Paul F. Seelig
70 Reynolds Drive
Watchung, NJ, 07069
908-757-9835 (voice/fax)
email: paulseelig@stonyhillsolutions.com

SUMMARY

Automation Quality Assurance and Project Management consultant with extensive experience in international regulatory requirements, risk assessment, computer validation, electronic records/signature, automation auditing, project management, strategic planning, and managing personnel. Experienced working with pharmaceutical senior executives in communicating regulatory requirements, developing compliance plans and interpreting guidance from FDA, EMEA, PIC/S, TGA and WHO.

PROFESSIONAL EXPERIENCE

Consultant, Stony Hill Solutions, LLC **2004-present**

- Designed a program and directed consultants in conducting risk based assessments to assure computer validation compliance at pharmaceutical manufacturing sites in U.S.A., Europe, and China.
- Analyzed and recommended organization changes in quality, validation, and IT departments that improved customer support and reduced cost in implementing computer systems.
- Conducted computer system validation audits of global information systems in areas of clinical, labeling, complaint management, and SAP.
- Created risk based assessment tools, implementation guidance, and project plans for legacy computer system compliance programs regulated by US and non-US health authorities.
- Wrote guidance for computer system validation based on U.S.A., European, and Japanese regulations.
- Led team-building workshops to improve working interaction between departments.
- Participated in writing and reviewing industry trade publications for ISPE-GAMP Americas.
- Designed and implemented new microcontroller technology for remote sensors.

Merck & Co., Inc, Whitehouse Station, NJ **1979-2003**

Director, Quality Assurance – Automation and Data *(1999-2003)*

- Directed automation audits and data auditing at 31 manufacturing sites worldwide.
- Wrote responses and developed action plans for automation citations from regulatory agencies (FDA, MCA, EMEA).
- Assured regulatory compliance of automated systems through audits of GMP systems, (e.g. material control, SCADA/PLC, DCS, maintenance, training, LIMS, laboratory automation).
- Implemented site based data audit program to improve data integrity for regulatory filings.

Director, Merck Manufacturing Computer Validation *(1996-1999)*

- Assured compliance with regulatory requirements while optimizing resources requirements by developing a manufacturing computer validation strategy for all existing GMP computer systems at 31 plant sites and managing implementation of the strategy.
- Reduced resource requirements for computer validation of new GMP computer systems by organizing worldwide computer validation guidance and consulting.

Executive Director, Merck Manufacturing Strategic Planning *(1992-1996)*
Director, Merck API Strategic Planning *(1989-1992)*

- Enabled savings of $700 million by leading the development of the strategic plan and facilitating implementation.

- Reduced operating costs and decision making time by developing an Information Strategic Plan that provided a worldwide common infrastructure for networks, email and desktops.
- Assessed viability of business opportunities to cost effectively manufacture potential new compounds.
- Reduced operating costs and improved inventory controls through implementation of material management systems (e.g. MRPII).

Director, Automation & Information Systems *(1987-1989)*
- Directed planning and implementation of automated systems at nine Active Pharmaceutical Ingredient (API) manufacturing sites.
- Directed approval and implementation of computer systems covering financial, procurement, manufacturing control, laboratory, laboratory robotics, material management, and maintenance management functions at sites and central groups.
- Wrote information strategic plan covering infrastructure, applications and data that optimized resource utilization.

Project Manager, Automation & Control *(1979-1987)*
- Developed new technology that allowed centralized monitoring and reporting of alarm conditions on remote field equipment.
- Managed implementation of laboratory and manufacturing systems.
- Developed an information system strategy for Calgon Corporation (a division of Merck).

EDUCATION

Post Doctoral Fellow, Physical Electrochemistry, Georgetown University, Washington, DC.
Ph.D., Analytical Chemistry, University of Delaware, Newark, Delaware
B.S. Chemistry, University of Delaware, Newark, Delaware
(College Freshman and Varsity Basketball)

PROFESSIONAL DEVELOPMENT

Management Development Program, Northeastern University, College of Business Administration

ACADEMIC AWARDS

University of Delaware (UD) Research Foundation Fellowship
UD Chemistry Department and Analytical Fellowships
UD Chemistry Department Teaching Award
Glenn S. Skinner Award and Sigma Xi

PROFESSIONAL SOCIETIES

International Society of Pharmaceutical Engineers (GAMP Americas, eight years)
New Jersey School Board Association (eighteen years)

OTHER ACTIVITIES – School Board and Coaching

Community Service Watchung Hills Regional High School Board of Education (five years)
Community Service Watchung Borough Board of Education (twelve years)
Construction Committee Chairman for $24 million expansions
Labor Relations Negotiation Team (ten years, lead two years)
Long Range Planning and Finance Committee (six years)
Board of Education President (seven years)
Little League Baseball Head and Assistant Coach (nine years)
Organized and Headed Travel Basketball (seven years)

PRESENTATIONS/TALKS

Proc. Conf. on Comp. in Chem. Ed., Kingston, Ontario, Canada, 1974, p. 58.

ACS 168th National Meeting, Atlantic City, NJ, 1974, Abstracts of Papers ANAL-64.

ACS Symp. Recent Adv. Anal. Voltammetry, 169th National Meeting, Philadelphia, PA, 1975, Abstracts of Papers ANAL-20.

ACS 7th Northeast Regional Meeting, Albany, New York, 1976, Abstracts of Papers 4.

ACS 172nd National Meeting, San Francisco, CA, 1976, Abstracts of Papers ANAL-119.

ACS 11th Middle Atlantic Regional Meeting, Newark, DE, 1977, Abstracts of Papers 12.

"Laboratory Data Management Systems at Merck", Society for Analytical Chemists of Pittsburgh, 1983.

PUBLICATIONS

Paul F. Seelig and Henry N. Blount, "A Time-Share Based Simulator to Teach the Use of Digital Computers", J. Chem. Ed., 52, 469(1975).

Paul F. Seelig and Henry N. Blount, "Kalman Filter Applied to Anodic Stripping Voltammetry Theory", Anal. Chem., 48, 252(1976).

Paul F. Seelig and Henry N. Blount, "Experimental Evaluation of Recursive Estimation Applied to Linear Sweep Anodic Stripping Voltammetry for Real Time Analysis", Anal. Chem., 51, 327(1979).

R. deLevie, S.K. Rangarajan, P.F. Seelig, and O.S. Anderson, "On the Adsorption of Phloretin Onto A Black Lipid Membrane", Biophysical Journal, 25, 295(1979).

Paul F. Seelig and Henry N. Blount, "Application of Recursive Estimation to the Real Time Analysis of Trace Metal Analytes by Linear Sweep, Pulse, and Differential Pulse Anodic Stripping Voltammetry", Anal. Chem., 51, 1129(1979).

S.K. Rangarajan, P.F. Seelig, and R. deLevie, "On the Admittance of Lipid Bilayer Membranes Part I. Membrane-Permeable Ions", J. Electroanal. Chem., 100, 33(1979).

P.F. Seelig and R. deLevie, "Double Layer Capacitance Measurements with Digital Synchronous Detection at a Dropping Mercury Electrode", Anal. Chem., 52, 1506(1980).

Sterling A. Tomellini, David D. Saperstein, James M. Stevenson, Graham M. Smith, Hugh B. Woodruff, Paul F. Seelig, "Automated Interpretation of Infrared Spectra with an Instrument Based Minicomputer", Anal. Chem., 53, 2367(1981).