

# Leonard Buchner

## Capabilities and Experience

### Work Experience

#### Senior Director: MyRAQA, Inc. 2010-present

Lead efforts to build a new statistical competency in the organization. Provide consultation to clients regarding study design and data analysis. Provide program management services.

#### Senior Director: Broncus Technologies 2008-2010

Directed staff in the management of pivotal EASE clinical trial. Provided biostatistical support to clinical and preclinical study design. Lead data mining, statistical modeling and analysis planning.

#### Senior Director: FoxHollow Technologies 2006-2008

Established and built a Biostatistics and Data Management group. Ensured that proper trial design and data management procedures were employed. Provided data management support to the Merck collaboration.

#### Senior Director: Guava Technologies 2002 – 2006

Directed program management, statistical support and quality function. Directly managed or assisted in the release of two new instruments, several applications and key enhancements. Managed development of a new diagnostic product including performing all of the biostatistical functions for the clinical trials and 510(k) filing. Brought company into QSR/ISO compliance.

#### Program Director: Becton Dickinson 1987 - 2002

Brought the BMI product line of clinical products back to market, managed the launch phase of a new benchtop research flow cytometer and directed problem-solving teams on existing products. Established and built a department focused on the systems development and evaluation of flow cytometry based medical diagnostic products through all phases of product development, clinical feasibility, custom formulation and product support.

#### Senior Development Supervisor: Syva Company 1981 - 1987

Established a biostatistics and internal software development group. Major projects involved optimization of enzymatic reactions, process validation, quality control, and computerization of laboratories.

### About MyRAQA

MyRAQA is a full-service IVD Regulatory consulting firm. Founded in 1998, MyRAQA has grown to include leading experts in RA, QA, Design Control, Process Development, Study Design, and Statistical Analysis.

MyRAQA has worked on the full range of US and EU IVD applications, including PMAs, IDEs, 510(k)s, *de novo* 510(k)s and EU technical files.

### Experience Highlights

- » 20+ years of experience building, directing and managing biostatistics teams to support all phases of medical diagnostic, medical device, research, product development and manufacturing
- » 10+ years of experience in program management as program manager and director for both research and clinical diagnostic products involving flow cytometry, monoclonal antibodies and software.
- » Extensive experience building and directing clinical groups in medical device pre-market and post-market clinical trials. From first in man to large world wide pivotal studies.

### Education

- » Master of Science in Biometry / Biostatistics: Medical College of South Carolina
- » Master of Science in Biological Sciences / Biometry: California Polytechnic State University
- » Bachelor of Science in Biological Sciences: University of California, Davis

