

about our principal

Dr. George Samaras is a registered Professional Engineer (MD#13006) and a Certified Professional Ergonomist (BCPE#950). He received his basic training in Electrical Engineering (BSEE) and earned doctorates in both Physiology (PhD) and Industrial Engineering (DSc); he has a number of biomedical equipment patents and an extensive list of scientific publications in biomedical research. Dr. Samaras worked for the U.S. FDA/CDRH as a scientific reviewer and as Associate Director of Electronics and Computer Science. He was the CEO of a FDA-listed biomedical engineering firm for a decade. He has conducted clinical and laboratory biomedical research, while on the faculty of a major medical school; he has been on the faculty at two major engineering graduate schools teaching technical management, project management, and ergonomics. He is a member of the NSPE, IEEE, IIE, and ISPE.

about our firm

Samaras & Associates, Inc. **provides expert *engineering consulting*** services to regulatory consulting firms and to the technical staffs of FDA-regulated medical device and pharmaceutical businesses. We combine a comprehensive and up-to-date understanding of your ***business model***, the ***pertinent federal regulations***, and an expert understanding of the ***requisite engineering technology*** - especially in the areas of electronics & electromagnetics, software, human factors, and validation engineering. We can help your firm with validation problems. We can train your staff, identify requisite tools, provide customizable templates, and assist in project management, protocol development and data analysis

Samaras & Associates, Inc.

Validation Engineering

7755 Soda Creek Road
Pueblo, CO 81005-9763
george@samaras-assoc.com
www.samaras-assoc.com
www.qsr-validation.com
www.gmp-validation.com

(719) 485-3751
(719) 485-3819 Fax

Consulting since 1996

VALIDATION ENGINEERING

Compliance for FDA regulated firms:
21 CFR §211.68 and §820.30(g)/70(i)

Validation engineering training and consulting for automated systems (medical devices and pharmaceutical manufacturing systems – hardware, software, & human factors)

Using *a priori* and *a posteriori* methods

We will help you solve your automated system validation problems expeditiously, efficiently, and economically – which will delight your management and regulators.

Call us for a no-cost discussion

719.485.3751

automated system validation

There is a correct way of validating an automated system (*a priori* validation), an acceptable way (*a posteriori* validation), and a myriad of incorrect or incomplete ways of validating a system. The correct way, consistent with ISO/IEEE guidelines, is to implement the requirements management process concurrently with the conceptualization, design, development, and testing processes. When this has not been done correctly - since one cannot travel back in time - there still exists an acceptable means of system validation. This consists of developing a thorough hazard analysis, usually based upon the system's operative specifications and a HAZOP study (occasionally augmented by a FTA or FMEA). From this is derived a comprehensive validation test plan which addresses issues such as critical decision paths, alarms & sensors, security, ergonomics, algorithms & recipes, power loss & restoration, and application code evaluation. Specific test protocols are developed, executed, and the results analyzed and documented.

specialized packages

We offer two standard validation packages. Both packages are a fixed price (including all travel-related expenses to your site):

- ***a priori* validation** for NEW product development: commercial development planning software, industry standard requirements templates, custom hazard analysis and ergonomics templates, one week on-site consulting, plus 10 hour follow-up telephone consultations
- ***a posteriori* validation** for EXISTING (acquired or inherited) products: one week on-site consulting, departmental license for set of custom templates, plus 10 hours follow-up telephone consultations

routine consultations

We also offer follow-on consultations at both daily and weekly rates; for administrative ease, we routinely quote fixed-price arrangements, when the specific objectives, the scope of work, and the time frame can be adequately defined. We endeavor to help your technical staff solve your automated system validation problems expeditiously, efficiently, and economically.

services

Samaras & Associates, Inc. provides training, consultations, and technical assistance to your firm's technical staff responsible for solving FDA-mandated (21 CFR §211 and §820) regulatory engineering problems. Samaras & Associates, Inc. has worked with the full range of FDA-regulated clients, including members of the top-ten pharmaceutical firms, biomedical equipment vendors, R&D firms, and brand new start-ups. We specialize in validation problems related to automated system development, from both the equipment manufacturers' perspective (software V&V) and the equipment user's perspective (computer systems validation). We bring to these activities a detailed, comprehensive, and modern understanding of electronics, electromagnetics, software, and human factors engineering knowledge that often are not adequately dealt with in such endeavors.