

**CLIENT LIST FOR  
AKERS KENNEDY & ASSOCIATES, INC.**

ABC Laboratories - Columbia, Missouri

Assistance with clean room design, protocol writing, and clean room procedures

Abbott Laboratories - North Chicago, Illinois/ Rocky Mount, North Carolina/ McPherson, Kansas

Isolation Technology course and discussion including specific aseptic processing issues, conducted with Agalloco & Associates, Inc.

Technical Assistance and consultation on isolator technology.

GMP/Quality Audit of manufacturing/filling facility

Consultation with Management in NY on future trends

Alcon Laboratories - Fort Worth, Texas

GMP review and evaluation of building expansion plans

GMP/Quality Audit of Process Development Manufacturing operations and facilities

Alcon Puerto Rico - Humacao, Puerto Rico

Protocol writing and execution for isolator sterility testing system including a sterilizer and incubators

Alkermes - Cambridge, MA

Assist with aseptic processing and isolation technology issues

Allergan - Irvine, CA

Assist with the design of production and research isolators

Alpha Therapeutics Corp. - Los Angeles, California

Isolation Technology course and discussion including specific aseptic processing issues, conducted with Agalloco & Associates, Inc.

Alza Corporation, - Palo Alto, California

Consultation on aseptic manufacturing processes and validation of pharmaceutical products

Protocol writing and validation execution for an isolator sterility testing system

Assistance with CMC writing

American Cyanamid Co. - Princeton, New Jersey

Isolator training and process validation consultation

American Red Cross - Rockville, Maryland/ Costa Mesa, CA

GMP review and evaluation of water system, validation protocol writing, and technical assistance with water system design

Assistance with Environmental Issues and Documentation

Amgen Corporation - Thousand Oaks, California

Consultation on sterile product manufacturing and isolation technology

Amsco Scientific - *see Steris Co.*

Applied Analytical Industries, Inc. - Wilmington, North Carolina

Consultation on laboratory testing procedures

Presentations and seminars on regulatory compliance and microbiological issues for the training division.

Aradigm Corporation - Hayward, CA

Process Qualification validation of Sterility Testing Isolator based system

Armour Pharmaceutical Company - Kankakee, Illinois

Technical assistance and consultation on isolator sterility testing system.

Asahikasei Co. - Nagoya, Japan

Protocol writing and execution assistance on steam sterilizers with Shibuya Kogyo Co., LTD

Astra Tech AB - Molndal, Sweden

Review of sterilization validation issues for a dental implant product

Aventis - LeTrait, France /Rochester, New York / Cheshire, England/ Dagenham, England/ Paris, France

Facility design for aseptic processing area.

Validation and regulatory compliance status of production process

Regulatory GMP Consultation

Facility audit and technical consulting for manufacturing and quality testing

Technical assistance and consultation on isolation technology and sterilization processes.

Master Validation Plan writing with David Begg Associates, England.

Project review and validation planning

BBraun/McGaw, Inc – *see BBraun Medical*

BBraun Medical., - Irvine, California

Technical review and consultation on new production process throughout project phases

Consultation on isolation technology for production purposes

Protocol writing for a filling line/isolator system

Master Validation Plan writing for isolator based production line

Standard Operating Procedure review and editing

Long term agreement for ongoing technical consultation

Baxter Healthcare - Los Angeles, California

Participation in GMP/Validation Training. Discussed FDA Inspectional Trends.

Becton-Dickinson - Le Pont de Claix, France/Columbus, Nebraska

Facility layout and design review

Consultation on sterilization and validation issues, and conducted cGMP training

Biocine Sclavo – *see Chiron*

Biogen - Cambridge, Massachusetts

GMP review of P&IDs, review of validation plans

Biomira, Inc. - Edmonton, Alberta, Canada

Technical review and consultation on isolation technology , process validation, and validation practices/policies

BioReliance - Gaithersburg and Rockville, Maryland

Training on aseptic processing, and technical support

Review of audits and technical consulting on laboratory testing

CarboMedics, Inc. - Austin, Texas

Technical review and consultation on isolation technology

Cardinal Health – Basking Ridge, New Jersey

Assisted with aseptic processing and analytical issues

Carlisle Barrier Systems – New Lisbon, Wisconsin

Developed isolator validation criteria and decontamination cycles for their isolators

Charles River Laboratories - Raleigh, North Carolina

GMP Audit of validation and calibration procedures

Chiron – Siena, Italy

Purification process, validation, and GMP review with Pharmacia Fast Trak Validation

Clark Richardson Biskup - Kansas City, Missouri

Technical consultation on validation methods and procedures

Covance Biotechnology Services, Inc. - Research Triangle Park, North Carolina

System, facility, validation and documentation review in preparation for FDA Pre-Approval Inspection (PAI).

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DMV International - Veghel, The Netherlands

Consultation on general cGMP compliance issues

DSM International - Delft, The Netherlands/ Caserta, Italy/ Cairo, Egypt/ Mexico City, Mexico  
General GMP and Validation consultation of a Bulk Pharmaceutical Chemical (BPC) facility.

Yearly GMP Compliance audits conducted at the Delft site

Project assistance and regulatory compliance consultation for production of Nutripharmaceutical. Evaluation and consultation at sites in Egypt, The Netherlands, and Italy.  
Drug Master File review, GMP guidance and assistance with Agalloco & Associates, Inc. at Orfaquim Facility in Mexico

Difco Laboratories - Detroit, Michigan

Technical consulting on microbiological issues

DuPont Chemical - North Billerica, Massachusetts

Process Qualification validation of clinical isolator

DuPont Merck - Wilmington, Delaware /N. Billerica, Massachusetts

Master Validation Plan review, technical assistance on policies and procedures

Troubleshooting assistance with manufacturing and testing processes

Performance/Process protocol writing and decontamination validation execution for clinical fill isolator and VHP 1000 generator

Dyanamic Design – Laguna Niguel, CA

Equipment design review

Eli Lilly – Indianapolis, IN/ Fergesheim, France/Sesto, Italy /Brazil

VHP 1000 Generator protocol writing (Brazil)

Aseptic processing assessments and general consultation for various Lilly facilities

Ethicon, Inc. - Somerville, NJ /San Angelo, Texas

Protocol writing and execution of isolator sterility testing system in NJ and

Technical Consulting on Environmental Control in TX with Agalloco & Associates, Inc.

Fisons Corporation - *see Aventis*

Fisons Pharmaceuticals - *see Aventis*

Fluor Daniels - Greenville, South Carolina

GMP facility process review, performed with Eli Lilly and Agalloco & Associates, Inc.

FDA – *see US Food and Drug Administration*

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Fort Dodge Animal Health - Princeton, New Jersey / Fort Dodge, Iowa

Facility layout and design review

Genentech, Inc. - South San Francisco, California  
General technical and scientific consultation

Gensia Sicor Pharmaceuticals - Irvine, California  
Performance/Process protocol writing and decontamination validation execution for isolator based sterility testing system and clinical fill isolator

G.C. Hanford Manufacturing - *see Hanford Manufacturing Co.*

Gist Brocades B.V. - *see DSM International*

Glaxo Smith Kline - Conshohocken, Pennsylvania  
Technical consultation on process validation with Pharmacia Fast Trak.

Hanford Manufacturing Co. – Syracuse, New York  
GMP/Quality Audit of contract testing facility, manufacturing facility and proposed testing facility  
Validation of Isolator Sterility Testing System, including VHP Sterilization system  
General technical and scientific assistance, and regulatory compliance consultation  
Long term agreement for ongoing consultation  
Batch record writing for production areas

Helm New York Chemical Corporation - Piscataway, New Jersey  
Review of Drug Master Files (DMF) for FDA submission  
General technical and scientific consultation

Hikma Pharmaceuticals - Lisbon, Portugal /Amman, Jordan  
GMP review and audit of manufacturing facility under construction, technical assistance with procedures, policies and meeting with the FDA  
Protocol writing for Isolator Sterility Testing System, including VHP Sterilization

Hoffman LaRoche - Nutley, New Jersey  
Validation of Isolator Sterility Testing System, including VHP sterilization and training  
Drafted the executive summary for the restart program, performed with Agalloco & Associates, Inc.

Houston Biotechnology - Houston, Texas  
Facility design review for pilot plant, and GMP and Validation consulting with Pharmacia Fast Trak Validation

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Institute for International Research - New York, New York

Conducted training seminars on Aseptic Processing, Environmental Monitoring, Contamination Control and Isolation Technology (with J. Agalloco)

Jacobs Engineering - Narberth, Pennsylvania

Technical consultation on validation projects, assistance with protocol review with J. Agalloco & Associates, Inc.

Japan Tobacco - Hofu City, Japan

GMP audit and review of clinical manufacturing facility (with Shibuya Kogyo Co., Ltd)

Jet Propulsion Laboratory (JPL) and National Aeronautical and Space Administration (NASA – Pasadena, California/ Moffit Field, California

Assistance with isolation technology for future projects

Johnson & Johnson - New Brunswick, New Jersey

Technical consultation on sterilization technology

Kissei Pharmaceuticals - Shiojiri, Japan

Protocol writing for various pieces of equipment on an automated packaging line

La Calhene, Inc. - Rush City, Minnesota / Paris, France

Technical and validation assistance/consultation for isolation technology, review of proposed project installations for validation ease and compliance

MA BioServices – see BioReliance

Maryland BioScience Corp. - Baltimore, Maryland

Technical and regulatory review and consultation on new bioprocessing center with Ed Calamai and Associates

McDowell Pharmaceuticals - North Kansas City, Missouri

Assist with facility assessment and new product development

Megabios Corp. - Burlingame, California

Protocol writing and execution for an aseptic processing isolator for clinical manufacturing

Merck Manufacturing Division - West Point, Pennsylvania

Consultation with contamination control, aseptic process validation and environmental Monitoring procedures

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Meridian Medical Technologies - St. Louis, Missouri

Consultation on microbiological, validation and aseptic processing issues.

Nisso Engineering Co. - Tokyo, Japan

Technical and validation consultation for the building of new Bulk Chemical Pharmaceutical (BPC) facility

Training on validation procedures and GMPs to Engineering and Sales staff

Nissho/Hishiyama Pharmaceutical Co - Ise, Japan

Master Validation Plan and Protocol writing for Kit Production Line

Technical assistance on the design of the assembly line in isolators, including validation assistance, with Shibuya Kogyo Co., LTD

Oread Laboratories - Lawrence, Kansas /Palo Alto, California

Protocol writing and execution of isolator based sterility testing system, including steam sterilizer

Validation of Isolator Sterility Testing System, including steam sterilizer, with J. Agalloco & Associates, Inc.

Orfaquim S.A. de C.V. - *see DSM International*

Organon, Inc. - West Orange, New Jersey

In-house isolator course and technical consulting with Agalloco & Associates, Inc.

OrthoMcNeil Janssen Pharmaceuticals - Puerto Rico

Cost estimations for sterilization options for lyophilizers, with Agalloco & Associates, Inc.

Otsuka Pharmaceuticals - Tokoshima, Japan

Validation Services with Shibuya Kogyo Co., LTD

Parkedale Pharmaceuticals - Rochester, Michigan

Consultation on aseptic processing and environmental monitoring, and performed Documentation review

PharmaConsult – Bridgewater, New Jersey

Isolator operations and design consultation

Pharmacia, Inc. - Kalamazoo, Michigan

Consultation on aseptic processing and sterile product manufacturing

Pharmacia LKB Biotechnology - Piscataway, New Jersey /Uppsala, Sweden

Validation training for their Fast Track Validation team, technical assistance, protocol writing Assistance with client evaluation and validation study

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Pharmacia & Upjohn - *see Pharmacia, Inc.*

Phoenix Scientific, Inc. - St. Joseph, Missouri

Review of technical documents and scientific input

Quintiles - Kansas City, Missouri

Sterile production facility design, isolator consultation, validation consultation and regulatory support for new area

Radix Pharmaceuticals - North Kansas City, Missouri

Technical consultation on the start-up and manufacture of a new inhalation therapy drug.

Rhone-Poulenc Rorer - *see Aventis*

Sanofi-Winthrop Pharmaceuticals - *see Abbott Labs*

Sartorius Corporation - Yauco, Puerto Rico/Edgewood, New York

Review of sterilization procedures and proposed plans at the Puerto Rico facility, conducted with Rocky Mountain Compliance Specialists.

Schering Plough Corporation - Union, New Jersey

Conducted training on pharmaceutical microbiology, contamination control, and isolation technology

Shibuya Kogyo Co., LTD - Kanazawa, Japan

Long Term venture - Validation and project management training for the newly developed validation team, includes GMP audits of Japanese facilities, consulting Japanese clients with FDA procedures and philosophies, master validation plan and protocol writing, overseeing the execution of validation work, GMP facility review, isolation technology assistance, VHP sterilization assistance, training, equipment design and configuration into new technologies

Shinko Pantec Ltd - Osaka Japan

General GMP and validation consultation for a new Bulk Pharmaceutical Chemical (BPC) facility, Validation Master Plan writing

Shionogi and Co.- LTD, Osaka, Japan

GMP Audit, validation status review, and technical consulting with Shibuya Kogyo Co.,LTD.

Siemens Building Technologies - Buffalo Grove, Illinois

Review of quality systems documentation

Smith Kline Beecham - *see GlaxoSmithKline*

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Somatogen - Boulder, Colorado

GMP review and evaluation of facility layout, philosophies and procedures

Steris Co - Apex, North Carolina /Mentor, Ohio



Technical assistance and consultation on new technologies and international sales

Sumitomo Chemicals - Misawa, Japan

General consultation on BPC manufacturing and validation requirements

Sumitomo Pharmaceuticals - Osaka, Japan

General consultation on biological product manufacturing

Clinical product manufacturing and quality assurance consultation

Facility and documentation audits of Sumitomo contractors

Long term agreement for ongoing technical consultation

Syntex, USA, - *see Oread Labs*

Taiyo Pharmaceutical, Inc. - Takayama, Japan

Validation of injectable manufacturing area with Shibuya Kogyo Co.,LTD, including master validation plan writing, protocol writing and execution on-site training, and on-going consultation

TechniCAL, Inc. - New Orleans, Louisiana

Technical consultation on terminal sterilization and equipment possibilities in the pharmaceutical industry. Also included was RetroTEC, Inc. of Wisconsin

Teijin, LTD - Osaka, Japan

Review of manufacturing capabilities and validation status with Pharmacia Fast Trak Validation

Teva Pharmaceutical Industries, LTD - Jerusalem, Israel

Training and consultation of aseptic processing and sterile products

The Sigel Group, - *see Jacobs Engineering*

U.S. Bioscience - Conshohocken, Pennsylvania

Audit of contract manufacturing facility

U.S. Food and Drug Administration - Rockville, Maryland

Sterilization, Aseptic Processing, and Isolation Technology training for FDA personnel during the years 1996 to present

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Vital Pharma – Riviera Beach, Florida

Aseptic processing technical consultation

Warner Lambert Co. - Vega Baja, Puerto Rico

Technical review and consultation on cleaning validation program with J. Agalloco &

Associates, Inc. and TechniPharm Consulting Group

Yamanuchi LTD - Takahagi, Japan

Technical consulting on facility utilization with Shibuya Kogyo Co. LTD

Yonkers Industries - Cary, North Carolina

Technical consultation on validation procedures and concepts

Yoshindo LTD - Toyama, Japan

Protocol writing and execution supervision for solid dosage formulation facility  
with Shibuya Kogyo Co., LTD