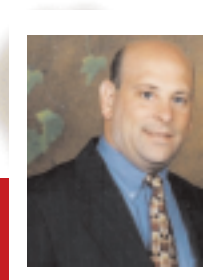




Final Word

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Statisticians Tackle More Than Clinical Trials

Capitalize on their expertise for optimum productivity

When you think about statisticians in your organization, usually the first thing that comes to mind is clinical trials. Pharmaceutical, biotechnology, and medical device companies have always hired statisticians as essential personnel for bringing new drugs and devices through the regulatory process. But why are statisticians overlooked as partners in other areas? Part of the problem is statisticians' inability to speak the language of their non-statistical counterparts. And part of the problem is an organization's inability to recognize what statistics can do to help foster the corporate mission.

LEAN MANUFACTURING AND SIX SIGMA

With a greater emphasis on improving efficiency and lowering costs, programs such as Lean Manufacturing and Six Sigma are now integral to any organization. These programs rely upon statistics as the foundation for success, but very few companies use statisticians in their efforts. These initiatives start at a senior level and are usually managed by manufacturing or quality assurance/control personnel. Statisticians trained in utilizing quality tools can be of assistance to these efforts ensuring that the metrics are meaningful.

QUALITY

In the biotech industry, quality usually means current Good Manufacturing Practices (cGMP) where compliance is paramount. There is more to quality than just documentation and inspection. Many of the International

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Conference on Harmonization (ICH) guidelines require statistical methods in establishing specification, stability claim, and method validation. Often the statistical methods are misapplied or misinterpreted. Statisticians partner with technical experts to design statistically valid studies to construct the appropriate analysis. They could also participate on the Material Review Board (MRB) to help establish the required testing needed to meet any Out of Specification (OOS) procedures.

BUSINESS INTELLIGENCE

Business intelligence, or methods for gathering, storing, analyzing, and providing access to data to help organizations make better business decisions, is an area that is underserved by statisticians. For exam-

ple, supply chain management is a purchasing department responsibility. With the help of a statistician, it is possible to get a more robust level for safety stock and inventory management. Customer relationship management is a marketing responsibility, though a statistician can assist in this area by developing predictive models. In both cases, good statistical models and appropriate data mining are essential to success.

Statisticians have long been relegated to clinical trials analysis, but as business becomes more data-driven, they will become an integral part of the entire organization. If we follow the philosophy of Quality Guru W. Edwards Deming, every organization should have a master statistician whose responsibility is to help the organization make data-driven decisions. ♦