.45	NIR	
RC10	L5	010918	1.44	2.48	3.57	UR	
RC11	L3	150818	1.20	0.80	0.96	UR	
RC12	L1	19-200718	3.00	3.19	9.57	ER	
RC13	L2	23-240118	1.14	0.80	0.91	UR	
RC14	L6	091118	1.27	1.20	1.52	UR	
RC15	L1	8-90818.	2.06	2.60	5.36	NIR	
RC16	L7	12-131118	2.19	2.24	4.91	NIR	
RC17	L5	14-151118	2.51	3.19	8.01	GR	
RC18	L1	22-231118	2.09	2.91	6.08	NIR	
RC19	L8	12-131118	2.03	2.12	4.30	NIR	
RC20	L1	14-151118	2.86	1.27	3.63	UR	
RC21	L3	10-111218	2.67	2.90	7.74	NIR	
RC22	L5	12-131218	2.39	2.54	6.07	NIR	
RC23	L9	10-111218	2.09	2.56	5.35	NIR	
RC24	L1	18-191218	1.64	3.34	5.48	NIR	
RC25	L1	13-141218	3.04	2.88	8.76	GR	

Note: ER – Excellent Report, GR – Good Report, NIR- Needs Improvement Report, UR - Unacceptable Report, RC No. – Report code numbers and L – Company Location, CA – Coverage attribute and PA – Practice attribute

Scale Score - Excellent Report - (12.00 -15.00), Good Report – (8.00 – 11.00),
Needs Improvement Report -– (4.00 – 7.00), Unacceptable Report – (0.00-3.00)

Appendix 5

Rubrics for Evaluating GMP Inspection Report

Report			
Excellent	**Good**	**Needs Improvement**	**Unacceptable**
Shows consistent command of standard, grade level proficient to writing requirement. Error free, as such they do not disrupt readability and understanding.	Shows some command of standard, grade level above average to writing requirements. Errors are so few and so minor that they slightly disrupt readability and understandability.	Shows scanty command of standard, grade level marginal to writing requirements. Errors are noticeable in such a way that they significantly disrupt readability and understandability in several parts of the report.	Shows consistent error of standard, grade level unacceptable to writing requirements. Errors impede both readability and understandability
Format			
Meet expectation	**Near expectation**	**Not Near expectation**	**Not Acceptable**
Followed approved layout that should be used for the preparation of reports	A few errors in the layout used for the preparation of reports	So many format errors as to make report ineffective	Does not follow specified format
Technical Content			
Excellent knowledge	**Good Knowledge**	**Fair knowledge**	**Poor knowledge**
Content is thorough, accurate, explicit, or covered in as much depth as expected, and is proficiently described using relevant performance. standards in all sections of the report.	Content is accurate, and is reasonably described by using relevant performance standards in most sections of the report	Content is partway accurate, and not as explicit or covered as expected, and is not adequately described by use of relevant performance standards in different sections of the report	Content is not accurate or complete, and is not described by use of relevant performance standards in most sections of the report
Objective evidence			
Mastery	**Partial Mastery**	**Emerging Mastery**	**No Mastery**
Expressed using the specific GMP terms. Use of relevant standards of quality. Core reasoning was drawn from textual evidence.	Expressed in general GMP terms. Use of relevant standards of quality with slight gaps. Core reasoning was partially drawn from textual evidence	Not expressed in the right GMP terms. Use of irrelevant standards of quality is applied with significant gaps or misinterpretation. Core reasoning was tangential or invalid in relation to the textual evidence.	Not expressed in GMP terms. No use of unit quality standards. Core reasoning showed no idea of evidence
Use of third person narrative past tense			
Excellent use	**Good use**	**Needs Practice**	**No Use**
The right tense and voice were incorporated in more than 76% of the report. Ideas display in a creative way further enhanced readers' understanding	The right tense and voice were applied in about 51-75 % of the report and ideas were comprehensive	The right tense and voice were incorporated in about 26-50 % of the report. Also, the ideas were not comprehensive enough.	Used only present tenses to communicate. The tense usage interferes with reader's understanding,

Appendix 6

Impact on Teams' Performance levels on Report Quality Attribute Element (Components).

S/N	Quality Attribute	Above normal [> 76]		Normal [51-75]		Under normal [26-50]		Very under normal [0 – 25]	
		Before	After	Before	After	Before	After	Before	After
	Coverage								
1	Format	12[100]	12[100]	-	-	-	-	-	-
2	Technical content	1[8.3]	2[16.7]	1[8.3]	5[41.7]	2[16.7]	5[41.7]	8[66.7]	0[0.0]
3	Objective Evidence	0[0.0]	0[.0.0]	2[16.7]	3[25.0]	2[16.7]	5[41.7]	9[75.0]	4[33.3]
4	Third person narrative past tense	0[0.0]	1[8.3]	3[25.0]	5[41.7]	1[8.3]	5[41.7]	9[75.0]	1[8.3]
	Practice								
1	Risk-based classification of GMP deficiencies	4[33.3]	7[58.3]	2[16.7]	3[25.0]	0[0.0]	1[8.3]	6[50.0]	1[8.3]
2	Reference to the right GMP text	2[16.7]	5[41.7]	1[8.3]	2[16.9]	1[8.3]	4[33.3]	9[75.0]	1[8.3]
3	Signing off on an inspection report by members of inspection team	9[75.0]	7[58.3]	1[8.3]	0[0.0]	1[8.3]	1[8.3]	1[8.3]	3[25.0]
4	Report submission in a timely manner	4[33.8]	5[41.7]	0[0.0]	0[.0.0]	0[.0.0]	1[8.3]	9[75.0]	6[50.0]

Note: The values of the performance parameters (Above normal, normal, under normal and very under normal levels) are in numerical form for the values before the parenthesis and in percentage for those inside the parenthesis.

Appendix 7

Program Impact Analysis Matrix on Team's Ability to explain Status of Report Components

	Components' Performance Levels in each Team's Inspection Report				
Numeral Change in Reports' Components after Intervention Program		*Above Normal (> 75%)*	*Normal (51-76%)*	*Under Normal (26-50%)*	*Very Under Normal (0-25%)*
	Substantial change (7- 8)	Strong Impact		Moderate Impact	
	Significant Change (5 - 6)				
	Slight Change (3--4)	Weak Impact		No Impact	
	Insignificant Change (1-2)				

Appendix 8

Impact Score Calculation for each Inspection team

	Before					After					CNC					Impact
Ta	***A***	***N***	***UN***	***VUN***	***Tb***	***A***	***N***	***UN***	***VUN***	***Tb -Ta***	***A***	***N***	***UN***	***VUN***	***I_T***	
T1a	*3*	*0*	*0*	*5*	*T1b*	*5*	*0*	*2*	*1*	*T1b –T1a*	*2*	*0*	*2*	*4*	*4.00*	*Weak*
T2a	*2*	*0*	*0*	*6*	*T2b*	*3*	*0*	*1*	*4*	*T2b –T2a*	*1*	*0*	*1*	*2*	*2.00*	*Null*
T3a	*3*	*0*	*2*	*3*	*T3b*	*3*	*1*	*2*	*2*	*T3b –T3a*	*0*	*1*	*0*	*-1*	*1.00*	*Null*
T4a	*1*	*1*	*1*	*5*	*T4b*	*6*	*1*	*1*	*0*	*T4b –T4a*	*5*	*0*	*0*	*-5*	*6.25*	*Moderate*
T5a	*3*	*0*	*0*	*5*	*T5b*	*3*	*3*	*0*	*2*	*T5b –T5a*	*0*	*3*	*0*	*-3*	*3.00*	*Weak*
T6a	*3*	*1*	*0*	*4*	*T6b*	*2*	*0*	*6*	*0*	*T6b –T6a*	*-1*	*1*	*6*	*-4*	*3.75*	*Weak*
T7a	*3*	*3*	*1*	*1*	*T7b*	*2*	*2*	*2*	*2*	*T7b –T7a*	*1*	*1*	***1***	*1*	*2.50*	*Null*
T8a	*2*	*3*	*1*	*2*	*T8b*	*4*	*4*	*0*	*0*	*T8b-T8a*	*2*	*1*	*-1*	*-2*	*3.75*	*Weak*
T9a	*3*	*0*	*0*	*5*	*T9b*	*3*	*2*	*1*	*2*	*T9b-T9b*	*0*	*2*	*1*	*-3*	*2.75*	*Weak*
T10a	*2*	*0*	*0*	*6*	*T10b*	*3*	*0*	*4*	*1*	*T10b-T10a*	*1*	*0*	*4*	*-6*	*4.50*	*Weak*
T11a	*5*	*2*	*0*	*1*	*T11b*	*4*	*0*	*2*	*2*	*T11b-T11a*	*-1*	*-2*	*2*	*1*	*-1.25*	*Null*
T12a	*2*	*0*	*0*	*6*	*T12b*	*5*	*2*	*1*	*0*	*T12b-T12a*	*3*	*2*	*1*	*-6*	*6.25*	*Moderate*

I_T - Program impact score on each team writing effectiveness.
TP - Total number of performance levels
Ta – Team performance status before program.
Ta – Team performance status after program.
CNC – Change in number of report components at four performance levels of an inspection team

A – Above normal level – >75%
N – Normal level – Between 51-75%
UN- Under normal level - Between 26-50%
VUN – Very under normal level - Between 0-25%

VA – Impact factor score at above normal level (4)
VN – Impact factor score at normal level (3)
VUN – Impact factor score at under normal level (2)
VVUN – Impact factor score at very under normal level (1)

CCA – Change in number of report components at A
CCN -- Change in number of report components at N
CCUN - Change in number of report components at UN
CCVUN - Change in number of report components at VUN

Impact score formula

$$I_T = \frac{CCA \times VA}{TP} + \frac{CCN \times VN}{TP} + \frac{CCUN \times VUN}{TP} + \frac{CCVUN \times VVUN}{TP}$$

Impact scale on team writing effectiveness.
Strong Impact - (7.00 -8.00), Moderate Impact – (5.00 – 6.00), Weak Impact -– (3.00 – 4.00), Null Impact – (1 00 – 2.00)

Note
A Negative CCA, CCN value leads to subtraction during calculation of I_T.
A Negative CCUN and CCVUN does not result in subtraction of figure when calculating I_T.

Appendix 9

Compliance status of individual reports with NMRA guidelines, and WHO standards and PIC/S requirements

	Inspection Report Writing Standards	**Compliance Scale Score**				**Total**
		High	**Moderate**	**Low**	**Very low**	
Compliance Scale Score		[9 -11]	[6 – 8]	[3 – 5]	[0 – 2]	
Inspection Reports	NMRA WHO PIC/S	1 - 2	7 6 8	8 10 7	9 9 8	25 25 25

Appendix 10

Percentage Compliance of Report Components that exhibit Content Variation in the three Regulatory Standards for Inspection Report Writing

Report Component	NMRA and other Regulatory Standards	Percentage Compliance [%]				Total
		High [> 76]	Moderate []	Low [26-50]	Very low [0-25]	
Format Content						
Introduction	NMRA	23[92.0]]	1[4.0]]	0[0.0]	1[4.0]	25
	WHO	0[0.0]	21[84.0]	3[12.0]	1[4.0]]	25
	PIC/S	24[96.0]]	0[0.0	1[4.0]	0[0.0]	25
Scope and limitation of inspection	NMRA	7[28.0]	12[48.0]	6[24.0]	0[0.0]	25
	WHO	25[100.0]	0[0.0]	0[0.0]	0[0.0]	25
	PIC/S	18[72.0]	0[0.0]	7[28.0]	0[0.0]	25
Key Personnel met	NMRA	25[100.0]	0[0.0]	0[0.0]	0[0.0]	25
	WHO	22[88.0]	1[4.0]	1[4.0]	1[4.0]	25
	PIC/S	22[88.0]	1[4.0]	1[4.0]	1[4.0]	25
findings and Observation	NMRA	21[84.0]	4[16.0]	0[0.0]	0[0.0]	25
	WHO	21[84.0]	4[16.0]	0[0.0]	0[0.0]	25
	PIC/S	21[84.0]	4[16.0]	0[0.0]	0[0.0]	25
Sample taken	NMRA	12[48.0]	0[0.0]	0[0.0]	13[52.0]	25
	WHO	13[52.0]	0[0.0]	0[0.0]	12[48.0]	25
	PIC/S	13[52.0]	0[0.0]	0[0.0]	12[48.0]	25
Submission timeline						
Timely submission	NMRA	6[24.0]	0[0.0]	0[0.0]	21[84.0]	25
	WHO	15[60.0]	0[0.0]	0[0.0]	10[40.0]	25
	PIC/S	15[60.0]	0[0.0]	0[0.0]	10[40.0]	25

Note: The values are in numerical form for those before the parenthesis and in percentage for those inside the parenthesis.

Appendix 11

Competence of Inspection teams' lead inspectors after intervention program

Team code	K_c	S_c	A_c	Competence score	Proficiency Level
T1b	1.68	1.92	1.20	0.60	Partly competent
T2b	1.27	0.40	0.80	0.31	Advanced beginner
T3b	2.19	2.24	0.00	0.55	Partly competent
T4b	2.51	2.39	0.80	0.71	Partly competent
T5b	2.09	2.11	0.80	0.63	Partly competent
T6b	2.03	1.86	0.26	0.52	Partly competent
T7b	2.86	1.27	0.00	0.52	Partly competent
T8b	2.67	1.64	1.26	0.70	Partly competent
T9b	2.39	2.54	0.00	0.62	Partly competent
T10b	2.09	1.76	0.80	0.58	Partly competent
T11b	1.64	2.54	0.80	0.62	Partly competent
T12b	3.04	1.68	1.20	0.74	Partly competent

Note: a) Score range = from minimum score (0) to Maximum score (1)

b) Range of competence borders: Novice (0.00-0.25), Advanced beginner (0.26 – 0.50), Partly Competent (0.51-0.75), Competent (0.76-1.00)

c) K_c = Knowledge competence = Sum up of (Value of F x Weight for F) + (Value of TC x Weight for TC) + (Value of OE x Weight for OE) + (Value of TP x Weight for TP)

d) S_c = Skill competence= Sum up of (Value of RCD x Weight for RCD) + (Value of RRT x Weight for RRT)

e) A_c = Attitude competence = Sum up of (Value of SO x Weight for SO) + (Value of ST x Weight for ST)

Competence Score = $K_c + S_c + A_c$ /Sum up of (Weight for F + Weight for TC + Weight for OE + Weight for TP + Weight for RCD + Weight for RRT + Weight for SO + Weight for ST)

Where F = format, TC = Technical content, OE= Use of Objective Evidence, TP = Use of third person narrative past tense RCD = Risk-based classification of GMP deficiencies, RRT= Reference of deficiencies to right applicable laws, regulations and GMP text, SO = Signing off on a report by members of inspection team, ST = Timely submission of inspection report.

Appendix 12

Competence of Inspection Teams' Lead Inspectors

Team code	K_m	S_m	Mean gap score.	Competence score	Proficiency Level
T1	0.75	0.00	1.04	0.22	Novice
T2	1.20	0.00	0.80	0.25	Novice
T3	1.93	0.00	1.20	0.40	Advanced beginner
T4	1.18	1.14	0.26	0.32	Advanced beginner
T5	1.25	0.00	0.64	0.24	Novice
T6	1.25	1.25	0.80	0.41	Advanced beginner
T7	2.38	2.10	0.80	0.66	Partly competent
T8	1.68	1.92	1.20	0.60	Partly competent
T9	2.21	2.39	0.53	0.64	Partly competent
T10	1.44	1.28	1.20	0.49	Advanced beginner
T11	1.20	0.00	0.80	0.25	Novice
T12	3.00	2.39	0.80	0.77	Competent
T13	1.14	0.00	1.60	0.24	Novice
T14	1.27	0.40	0.80	0.31	Advanced beginner
T15	2.06	1.80	0.80	0.58	Partly competent
T16	2.19	2.24	0.00	0.55	Partly competent
T17	2.51	2.39	0.80	0.71	Partly competent
T18	2.09	2.11	0.80	0.63	Partly competent
T19	2.03	1.86	0.26	0.52	Partly competent
T20	2.86	1.27	0.00	0.52	Partly competent
T21	2.67	1.64	1.26	0.70	Partly competent
T22	2.39	2.54	0.00	0.62	Partly competent
T23	2.09	1.76	0.80	0.58	Partly competent
T24	1.64	2.54	0.80	0.62	Partly competent
T25	3.04	1.68	1.20	0.74	Partly competent

Appendix 13

Gap in Teams' Ability to Report of Status of Quality Attribute Elements

S/N	Gap level	Benchmark for gap level definition	Quality Attribute Elements	Number of teams	Percentage score
1	Substantial gap	When more than 75% of Inspection teams score less than or equal to 75% Number of teams ≥ 19	Technical Content	21	84.0
			Objective Evidence	25	100.0
			Third Person Narrative Past tense	23	92.0
2	Significant gap	When between 51 and 75% of all the inspection teams score less than or equal to 75% Number of teams = ≥ 13 <χ ≤18	Risk-based classification of GMP deficiencies	14	56.0
			Reference of GMP deficiencies to the right GMP text	18	72.0
			Submission of reports within the approved timeline	16	64.0
3.	Slight gap	When between 26 and 50% of all the Inspection teams score less than or equal to 75% Number of teams = ≥6< x ≤12	Signing off on a report by members of inspection team	6	24.0
4	Insignificant gap	When between 0 and 25% of all the inspection teams score less than or equal to 75% Number of teams = ≥0< x ≤ 5	Format	5	20.0

Appendix 14

Gap in Teams' Ability to Report Sub-components of Technical Contents

S/N	Gap level	Benchmark for gap level definition	Quality Attribute component	Sub-components	Number of teams	Percentage score
1	Substantial gap	When more than 75% of the number of team score less than less than or equal to 75% Number of teams ≥ 19	Technical content	Sanitation and hygiene	25	100.0
				Personnel	22	88.0
				Training	25	100.0
				Personnel hygiene	24	96.0
				Documentation and procedure	20	80.0
				Qualification and validation	20	80.0
				Production and process control	23	92.0
				Quality control	23	92.0
				Premises	19	76.0
				Good practice in production	22	88.0
				Equipment	21	84.0
				Complaint	23	92.0
				Product recall	23	92.0
				Contract production and analysis	20	80.0
				Self-inspection	23	92.0
2	Significant gap	When between 51-75% of the number of team score less than less than or equal to 75% Number of teams = ≥ 13 x ≤18	Technical content	Pharmaceutical quality system	15	60.0
				Material management system	17	68.0