

**From:** "Nan Matthews" <rmras@themattgrp.com>  
**Subject:** **Statistics for 510(k) Submissions - AUDIOCONFERENCE**  
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**Please join the Rocky Mountain Regulatory Affairs Society at Intelligent Office in Lakewood to take advantage of discounted fees for the following audioconference. This is only available at Intelligent Office, not at your company.**

## **Statistics for 510(k) Submissions** **Thursday, March 4, 11:00am – 12: 30pm**

### **Location:**

Intelligent Office  
Financial Plaza  
225 Union Blvd, #150  
Lakewood, CO 80228  
Phone: 303-974-6600

The FDA guidance for Premarket Notification [510(k)] requires the manufacturer to show "substantial equivalence" of a new device before it may be marketed. You know that substantial equivalence requires that your new device be very similar to one already allowed on the market AND that it be at least as safe and effective as the predicate. But how do you prove it?

Rigorous attention needs to be paid to statistical elements from the beginning of the design stage through the manufacture of the device, including hypothesis testing, analyses and sample size. So even if you're not the statistician, you need to familiarize yourself with the statistical methods used and the data required to clearly show equivalence to FDA in your premarket notification.

Steven Walfish, President, Statistical Outsourcing Services, will examine the techniques commonly and successfully used in 510(k) submissions. Combining a basic introduction to how statistics are used in actual 510(k) submissions and examples of common mistakes, this teleconference will give you practical approaches, background and guidance on how statistical methods are selected and used.

No previous statistical analysis experience is needed to benefit from this presentation -- just a desire to learn. (If you're a statistician already, encourage colleagues from other departments to sign up -- and make it easier for everyone to understand the data you need and the rationale underlying your analyses.) This presentation will also address when novices can effectively do the needed statistics on off-the-shelf software or even Excel -- as well as how to recognize when you're in over your head and need to bring in an experienced statistician.

### **The Presentation Will Cover:**

- Summary statistics
- Effective use of tables and graphs
- Common statistical methods and terminology, such as P-value and R2
- Calculating sample size
- Equivalence – Two One Sided Test (TOST)
- The "at least good as" criterion
- Special considerations for In-Vitro Diagnostics (IVDs)
- Basic software tools for analysis
- When are you in over your head?
- When do you call in a consultant?

### **What You'll Get:**

- Easy-to-understand instructions for doing simple data analysis
- Clarification of common misperceptions about statistics
- An understanding of what NOT to do
- Case studies drawn from existing 510(k)s
- An engaging, experienced instructor
- Time for question & answers

### **Speaker Bio:**

Steven Walfish is President of Statistical Outsourcing Services, a consulting company which provides statistical analysis and training to FDA-regulated firms. Prior to starting this firm, Mr. Walfish was the Senior Manager Biostatistics, Non-Clinical at Human Genome Sciences in Rockville MD, a Senior Associate at PricewaterhouseCoopers specializing in the pharmaceutical industry and Manager of Non-Clinical Statistics at Chiron Diagnostics. This variety of experience all contributes to over 20 years of expertise in the development and application

of statistical methods for solving complex issues including data collection, analysis and reporting. Mr. Walfish has been an invited lecturer at many industry educational meetings, and an editorial board member for BioPharm International, as well as a regular contributor to the magazine.

**The cost of this audioconference is \$70.00. To register, please go to [www.regonline.com/statistics](http://www.regonline.com/statistics)**

**We must have at least 10 people register in order to host this meeting. Your credit card will not be charged until we reach that number.**

**For questions, please contact Nan Matthews, [rmras@themattgrp.com](mailto:rmras@themattgrp.com) or 303-843-6414**