

Lancaster Laboratories

A Contract Outsourcing Approach to Quality Metrics Reporting

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Introduction -

Industry partners are attempting to understand the requirement of the FDA draft guidance regarding the Quality Metrics Program which was released in July, 2015. Whether firms are large pharmaceutical conglomerates, start-up biotech companies, or contract outsourcing partners, the Bio/Pharmaceutical industry is seeking to meet regulatory requirements in order to safeguard product quality and patient safety.

Moreover, suppliers and contractors providing services to a firm are viewed as a strategic "extension" of the firm's own facility rather than an independent resource, producing a unique relationship for this reporting program.

The process of maintaining control over suppliers requires effective organization, risk management, implementation of a strong quality culture, and quality oversight, which can lead to an extensive amount of time and resources if not managed appropriately. It is important to build a dynamic working relationship with contract partners to develop a quality surveillance program allowing for a proactive environment of continuous improvement.

Methods

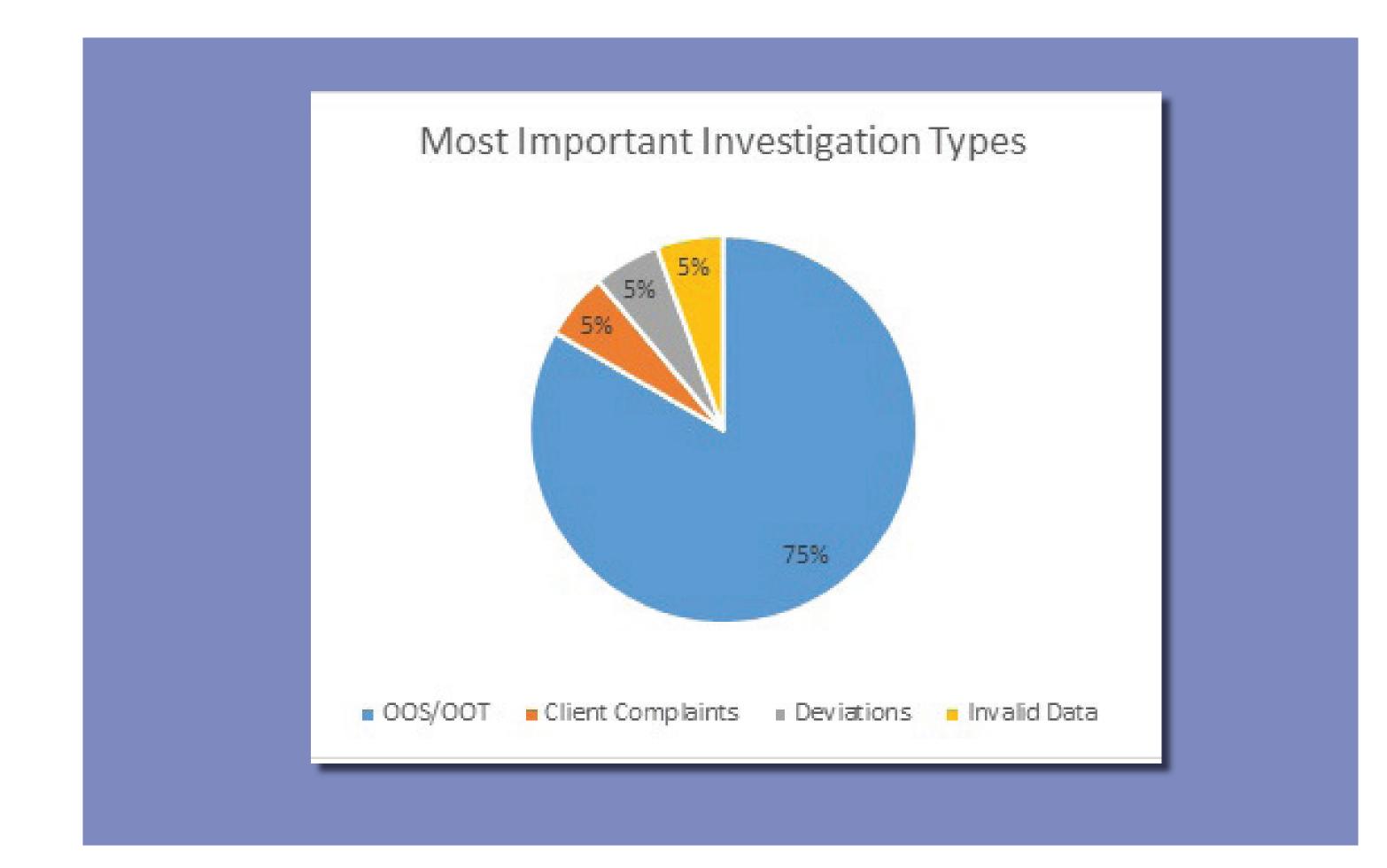
The FDA Guidance was reviewed and assessed by Eurofins Lancaster Laboratories' Quality Compliance Specialists and Management to determine metrics that are most applicable to contract outsourcing work, specifically applicable to contract laboratories.

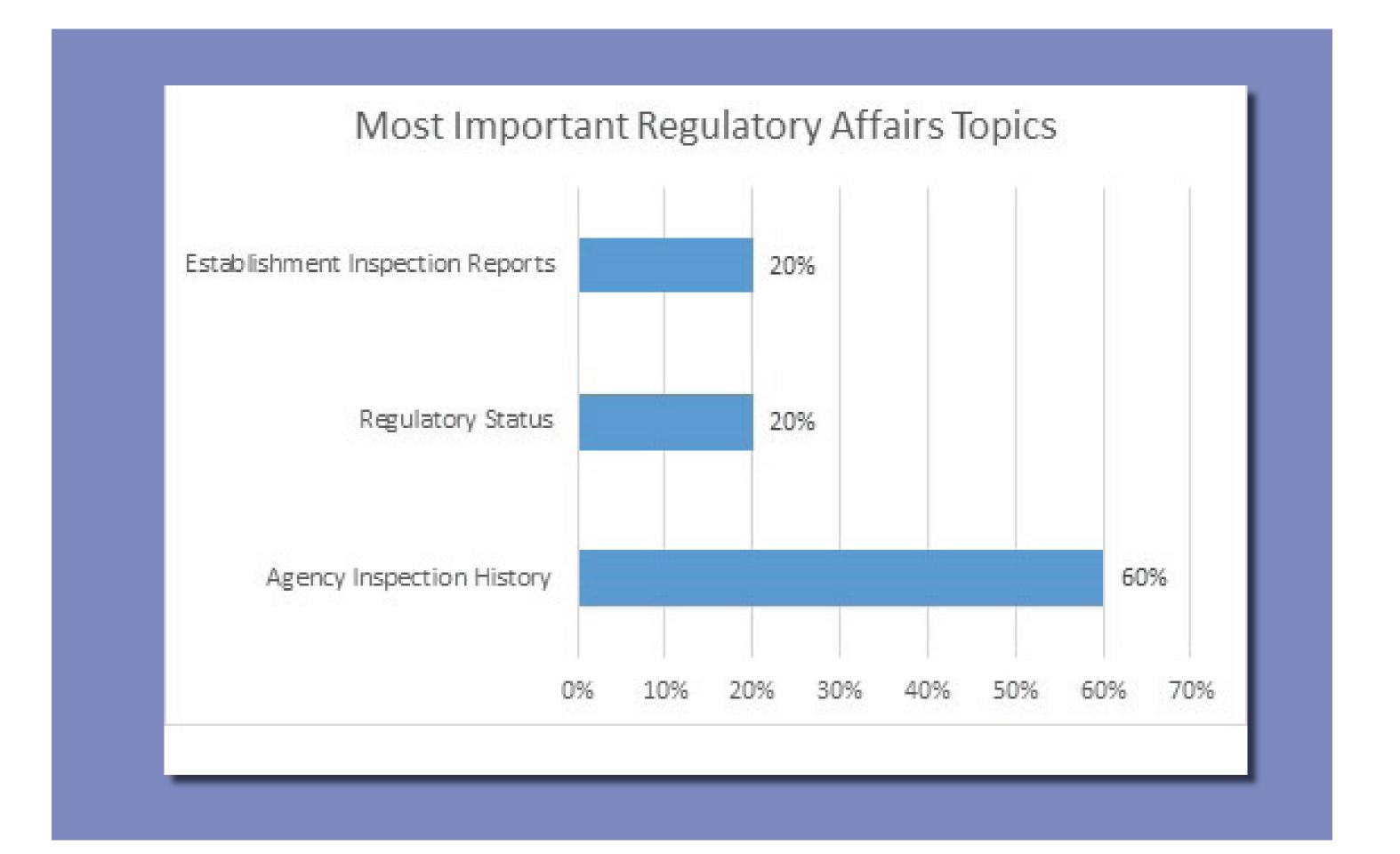
Our client facing personnel (Project Managers and Business Development Representatives) were surveyed regarding client quality requests. The representatives were asked about topics they receive the most queries from clients about to determine subjects that are important to the quality relationship.

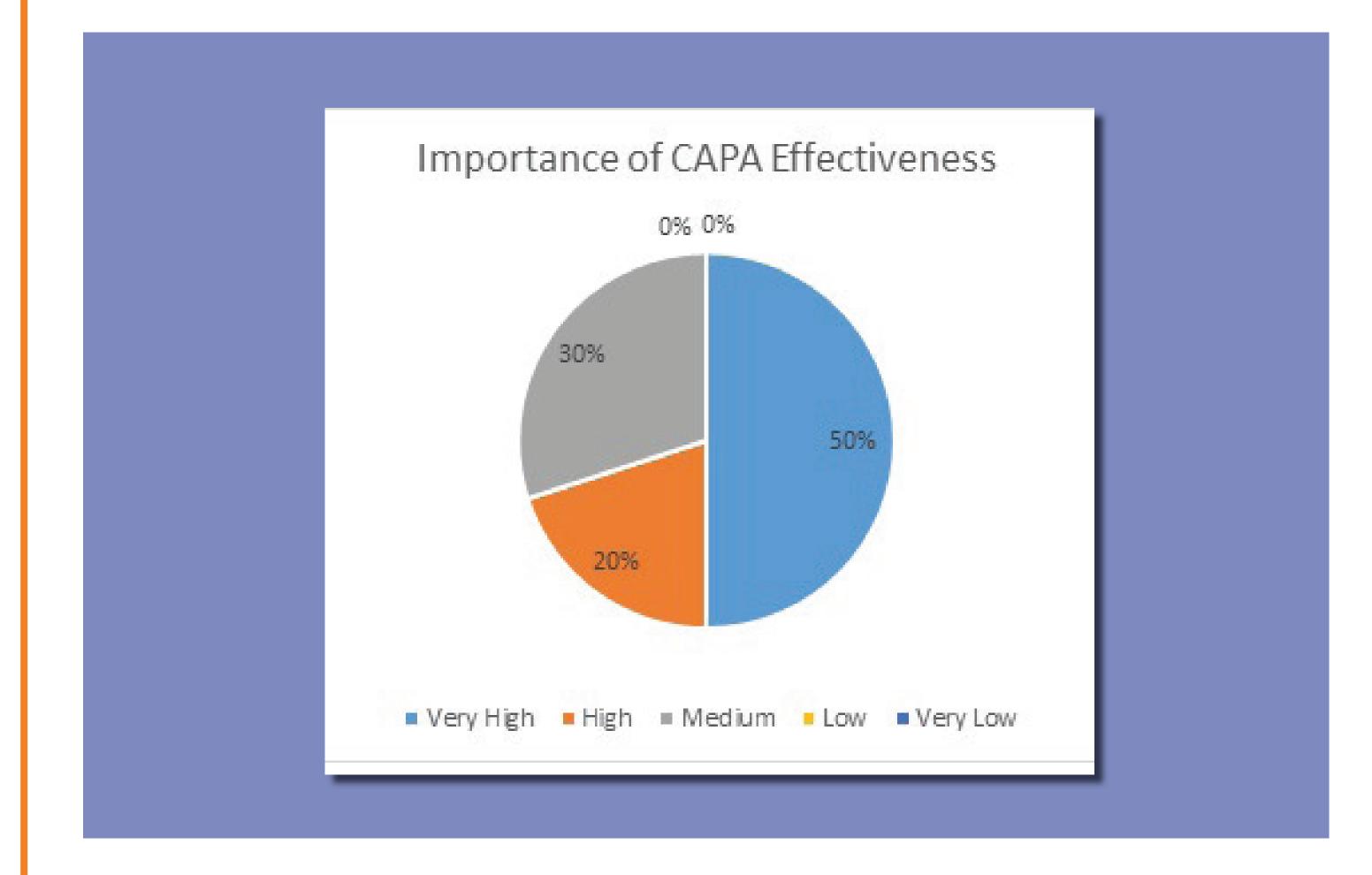
The results of the survey in tandem with the FDA Guidance were analyzed by Quality Compliance Specialists to determine a key set of Quality Metrics.

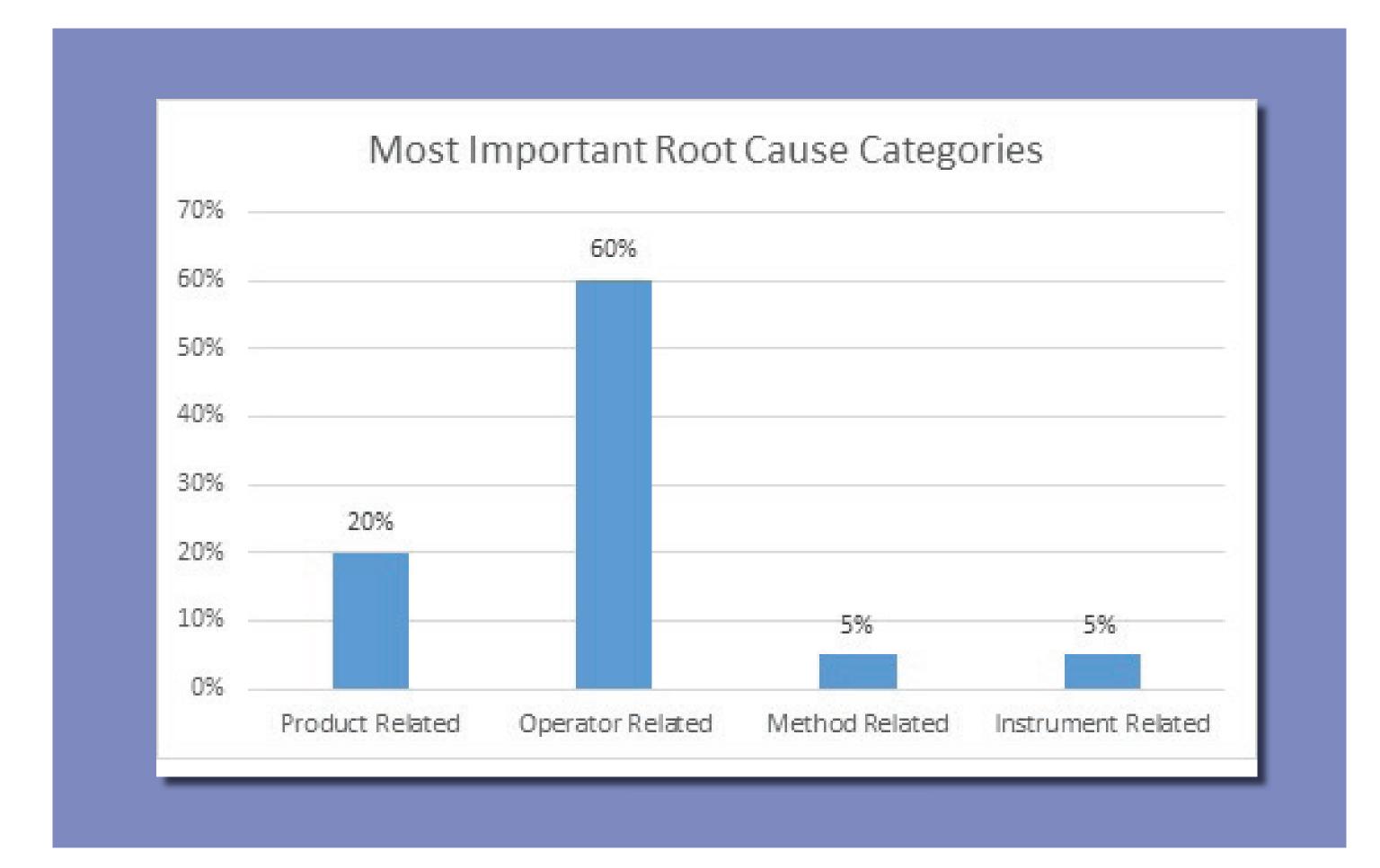
Results

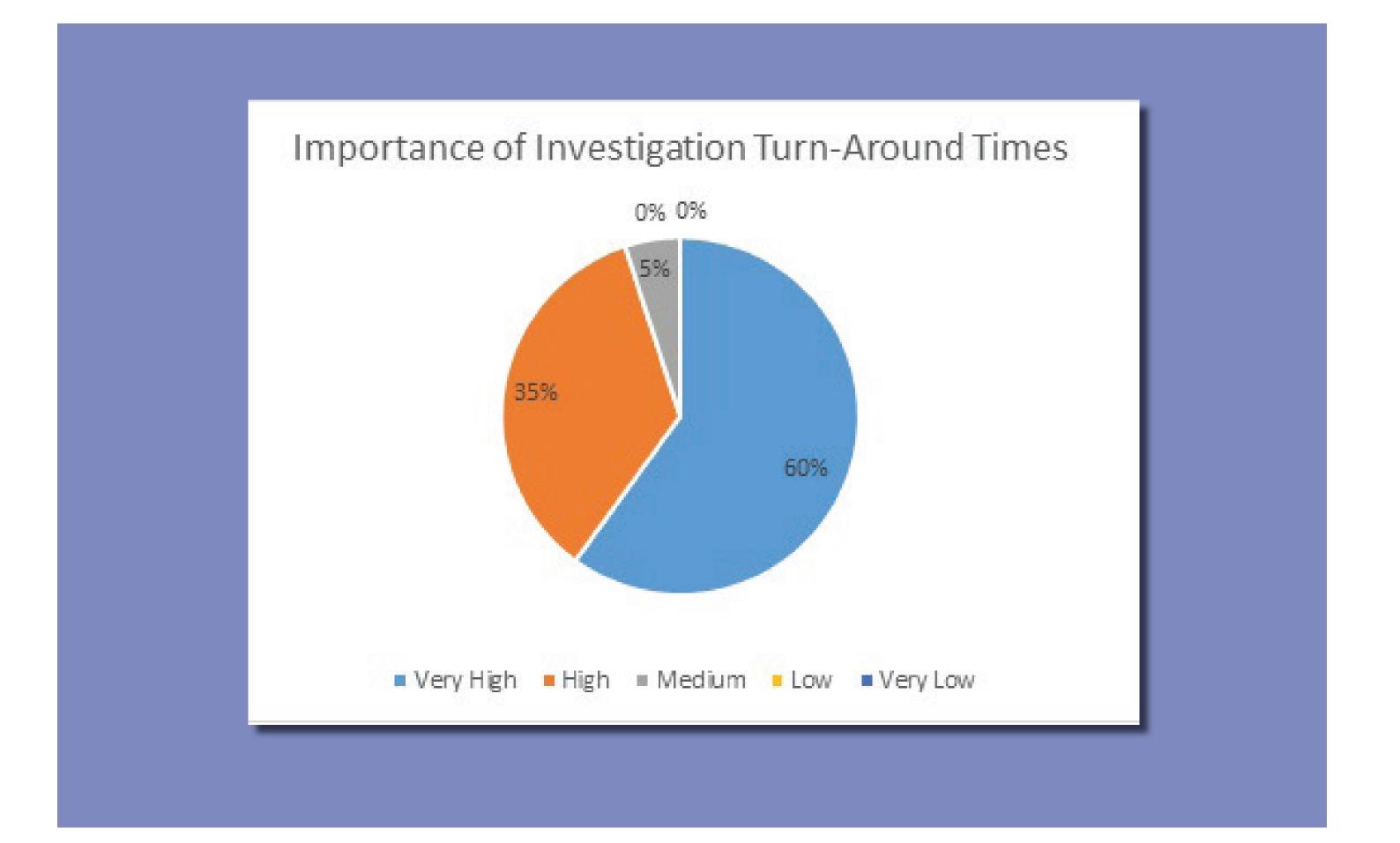




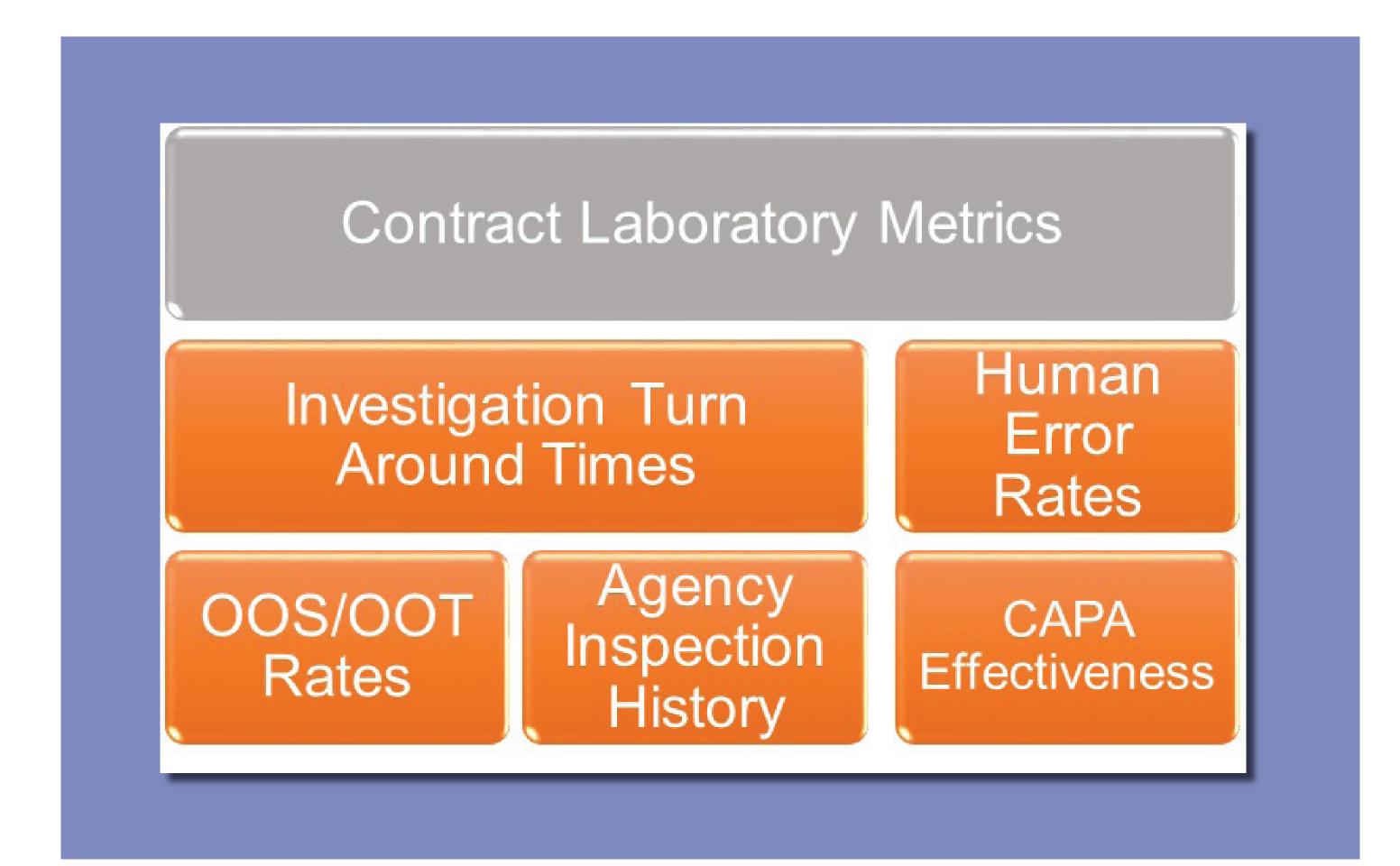












Conclusion -

The results obtained from this study provide a comprehensive list of Quality Metrics that can be used to report meaningful key quality indicators. Through implementation of a strong Quality Metrics Program and maintaining effective and dynamic relationships with clients, contract outsourcing partners can ensure a high level of continued excellence in safeguarding drug quality and patient safety. As new guidance is developed, it is imperative that firms create a dynamic program that adheres to current thinking.

References

U.S. Department of Health and Human Services Food and Drug Administration. (2015). Request for Quality Metrics Guidance for Industry (Draft).