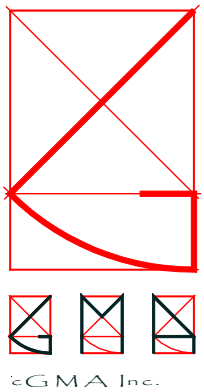
Geoff Middleton
Architect

cGMA, Inc.
443 West Woodland Avenue
Springfield, PA 19064

+1 484 433-7523
GM@GeoffMiddleton.com



PROJECTS

Mr. Middleton has over 25 years of architectural and design experience for both technical and non-technical facilities. He has worked in the United States, Puerto Rico, the Netherlands, Ireland, Switzerland, South Korea, Germany, India, and Japan. Services include programming, master planning, feasibility study, site selection, conceptual design, and oversight and client consultation for design development, preliminary engineering, contract documents, and contract administration phases, as well as cGMP design review services.

His experience in the pharmaceutical industry includes projects ranging from $15 million to over $1 billion in scope; from laboratories and pilot plants to production and fill finish facilities by building type; and for products derived from both biologics and chemical synthesis.

Mr. Middleton's Experience includes:

- Dong Woo Pharma Synthech, New API Manufacturing Facility, South Korea.

Conceptual Design for a new, multi-product small molecule, active pharmaceutical ingredient, bulk manufacturing facility outside of Seoul, South Korea. The facility designed is over 11,500 m² in area, and included staff facilities, quality laboratories, material handling and dispensing, and both plant and sanitary utility generation capabilities. Challenges included a compact site, and the introduction of material handling methods new to the client organization.

- PacificPharma, Major Additions and Alterations, Secondary Manufacturing Facility, South Korea.

Conceptual Design and Master Plan for expansion of an existing health foods and ethical pharmaceutical, secondary manufacturing facility outside Seoul, South Korea. The design included additions totaling over 32,000 m² that constitute a 150% area expansion of existing facilities, and was designed for further expansion in the future. The design incorporated the existing facilities into a single, state of the art composite facility in full conformance with cGMP requirements of US FDA and EMEA. In addition to the existing topical, oral solid, and liquid product lines, the project introduced aseptic syringe filling capabilities to the site.

- Novartis, Unites States Flu Cell Culture Vaccine Manufacturing Facility, Holly Springs, North Carolina.

Design Concept Review of cell culture based, influenza vaccine manufacturing facility to be constructed in North Carolina. The project design was at approximately 25% complete with foundation construction about to begin. The review concluded that the plan could be reduced by

nearly 30% in area, with a parallel reduction in AHU capacity of 40%, for an estimated capital cost savings of $20 million. All program requirements, process equipment and interconnections to adjacent facilities were maintained in the proposed redesign.

- Centocor, Additions to Manufacturing Building, Manati, Puerto Rico.

Conceptual Design Architect for programming, and conceptual design for additions to an existing production facility to provide capacity and equipment to permit the production of a new product. Accelerated conceptual design process assisted client management in evaluation of alternative product delivery strategies.

- Bristol-Myers Squibb, Large Scale Cell Culture Manufacturing Campus, Devens, Massachusetts.

Client representative Architect for development of a grass roots Biologics Manufacturing Campus to be constructed on the former Devens Army Base in Massachusetts. Responsibilities included site selection, master planning, programming, facility conceptual design, oversight of design development, and detailed design performed by Fluor Enterprises Inc. as well as construction period assistance. Additional responsibilities included direction and oversight of civil and structural design work. Facilities on the site include, a quality lab, office and cafeteria building, a manufacturing facility, connecting spine, parking garage, site central utility generation, maintenance and engineering building, site central raw material warehouse, chemical storage building, and a waste water pretreatment facility.

- Centocor, Renovations for New Product Production, Leiden, The Netherlands.

Conceptual Design Architect for programming, and conceptual design for renovations to an existing biologics production facility to provide capacity and equipment to permit the production of a new product. Accelerated conceptual design process assisted client management in evaluation of alternative product delivery strategies.

- Centocor, Green Field Biologics Manufacturing Campus, Ringeskiddy, Ireland.

Design Leader / Architect for programming, and conceptual design for a fully integrated, stand alone mammalian cell culture biologics manufacturing facility to be constructed on a new, green field site. The design is intended to serve as the root of a multi-facility campus of manufacturing facilities to be developed in the coming decade.

- Amgen, MAb Project, Boulder, Colorado.

Design Leader / Architect for programming, design and preliminary engineering for a mammalian cell culture addition to an existing microbial manufacturing facility. The addition incorporates inoculum through seed train up to 15,000 liter production scale bioreactors and includes associated support spaces.

- Amgen, Lyophilizer Retrofit Project, Juncos, Puerto Rico.

Design Leader / Architect for programming and design for the retrofit of two 500 SF lyophilizers and auto loading system within an existing aseptic filling facility interconnecting them with two existing vial filling operations. The project included careful staging and construction access planning in order to maintain ongoing aseptic operations.

- Centocor, Bulk Biologics Expansion, Leiden, The Netherlands.

Design Leader / Architect for feasibility study, master planning, programming and conceptual design for the capacity increase of Centocor's European bulk biologics manufacturing plant. The original manufacturing facility, constructed nearly 20 years ago on the campus of Leiden University had experienced multiple modifications and expansion projects in an organic fashion. Additionally the site had outgrown its available area in permanent, temporary, and off-site facilities. The master plan included production facility expansion, a new central utility and maintenance building, laboratory expansion in an adjacent facility to be acquired, and a multi-floor office and parking facility on a new, adjacent site.

- Amgen, Neupogen Project, Juncos, Puerto Rico.

Design Leader / Architect for programming and schematic design. Amgen determined to substantially increase its manufacturing capabilities on its existing manufacturing site in Puerto Rico. The project included multiple firms in the master planning and design of this multi-facility site expansion including Fluor Daniel and Kohn Pedersen Fox. The project included the programming and schematic design of a new, free standing microbial, Biologics bulk manufacturing facility.

- Johnson & Johnson / Centocor Biologics Campus, Location to be determined.

Design Leader for the conceptual design of a new biologics manufacturing campus for the manufacture of bulk active ingredients derived from mammalian cell culture. The campus includes: a bulk active ingredient manufacturing facility, central warehouse and raw material dispensing unit, QA / QC Laboratory, Administration building, Cafeteria, Central Utilities Plant and Maintenance facility, Waste Treatment facility and utility yard; and is designed to expand with up to three additional manufacturing modules in the future. In total the campus includes over 900,000 SF of facility area on a site of 45 acres.

- JRH Medias, Denver, Pennsylvania.

Design Leader for a schematic design study for a new dry powder cell culture media concentrate manufacturing plant. The 130,000 SF facility is designed to be capable of producing 100 metric tons of product per month initially with expansion planned to increase output to 350 MT / month in the future; and includes all required staff, QC, and warehousing. The process incorporates pin milling of raw materials and cone blending of batches ranging from 5 kg. to 10,000 kg.

- Searle Pharma Biologics Pilot Plant, Chesterfield, Missouri.

Design Leader / Architect for a multi-purpose biologics clinical manufacturing facility producing bulk active ingredient utilizing either mammalian cell culture, or microbial methods. The 55,000 SF facility is designed to utilize bag technology for the provision of medias and buffers in lieu of fixed tankage.

- Confidential Client.

Design Leader for the conceptual design of a research laboratory and clinical manufacturing potent solids pilot plant. The research lab portion of the design will accommodate 134 research personnel in standardized lab modules along with all required lab support and officing. The pilot plant is designed for scale up, development and clinical manufacture of phase I, II, and III bulk active materials; capable of handling PB-ECL category 4 potent / toxic materials utilizing closed

systems and isolator technology wherever feasible. Overall the facility comprises 175,000 SF of which 120,000 SF accommodate laboratory functions, and 55,000 SF of Pilot Plant area.

- Wyeth Ayerst / American Home Products BIOS Campus, Grange Castle, Ireland.

Design Leader for the programming and schematic design of a Clinical Manufacturing facility, QA/QC Laboratory facility, Administration building, and Campus Cafeteria for Wyeth's Biologics manufacturing campus outside Dublin, Ireland. The overall campus also includes a bulk active ingredient commercial scale manufacturing plant, a formulation, filling and packaging secondary plant, a central warehouse and raw material dispensing unit, and a central utility generation plant all connected with an enclosed spine.

- Amgen Puerto Rico, Site Master Plan, Juncos, Puerto Rico.

Consultant Architect for the development of a ten year master plan for future development of Amgen's manufacturing site in Juncos, Puerto Rico. The existing secondary parenterals filling manufacturing plant is to be supplemented with potent powder filling, small molecule manufacturing, additional secondary capacity, and secure warehouse facilities. Included in the study is the opportunity to purchase additional, adjacent land. The master plan incorporates centralized Utility Generation, Warehouse, and Staff facilities arranged along a site "spine" serving all future facilities.

- SmithKline Beecham, Factive IV Lyophile, Cidra, Puerto Rico.

Project Architect for schematic studies supplementing existing parenteral filling operations with up to 4, 350 – 400 SF auto-loading lyophilizers.

- USDA Plum Island Animal Disease Center, Renovations and Additions, Plum Island, New York.

Programming and Schematic Design for USDA's primary research facility dealing with foreign animal diseases potentially effecting the US agricultural industry. The project comprised the complete, gut renovation of the original facility built in the '50's and supplementary areas in building additions. Activities to be accommodated in the program included laboratory and farm scale animal housing areas, both at BSL-3AG and BSL-4 containment levels. When constructed the facility will be only the third facility world wide that has the capability to house farm scale animals in BSL-4 containment conditions, and will be the largest BSL-4 facility anywhere in the US.

- Laboratories Serono, S.A., New Development and Production Facility, Corsier-sur-Vevey, Switzerland.

Project Architect for design development and contract document phase for a $200 MM, 25,000 M2, "grass roots", multi-product biologics production facility located in Corsier-sur-Vevey, Switzerland. The project utilized a small portion of existing structure of what was originally a tobacco manufacturing plant, along with significant additional structure and an entirely new exterior shell.

The facility incorporated four entirely independent commercial production suites, large scale non-GMP production development labs and process areas, Quality Control and Assurance labs, media and buffer preparation and reconfigurable feed areas, warehouse facilities, offices, and

personnel and visitor accommodations. Challenges for this project included a small and steeply sloping site, and a late stage change in the schedule to incorporate three stages of construction and occupancy.

- Confidential Client, West Point, Pennsylvania.

Project Architect for a conceptual design study for a 140,000 SF, $125 MM, grass roots, biologics pilot plant. The facility incorporates independent process suites for the production of safety assessment, clinical phase I, II and efficacy lot materials, arranged in isolatable trains in order to support the clients intent to simultaneously produce microbial and viral based products. The program included all support and ancillary spaces and equipment to be an independent facility, including: warehouse, dispensing and buffer/media preparation, QA labs, a non GMP development lab wing, maintenance areas, utility generation, production suites, fill, finish and packaging facilities.

- Hoffmann-La Roche, EU cGMP Upgrades, Nutley, New Jersey.

Project Architect for extensive upgrades to an existing production facility on Roche's Nutley campus in order to satisfy European licensing concerns. Project included re-evaluation of flows, construction of new locker and shower areas and internal stairs and corridors to facilitate improved material, personnel, and waste flows.

- Parke-Davis, Secondary Pharmaceutical Production Facility, Ann Arbor, Michigan.

GMP review consultant to this 120,000 SF new Formulation, Fill and Finish facility to be constructed on Park-Davis's plant site in Ann Arbor, MI. Responsibilities included the production of FDA review documentation.

- Bayer Corporation, Fractionation Capacity Increase, Clayton, North Carolina.

Project Architect responsible for the programming, conceptual design, and design development for a $75 MM dollar "grass roots", blood production fractionation facility in Clayton, North Carolina. The plant is designed to receive frozen paste from the site warehouse, carry out two fractionation steps, and finally virally inactivate the product prior to transport via an enclosed upper level bridge to an adjacent fill / finish facility. The design provides complete separation of building systems and personnel between those portions of the process that occur before and those that are after the viral inactivation step; in order to avoid contamination of the final product.

- Bristol-Myers Squibb Company, General Purpose Biologics Pilot Plant, Syracuse, New York.

Project architect responsible for the programming, conceptual design and early design development of a thirty-five million dollar, "grass roots", fermentation, biological products pilot plant. In addition, represented the client as owner's representative architect during document development by a consulting firm, and during the contract administration phase including site visits and shop drawing review.

The facility included warehouse and gowning areas as well as labs, seed fermentation large-scale fermentation, and purification areas.

• Bristol-Myers Squibb Company, Pilot Scale Conjugation Facility, Syracuse, New York.

Project Architect responsible for the programming and conceptual design of a $10 MM dollar, conjugation pilot plant intended to produce clinical trial and commercial launch scale quantities of product. The facility was constructed as an addition to an existing building.

• Bristol-Myers Squibb Company, Anti-Cancer Development Facility, Syracuse, New York.

Project Architect for a $50 MM, grass roots pharmaceutical fermentation pilot and semi works plant on the company's Syracuse, New York site. The facility is designed to NIH guidelines and cGMP's incorporating three levels of internal gowning and containment. The facility is designed to produce late phase clinical trial and market launch quantities of bulk active materials in equipment ranging from bench top scale to 4000L production fermentors. Various areas within the facility incorporate blast relieving exterior walls and skylights. The building is self-contained with warehouses, utility generation and maintenance areas, QA, high containment, and research laboratories.

• Bristol-Myers Squibb Company, Non-Beta Lactam Bulk Plant, Barceloneta, Puerto Rico.

Project Architect for a $40MM grass roots, pharmaceutical bulk chemical production plant in Barceloneta, Puerto Rico. The facility included warehouse, office, lab, mechanical and production areas. A four-story process wing was separated from the service portion of the building by a concrete blast retaining wall, and incorporated a blast relieving exterior skin.

• Dupont Biologics Research Center, Experimental Station, Delaware.

Programmer for 250,000 SF new Discovery Research Laboratory facility to be constructed on Dupont's experimental station campus in Delaware. Programming and Schematic Design included multiple studies for various combinations of research groups to be included in the facility. Design development proceeded without final approval of research mix and required a "kit of parts" approach permitting specific fit out decisions late in the project development.

• PF Laboratories, Inc., Biologics Discovery Laboratories, Princeton, New Jersey.

Project Architect for Programming and Design for a 58,000 SF renovated biologics discovery laboratory facility and 10,000 SF addition. The existing facility contained cGMP production facilities that were to be retained as Clinical Production capability.