

White Paper

Quality in Pharmaceutical Research



“Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives.”

– **William A. Foster**

Organizations conducting business within the pharmaceutical industry, regardless of whether they are a sponsor or a service provider, should always hold **Quality** as a first priority. Unfortunately, even though a quality mindset is usually integrated as part of a company in the form of a department, system, or a series of processes, many companies lose sight of its utmost importance when conducting their day-to-day business. In other words, although a diamond may seem flawless and of high quality upon first glance, the truth is revealed when you look more closely at its facets with a microscope and discover numerous flaws within its structure.

For this reason, and since our company’s inception, we wanted to ensure that Quality is in the forefront of all of our day-to-day business activities and therefore the above quote from William A. Foster was chosen to be placed on our website and brochures as a constant reminder to our clients and employees of our obligation to constantly deliver the best that is expected from us.



But is this enough? After observing over the last decade continued Quality issues throughout our industry, we wanted to reach out and ask individuals what William A. Foster’s quote means to them. Where better to begin than where quality starts - within our own organization! The responses we received below from our employees proved very informative, and confirm that the processes we have put into place are actually working.

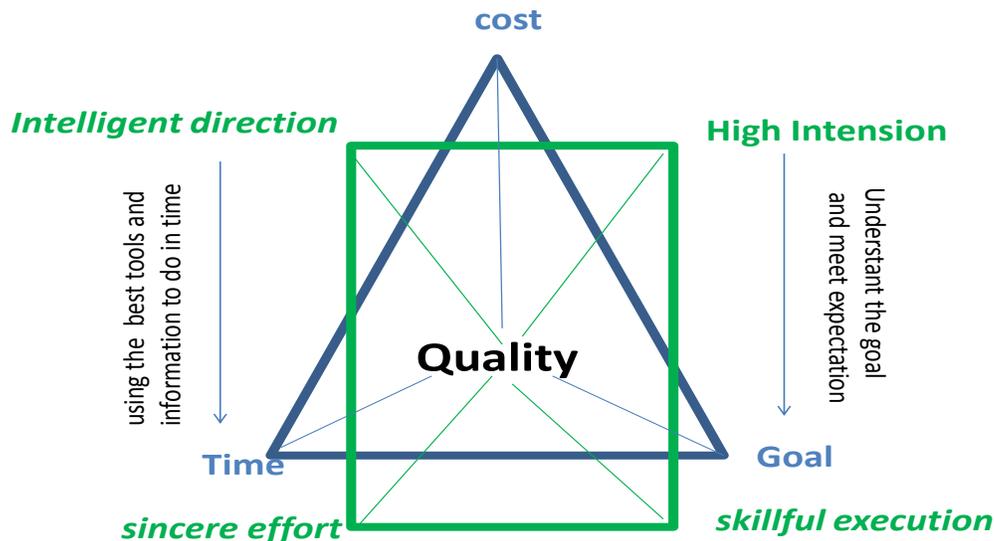
Quality – Four Personal Perspectives

Perspective #1 - from our Clinical Research Scientist:

The clinical research industry faces challenges such as constantly changing regulations, working on complex protocols with multiple endpoints, and complex trial designs including the development of Adaptive Trial protocols. These challenges put pressure on Clinical Trial Management Organizations to be more flexible when delivering the highest quality services to their clients.

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In my opinion, the implementation of Foster's statement is the key to success in building an organization's reputation in the industry. This, however, cannot be achieved without a good project management system. If we look at the Project Management Triangle model (below), where each side of the triangle is represented by "goal", "time", and "cost", we can see that changing one side of the triangle directly affects the other sides, as well as the overall level of quality produced. It is crucial for project managers and supporting staff to realize that these three factors are closely interrelated, and that any change in one of these areas will require a re-adjustment in the other factors. For example, if the overall goal or scope of a project is altered to involve more requirements, then this will likely result in an increase in the overall cost and time required for completion of the project. Without taking these adjustments into account, the quality of the project will be highly compromised.



Quality is not an accident

Perspective #2 – from our CRA:

“People forget how fast you did a job-but they ALWAYS remember how well you did it.”

- **Howard W. Newton**

Quality reflects the combined personalities, motivation and performance of all personnel involved in a given project. Personality influences how people approach and react to pressures arising from critical situations and issues relating to the maintenance of quality throughout a project timeline. To also paraphrase

what Howard W. Newton once said, it is important to keep in mind that clients and business partners will remember first and foremost the degree of quality of the work that was completed,

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rather than how quickly it was done. Motivation also plays a central role in the degree of quality achieved within an organization. Companies should strive to create and maintain a work culture which ensures that all employees feel valued and appreciated, as well as consistently challenged to put forth their best work possible and strive to improve the magnitude of their contributions for the collective benefit of the organization. Working together as a team and recognizing the importance of each role within a company in reaching the overall project goal will lead to increases in motivation. In summary, positive attitudes and personalities, as well as strong levels of motivation will improve overall performance and the quality of work produced.

Perspective #3 – from our CTA:

The way I interpret this quote is as follows: “Quality is obtained and accomplished by the knowledge, capabilities and determination of qualified individuals, and is attributed to the well-planned management of the development of the skills and expertise of employees.” In order to maintain an exceptional level of quality within an organization, employees must be continually trained and evaluated in order to ensure that the company is producing the best possible work for their clients. This is possible through the efficient organization of upper management in a company, as well as each employee’s desire to succeed and improve.

Perspective #4 – from our Scientific Project Manager:

My view on this is that usually, most people see quality only from a tactical angle- focusing primarily on following procedures, meeting pre-defined specifications and other standards, and verifying whether the work that was done directly agrees with what was required as a minimum.

However, quality has a broader scope, which of course includes the methodically driven approach described above, but should also include what I like to call “strategic quality”. “Strategic quality” goes beyond basic regulatory requirements and incorporates creating project plans specifically tailored to each client’s needs and expectations. By designing a project plan concentrated on fulfilling the unique needs of the customer, companies are able to provide a consistent high standard of quality. If this concept of “strategic quality” is implemented, then excellence in quality easily becomes second nature for employees working in any department in an organization, whether they are an individual working in the HR department, or in manufacturing operations.

The First and Last Thing on Our Minds

Every company needs to understand that Quality is the key to success. Based on the perspectives outlined above, we can see that exceptional levels of quality are achieved based on the combination of several equally important factors. At the level of project management within a pharmaceutical research organization, the coordination of the three main functions of scope/goal, time and cost, and the need to continuously adjust these factors if one changes, is an important determinant of quality. Since the clinical research industry is frequently

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unpredictable and projects are continually changing and being adjusted, this principle is particularly important. Management within an organization must also ensure that employees are fully trained and qualified to ensure that quality is upheld at all times, especially since industry regulations are constantly evolving. Quality is also a reflection of the combined efforts and performance from each employee, resulting from strong levels of motivation and team work, as well as positive attitudes. Ultimately, by implementing “strategic quality” and focusing on the needs of the client first and foremost, each client will be uniquely satisfied with the quality of the work done.

At Vantage BioTrials, we strive to fully implement all of these factors in order to guarantee exceptional quality every time.

Look for one of our upcoming issues when we discuss “Quality by Design” in clinical trials.

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References:

1. http://en.wikipedia.org/wiki/File:Foster_WA_USMC.jpg
2. <http://www.qualitydigest.com/may98/html/strateg.html>

About Vantage BioTrials Inc.

Vantage BioTrials Inc. is a privately owned Clinical Trial Management Organization (CTMO) based in Montréal, Canada, that provides superior trial management services and combines a precise blend of clinical development knowledge, talent and resources that will ensure a clinical study’s full potential. By servicing our global Pharmaceutical, Biotech, Medical Device and Generic clients who perform Phase I, II-IV clinical trials, our goal is to exceed their expectations by offering outstanding monitoring, project management and clinical operation services.

To learn more about Vantage BioTrials, please visit us at www.vantagebiotrials.com.