James Agalloco

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Agalloco & Associates

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Forty+ years of management experience in pharmaceutical manufacturing, pharmaceutical process engineering, technical services and research and development. Internationally recognized expert on process validation, sterilization, aseptic processing, pharmaceutical manufacturing and isolation technology. Extensive knowledge of pharmaceutical, biological and API manufacturing technology.

EXPERIENCE

Agalloco & Associates Belle Mead, NJ (12/91 to present) - President - Provides a wide range of technical services to the pharmaceutical, biotechnology and medical device industry in the areas of process and product validation, sterilization, aseptic processing, isolation technology, sterility assurance, compliance and facility design. Works closely with other consultants on larger projects. Assisted more than 200 clients in the United States, Puerto Rico, Western Europe and elsewhere.

Bristol-Myers Squibb Technical Operations New Brunswick, NJ (5/90 to 12/91) - Director, Validation and Technology - Directed validation, automation, and technical documentation activities for BMS New Brunswick. Served as an important technical resource for worldwide pharmaceutical manufacturing. Active participant on product introduction and facility upgrade task forces.

Squibb Technical Operations New Brunswick, NJ (4/88 to 5/90) - Director, Worldwide Validation and Automated Technology – Responsible for Squibb facilities in 27 countries around the world. Served as major technical resource for facility design, facility start-up, sterilization, aseptic processing, validation, and automation. Participated actively on major product, process, facility, and equipment projects within STO. Directed the validation and automation phases of a $25 MM expansion of existing parenteral facility in New Brunswick. Major support provided to sterile bulk manufacturing.

Pharmaceutical Engineering, Department Manager (2/80 to 4/88) - Managed the development, execution, and documentation of validation efforts for STO worldwide. Served as the principal source of validation expertise within Squibb Corporation. Successfully led the validation of a $62 MM sterile facility through FDA review. Primary spokesperson for validation to FDA and other regulatory agencies. Responsible for validation of all dosage forms.

Pfizer Pharmaceuticals New York, NY (9/73-2/80)
Engineering Project Manager (6/79-2/80) - Prepared capital project proposals for dosage form and BPC facilities. Provided facility planning, feasibility analysis, cost estimation, ROI, and technical input.

Senior Production Supervisor (9/75-6/79) - Managed production operations for sixty (60) different sterile and oral liquid and powder products. Major areas of responsibility included cost control, cost reduction, CGMP compliance, scheduling, equipment selection, and process trouble shooting.

Manufacturing Engineer (4/74-8/75) - Formulated, piloted and scaled-up numerous pharmaceutical dosage forms. Coordinated technology review for new products from R&D to commercial sites.

Research Engineer (9/73-4/74) - Managed the ongoing development and isolation of an anti-cancer agent from fermentation extract through finished bulk drug. Managed this activity part-time (1976 and 1979) while serving full time in other capacities.

Merck & Co. Rahway, NJ (3/71-8/73)
Junior Chemical Engineer - Assisted in the scale-up/start-up and troubleshooting for new and existing bulk pharmaceutical chemicals. Served on API facility start-up team in Puerto Rico for 3 months.

EDUCATION
M.B.A. (Pharmaceutical Studies) Fairleigh Dickinson University, Teaneck, NJ, 1983
M.S.Ch.E. Polytechnic Institute of New York, Brooklyn, NY, 1979
B.E.Ch.E. Pratt Institute, Brooklyn, NY, 1968

MILITARY
1st Lieutenant, United States Army (11/68-10/70) - Transportation Corps, platoon leader / convoy commander in continental United States and the Republic of Vietnam. Honor Graduate, TOBC 5-69.

AFFILIATIONS
USP, Member: Microbiology Expert Committee, 2005-2025; lead author / thought leader on completed revisions of <1211> *Sterilization* & <1229> *Sterility Assurance.* Active participant in all other activities of the MEC.

Parenteral Drug Association (1980 to present): Honorary Member; President; Second Vice President; Director; Chairman, Scientific Advisory Board; Committee Chairman; Interest Group Leader; Committee and Task Force Member; Course Leader; Speaker; Volunteer; Founder, Metro Chapter.

Validation Discussion Group: Co-founder and Member, 1980 to present
Pharmaceutical Manufacturers Association: Member, CSVC, 1983-1991
International Society for Pharmaceutical Engineering - Member, 1980 to present

SCIENTIFIC & EDITORIAL ADVISORY BOARDS
Eniware – developer of novel sterilization equipment – Scientific Advisory Board
MedInstill – innovative developer of aseptic processing technologies – Scientific Advisory Board
Pharmaceutical Technology – Editorial Advisory Board
Pharmaceutical Manufacturing - Editorial Advisory Board

PRESENTATIONS & TRAINING PROVIDED
Presentations at numerous PharmTech, PDA, PhRMA, ISPE, ASQC and other industry meetings. Provides training courses on aseptic processing, sterilization and process validation domestically and internationally. In-house presentations and training sessions provided on a variety of subjects.

PUBLICATIONS
Co-editor, Validation of Pharmaceutical Processes, expanded third edition with 58 chapters, published in November 2007 by InformaUSA. Two prior editions published in 1986 &1997. Fourth edition is currently in-process.
Co-editor, Advanced Aseptic Processing Technology 42 chapter text, published August 1010 by InformaUSA.

Authored or co-authored more than 40 book chapters and over 150 technical papers on: process validation, aseptic processing, sterilization, change control, sterility assurance, sterilization-in-place, cleaning validation, environmental monitoring, and isolation technology.

Agalloco & Associates

Agalloco & Associates is a New Jersey corporation led by James Agalloco, an internationally recognized expert on pharmaceutical technology, sterilization, aseptic processing, and process/system validation. A&A provides a wide range of technical services to the pharmaceutical and biotechnology industries. Our experience base includes all types of pharmaceutical dosage forms, medical devices, bulk pharmaceutical chemicals and biological products. A&A has particular expertise in the areas of validation, aseptic processing, sterilization, sterile bulk preparation, isolation / barrier technology, quality assurance and facility design. A&A draws upon a network of highly qualified individuals and organizations for the execution of larger tasks. A&A has assisted more than 200 clients since its founding in 1991.

Completed Assignments

Aseptic Processing

Review of current and future technology; evaluation of contract facilities; review of parenteral technology and regulatory compliance; in-house training of professional staff; evaluation of facility design concepts; development of environmental monitoring program; review of classified environment design proposal; facility modification and reopening; conversion of aseptic fills to terminal sterilization; assistance in regulatory compliance; assessment of international sites for US registration, evaluation of corporate policies and procedures; application of practices for medical devices; audit of admixture facilities; risk analysis for sterile products; design concept for pre-filled syringe manufacture; evaluation of aseptic sites for acquisition

Biologics

Assist in biological drug pre-approval inspection preparation; trouble shoot bioreactor contamination problem; conceptual design of isolator facility for fermentation / purification / formulation / filling; conceptual design review for facilities; application of isolation technology; review of facility and utility systems; definition of cleaning validation program; review of validation requirements for CGMP operations; development of environmental monitoring program; review of vaccine facility design and construction details; validation of aseptic processing; qualification of laboratory equipment; detailed design, validation and start-up of vaccine filling suite; design and validation of a blow-fill-seal facility; qualification / validation of cell processing facility; evaluation of contract manufacturers; pre-approval audits for bulk biological production; due diligence assessments

Bulk Pharmaceutical Chemicals / Active Pharmaceutical Ingredients

Review of BPC validation requirements; validation of process control systems; review of design specification for distributed control system; definition of cleaning validation program; assistance in facility qualification / validation; validation master planning; assistance in aseptic processing and sterilization-in-place for sterile bulk operations; project manager for validation of BPC facility; review of Drug Master Files; conceptual development of facility renovation for sterile bulk operations; design review for sterile bulk manufacturing facility; development of protocols for production scale-up; assistance with regulatory interaction for sterile bulks; cost estimate for major API facility; design of sterile bulk packaging system

Isolation and Barrier Technology
In-house training programs; assistance with liquid fill isolator qualification / validation; isolator based sterility test system validation; application of isolation technology concepts for clinical production; conceptual design of isolation technology based filling system; design concepts for integration of isolation technology to solid dosage formulation; validation master plan for cytotoxic parenteral facility; design and validation of microbial sampling system; application for medical device production; application for radio-pharmaceutical production; application for medical device pilot plant; design concept for parenteral pilot plant; applications for sterile API's; design of systems for rapid decontamination

Medical Devices & Diagnostics
Conceptual review of facility design; conduct custom validation training program; validation of controlled environments; validation of aseptic processing; design of environmental monitoring program; isolator based sterility test system validation; qualification / validation of medical device intermediates; application of isolation technology; review of cleaning validation program; assistance with clean room design, classification and operation; review of process validation program; regulatory submission of device sterilization methods; qualification of medical device production equipment; selection of clean room contractor; assistance with clean room injection molding; process design review for novel drug delivery system; integration of drugs and device manufacture on single site; preparation of corporate quality manual; assistance with component depyrogenation

Oral & Solid Dosage Forms
Review of facility design concepts; development of cleaning validation program; cost estimate for oral products facility; review of standard operating procedures; evaluation of contract manufacturing site; assistance in manufacturing process development; validation support for non-sterile products facility start-up; validation protocols and reports for tablet products; validation of cleaning procedures; dust control assessment; development of environmental monitoring program; assistance with validation deviations; definition of microbial controls

Pharmaceutical Manufacturing
SOP and validation audits; facility design reviews; sterile powder manufacturing technology; facility conversion from cephalosporin production; facility and equipment design review; qualification / validation of parenteral facilities; preparation and review of standard operating procedures; SOP preparation; preparation of components; pre-approval inspections; development of manufacturing instructions; facility layout assistance; troubleshooting ampoule filling; conceptual design for compounding area; evaluation of contract manufacturers; validation of manual and automated inspection; arbitration of client-CMO dispute

Processing Equipment
Design and validation of sterilizer control systems; conceptual and detailed design of novel sterilization system; development of equipment manuals and qualification documentation; design of isolators for various applications; development of factory acceptance test protocols; bench-marking for injectable filling equipment; design of tanks for SIP compatibility; design of formulation / filling system for sterile suspension; design of SIP systems for process trains; design of self-contained sterilization equipment: design of H_2O_2 decontamination system; design of BIER vessels for various sterilization processes,

Regulatory Affairs & Compliance
Assistance in regulatory interaction; assistance with FD 483 response; assistance with regulatory letters; assistance with regulatory interface; NDA submission preparation assistance; assistance with international regulatory compliance; critique of internal development reports prior to regulatory submission; validation readiness assessment; conduct of internal and external audits; screening formulations for terminal sterilization potential; actively participate in FDA meetings with clients; preparation of NDA sterilization sections for EEC submission; preparation of site reference file; assistance with container-closure integrity confirmation; review of facility master plans; assistance with comprehensive sterility failure investigation; development of corporate quality manual; conduct of PAI preparation audits; consent decree remediation activities; due diligence support for acquisitions; assistance with DMF preparation; assistance with 510(k) preparation; expert witness on compliance

Research & Development
Preparation of process development reports for oral products; cleaning validation master plan for clinical operations; review of parenteral formulation design; review of operating procedures and test methods; audit and review for pre-PAI assessment; pre-approval inspection preparation; assistance in scale-up/validation of lyophilized formulation; design and implementation of isolator based manufacturing system; development of qualification protocols for analytical laboratory equipment; development of experimental plans; qualification / validation of clinical / stability facility; packaging of sterile bulk clinical materials; scale-up of ointment processes; assistance with patent litigation

Sterilization
Development and validation of sterilization processes; validation of sterilization-in-place procedures; sterilization science training program; validation of terminal sterilization; conceptual design of CIP/SIP systems; sterilization process trouble shooting; validation of radiation sterilization; sterilization of packaging components; assistance in patent litigation; literature search for novel sterilization methods; validation of C_2H_4O, H_2O_2, ClO_2 and CH_2O sterilization procedures; implementation of in-line electron beam sterilization; terminal sterilization of pre-filled syringes; dry heat sterilization of API's; terminal sterilization by irradiation; validation of liquid chemical sterilization; expert witness on patent litigation; establishment and development of novel sterilization methods

Training
Established courses on Aseptic Processing; Sterilization; Isolation/Barrier Technology; Sterilization-In-Place; Master Planning; Process Validation; Cleanroom Qualification; Pharmaceutical Compliance; open and in-house course; participate in corporate training programs; assistance in development of curriculum content; development and presentation of custom training content

Validation
Validation master plan preparation and review; development of validation master summary; review & refinement of corporate validation programs; preparation of validation protocols and reports; process and system validation; review of validation programs; systems and documentation; develop WFI and DI water system validation program; audit of critical utility system validations; design of retrospective validation program; preparation and review of NDA CMC sterilization section; management of major re-validation program for parenteral facilities; conformance to FDA & EMA Process Validation Guidance.

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