ROBERT SCHIFF, Ph.D., R.A.C., C.Q.A., FRAPS

EDUCATION

1969	Post Doctoral Fellow, University of California School of Medicine, Davis, Histochemistry
1968	Ph.D. University of California, Davis Immunogenetics
1966	M.S. Iowa State University, Ames Cytology major, Biochemistry minor
1964	B.S. City College of the City University of New York Biology major, Chemistry minor

PROFESSIONAL EXPERIENCE

1982 - Present **SCHIFF & COMPANY, INC.**
West Caldwell, NJ
Chairman and Chief Executive Officer

- Schiff and Company is an international Regulatory Affairs, Compliance and Clinical Research Organization. Its fields of expertise include drugs, biologics, devices, foods and cosmetics. The company represents both domestic and international organizations to the FDA and to foreign regulatory bodies. It conducts and monitors clinical studies and writes all appropriate regulatory filings, i.e., NDA's, BLA's, PMA's and 510(k)s. The staff plans regulatory strategy, prepares clinical development plans, performs GMP, GCP, GLP and GTP audits, writes SOPs and conducts due diligence. The company has performed various regulatory and compliance activities for many of the top 100 drug and device companies, as well as small organizations.

1980 - 1982 **THE WARNER-LAMBERT COMPANY**
Morris Plains, NJ
Group Vice-President, Research & Development Diagnostics Group

- Globalized R & D for this $100 million business and eliminated redundancy by managing activities at General Diagnostics (New Jersey), Nuclear Medical Laboratories (Texas), and the Institute for Immune Research (West Germany).

- Positioned the organization with high technology, high yield programs.

- Developed a five-year R & D Strategic Plan to interface with the Business Plan.
- Increased personnel from 65 to 93 and the budget from $3 to $8 million to support plan.
-Led the R & D team which incorporated the Pfizer Automated Microbiology Instrument (Autobac) into Diagnostics Group.
- Added cell and tissue culture capability through the acquisition of a group in Michigan.
- Introduced and championed a major tumor marker and genetic engineering program.
- Unified Instrument Research which resulted in several new instruments.
- Actively involved in acquisition program (i.e., Pfizer Diagnostics).
- Interfaced group with all regulatory and compliance audits.

1977 - 1980 **HOFFMANN LA ROCHE, INC.**
Nutley, NJ
Director, Department of Diagnostic Research and Product Development.

- Created a multidisciplinary department, expanding from a core of 27 professionals to 41.
- Introduced Sensi-Tex, Sensi-Slide, Isomune LD, Enterotube II and developed a non-isotopic CEA test.
- Developed planning and project tracking procedures which were non--existent prior to 1977.
- Interfaced with compliance and regulatory groups.

1974 - 1977 **J.T. BAKER DIAGNOSTICS, Division of the J.T. Baker Chemical Company (Richardson-Vicks)**
Bethlehem, PA
Director of Research & Development

- Forty + product releases included chemistries for Technicon instrumentation, reagents and controls for Coulter instruments, enzyme tests for Centrifichem, ABA 100, Guilford Series and Gemsaec analyzers and immunology tests for drugs of abuse.
- Organized R & D into four operating sections; Clinical Chemistry, Hematology, Immunology and Regulatory Affairs.
- Built the staff from 6 to 17 professionals.
- Designed laboratory facilities.
- Planning responsibilities incorporated five-year R & D product and financial forecasts to Baker Chemical and parent, Richardson-Vicks.
- Managed group regulatory activities.

1972 - 1974 **HYLAND DIVISION TRAVENOL LABORATORIES (Baxter)**
Costa Mesa,CA
Chief and Manager, Serology Research

- Researched and developed diagnostic kits for autoimmunity, rheumatology, coagulation, mycotic infections, basic serology and serum proteins.
- The development of quality control and manufacturing specifications for large-scale operations, the writing of direction inserts and technical applications and the design of FDA compliance protocols were routinely accomplished.
- Managed four project teams which resulted in rapid product introduction.
- New products were Mono-Chek, Syphla-Chek and Pregna-Chek.
- Interaced with the Centers for Disease Control on Product Proficiency Testing.

1969 - 1972 **TUFTS UNIVERSITY SCHOOLS OF MEDICINE AND DENTAL MEDICINE**
Boston, MA
Assistant Professor of Anatomy

- Member of the graduate faculty, taught Medical and Dental Histology and graduate courses in Histochemistry and Mammilian Genetics.
- Reviewer for *Journals of Enzymologia* and *Journal of Histochemistry and Cytochemistry.*
- Consultant to Dr. Kevin Barron, Chairman, Department of Neurology, Albany Medical College and Dr. Robert Allen of Ortec, Inc., for vertical flat-bed polyacrylamide electrophoresis.

PROFESSIONAL SOCIETIES

American Association for the Advancement of Science (Emeritus)
American Association of Anatomists
American Association of Blood Banks
American Association of Clinical Chemistry (Emeritus)
American Association of Pharmaceutical Scientists
American Genetics Association
American Hospital Association
American Management Association
American Public Health Association
American Society for Medical Technology
American Society for Microbiology
American Society of Clinical Pathologists
American Society of Human Genetics
American Society for Quality (Senior)

Association for the Advancement of Medical Instrumentation
Association of Clinical Research Professionals
British Institute Of Regulatory Affairs
Clinical Laboratory Management Association
Drug Information Association
Food and Drug Law Institute
Genetics Society of America
Histochemical Society
International Society for Animal Blood Group Research
New York Academy of Science
Parenteral Drug Association
Regulatory Affairs Professional Society (Fellow)
Sigma Xi
Society for Clinical Data Management
Society of Research Administrators

REVIEWER

2006-Present
-*MD&DI*-Member of Reader's Board

1998 – Present
- *IVD Technology* – Reviewer and member of Reader's Board

1994 - Present
- Book reviewer for *BioPharm Magazine*

1993 - Present
- *Medical Device and Diagnostics Industry* Reader's Board

1992 - 1996
- Judge for the "R & D 100" Awards

1969 - 1972
- *Journals of Enzymologia* and *Journal of Histochemistry and Cytochemistry*

BOARDS & DIRECTORS

2009 – 2011	Regulatory Affairs Professional Society Fellows – Vice Chairman
2007 – Present	Drug GMP Report, Editorial Advisory Board
2007 – 2008	Pharmaco-Kinesis Corporation, Inglewood, CA, Director

2006 – Present	Regulatory Affairs Professional Society, Board of Editors
2002 – Present	Pharmaceutical Training Institute, New York City, Instructors' Advisory Board
2001 – Present	Anastasia Marie Laboratories, Inc. International, Advisory Board
1991 - 1997	E.P.I. Inc., Subsidiary of E-Z-EM, Inc., Westbury, NY, Director
1991 - 1992	Anastasia Marie, Inc., Oklahoma City, OK, Director
1980 - 1982	Research and Development Council of New Jersey, Vice Chairman
1979 - 1980	National Committee for Clinical Laboratory Standards, Delegate

CERTIFICATION

1995	C.Q.A. - Certified Quality Auditor Examination American Society for Quality Control
1991	R.A.C. - Regulatory Affairs Certification

ADDITIONAL FACULTY APPOINTMENTS

1982 - 1990	Fairleigh Dickinson University Graduate College of Business Administration Taught 4 courses in the MBA for Executive Program

BIOGRAPHY

1997	Listed in *Who's Who in Medicine and Healthcare*, Marquis Who's Who, Chicago.
1997	Listed in *Who's Who in America*, Marquis Who's Who, Chicago.
1996	Listed in *Who's Who in Science and Engineering*, Marquis Who's Who, Chicago.

1996	Listed in *Who's Who in the East*, Marquis Who's Who, Chicago.
1996	Listed in *Who's Who in the World*, Marquis Who's Who, Chicago.
1995	Listed in *Who's Who in the West*, Marquis Who's Who, Chicago.
1970	Listed in *American Men of Science*, 11th ed., Suppl. 6 R.R. Bowker Company, New York.

PRESENTATIONS

2012	"International Audits for Good Clinical Practice." Regulatory Affairs Professional Society. Seattle. October 29.
2012	"Regulatory Perspective on Reprocessing and 510(k) Requirements for Microbial Claims". Gibraltar Institute. Fairfield, NJ. October 2.
2011	"How to Qualify a Principal Investigator." Regulatory Affairs Professional Society. Indianapolis. October 25.
2011	"GMP Auditing Internationally." Regulatory Affairs Professional Society. Indianapolis. October 25.
2011	"30 Years of Regulatory and Compliance Consulting." Regulatory Affairs Professional Society. Indianapolis. October 24.
2011	"Over the Counter Drugs: Classification, Approval and Compliance." Workshop. Regulatory Affairs Professional Society. Indianapolis. October 23.
2011	"Dealing with the FDA for 29 Years: Mistakes I have seen." MD&M East 2011 Conference. New York City. June 7.
2010	"Clinical Trials Design for Medical Devices".-

	The Center for Professional Innovation & Education: Costa Mesa, CA. December 2-3.
2010	"Dietary Supplements and Neutraceuticals: Compliance with FDA Manufacturing Requirements". Webinar. Regulatory Affairs Professional Society. August 18.
2010	"Complying with cGMP and GMP Requirements – Advanced Level". Pharmaceutical Training Institute (PTi). Waltham, MA. August 11-12.
2010	"Clinical Trials Design for Medical Devices".- The Center for Professional Innovation & Education: Berlin, Germany. May 24-25.
2010	"GMP and Compliance in the Drug Industry. ASQ North Jersey SectionSpring Quality Conference. April 15.
2010	"CGMPS from an Auditor's Perspective: Violations to Avoid". Webinbar. FDANEWS. March 31.
2009	"Good Manufacturing Practice". BioNebraska Research and Innovation Conference. Omaha, NE. September 29.
2009	"Clinical Trials Design for Medical Devices".- The Center for Professional Innovation & Education: Dublin, Ireland. September 24-25.
2009	"Key Points for GMP-Production Compliance". Regulatory Affairs Professional Society. Philadelphia, PA. September 15.
2009	"Botanical Drugs: Practical Issues with FDA Prescription Drug Approval". Webinar. Regulatory Affairs Professional Society. August 12, 2009.
2009	"Clinical Trials Design for Medical Devices".- The Center for Professional Innovation & Education: Malvern, Pa. March 16-17.

2009	"Recall or Not to Recall". Webinar. Regulatory Affairs Professional Society. February 18.
2008	"Clinical Trials Design for Medical Devices".- The Center for Professional Innovation & Education: Costa Mesa, CA. December 1-2.
2008	"Drug Master File (DMF) Preparation and Maintenance-A Regulatory Perspective". International Pharmaceutical Academy: Toronto, Canada-September 25-26.
2008	"GMPs for Dietary Supplements". Webinar. Regulatory Affairs Professional Society. July, 9.
2007	"Complying with Chemistry, Manufacturing and Controls (CMC) Requirements for Biopharmaceuticals": Pharmaceutical Training Institute: San Francisco, CA. November 27-28.
2007	"Complying with Chemistry, Manufacturing and Controls (CMC) Requirements for Biopharmaceuticals": Pharmaceutical Training Institute: Philadelphia, PA-November 5-6.
2007	"Good Clinical Practices Training for Investigators and IRBs": Envita Natural Medical Center, Scottsdale, AZ-October 12.
2007	"Advertising and Promotion (DDMAC): What Not To Do": CLB Behring, King of Prussia, PA-September 26.
2007	"Complying with Chemistry, Manufacturing and Controls (CMC) Requirements for Biopharmaceuticals": Pharmaceutical Training Institute: Boston, MA-September 17-18.
2007	"Complying with Chemistry, Manufacturing and Controls (CMC) Requirements for Biopharmaceuticals": Pharmaceutical Training Institute: Seattle, WA-June 25-26.

2007	"Complying with Chemistry, Manufacturing and Controls (CMC) Requirements for Biopharmaceuticals": Pharmaceutical Training Institute: Boston, MA-January 29-30.
2007	"Risk Management in Pharmaceutical Outsourcing" : DCAT: Sheraton Hotel, Newark, NJ, January 24.
2006	"Complying with Chemistry, Manufacturing and Controls (CMC) Requirements": Pharmaceutical Training Institute: Morristown, NJ-November 13-14.
2006	"Recent Trends in FDA Untitled and Warning Letters & Avoiding Misleading Use of Medical Data". Drug Advertising and Promotion. American Conference Institute: Philadelphia, PA – March 13
2005	"The Evolution of cGMPs". DCAT: Newark, NJ - December 6
2005	"GMP Auditing of the Manufacture by the FDA and the Prospective Customer". DCAT: Newark, NJ - December 6
2005	"Corrective and Preventive Action (CAPA) for Product Failures and Deviations". DCAT: Newark, NJ - December 6
2005	"Complaint Handling". DCAT: Newark, NJ - December 6
2004	"GMP Auditing of a Contract Manufacturer". Barnett International: Philadelphia, PA.
2005	June 24
2003	"Writing Reports for Failure Investigations and Process Deviations": Pharmaceutical Training Institute: Morristown, NJ – October 9-10
2003	"Batch Record Reviews and Investigations – Advanced Level": Pharmaceutical Training Institute: San Francisco, CA – May 20--21

2003	"Complying with GMPs for Clinical Manufacturing": Pharmaceutical Training Institute: Research Triangle Park, NC - February 26-27
2002	"Validation and Qualification for the QC and Clinical Laboratories": Pharmaceutical Training Institute: Chicago, IL - November 13-14
2001	"Validation and Qualification: Complying with Bioanalytical Methods Validation Requirements". Pharmaceutical Training Institute: Los Angeles, CA - October 9-10
2001	"Ensuring Compliance While Outsourcing Manufacturing" and Establishing Compliance". Global GMP 2001: June 25-26.
1998	"Parallel Clinical Trials in Multiple Countrys". Regulatory Affairs Professional Society. Newark, NJ. August 24 – 25.
1998	"Clinical Trial Design, Drug, Devices, Biologics: Testing for Safety and Effectiveness". Regulatory Affairs Professional Society. Baltimore, MD. March 9 – 10.
1997	"Making Sure It's Done Right: Inspections and Sponsor Audits". Mastering the Clinical Review Process. The National Managed Health Care Congress. Philadelphia, PA. May 8 – 9.
1997	"How to Negotiate with the FDA: A Roadway for Success". Drug Discovery and Development Partnerships. National Managed Care Congress. Philadelphia, PA. April 24-25.
1997	"Clinical Development for IVDs". Chairman. Barnett International. San Francisco, CA. February 26 - 28.
1995	"Regulatory Aspects of Intellectual Property". Institute for International Research, Pharmaceutical and Healthcare Division. Washington, DC. December 7 - 8.

1995	“Dealing with the FDA”. Drug, Chemical and Allied Trade Associations Regulatory and Legislative Conference. New York, NY. November 15.
1993	“Good Manufacturing Practices, ISO 9000 and FDA Compliance”. Association of Biotechnology Companies 7th International Meeting. Research Triangle Park, NC. April 12 - 16.
1989	“Opportunities in Veterinary Diagnostics: An Era of Growth. In Vitro Clinical Diagnostics: High Growth Segments in a Mature Marketplace”. Biomedical Business International. Atlanta, GA. July 26.
1987	“An Overview of Immunotherapy in the 80’s and 90’s”. Therapeutic Medicine in the 1990’s. Frost and Sullivan, Inc. New York, NY. June 1 - 2.
1978	“Successes in Reclassification” Health Industry Manufacturers Association, Medical and Scientific Section, Chicago, IL. Dec. 5-6

PERSONAL

1958	Silver Award, Explorers, BSA
1975-1977	District Chairman for Cub Scouting, Minsi Trails Council, Allentown, PA
1977-1978	Cubmaster, Pack 4, Allentown, PA
1985	Licensed Pilot

ROBERT SCHIFF, Ph.D.

Supplement

1968-1969	N.I.H. Health Science Advancement Award Postdoctoral Fellow in the Dept. of Human Anatomy, University of California School of Medicine, Davis.
1966-1968	U.S.P.H.S. Predoctoral Trainee, Dept. of Veterinary Microbiology (Genetics Group), University of California, Davis.
1966	Guest lecturer of the National Science Foundation. Summer Institute for High School Biology Teachers (Iowa State Univ.).
1966	Electron Microscopist, Veterinary Medical Research Institute, Iowa State University.
1965	Guest lecturer of the National Science Foundation. Summer Institute for High School Biology Teachers (Iowa State University).
1965-1966	Research Assistant, Dept. of Bacteriology, Iowa State University.
1964-1965	Graduate Teaching Assistant, Dept. of Zoology, Iowa State University, taught courses in general Zoology, Vertebrate Embryology and Cell Physiology.
1964-1966	Graduate Student, Dept. of Zoology, Iowa State University.
1963	Undergraduate Teaching Assistant, City College of the City University of New York.

TEACHING CREDENTIALS

1964	New York City Substitute licenses for teaching biology and general science in high school and general science in junior high school.

AWARDS

2009	Fellow of the Regulatory Affairs Professional Society
1970	$5,200 award from the Aid to Cancer Research Foundation of Massachusetts.
1963	Farquhar Award of the Caduceus Society of the City College of the City University of New York.

RESEARCH SUPPORT

1971-1972	National Institutes of Health (National Cancer Institute)
1969-1972	Massachusetts Division of the American Cancer Society
1969-1970	Charlton Fund of Tufts University

PATENTS

1. Schiff, R. and Wilson, J.C.: Diagnostic Slide. Issued April 13, 1976. U.S. Design Patent 239, 548.

2. Wilson, J.C. and Schiff, R.: Diagnostic Display Package. Issued April 26, 1976. U.S. Patent 3,935,944.

3. Schiff, R. and Lehnus, G.: Polymer Coated Solid Matrices and use in Immunoassays. Issued, May 1, 1990. U.S. Patent 4,921,809.

CONTINUING MANAGEMENT EDUCATION

1976	1.	"On Leadership", Levinson Institute, Andover, MA.
	2.	"Finance and Accounting", Schrello Workshop, Paterson, NJ.

CONTINUING MEDICAL EDUCATION (ASCP WORKSHOPS)

March, 1974	1.	Diagnostics of Autoimmune Disorders
	2.	Tumor Immunology
October, 1974	1.	Cellular Immunity Diseases
	2.	Immunological Aspects of Complement
	3.	Immunomicroscopy in Clinical Immunology
March, 1976	1.	Quality Control in the Clinical Chemistry Laboratory I and II
March, 1977	1.	Immunological Tests in the Diagnosis and Management of Patients with Cancer
	2.	Platelet Aggregation

EXHIBITS

1. Schiff, R. 1973. Fibrinogen split products as a measurement of disseminated intravascular coagulation. Proceedings Conference on Amniotic Fluid. May, 1973 Chicago

2. Schiff, R. and Creveling, R.L. 1974 Disseminated intravascular coagulation in obstetrics and gynecology. 22nd. Annual Clinical Meeting of the American College of Obstetricians and Gynecologists. April, 1974. Las Vegas

PUBLICATIONS

1. Schiff, R. 1966. "Characterization of mouse leukocytes in tissue culture: A cytological investigation". M.S. Thesis. Iowa State University, Ames. 128pp.

2. Schiff, R., Quinn, L.Y. and Bryan, J.H.D. 1967. "A safranin-fast green stain for the differentiation of the nuclei of rumen protozoa". Stain Tech. 42:75-80

3. Schiff, R. and Stormont, C. 1967. "Electrophoretic properties of rabbit red-cell esterases". (Abstr.) Genetics 56:588

4. Schiff, R. 1968. The biochemical genetics of rabbit erythrocyte esterases: Genetic control, classification and electrophoretic properties. Ph.D. Dissertation. University of California, Davis. 172 pp.

5. Schiff, R. and Stormont, C. 1968. The genetic control of rabbit red-cell esterase variation. (Abstr.) Proc. XII Int. Congr. Genet. 1:127.

6. Schiff, R. and Stormont, C. 1968. Close linkage between genes controlling two systems of rabbit esterases. (Abstr.) Genetics 60:222-223.

7. Schiff, R., Vasudeva, R. and Stormont, C. 1968. A method for the electrophoretic separation of rabbit red-cell esterases. Immunogenetics Letter 5:130-131.

8. Brunstetter, M.A., Hardie, J.D., Schiff, R., Lewis, J.P. and Cross, C.E. 1970.New evidence for bone marrow stem cell origin of the pulmonary alveolar macrophage (PAM). (Abstr.) Clin. Res. 18:437.

9. Schiff, R. 1970. The biochemical genetics of rabbit erythrocyte esterases: Histochemical classification. J. Histochem Cytochem. 18:709-721

10. Schiff, R., Brunstetter, M.A., Hunter, R.L. and Cross, C.E. 1970. Electrophoretic separation of esterases of pulmonary alveolar cells. J. Histochem. Cytochem. 18:167-177.

11. Schiff, R. and Jacobson, S. 1970. Genetic control of esterase isozymes from rabbit brain. (Abstr.) Genetics 64:s56-s57.

12. Schiff, R., Krieg, R.J. and Hunter, R.L. 1970 Localization by peroxidase labeled antibodies of bovine chymotrypsin. J. Histochem. Cytochem. 18:195-200

13. Schiff, R. and Stormont, C. 1970. The biochemical genetics of rabbit erythrocyte esterases: Two new esterase loci, Biochem. Genet. 4:11-23

14. Schiff, R., Titford, M. and Sonnenschein, C. 1970. Electrophoretic variation of esterases from mouse x rat somatic cell hybrids. (Abstr.) Anat. Rec. 166:372

15. Blanchard, G.C., Schiff, R., Garfield, L., Burton, D. and Ulrich, F. 1971 Water soluble proteins of ragweed pollen. (Abstr.) Fed. Proc. 30:411

16. Brunstetter, M.A., Hardie, J.J., Schiff, R., Lewis, J.P., and Cross, C.E. 1971 The origin of pulmonary alveolar macrophages: Studies of stem cells using the Es-2 marker of mice. Arch. Int. Med. 127:1064-1068

17. Estabrooks, L., Schiff, R. and Murname, T. 1971. Esterase isozymes of rabbit synovial fluid. Int. Assoc. Dent. Res. program and abstract of papers. No. 393

18. Schiff, R. and Borysenko, M. 1971. Phylogeny of esterase isozymes. (Abstr.) Genetics 68:s58

19. Schiff, R., Demicco, W. and Hochman, R. 1971. Rabbit esterase zymograms: Effects of various agents on activity. (Abstr.) Anat. Rec. 169:419

20. Smith, R.J., Frommer, J. and Schiff, R. 1971. Histochemical determination of amylase onset in mouse salivary glands. Int. Assoc. Dent. Res. program and abstract of papers. No. 631.

21. Smith, R.J., Frommer, J. and Schiff, R. 1971. Localization and onset of amylase activity in mouse salivary glands determined by a substrate film method. J. Histochem. Cytochem. 19:310-319

22. Estabrooks, L. and Schiff, R. 1972. Esterase isozymes from rabbit synovial fluid: Normal and artificial joints. J. Histochem. Cytochem. 20:211-219

23. Matteo, M. and Schiff, R. 1972. Esterase polymorphisms in the marine snail, Littorina littorea. (Abstr.) Genetics 71:s38

24. Schiff, R., Lewis, J.P. and Cross, C.E. 1972. Esterase markers in mouse radiation chimeras. J. Histochem. Cytochem. 20:472-473.

25. Schiff, R. and Sonnenschein, C. 1972. Enzymatic variations in somatic cell hybrids. (Abstr.) Genetics 71:s55-s56.

26. Schiff, R. and Sonnenschein, C. 1972. Somatic cell hybridization: Cellular interaction upon esterase isozymes. Exp. Cell Res. 70:269-278.

27. Matteo, M., Schiff, R. and Garfield, L. 1975. The non-specific esterases of the marine snail: Littorina littorea. Histochemical characterization. Comp. Biochem. Physiol. 50A:141-147

28. Schiff, R. and Devlin, R.F. 1973. Latex fixation tests in the diagnosis of the rheumatic diseases. (Abstr.) Excerpt. Med. 299:145.

29. Schiff, R. 1973. Fibrinogen split products as a measurement of disseminated intravascular coagulation. (Abstr.) Proc. Conf. Amniotic fluid. Chicago.

30. Schiff, R. 1973. Latex fixation tests in the diagnosis of the rheumatic disorders. Japan Travenol. Osaka, Japan

31. Schiff, R. 1973. Immunological and biochemical tests for the diagnosis of rheumatoid arthritis: A selected bibliography. Hyland Division Travenol Laboratories. Costa Mesa, California.

32. Schiff, R., O'Meara, R.J. and Maxwell, K.W. 1974. Disseminated intravascular coagulation in obstetrics. In Amniotic fluid, Natelson, Scommega, Epstein, eds. J. Wiley, New York. pp. 155-170

33. Schiff, R. and Maxwell, K.W. 1974. Comparison of the RA-TEST^{R} with the sheep cell agglutination test for rheumatoid factor determination. (Abstr.) VI Pan-American Congress on Rheumatic Diseases. Toronto.

34. Schiff, R., Chapman, D.L., Heffernon, U. and Maxwell, K.W. 1974 The correlation between the Paul-Bunnell Presumptive/Davidsohn Differential tests and the Hyland MONO-CHEK^{TM} Test. Technical Discussion No. 25. Hyland Division Travenol Laboratories, Costa Mesa, California.

35. Schiff, R. 1975. Esterase isozymes as markers in normal and disease processes. In Isozymes III. Developmental Biology, Market, C.L. ed. Academic Press, New York. pp. 775-797

36. Rosenberg, B.J., Kafader, C.D. and Schiff, R. 1976. A rapid hemagglutination test for urinary estriol. (Abstr.) Amer. J. Clin. Path. 66:463-464.

37. Schiff, R. 1978. Diagnostic chemicals. In Encyclopedia of Chemical Technology, 3rd. Ed. John Wiley & Sons, New York.

38. Schiff, R. 1978. Successes in reclassification in getting new products to the market. Proceeding of the HIMA, December 12, 1978.pp. 137-139.

39. Schiff, R., Kenoff, M., Schutt, E., Heveran, J. and Reynoso, G. 1981.Preliminary evaluation of a new tumor specific glycoprotein marker. (Abstr.) Oncodevel. Biol. Med. 2:60.

40. Reynoso, G., Keane, M., Schiff, R., Kenoff, M., Schutt, E., and Heveran, J. 1982. Preliminary evaluation of a new "tumor specific glycoprotein" marker. (Abstr.) 5th. Int. Symp. on Prevent. Detect. Canc.

41. Schiff, R. 1983. Guest editorial: Do organizations effectively evaluate R & D activities? Medical Device & Diagnostics Industry. 5:10-11.

42. Schiff, R. 1989. A particle agglutination test for detecting HIV antibodies. (Abstr.) IX Congreso Latinoamericano de Bioquinica Clinica.

43. Schiff, R., Piccirilli, R., Busch, M., Peetoom, F., and Tegtmeier, G. 1989. Multisite study of a particle agglutination test for detection of HIV antibodies. (Abstr.) V International Conference on AIDS. pp. 191

44. Schiff, R., Lutz, H. 1991. A topical combination drug with phototherapy treatment for psoriasis. (Abstr.) Fifth International Psoriasis Symposium.

45. Schiff, R. 1998. Internal audits help companies stay in compliance. Regulatory Affairs Focus. 3:15-17.

46. Ostrosky-Zeichner, L., Alexander, B.D., Kett, D.H, Vazques, J., Pappas, P.G., Saeki, F., Ketchum, P.A., Wingard, J., Schiff, R., Tamura, H., Finkelman, M.A., Rex, J.H. 2003. Multicenter Clinical Evaluation of the (1-3) § -- Glucan (BG) Assay (Glucatell™) as an Aid to Diagnosis of Invasive Fungal Infections (IFI in Humans. (Abstr.) American Society of Microbiology, Sepember 14-17, Chicago, IL.

47. Ostrosky-Zeichner, L., Alexander, B.D., Kett, D.H., Vazques, J., Pappas, P.G., Saeki, F., Ketchum, P.A., Wingard, J., Schiff, R., Tamura, H., Finkelman, M.A., Rex, J.H. 2005. Multicenter Clinical Evaluation of the (1→3) §-D-Glucan Assay as an Aid to Diagnosis of Fungal Infections in Humans. CID: 654-659

48. Schiff, R. 2005. The FDA Inspection Process as a Learning Tool. Genetic Engineering News 25:8-12.

49. Schiff, R. 2007. Auditing a Device Company. Regulatory Affairs Focus. 12(4):8-11.

50. Schiff, R. 2007. Dietary Supplements: Past Compliance and the Future. Regulatory Affairs Focus. 12(12):14-16.

51. Schiff, R. 2008. An NDA for Water. Regulatory Affairs Focus. 13(2):40-41.

52. Schiff, R. 2008. Some Thoughts on Current Good Manufacturing Practices. Regulatory Affairs Focus. 13(7):44-47.

53. Schiff, R. 2008. Book Review: Good Clinical Practice. Edited by Mark P. Mathieu. Barnett International. Centerville, VA. Regulatory Affairs Focus. 13(7):48

54. Schiff, R. 2008. Compliance Auditing of a Medical Device Company. Journal of Medical Device Regulation. 5(4):15-23.

55. Schiff, R. 2009. Book Review. Medical Device Development: A Regulatory Overview . Parexel International Corporation. Waltham, MA. Regulatory Affairs Focus. 14(4):8.

56. Schiff, R. 2009. Botanical Products: Drugs and Dietary Supplements. Regulatory Affairs Focus 14(8):12-16.

57. Schiff, R. 2009. Medical Device Submissions. In Fundamentals of US Regulatory Affairs, 6th Ed., Berry, P.J. and Takes, P.A., eds. Regulatory Affairs Professional Society. Rockville, MD. pp. 201-215.

58. Schiff, R. 2010. Compliance and the Start-up Company. Regulatory Affairs Focus. 15(5) :8-10.

59: Schiff, R., Pannucci, J. and Weinberg, M.A. 2010. Good Clinical Practice Compliance and the Start-up Company. Regulatory Affairs Focus. 15(5):26-32.

60. Schiff, R., Stroud, A., and Tilman, J. 2011. Pharmaceuticals: Compliance and Audits. Regulatory Affairs Professional Society On-Line Course.

61. Schiff, R. 2011. A Historical Perspective on Regulation of In Vitro Diagnostics. Regulatory Focus 16(5):22-25.

62. Schiff, R. 2011. Book Review. Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA. Daniel Carpenter. Princeton University Press. 2010. Regulatory Focus 16(6):33.

63. Schiff R. 2012. Pitfalls in Good Clinical Practice. *Regulatory Focus*. www.raps.org/focus-online/features/features-article-view/article/1768/pitfalls-in-good-clinical-practice.aspx. Accessed 18 June 2012.

64. Schiff, R. and Padula, T. 2012. Quality Systems and Inspectorate Process-Medicinal Products. In Fundamentals of EU Regulatory Affairs, 6th Ed., Jones, P., ed. Regulatory Affairs Professional Society. Rockville, MD. pp. 197-204.