Assessment of Good Review Practices at the FDA Ghana as it strives to become a WHO Listed Agency

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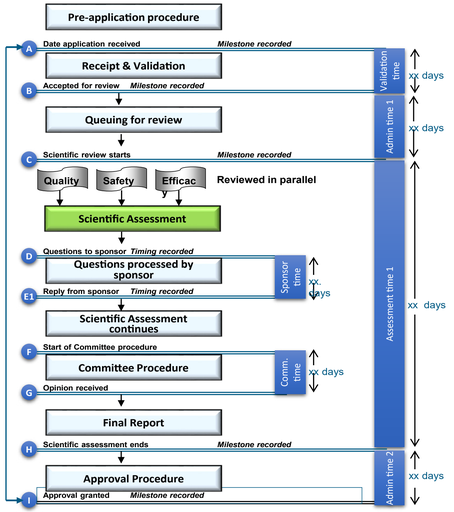
Background
Good Review Practice – Building Blocks for a Quality Review

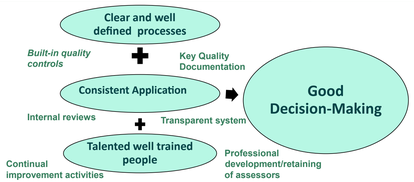


Documented Best Practice
- related to the process, format, content, and/or management of a review

Goal to promote:
timeliness, predictability, consistency, transparency, clarity, efficiency and high quality of the content and the management of reviews

Achieved through:
Use of review tools (SOP, templates etc) reviewer learning activities (training; mentoring)

Background
Key measures essential for Good Regulatory Review Practices



AIMS
- Identify the current perspective of the FDA Ghana in the implementation of GRevP
- Provide a baseline on the knowledge, attitude, practices
- Identify areas for improvement
- Determine how these procedures relate to the continuous process improvement within the FDA Ghana.

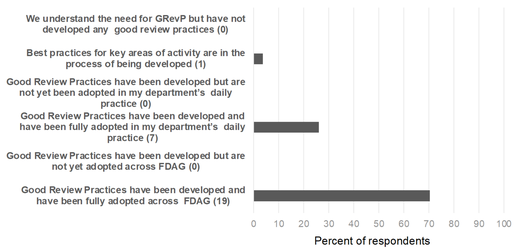
Method
– Questionnaire: 27/30 Assessors completed the Questionnaire

- The questionnaire consists of 17 different types of questions intended to establish a baseline with respect to the staff of the agency's knowledge, attitude and practice regarding GRevPs.
- 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 for identifying these practices 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 agency'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 both the departmental/individual and agency levels including how they could be improved.

Results - Knowledge
- According to nineteen (70%) of the respondents GRevPs have been developed and fully adopted across the agency (Figure 1).
- This supports the findings in the previous study (Owusu-Asante et al, 2023) that guidelines, standard operating procedures and review templates were in place and the majority of indicators for good review practices were implemented.

Fig.1

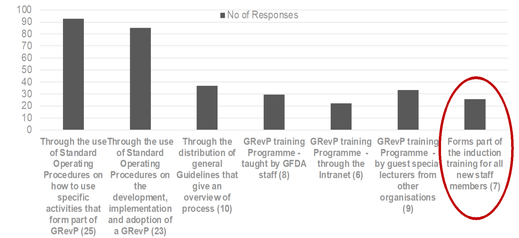
Q1, To what extent do you feel GRevP are in development at FDA Ghana? Please mark only ONE of the following Statements: Percentage of respondents (N=27)



Results - Practice
- 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 (Figure 2).

Fig.2

Q 3 , If you feel that GRevP are now in place (Formally/Informally) - How is this being implemented? Mark all that apply (N=27) Percentage of respondents



Results - Attitude
- Twenty-five (93%) of the participants 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 GRevPs system is in an evolving phase within the Agency and believed that additional training would be a value to understand how GRevPs should be incorporated into their daily work.

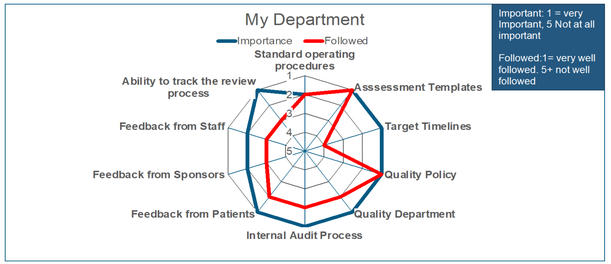
Results
- Twenty-five (93%) of the participants rated the process for the implementation of GRevP within the FDA Ghana as satisfactory.
- GRevPs have been implemented based on best practices identified through the collective experience of FDA Ghana and the reviewers.
- Two participants stated that while 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. This includes 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 agency needs to implement as part of good review practices.

Results
- Gap Analysis re Department

- 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 the practices are mostly in parallel with perception for most aspects of GRevPs, but that regarding target timelines the median value showed that there is considerable difference between perception and practice. (Figure 3).

Fig. 3

Q17: GAP Analysis - How important are the activities/functions to build Good Review Practices and how well do you feel these are actually followed: **My Department**



Results- Gap Analysis re Agency

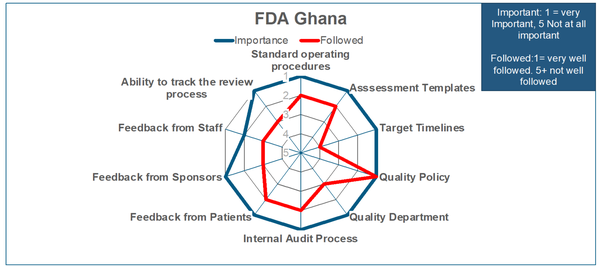
A gap analysis of the importance of GRevPs for the agency and how closely these were followed showed that participants perceived that all aspects of GRevPs were important.

It was however noted that the practices are mostly in parallel with perception for most aspects of GRevPs, however with regard to target timelines and quality department, the median values showed considerable differences between perception and practice.

Lastly, It was remarkable that the quality policy was so well followed by the agency (Figure 4).

Fig. 4

Q17: GAP Analysis - How important are the activities/functions to build Good Review Practices and how well do you feel these are actually followed: **FDA Ghana**



Conclusions
- This study showed that target timelines are not well followed either by the department or agency.
- This gap has adverse implications regarding patients' access to medicines.
- 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.

Recommendations
1. Improve the transparency and consistency of the scientific review system by implementing a structured framework for decision making and benefit-risk assessment
2. Enhance transparency and communication through the development of summaries of the basis of approval that may be made available in the public domain.
3. Formalise the full implementation of Good Review Practices within the agency which would continue to build quality into the review process to achieve consistent, predictable, transparent and timely regulatory reviews
4. Involve patient advocacy groups in regulatory review activities.
5. Make provisions to include feedback from pharmaceutical manufacturers in regulatory review activities