CURRICULUM VITAE
ALAN P. SCHWARTZ
mdi Consultants, Inc.

EXPERIENCE:

1978 to Present mdi Consultants, Inc.
Executive Vice President

Set up over 350 Quality System for both QSR/cGMP compliance and/or ISO13485/9000 (ISO13485) certification. Many of these systems are in still in place for over 20 years and have consistently passed FDA inspections.

Audited over 400 medical device/pharmaceutical manufacturers and food companies worldwide for FDA compliance.

Participated in over 210 FDA GMP audits of FDA regulated companies, Medical Devices, Pharmaceuticals, IVD, Bio-Clinical Monitoring, Foods Processors and Blood Banks in the USA and worldwide. Last few inspections were in Feb, 2013 in China and another in Canada. Assisted in the FDA-483 and W/L responses for over 200 FDA audits.

Provided strategic planning, FDA liaison and documentation review. Prepared and/or assisted with over several hundred 510(k)/PMAs.

Trained over 250 companies and 20,000 attendees in the FDA's Quality System Regulations and Regulatory Requirements, FDA Strategic Planning and Dealing with the FDA Inspections - worldwide.

Trained companies in HACCP and Food Safety requirements. Prepare food HACCP programs for all types of food establishments. Achieved AIB/BRC and ISO22000 certification for food establishments.

Accepted as third party GMP Expert by US FDA for mediating and addressing FDA Warning Letters and Injunctions Compliance.

Certified over 18 Pakistani companies for GMP compliance to US FDA.

Given seminars on FDA regulatory affairs and quality assurance worldwide including Thailand, Brazil, Japan, Taiwan, China (in conjunction with CCPIT/CCUS), Korea, Pakistan, Nicaragua, El Salvador.

Formulated and Signed agreement with CCPIT/CCUS (Chinese Committee for the Promotion of International Trade/Chinese Committee for International Standards) to act as their US FDA consulting group to assist Chinese Companies.

Act as the Official Correspondent/US Agent for more than 250 foreign companies

1998 to 2002 A member of the U.S. FDA Advisory Board for implementing the HACCP as an inspectional approach.

1997 GMP Expert Witness - deposition - Becton Dickinson.

1985 Expert Witness - Court Trial - U.S. vs. Gel Spice Co., Inc.

1987 to Present CST Technologies, Inc.
Executive Vice President

1976 to 1978 US Food and Drug Administration
Supervisor of Field Investigations - NY District Office

1972 to 1976 US Food and Drug Administration
Supervisor of Field Investigations in NY District Office

EDUCATION: City College of New York, B.S. Biology (1972)
Graduate Studies in Regulatory Affairs

CERTIFICATIONS: RAB International Certificate Lead Assessor for ISO9000/ISO13485
FDA HACCP Training Course, July 1997

AFFILIATIONS: Who's Who in Industry and Finance

International Toastmasters

Editorial Review Board for the Journal of cGMP Compliance

Editorial Advisory Board for Medical Device Technology

PUBLICATION/PAPERS: "Evaluation of SeraSub® (Synthetic Serum) and UriSub® (Synthetic Urine) a Substitute for Human and Mammalian Blood and Urine Products for Making Calibrators and Controls", 1990, International Congress of Clinical Chemistry.

LECTURES/SEMINARS: "Seminar on FDA Regulations as They Pertain to the Examination Glove Industry", Taiwan Glove Assoc., Taipei, Taiwan, April, 1989
"FDA Regulatory Affairs Seminar", Schneider Corp., Div. Pfizer, July, 1989
"New Methods of GMP Training", ASQC 1990, Minnesota branch.
"The FDA and the 1990's", Pfizer Inc., 1990.
"Getting from GMP to ISO: The Trip is Not a Long or Expensive Journey'', OEM Electronics, May 1997
"The New FDA and Cost to the Medical Device Industry", IMDEX, Feb., 1992
"The FDA Regulations and the Medical Device Distributor", Future Show, May, 1992

"FDA Training in GMP and Regulatory Affairs", Somanetics Corp., Sept, 1992

"The FDA's SMDA Regulations and the Medical Device Distributor", NHHCE, Nov., 1992

"FDA GMP Training Seminar", Fukuda Denshi Ltd., Tokyo, Japan, Jan., 1993

"Update on the FDA 1993", IMDEX, Feb., 1993

"FDA Panel Discussion Participate", IMDEX, Feb. 1993

"FDA Regulations & Procedures Related to the Drug Manufacturer", Beijing Medical University, March, 1993

"FDA Regulations & Procedures Related to the Food Industry", Beijing Medical University, March, 1993

"FDA and the Medical Device Distributor-Update", Future Show, Las Vegas, NV, May l995

"GMP/ISO for Medical Device Industry," National Science & Technology Development Agency, Bangkok, Thailand, May 1996

"Going from GMP to ISO", OEMED Conference, Boston, Mass., September 1996

"Marketing Medical Devices in the U.S.," Medical Device Manufacturer Associate, Sao Paulo, Brazil

ARTICLES:

"FDA's New Strategy for Compliance", Medical Industry Executive, August/September, 1992

"Eulogy for the Small Medical Products Manufacturers", Medical Industry Executive, Feb., 1993

"Device Integrity", Homecare, February 1993

"FDA Update - Survival Guide to the New Regulations", Home RX Magazine, Feb. 1993

"GMP Compliance & ISO Certification", Medical Industry Executive, January l994

"Preparing Responses to 483s, Warning Letters", Infoexchange, February 1994

"Revised GMPs", Medical Industry Executive, February/March 1994

"Contract Manufactures and Suppliers--A Part of the Team", Medical Industry Executive, April/May l994

"The Consultant, the FDA and You", Medical Device Executive, Jan/Feb l995

"Reconditioning and Rebuilding" Homecare, October 1995.

"GMP vs ISO", The Validation Consultants, January 1997

"HACCP as an Inspectional Approach", Journal of cGMP Compliance, September 1998.

"The Art of Responding to FDA 483s and Warning Letters", Journal of CGMP Compliance, Volume 3 Number 2 January 1999

"CE Marks/IVD Directive, Computer Issues, and Complaint-Rate Data versus Risk Analysis", Medical Device & Diagnostic Industry, January1999