IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY | an informa business
Unlimited Validation Knowledge Awaits...
Published on *IVT Network* (http://www.ivtnetwork.com)

Statistics Roundtable #1: Invitation To Participate

Jeremy M. Ebersole

Paul L. Pluta

By ,

Aug 27, 2021 7:00 am EDT

Invitation to Participate

Statistics Roundtable is a new IVT feature that will provide readers an opportunity to discuss information about statistics and demonstrate the application of statistics to pharmaceutical problems. The use of statistics is fundamental in regulated industries. The statistical basis for decision-making is an expectation. Any effort to increase the understanding and application of statistics in daily work life will be useful to readers.

WE NEED THIS FEATURE

The idea for an ongoing statistics discussion in the IVT journals came from multiple sources. Validation and Quality Managers have repeatedly requested that statistics topics be addressed in the IVT journals; they heartily agree on the need to discuss the many individual topics associated with statistics applications. Statistics topics are not adequately addressed at technical professional meetings. Whenever there is an IVT meeting with a session “Statistics for Non-Statisticians,” the presentation room is usually filled, and post-presentation discussions on sampling, SPC, OC curves, and other statistics-related topics continue informally throughout the meeting. Virtual meetings have only hurt our ability to network and interact on these topics; discussion of statistics topics is needed more than ever at this time.

FDA Focus on Statistics

FDA has clearly stated their interest and expectations for statistics application in the manufacturing process validation lifecycle (1,2). References to statistical methods are numerous in the FDA process validation guidance. For example:

In Stage 1 Process Design,

"Design of Experiment (DOE) studies can help develop process knowledge by revealing relationships, including multivariate interactions, between the variable inputs (e.g., component characteristic or process parameters) and the resulting outputs (e.g., in-process material, intermediates, or the final product)."

In Stage 2 Process Qualification regarding sampling plans, sampling points, number of samples, and the frequency of sampling:

"The number of samples should be adequate to provide sufficient statistical confidence of quality both within a batch and between batches. The confidence level selected can be based on risk analysis as it relates to the particular attribute under examination."

In Stage 3 Continued Process Verification regarding data review, process trends and quality of incoming materials or components, in-process material, and finished products:

"The data should be statistically trended and reviewed by trained personnel. The information collected should verify that the quality attributes are being appropriately controlled throughout the process."

The Stage 3 discussion includes a clear FDA recommendation.

"We recommend that a statistician or person with adequate training in statistical process control techniques develop the data collection plan and statistical methods and procedures used in measuring and evaluating process stability and process capability."

STATISTICS ROUNDTABLE **- SCOPE AND CONTENT**

The potential scope of *Statistics Roundtable* content is extensive; statistics applications in validation and QA activities are numerous. Pharma and med device professionals use statistics to design and evaluate experiments, to characterize process data, to monitor ongoing performance, to determine significant differences, and many other applications – all of which add confidence and credibility to conclusions and decisions. The proper use of statistics requires personnel with appropriate expertise. Industry personnel with extensive education in statistics are part of all significant project activities to ensure correct application of statistics and credible decisions. Per the FDA recommendation above (1), we must involve people with statistics expertise as appropriate to successfully accomplish our function responsibilities.

Just as statistics professionals must understand pharma project content to appropriately provide statistics applications, validation and QA personnel must likewise have reasonable understanding of fundamental statistics to effectively interact with statistics SMEs. Pharma managers comment that their knowledge of statistics dates back to college courses, that language in statistics is too specialized and not understandable, and that they are intimidated by statistics mathematical expressions. We utilize readily available software to accomplish statistics calculations, but really don't understand why or what we are doing.

Our goal in *Statistics Roundtable* is to provide basic understanding of statistics concepts. We intend to focus on fundamentals specific to GMP applications. We will identify statistics concepts applicable to validation and QA and demonstrate their use in example problems. Readers have opined their preference for case studies describing practical applications of theory; we intend to emphasize fundamental theory and problem-solving. Our objectives are modest; it is unrealistic to expect readers to become statistics SMEs based on reading content in *Statistics Roundtable.* Statisticians sometimes speak with terminology unknown to non-statisticians; we intend to overcome these language barriers in *Statistics Roundtable* content. If we are able to provide a fundamental understanding of basic concepts to facilitate meaningful communication between validation, QA and statistics professionals in the daily work environment, Statistics Roundtable will be a success.

Discussion Topics. The first topics to be discussed will provide a baseline understanding of relevant topics:

- Data. Review of the fundamental classifications and measures of data
- Parametric and nonparametric statistics. Are tests appropriate for the data?
- Data and distributions. What is "Normal"? Discussion of normal distribution, central limit theorem, plotting data, and histograms

- Confidence intervals: How sure can you be? Overview, statistical significance, and sigma levels.

Discussion of the above is planned to include applications and relevant examples. Corresponding podcasts may also be presented to supplement the above.

WE NEED YOUR HELP

The title *Statistic Roundtable* was selected to emphasize our desire for reader involvement in this forum. We invite participation and contributions from industry professionals with statistics backgrounds to help in Statistics Roundtable. We envision manuscripts with brief discussions of individual statistics topics followed by example calculations – brief, clear, and simple. Joint submissions from project groups with project and statistics perspectives are most welcome.

Communication Methods. The multiple communication methods available through IVT will be utilized in Statistics Roundtable. Journal submissions for publication in the Journal of Validation Technology and Journal of GXP Compliance are invited. Blog discussions posted on the IVT Network are more informal and are also welcome. IVT “Voices in Validation” podcasts provide visual and verbal discussion by individuals and groups; information sharing through IVT podcasts has been very well received and very successful. Coupling written and podcast discussions have been effective methods of transmitting content and provide multiple preferred adult learning methods. The IVT Network is currently experiencing tremendous growth in each of our communication vehicles; applying their outreach will contribute to general website value as well as providing contributing individuals with global visibility and recognition. Please join us; *Statistics Roundtable* will be most successful when validation, quality, and statistics communities participate in this endeavor. Please respond in the comments section below with ideas, suggestions, or topics for discussion.

REFERENCES

1. FDA. Guidance for Industry. Process Validation: General Principles and Practices. January 2011.
2. Torbeck, Lynn. Validation by Design®. The Statistical Handbook for Pharmaceutical Process Validation. PDA, Bethesda, MD, and DHI Publishing, River Grove, IL, 2010.

Download the Article
