Cutler Solutions, LLC
206 Nathaniel Ave.
Cherry Hill, NJ 08003
Phone 856-287-0162
CutlerSolutionsLLC.com

EVAN S. CUTLER

EXPERIENCE

2012 – Present **Managing Director / Owner**
Cutler Solutions, LLC
Cherry Hill, NJ

Representing over 30 years of experience in FDA-regulated industry, including experience as an FDA Investigator, Evan Cutler and Cutler Solutions provide knowledgeable, professional consultants for the Pharmaceutical, Medical Device, and Biotech industries. Consulting Services include, but are not limited to:

- Regulatory Consulting, including Warning Letter Remediations
- High-level and lower-level Quality Assurance (QA) & Quality Control (QC) Functions and Systems
- Validation, Qualification and Commissioning Services
- Packaging Line, Serialization and Computer Systems Consulting
- Audits and Gap Assessments
- Document Creation, Revision, Review and/or Approval
- Staff Enhancement

Clients include leading manufacturing, packaging and warehousing companies throughout the U.S. We offer competitive rates and excellent service designed to increase operational productivity, improve Quality Systems and ensure the best possible outcome for your next Regulatory Inspection or Customer Audit.

Key projects include:

- **Fragrance Manufacturing, Inc. (FMI)**: *Senior Audit Consultant, 2026*. Performed a pre-certification audit against the requirements of ISO 22716, Cosmetics Good Manufacturing Practices, and generated an Audit Report containing observations and recommendations.
- **PCI Pharma Services**: *Senior Validation Consultant, 2021-2025*. Generated Validation documents including Validation Plans, Equipment IQ/OQ protocols, Process OQ/PQ protocols, Test Method Characterization and Validation protocols, Validation Final Reports, Equivalency Reports, Shipping Studies & Sterilization protocols. Performed protocol execution and generated Deviations to resolve events. Opened CAPAs and generated procedures/work instructions. Worked with numerous assembly and packaging line equipment, including bottling, vial labeling, syringe & autoinjector assembly & labeling, blister packaging, pouching, labeling, cartoning, and serialization/aggregation. Interfaced with customers regarding Validation strategies and expectations during project meetings, kickoffs, and customer audits. Worked with clients including BMS, Amgen, AstraZeneca, Biogen, Eli Lilly, Gilead, J&J/Janssen, Mitsubishi, Novartis, Regeneron and others.
- **Avantor Performance Materials**: *Validation Consultant, 2023-2024*. Consultants wrote and executed Validation protocols including IQ/OQ for laboratory equipment. Generated Investigation Reports for laboratory testing non-conformances. Generated procedures and worked on CAPAs. Wrote complaint investigatons, interfacing with customers.
- **Maruho Hatsujyo Innovations (MHI)**: *Validation Consultant, 2020-2021*. Wrote IQ/OQ and ES/PQ protocols for the Eagle-RX Thermoformer machine. Interfaced with the machine

manufacturer and client for testing requirements and validation strategy. Assisted in protocol execution and troubleshooting at the client site.

- **Sharp Packaging Solutions**: *Validation Manager, 2016-2019*. Managed a staff of seven to eleven Validation Engineers and Validation Technicians. Directed Validation, Qualification, Serialization, and Commissioning activities on numerous computer systems and packaging lines, including bottling, vial labeling, syringe & pen assembly & labeling, blister packaging, bag sealing, thin film strip packaging, pouching, cartoning, and back-end serialization. Reviewed and approved numerous documents such as Validation protocols, Validation Reports, Engineering Studies, FAT, SAT, Change Controls, Validation Memos and SOPs. Authored Validation Project Plans, Validation strategies and customer correspondences. Interfaced with customers during project meetings, kickoffs, and customer audits. Prepared metrics reports for QA.
- **B. Braun Medical**: *Audit Consultant*. Performed overseas Supplier Audits (China and Taiwan) at Medical Device suppliers per ISO and FDA standards.
- **Almac Pharma Services**: *Validation Consultant*. Wrote and executed Validation, Qualification, Engineering Study and Commissioning documents for numerous packaging lines, including serialization activities.
- **Compex Corp**.: *QA Consultant*. Assisted this manufacturer of single layer electronic components (e.g. capacitors, submounts, resistors, and thin film products) in improvement of their quality systems per ISO 9001 and ISO 13485, including complaint handling and investigations. Reviewed procedures and policies, and provided updates. Traveled to Rhode Island site for strategy and quality meetings. Developed/revised position descriptions for QA/QC and Document Control jobs. Assisted in the successful hiring of a QA Director position.
- **Fresenius Kabi**: *Audit Consultant*. Performed overseas Supplier Audits in India at API/Medical Device suppliers per ISO and FDA standards.
- **OptiNose**: *Audit Consultant*. Performed Supplier Audits in Connecticut for Medical Device suppliers per ISO and FDA standards.
- **MonoSol Rx**: *QA Director*. Led the QA Department for their Indiana pharmaceutical manufacturing facilities and was responsible for day-to-day QA functions and quality systems, including review and approval of complaints, events (deviations & nonconformances), laboratory investigations & ATRs (Atypical Test Results), CAPAs, Change Controls, Document Controls, and Validation/Qualification protocols. Managed approx. 15 full-time QA Department personnel, and performed all related administrative functions. Performed ongoing quality improvement activities and generated required QA documents. Interacted with customers & partners to address quality and regulatory issues.
- **J&J / JOM**: *QA/Audit Consultant*. Reviewed and approved Deviations, CAPAs, and Change Controls through the Trackwise system. Reviewed and approved SOPs and Work Instructions through the DocSpace system. Generated/revised SOPs and QA training curricula. Performed Internal Audits and generated Audit Reports. Reviewed Audit Responses and closed open Internal Audits. Created JOM's 2014 Internal Audit Schedule. Performed gap analyses for Quality Agreements.
- **Meridan Consulting**: *Consultant*. Performed various consulting projects including Shipping/Distribution system functions, internal auditing, supplier audits, and QA Management functions for the Pharmaceutical industry.

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- **Padtech, AS**: *Validation and QA Consultant*. Wrote and executed IQ/OQ and PQ/PV protocols, as well as Engineering Studies, for automated manufacturing and packaging equipment at this medical device drug delivery system company. Generated summary reports. Interacted with customers and vendors. Created batch records and SOPs.

2001 – 2012 **Director of Quality Operations**
VTS Consultants, Inc.
Amherst, MA

Responsible for audit, validation, training, and project management functions at numerous pharmaceutical (APIs and finished drugs), medical device and biotech facilities. Experiences include the development, field execution, and quality auditing/review of Installation, Operational, and Performance Qualification protocols, summary reports, and standard operating procedures. Experienced in performing/writing validation project management, facility global audits/gap analyses, FDA 483 and Warning Letter response letters, Validation Master Plans, Shipping Studies (using TempTales), Cleaning Validation Matrices, data analysis/review, and report generation. Experienced in validation/qualification of PLC- and DCS-based systems, software, utilities (including water, clean steam, compressed air, vacuum, and HVAC systems), sterile products, CIP/SIP systems, packaging lines (with a numerous variety of custom components), automated assembly equipment, process equipment, optical QC systems, and laboratory equipment.

Performed and oversaw audit, validation, training, and project management functions at numerous pharmaceutical, medical device and biotech facilities. Key projects included:

- J&J / JOM Pharmaceutical Services (Somerset, NJ & Shepherdsville, KY)
- McNeil Consumer Healthcare (Fort Washington, PA)
- B. Braun Medical (Carrollton, TX, Allentown, PA & Cherry Hill, NJ)
- J&J / Noramco, Inc. (Wilmington, DE & Athens, GA)
- Boston Scientific (San Jose, CA)
- Celeste Industries (Easton, MD)
- Pfizer (La Jolla, CA & Ann Arbor, MI)
- Amgen, Inc. (West Greenwich, RI)
- Sharp Corporation (Conshohocken, PA & Allentown, PA)
- Sharp Corporation/Ivers Lee (West Caldwell, NJ)
- Pharmacia/Pfizer (Kalamazoo, MI)
- The P.F. Laboratories (Totowa, NJ)
- Schering Plough (Kenilworth, NJ & Las Piedras, PR)

1998 – 2001 **Senior Project Manager**
VTS Consultants, Inc.
Westborough, MA

Responsible for managing validation projects: supervising teams of validation engineers, tracking the progress of document generation and execution, generating status reports and Microsoft Project files, performing quality reviews of validation documents, and attending client meetings. Wrote and executed GMP-related documents, including FAT, SAT, IQ, OQ, PQ, and PV protocols, final summary reports, and SOPs. Performed Quality and Regulatory functions.

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Projects included:

- Schering Plough (Union/Kenilworth, NJ & Manati, PR)
- Signature Pharmaceuticals (Gloversville, NY)
- Cryolife (Kennesaw, GA)
- Gliatech (Cleveland, OH)
- Wyeth-Ayerst/ESI/Lederle (Cherry Hill, NJ)
- ISP Technologies (Texas City, TX)
- Schein Pharmaceuticals (Phoenix, AZ)
- US Filter Corporation (various customer sites)
- Merck & Co. (Rahway, NJ)
- Bausch & Lomb Pharmaceuticals (Tampa, FL)
- Parkdale Pharmaceuticals (Rochester, MI)
- Pall Corporation (East Hills, NY)

1997 – 1998 **Validation Specialist**
The Validation Group, Inc.
Conshohocken, PA

Responsible for the performance of numerous validation and auditing functions at Pharmaceutical and Medical Device manufacturing sites. Duties included the development of Internal Audit Checklists, Installation, Operational, and Performance Qualification protocols, Standard Operating Procedures, the performance of field executions of protocols, generation of final reports, and the quality review and correction of data and documents.

1990 – 1996 **Investigator/Consumer Safety Officer**
U.S. Food & Drug Administration
New Jersey District / Voorhees Resident Post (originally NWK District / Camden Resident Post)
Voorhees, New Jersey

Responsible for conducting Establishment Inspections of manufacturing, packaging, and warehousing facilities to assure compliance with Federal regulations. Audited the quality systems and manufacturing processes of numerous medical devices, pharmaceutical products, and foods from receipt of components to finished product release. Evaluated design specifications, written procedures, master files, batch records, consumer complaints, failure investigations, and other QA/QC documentation. Audited the Validation of manufacturing and testing systems, as well as laboratory and process software. Issued FDA 483 forms to firms detailing inspection violations, and interfaced with FDA Compliance Officers regarding the issuance of Warning Letters and other regulatory actions. Wrote comprehensive reports detailing inspection and investigation findings. All actions were performed with the ultimate goal of protecting the consumer.

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Achievements include:

- Assumed the role of Lead Medical Device Investigator for the FDA Voorhees Resident Post (VRP) from August, 1991 to February, 1996.
- Coordinated and tracked all device inspections, investigations, recalls, and consumer complaints in the VRP region.
- Created computer programs which accessed and manipulated databases to monitor the Medical Device Program, organized the regional device firms, and assigned firms to be inspected.
- Aided in the formation of the district Medical Device Cadre, responsible for organizing workshops and conferences.
- Assumed the role of Information Systems Security Officer (ISSO) for the office, based on knowledge and experience with computer systems.
- Responsible for the installation, technical assistance and maintenance of all IBM-compatible computers and networks, as well as security of confidential data, computer virus protection, and software licensing issues.
- Received a Group Recognition Award from the Commissioner of Food and Drugs for development and implementation of effective strategies to achieve regulatory sanctions against a repeatedly violative Medical Device firm.
- Received a commendation and award from the New Jersey District Director for producing an instructional video on stress management that was shown to various FDA Districts across the United States.

EDUCATION

Bachelor Degree – Biological Sciences (1990)
Rutgers University/Rutgers College
New Brunswick, New Jersey

<u>FDA Training Included:</u>

- US FDA Basic Training
- Introductory Pharmaceutical Manufacturing
- Introduction to Medical Devices
- Advanced Pharmaceutical Inspections
- Drug Manufacturing Quality Control
- In Vitro Diagnostics
- Intermediate Medical Device Materials
- Food & Drug Law and Evidence Development
- Reid Technique for Investigative Interviewing
- Sterilization Issues for Medical Devices
- Fraud Training
- Computer System Validation
- Quality Audits for Improved Performance
- Numerous GMP Training/Update Sessions