Background

The function and activities of review processes across all regulatory agencies are very similar in terms of the missions, processes and steps required to assess a medicine for safety, quality and efficacy. Regulatory systems vary across countries as well as over time. However the characteristics that reflect the activities of a well-developed regulatory agency are recognized through frameworks that are embedded into their processes and procedures: transparency, timeliness, process predictability and quality reviews. These four characteristics have been measured in regulatory processes that have been characterized for selected agencies. However, not all agencies implement activities that facilitate a quality review process.

This study was conducted to characterize the processes that pharmaceutical companies believe can drive improvements in company-agency interactions thereby improving quality review processes implemented by agencies. CIRS conducted this study to identify "best agency interactions thereby improving quality review processes."

Objectives

• Characterize the regulatory practices which from a company perspective, enable companies to reflect Good Review Practices that can be used by emerging market (EM) agencies to ensure quality decisions.
• Identify attributes needed to add value to the regulatory process by recognizing key attributes that enables a transparent, timely, predictable and good-quality review
• Understand how companies believe regulatory agencies rate with regard to the attributes that underpin transparency, timeliness, process predictability and quality reviews.

Methods

Between June and September 2011, Microsoft Word 

Objectives

Part 1: Enablers of the Regulatory Review

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N = number of companies that gave rating

Results

Part 2: Company ratings of agencies

Part 2: Company ratings of agencies

Results cont

Conclusions

Key enablers of a quality review process were identified; the most critical was the ability for companies to maintain a dialogue with agencies through the review process. Some agencies were able to be more proactive and expedient in providing feedback; and were more responsive to requests for additional information. A number of agencies were unable to achieve any level of predictability; hence making the review process very inefficient.

This study has been presented at the DIA Global Forum.

Disclosures

The authors have no disclosures.

References

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