

Samaras & Associates, Inc.

Pueblo, CO USA www.samaras-assoc.com 719-485-3751 GMT-7:00

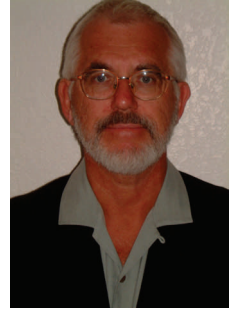
HUMAN-CENTERED PRODUCT & PROCESS ENGINEERING
IN A GLOBAL REGULATED ENVIRONMENT
SAFE, EFFECTIVE, EFFICIENT, AND SATISFYING

George Samaras PhD, DSc, PE, CPE, CQE



Objective

Consultant to FDA-regulated life-science firms or Sub-Contractor to their consultants; provide state-of-the-art **human-centered engineering** (hardware, software, human factors, quality, and validation), **technical management** advice (strategic planning, market analyses, macroergonomics), and **regulatory** services (quality engineering, auditing, training) (please see reverse).



Education

1992, **Doctor of Science** (Engineering Mgmt & Industrial/Organizational Psych), GWU
1976, **Doctor of Philosophy** (Physiology & Bio-Psychology), U of Maryland
1974, **Masters of Science** (Physiology), U of Maryland
1972, Bachelors of Science (**Electrical Engineering**), U of Maryland

Professional License & Certifications

2005, **Certified Quality Engineer** (CQE #47957), American Society for Quality
1998, **Certified Prof. Ergonomist** (CPE #950), Brd. Cert. Prof. Ergonomists (BCPE)
1980, **Professional Engineer** (MD #13004), State of Maryland

Positions Held

1996 – , Principal, Samaras & Associates, Inc.
Engineering and Regulatory consultant to various medical device & pharmaceutical firms
1997-1998, Adjunct Full Professor, Colorado State University-Pueblo
Taught graduates courses (Project Management & Human Factors Engineering)
1994-1996, Associate Director and Interdisciplinary Scientist, US FDA/CDRH
Managed staff of 40 with Director of Division of Electronics & Computer Science
Primary software engineering reviewer in Division of Ophthalmic Devices
1993-1995, Visiting (then Adjunct) Full Professor, Dept. Syst. Eng. & Eng. Mgmt., GWU
Taught graduate courses (Engineering Mgmt, Marketing Mgmt, & Entrepreneurship)
1981-1991, CEO, GMS Engineering Corp., Columbia, MD
Founded/managed contract biomedical engineering firm for federal & private clients
1976-1986, Asst./Assoc. Professor, U Maryland School of Medicine, Baltimore, MD
Founded/managed academic research & teaching lab; designed & participated in clinical trials; taught graduate courses (Histology, Physiology, Biophysics, & Bioengineering)

Selected Recent Publications (Total = 40 peer-reviewed plus 25 others, including 3 patents)

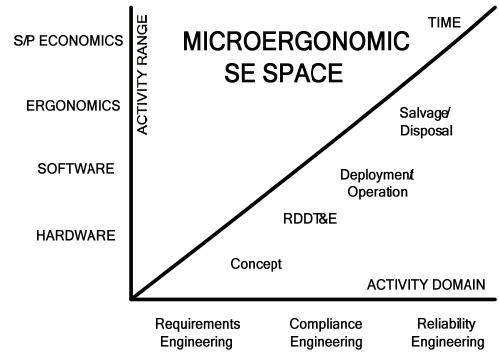
Samaras, GM, Horst, RL "A Systems Engineering Perspective on the Human Centered Design of Health Information Systems", **J. Biomedical Informatics**, 38(1):61-74, 2005
Samaras, GM "An Approach to Human Factors Validation", **J. Validation Technology**, 12(3):190-201, 2006. (Nominated for "Best Article of the Year")

Selected Recent Conference Presentations

Samaras, GM "Human-Centered Systems Engineering: A Workshop", IASTED Telehealth 2007, Montreal, QC May 31-Jun 1, 2007
Samaras, GM "Systems Engineering for the Human Factors Engineer: A Workshop", Proc. 16th Triennial World Congress on Ergonomics, Maastricht, NL, July 9-14, 2006
Samaras, G. M. "Engineering Complex Systems: Validating the Human Factors", Proc. 7th Annual Symp. on Human Interactions with Complex Systems, Greenbelt, MD, November 17-18, 2005.
Samaras, G. M., Horst, R. L., "A Systems Engineering Perspective on the Human-Centered Design of Health Information Systems", 8th Intl Symp HF Org Design and Mgmt, Maui, HI, 2005.
Samaras, G. M., "Validation Engineering in Ergonomics: Theoretical Perspectives", Proc. 47th Annual HFES Meeting, Denver, CO, October 13-17, 2003.

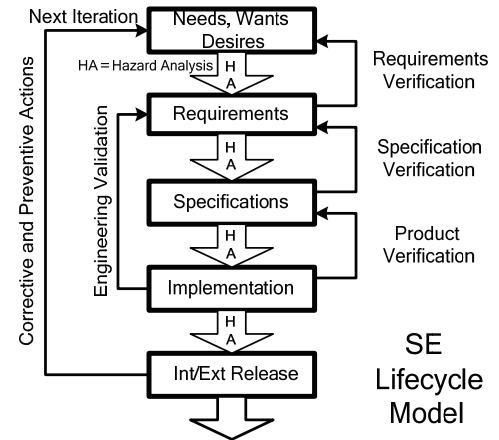
CONSULTING SERVICES

Samaras & Associates, Inc. specializes in supporting clients in their endeavors to design, develop, manufacture, and deploy products and processes that are **safe, effective, efficient, and satisfying to use** (human-centered). We take a holistic approach to R&D, engineering, manufacturing, maintenance, and user training. Our human-centered approach (a) yields validated results that satisfy all stakeholders (=quality!) and (b) requires less time and money to go to market. Our human-centered approach is based upon the classical systems engineering (SE) paradigm (see “**Microergonomic SE Space**”) that integrates hardware, software, human factors, and seller/purchaser economic considerations at every step from conceptualization to disposal throughout the lifecycle (see the condensed notation of “**SE Lifecycle Model**”). Contrary to some critiques, SE is a highly agile method, when implemented in the original form with proper project management.

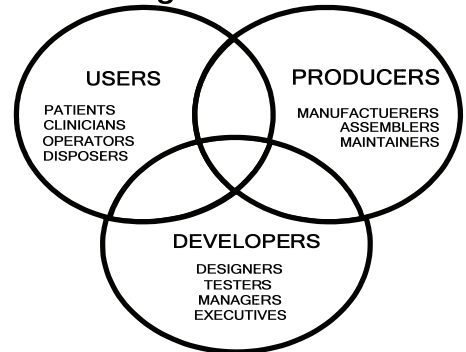


Technical Consulting

We assist clients in engineering (a) devices, (b) manufacturing equipment, and (c) health information systems. With expertise in hardware, software, ergonomics, and economics, as well as physiology and psychology, we provide technical assistance at all phases of the lifecycle from conceptualization to disposal. This begins with identification of the stakeholders (see “**Target Audiences**”). Their needs, wants, & desires are (a) continually assessed and (b) subjected to technical and economic risk analyses within the multiple iterations through the lifecycle model. Relevant laws, regulations, and standards (including ergonomics standards) are identified, assessed and incorporated in the risk analyses (compliance engineering). We provide advice on the experimental design (DOE) and implementation of quantitative engineering validation studies (a) for Development, (b) as part of Strategic Quality Management, and (c) for a Process Analytical Technology approach. We provide assistance with metrology issues related to human factors (see “**Metrology**”), as well as for hardware, software, and measurement instrumentation. Finally, we always provide Project Management assistance and (when requested) PM training for technical team members — so they may understand the advantages and constraints of PM.



Target Audiences



Management Consulting

We advise and assist executives and middle management in strategic planning, strategic quality management, market analyses, and macro-ergonomics, always in the context of their regulatory environment.

Regulatory Consulting

Our regulatory consulting practice is limited to FDA-regulated firms (from new start-ups to global multi-nationals). We assist clients in **establishing, validating and auditing** compliant Quality Systems (including requisite **training** throughout the firm). For device clients, this usually occurs prior to notifying the FDA of an intent to market a product (PMN) or study a new product (IDE). For pharmaceutical/biologics clients, this usually occurs with the introduction of new manufacturing equipment and facilities.

NB. All figures from journal articles (see reverse side)

METROLOGY					
		INDIVIDUALS		GROUPS	
		PHYSICAL	BEHAVIORAL	SOCIAL	CULTURAL
O V E R T	ANTHROPO-MORPHO-METRY	VERBAL & NON-VERBAL	COMMUNICATION & COORDINATION	LANGUAGE & ARTIFACTS	
	C O V E R T	BIOMECHANICS & SENSORY PRECEPTION	AFFECTIVE COGNITIVE PHYSIOLOGICAL	CONVENTIONS & EXPECTATIONS	BELIEFS CUSTOMS ETHICS MORALS

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