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Evaluation of good review practices at the Food and Drugs Authority of Ghana as it strives to become a World Health Organization-listed agency

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ABSTRACT

The aim of this study was to assess the good review practices (GRevPs) of the Food and Drugs Authority (FDA) Ghana in order to identify opportunities for improvement.

Reviewers of the FDA Ghana completed an established, structured and multi-dimensional questionnaire for the assessment of GRevPs. Twenty-seven of 30 assessors took part in the study; 70 % reported that GRevPs have been implemented and fully adopted across the authority. The three most common reasons quality measures were implemented at FDA Ghana were to be more efficient, ensure consistency, and to minimize errors. Most respondents believed that the current GRevPs framework could be improved and additional training to learn and understand how GRevPs are to be used and incorporated into daily work; 90 % reported that the FDA Ghana has a consistent method for documenting GRevPs that need improvement and a mechanism to facilitate updating. In general, the importance of GRevPs was well understood by the assessors; however, target timelines were not well followed at both the department and agency levels. This study provided a baseline for the FDA Ghana GRevP knowledge, attitudes, and practices as well as areas for improvement to work toward becoming a World Health Organization-listed authority.

1. Introduction

In 2020, the Food and Drugs Authority (FDA) Ghana achieved the World Health Organization (WHO) maturity level 3 status with regard to its medicines regulatory system. “Level 3 indicates that the system is well-functioning and integrates all required elements to guarantee its stable performance” (WHO, 2020). The World Health Organization has introduced an initiative for assessing and listing regulatory authorities that “operate at an advanced level of performance” as WHO-listed authorities (WLAs). Accordingly, regulatory authorities that have achieved maturity level 3 status qualify for consideration as a WLA (WHO, 2024; Owusu-Asante et al., 2023). In view of this initiative, regulatory authorities are increasingly seeking ways to improve their performance and ensure the quality of their regulatory systems. “Good review practices (GRevPs) are an integral part of overall good regulatory practices and focus on the medical product review aspect of the regulatory work” (WHO, 2015).

GRevPs do not only consist of defined processes and procedures, but also include behaviors, management action, culture, and an overall philosophy. Rather than just indicating the existence of GRevPs, regulatory authorities should understand these concepts and adopt them into daily review activities (Fig. 1).

In 2015, the WHO reported that regulatory authorities have included strategies to monitor and improve their review processes. Additionally, it stated that “regulatory authorities actively manage the process of reviewing medical product applications in order to maximize both the potential for a positive public health impact and the effective and efficient use of review resources” (WHO, 2015).

The extent to which implementation of GRevPs can affect patients’ access to medical products has been documented in the literature (WHO, 2015). Some of the important benefits of GRevPs are the consistency, transparency, efficiency, and timeliness of product review. According to the WHO “implementation of GRevPs helps to achieve these outcomes by ensuring that those involved in the review process have the critical

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thinking skills and tools needed to optimize scientifically sound, evidence-based decisions" (WHO, 2015).

As Ghana has achieved level 3 status, it is timely that this study aims to evaluate the implementation of GRevPs by the FDA Ghana. It is hoped that other similarly matured and maturing regulatory authorities would benefit from building such a system into their review processes, thereby becoming more effective and efficient in the management of their reviews.

The study objectives were to:

- Identify the current perspective of the assessors of the FDA Ghana in the use of GRevPs.
- Provide a baseline on the FDA Ghana's knowledge, attitudes, and practices, as well as identify areas for improvement.
- Explore the processes and procedures currently in place that relate to GRevPs.
- Determine how these procedures relate to the continuous process improvement within the FDA Ghana.

2. Methods

2.1. Questionnaire technique

The Good Regulatory Review Practices questionnaire was developed and validated by the Centre for Innovation in Regulatory Science (CIRS) for evaluation of how good review practices are introduced and implemented within a national regulatory authority. The questionnaire, which consists of 17 items with tick box response options was completed by reviewers of the marketing authorization applications for pharmaceuticals and biological products in the Ghana FDA. The questionnaire consists of questions intended to establish a baseline with respect to the knowledge, attitude and practice regarding GRevPs of the authority staff. The overall objective was to determine whether GRevPs were embedded into the processes and the culture while the authority moves forward in building both its capability and capacity. The questions were designed to elicit whether the participants understood the development, adoption and implementation of GRevPs. Satisfaction with the framework and process for the implementation of GRevPs was also assessed. The questionnaire was also designed to enable the understanding of how the participants evaluated the implementation of these practices in terms of achieving the authority's goals as well as supporting regulatory review activities. Finally, the participants were asked to state how well implementation of GRevPs were being evaluated at the departmental, individual, and authority levels, including how they could be improved.

3. Results

For the purpose of clarity, the results are presented in three parts, as follows:

Part I – Knowledge, which includes how GRevPs have been implemented within the agency, how GRevPs improve performance, and how important they are to both the department/individual and the authority in general.

Part II – Practice, which includes the adoption of GRevPs, their implementation and maintenance as well as identifying the assessors understanding as to how the agency ensures that GRevP is embedded into their review practices.

Part III – Attitude, which includes satisfaction with the framework and process for the implementation of GRevPs, how individual staff rate the implementation of GRevPs in terms of achieving the authority's

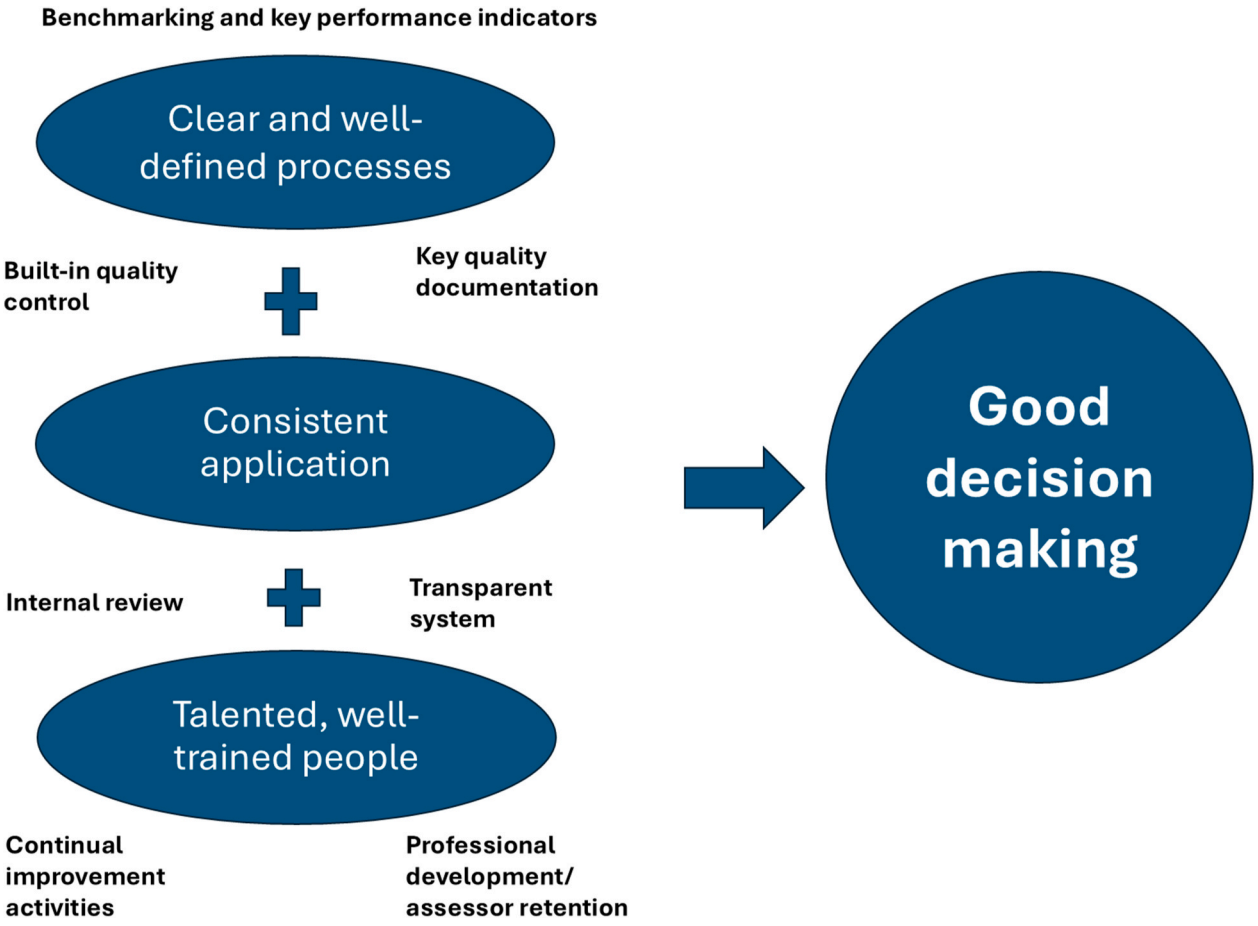

Fig. 1. Key measures essential for good regulatory review practice.

goals and their support of review activities; which aspects still require GRevPs and what could be done to improve their implementation and how well they are followed both at the departmental, individual, and authority levels.

3.1. Part I - knowledge

Twenty-seven out of 30 (90 %) assessors of marketing authorization applications for pharmaceutical and biological products of the FDA Ghana completed the GRevP-specific questionnaire for the assessment of GRevPs by the authority.

According to nineteen (70 %) of the respondents, GRevPs have been developed and fully adopted across the authority. This supports the findings in the previous study that guidelines, standard operating procedures and review templates were in place and the majority of indicators for good review practices were implemented (Owusu-Asante et al., 2023).

Respondents provided details indicating the reasons why they believe quality measures had been developed within the FDA Ghana (Fig. 2). The three most common reasons were to be more efficient, ensure consistency, and to minimize errors. Twenty-six respondents (96 %) indicated that the main reason for introducing GRevPs was to be more efficient, while twenty-five respondents (93 %) rated equally consistency and minimizing errors as key factors. However, increasing transparency, reducing cost, and improving communication within the authority were selected by very few respondents as important reasons for introducing quality measures in the authority (Fig. 2). It was noted that only one reviewer selected "to improve process predictability" as a reason for introducing quality measures in the authority, whilst none of the respondents selected "to achieve stakeholder consistency" as a reason for introducing quality measures in the authority. According to WHO TRS No. 992 (2015) GRevPs "help achieve timeliness, predictability, consistency, transparency, clarity, efficiency and high quality in both the content and management of reviews." These results, particularly relating to the quality measures that were not selected or selected by very few respondents are further discussed in the relevant section of this manuscript.

3.2. Part II - practice

Twenty-five study participants (93 %) responded to the question "In your view, how has FDA Ghana adopted GRevPs?"; twenty-four (88 %) of the respondents indicated that GRevPs have been formally adopted through the use of standard procedures, training, and compliance monitoring. Twenty-five (93 %) of the participants responded that GRevPs were being implemented through the use of standard operating procedures on how to use specific activities that form part of GRevP. Seven (26 %) of the participants who believed GRevPs were in place formally or informally, thought that they are implemented as part of the induction training for all new staff members (Fig. 3).

According to twenty-seven (100 %) of the participants, as GRevPs were rolled out, they were made available to the reviewers to adopt into their daily review activities. The department archives, trains, and encourages the consistent use of updated GRevPs. This is the main mechanism that is used to ensure the adoption of GRevPs as standard processes. Ten (37 %) participants indicated that staff were formally tested (oral or written) on their understanding of what GRevPs are and how they should be used.

3.3. Part III - attitude

The study participants were asked several "attitude-related questions" in order to achieve an understanding of their satisfaction with the framework and process for the implementation of GRevPs. Twenty-five (93 %) respondents believed that the existing GRevPs framework for FDA Ghana could be improved, with only two indicating that they were satisfied with the current framework. Most of the respondents commented that the GRevP system is in an evolving phase within the authority and believed that additional training would be of value to understand how GRevPs should be incorporated into their daily work.

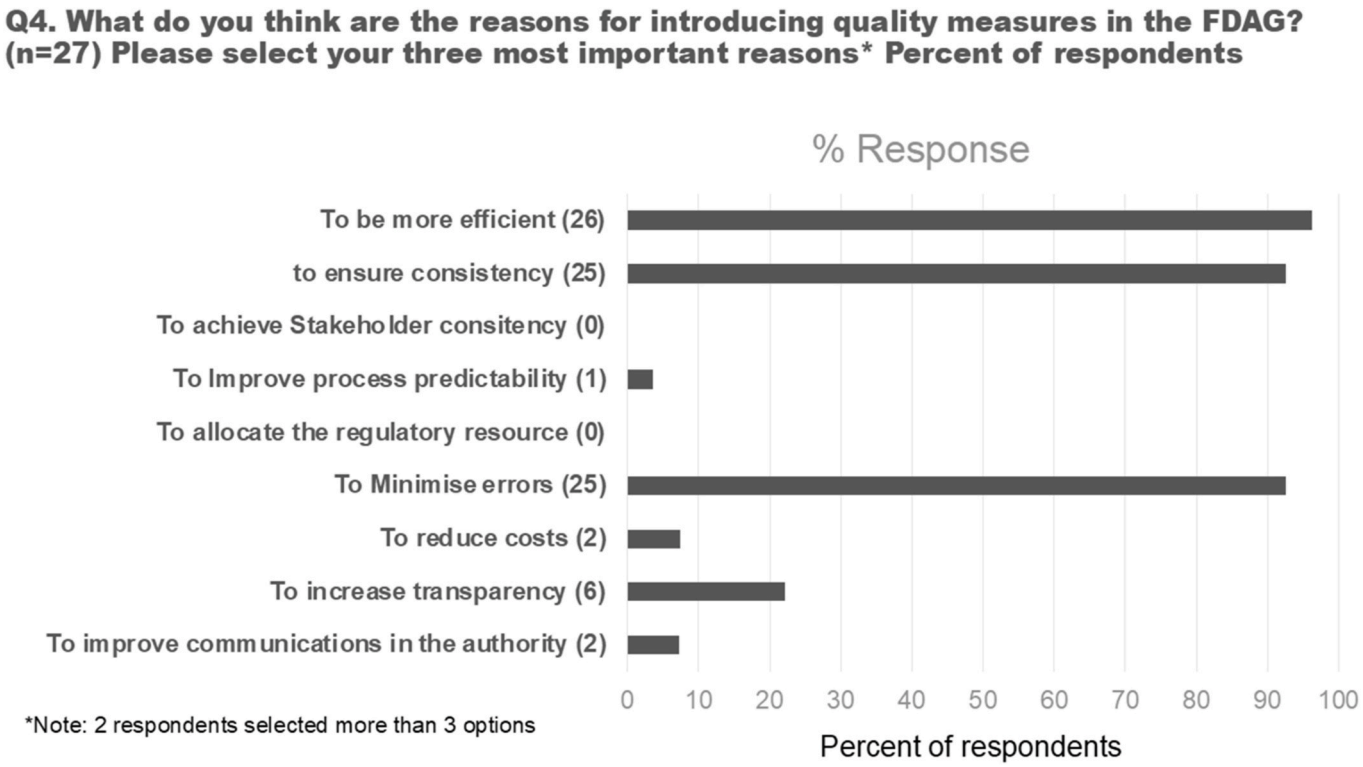

Fig. 2. Reasons for introducing quality measures in the agency.

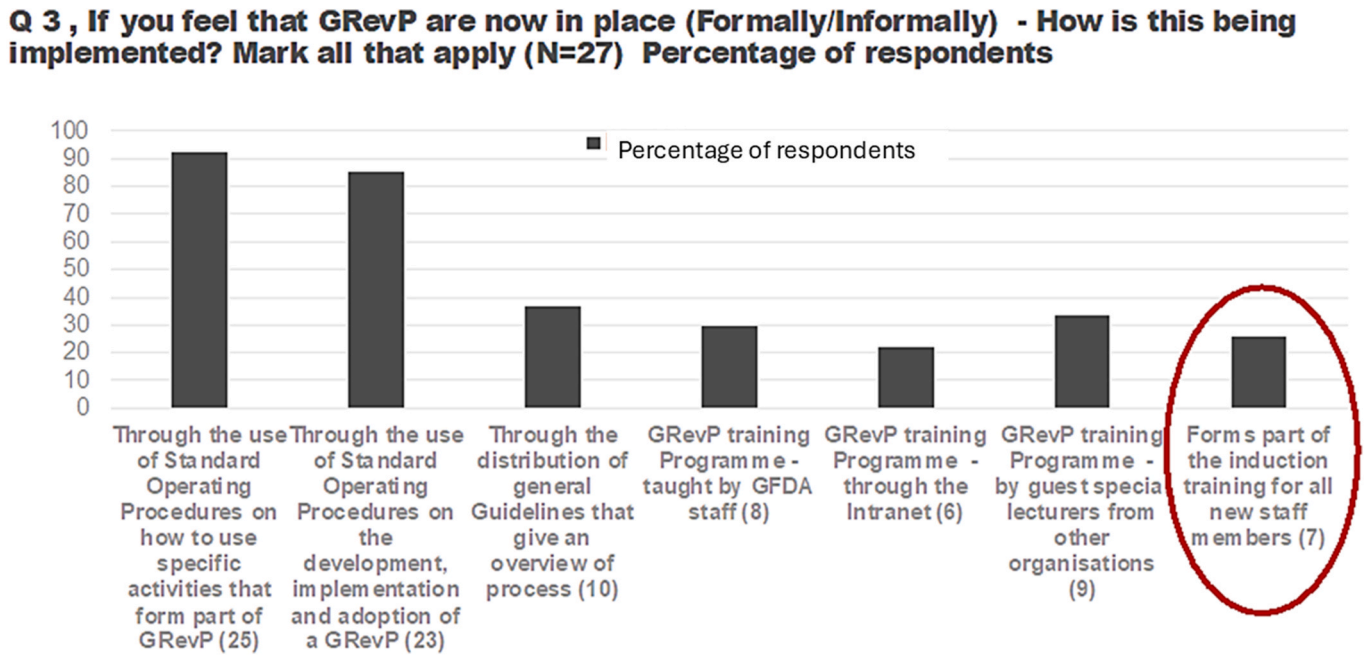

Fig. 3. How good regulatory review practices are implemented in the FDA Ghana.

Twenty-five (93 %) of the participants rated the process for the implementation of GRevP within the FDA Ghana as satisfactory. GRevPs have been implemented based on best practices identified through the collective experience of FDA Ghana and the reviewers. Two participants stated that while systems are being put in place and implemented, improvements could be made to make procedures more robust. All the participants indicated that there are still best practices that need to be implemented into the FDA Ghana GRevPs. Target timelines, feedback from companies, ability to track the review process, feedback from patients, feedback from staff/assessment teams were among the key areas that the authority needs to implement as part of good review practices.

The assessors acknowledged that the implementation of GRevPs helps to improve review goals, namely, quality of the review, quality of management of the review, consistency of the review, efficiency of the review through standardization, transparency of the review, clarity throughout the review process including critical review and decision activities and conflict or dispute resolution and the timeliness of the review process. Additionally, the respondents were of the view that the GRevP implemented within the authority are achieving these goals satisfactorily.

With regard to review principles and procedures, twenty (75 %) of the participants believed that the FDA Ghana GRevPs provide strong guidance to help them employ review processes and methodologies (decision making) and engage in multidisciplinary-based decision

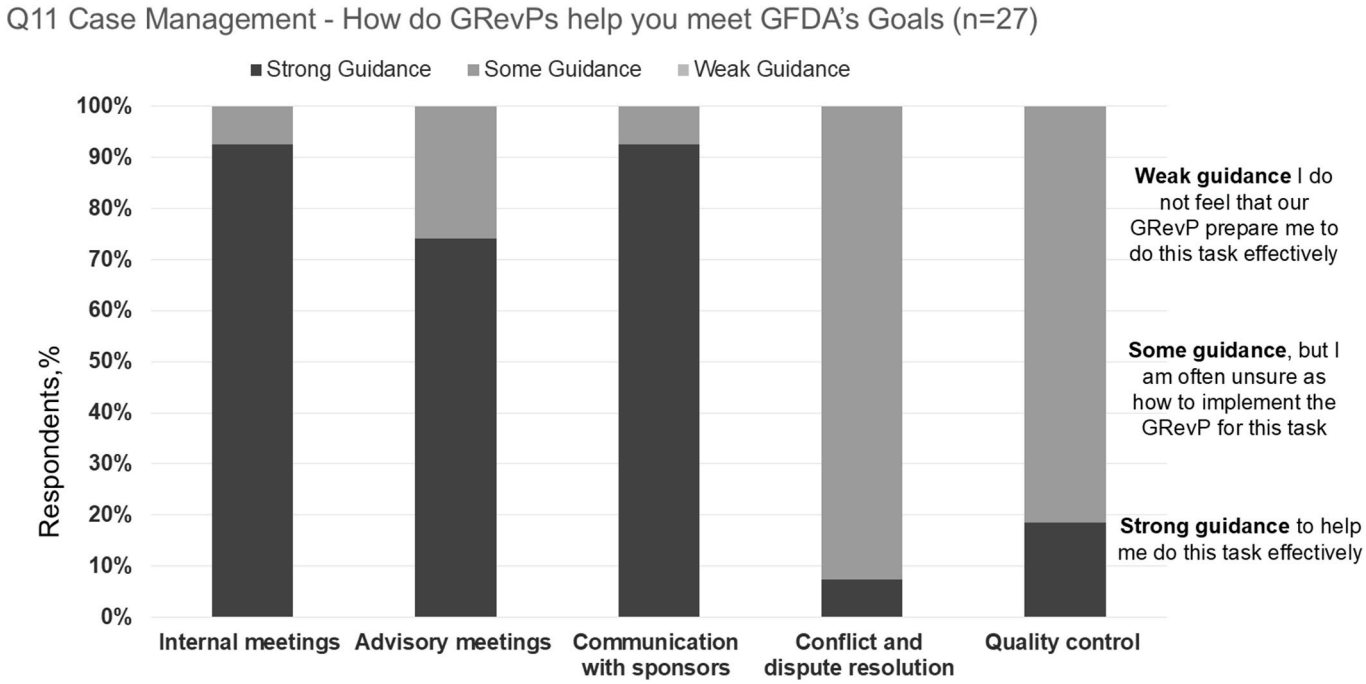

Fig. 4. How good regulatory review practices help to meet the FDA Ghana goals with regard to review principles and procedures.

making. Twenty-two (80 %) of the participants believed that at least some guidance is available for science-based decisions, risk-control methodology, and continuous training of high-quality staff (Fig. 4).

With regard to case management, twenty-four (90 %) of the participants believed that the FDA Ghana GRevPs provide strong guidance to help them effectively conduct internal meetings and communicate with sponsors. While twenty-two (80 %) of the participants believed some guidance is available for conflict and dispute resolution and quality control, only a small percentage considered that guidance to be strong.

Sixteen (60 %) of the study participants indicated that there is no formal or informal mechanism currently in use to ensure GRevPs are actually adopted and used consistently. However, twenty-one (78 %) of the participants indicated the main mechanisms that are being used to ensure adoption and use are mentoring by supervisors, training, and follow-up by training teams or people assigned to make sure that these GRevPs are implemented.

Some of the study participants suggested tasks that they could do at an individual level to improve the way GRevPs are implemented.

"Attend courses and training sessions with practical activities' regarding GRevP to enhance my knowledge"

"Intentionally use the GRevP guidelines in my line of work"

"Self-assessments, collaborating with other team members, undertaking continuous professional development courses"

"Reading, reviewing and following standard operating procedures that outline review steps, expectations and best practices"

Some of the participants suggested methods that their senior managers could use to improve the way GRevPs are implemented.

"Periodically train staff on GrevP, either orally or written"

"Increase the number of training programs with regards to GrevP"

"Consistent training, and monitoring as well as continuous feedback to enhance the development of good review practices"

"Continue to impact knowledge on the ways to effectively embark on quality assessment of dossiers"

"Implement a review checklist and template to promote consistent documentation and version control, make it easier to track and retrieve information"

According to twenty-four (90 %) of the participants, the statement that best represents how GRevPs are maintained/improved within the department and within FDA Ghana in general is "a consistent method for documenting those practices that need to be improved by GRevPs has been established which also follows the updating process".

A gap analysis of the importance of GRevPs for the department/individual and how closely these were followed up showed that the study participants perceived that all aspects of GRevPs were important. However, the internal audit process, quality department, quality policy, target timelines, assessment templates, feedback from patients, and ability to track the process were considered to be very important. It was noted that practices are mostly in parallel with perception for most aspects of GRevPs, except for target timelines, where the median value showed considerable difference between perception and practice.

A gap analysis of the importance of GRevPs for the authority and how closely these were followed showed that participants perceived that all aspects of GRevPs were important and practices are mostly in parallel with perception for most aspects of GRevPs, except for target timelines and quality department, where the median values showed considerable differences between perception and practice. Lastly, it was remarkable that the quality policy was so well followed by the authority (Fig. 5).

Within the FDA Ghana, the division responsible for monitoring and documenting the quality of the review process is the "Quality Department".

4. Discussion

In this study, the strategies and measures that are in place within the FDA Ghana for developing and maintaining the quality in the review processes have been assessed. The results provide valuable insights into the perception of the assessors within the FDA Ghana, and a baseline has been established regarding the current knowledge, practices, and attitudes within the authority together with an understanding of the contribution of existing processes and procedures that support GRevPs

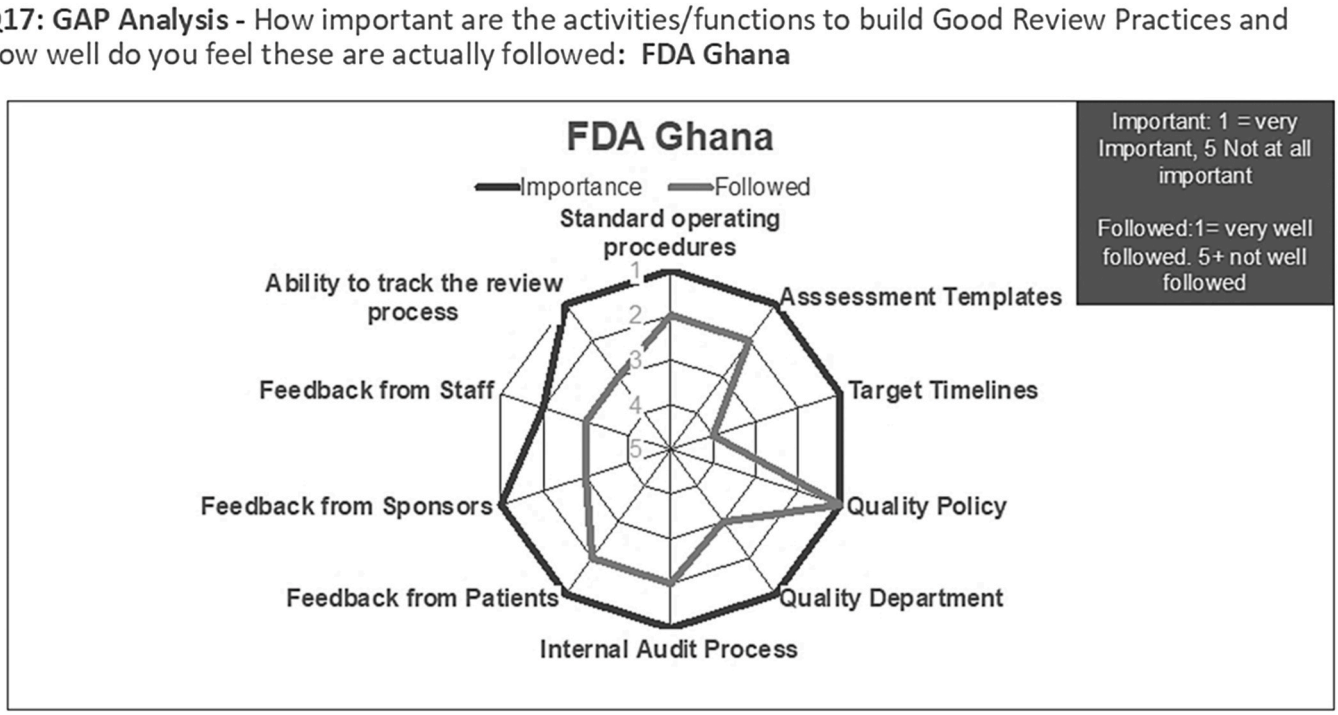

Fig. 5. Gap analysis for the FDA Ghana.

for their continuous improvement.

The knowledge base of the FDA Ghana with respect to the role and purpose of GRevPs was rated as good, and this serves as the foundation of implementing GRevPs and impacts the practices and attitudes of staff of the FDA Ghana. This is aptly presented by the WHO "capacity needs to be built on what exists" (Milen, 2001). The FDA Ghana may therefore consider building a solid GReVP system based upon its current knowledge profile.

According to Al-Essa and Al-Bastaki, "guidelines, standard operating procedures and review templates are the building blocks for good review practices in addition to other measures, which also have an impact on the quality of the review process such as having a formal framework to apply quality decision-making practices" (Al-Essa, Al-Bastaki, 2024). This points to the need to have all the requisite GRevPs in place in order to progress to the implementation of quality decision-making practices by the regulatory authority.

The results of this study show that five areas need further development at FDA Ghana: target timelines, feedback from companies, ability to track the review process, the quality department, and feedback from staff/assessment teams. It appears that two out of the five areas, ability to track the review process and target timelines are interlinked. The contribution of implementing target timelines to enhance patients' access to medicines cannot be overemphasized and the ability to track the review process to ensure compliance with those timelines has been documented in the literature (Al-Essa et al., 2015; Darrow et al., 2020; Patel et al., 2020; Bujar et al., 2021).

According to the literature, the extent to which GRevPs are implemented can affect patients' access to medical products, it is therefore appropriate that feedback from patients, companies and staff/assessment teams form part of the authority's GRevPs (WHO, 2015; Ndomondo-Sigonda et al., 2024; Kabir, 2024). In some countries, patients are directly involved in decision-making processes of regulatory authorities through patient associations (Muhlbacher et al., 2016; Richards, Hudson, 2016). The added-value of patient involvement in benefit-risk assessment and other regulatory processes in the European Union, which have been reported in the literature, could similarly be realized in patient involvement in the GRevPs of the Ghana FDA. Lowe and colleagues reported that "Patients have been invited by regulators such as the FDA, the European Medicines Agency, and the National Institute for Health and Care Excellence to provide their perspectives and advice during decision making" (Lowe et al., 2016).

It has been acknowledged that mentoring and on-the-job training would be valuable to train new reviewers and making use of readily available in-house resources is considered a sustainable way to implement GRevPs (Liu et al., 2013).

Most of the respondents believed that the current GRevP framework could be improved. Additional training to learn and understand how GRevPs are to be used and incorporated into daily work has been recommended in the literature (Liu et al., 2013). It is notable that most of the study participants offered several suggestions that they and senior management of FDA Ghana could do to improve the way GRevPs are implemented. These suggestions are worth considering by the FDA Ghana.

According to the majority of the participants, the FDA Ghana has a consistent method for documenting those practices that need to be improved by GRevPs and a mechanism has been established to facilitate the process of updating them.

Previous work has shown that patients benefit from strong regulatory systems; therefore, efforts should be made to strengthen national regulatory authorities in order that they function at optimal capacity to facilitate patients' access to medicines in Ghana and beyond (O'Brien et al., 2020). Regulatory capacity building is an ongoing challenge in the current regulatory environment in Africa; however, WHO, through its Coalition of Interested Parties for regulatory strengthening together with The African Medicines Regulatory Initiative New Partnership for Africa's Development (AMRH-NEPAD) have embarked on several initiatives, which will ultimately lead to stronger national and regional regulatory authorities, contributing to the operationalization of the AMA.

It is hoped that the FDA Ghana will take the necessary steps to address the gaps that have been identified in this study in order to have an improved regulatory review system.

4.1. Recommendations

The following recommendations were identified from this study:

- Formalise the full implementation of GRevPs within the authority, which would continue to build quality into the review process to achieve consistent, predictable, transparent, and timely regulatory review
- Make provisions to involve patient advocacy groups in regulatory review activities.
- Endeavor to include feedback from pharmaceutical manufacturers in regulatory review activities
- Provide more training opportunities for staff to continually improve the knowledge, attitudes and practices of GRevPs
- Introduce periodic monitoring of the implementation of GRevPs in the Ghana FDA.

5. Conclusions

This study has evaluated GRevPs and their implementation within the FDA Ghana. It has provided a baseline for the knowledge, attitudes and practices of the authority as well as areas for improvement. As a result of having a baseline it is possible now to work toward achieving an improvement in the regulatory performance of the FDA Ghana as it strives to become a WHO-listed agency.

CRediT authorship contribution statement

Mercy Owusu-Asante: Writing – review & editing, Writing – original draft, Formal analysis, Data curation, Conceptualization. **Delese Mimi Darko:** Writing – review & editing, Formal analysis, Data curation. **Seth Seaneke:** Writing – review & editing, Formal analysis, Data curation. **Neil McAuslane:** Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization. **Stuart Walker:** Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization. **Sam Salek:** Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization.

Ethics approval

The study was approved by Health, Science, Engineering and Technology ECDA, University of Hertfordshire, United Kingdom (Reference Protocol number: LMS/PGR/UH/05160).

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data availability

Data will be made available on request.

References

Al-Essa, R.K., Al-Bastaki, D.A., 2024. Building quality into the regulatory review practice for competent authorities. Pharm Sci. Available at https://www.intechopen.com/chapters/89197.

Al-Essa, R.K., Al-Rubaie, M., Walker, S., et al., 2015. Pharmaceutical Regulatory Environment: Challenges and Opportunities in the Gulf Region. Adis, Auckland, New Zealand.

Bujar, M., McAuslane, N., Liberti, L., 2021. The qualitative value of facilitated regulatory pathways in Europe, USA, and Japan: benefits, barriers to utilization, and suggested solutions. Pharm. Med. 35, 113–122.

Darrow, J.J., Avorn, J., Kesselheim, A.S., 2020. FDA approval and regulation of pharmaceuticals, 1983-2018. JAMA 323 (2), 164–176. https://doi.org/10.1001/jama.2019.20288.

Kabir, M., 2024. The role of quality assurance in accelerating pharmaceutical research and development: strategies for ensuring regulatory compliance and product integrity. J. Angiother. 8 (12), 1–11.

Lowe, M.M., Blaser, D.A., Cone, L., et al., 2016. Increasing patient involvement in drug development. Val Health 19 (6), 869–878. https://doi.org/10.1016/j.jval.2016.04.009.

Liu, L.-L., McAuslane, N., Tzou, M.-C., et al., 2013. Characterizing good review practices: a survey report among agencies of APEC member economies. Ther. Innov. Regul. Sci. 47 (6), 678–683. https://doi.org/10.1177/2168479013494394.

Milèn, A., 2001. World Health Organization what do we know about capacity building: an overview of existing knowledge and good practice [cited 15 March 2025]. Geneva, Switzerland. Available at https://iris.who.int/bitstream/handle/10665/67394/a76996.pdf.

Mühlbacher, A.C., Juhnke, C., Beyer, A.R., et al., 2016. Patient-focused benefit-risk analysis to inform regulatory decisions: the European Union perspective. Val Health 19 (6), 734–740. https://doi.org/10.1016/j.jval.2016.04.006.

Ndomondo-Sigonda, M., Azatyan, S., Doerr, P., et al., 2024. Best practices in the African Medicines Regulatory Harmonization initiative: perspectives of regulators and medicines manufacturers. PLOS Glob Public Health 3 (4), e0001651. https://doi.org/10.1371/journal.pgph.0001651.

O'Brien, J., Lumsden, R.S., Diehl, D.H., et al., 2020. Building a better approach for the enefit of patients: 10 pillars to strengthen regulatory review systems globally. Ther. Innov. Regul. Sci. 54, 283–292. https://doi.org/10.1007/s43441-019-00055-9.

Owusu-Asante, M., Darko, D.M., Asamoah-Okyere, K.D., et al., 2023. Evaluation of the food and Drugs Agency, Ghana regulatory review process: challenges and opportunities. Ther. Innov. Regul. Sci. 57 (2), 372–385.

Patel, P., Cerqueira, D.M., Santos, G.M.L., et al., 2020. A baseline analysis of regulatory review timelines for ANVISA: 2013–2016. Ther. Innov. Regul. Sci. 54, 1428–1435. https://doi.org/10.1007/s43441-020-00169-5.

Richards, N., Hudson, I., 2016. UK medicines regulation: responding to current challenges. Br. J. Clin. Pharmacol. 82 (6), 1471–1476. https://doi.org/10.1111/bcp.13077.

World Health Organization Africa, 2020. Brazzaville, Republic of Congo: World Health Organization Regional Office for Africa; 2020 [cited 15 March 2025]. Ghana Food and Drugs Agency (FDA) attains maturity level 3 regulatory status [internet]. https://www.afro.who.int/news/ghana-foods-and-drugs-agency-fda-attains-maturity-level-3-regulatory-status.

World Health Organization, 2015. Tech. Rep. Series, No. 992-Annex 9 [cited 15 March 2025]. Available at https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/regulatory-standards/trs992-annex9.pdf?sfvrsn=f94751de_2&download=true.

World Health Organization, 2024. A framework for evaluating and publicly designating regulatory authorities as WHO Listed Authorities (WLA) [cited 10 July 2025]. Available at https://www.who.int/initiatives/who-listed-authority-reg-authorities.