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Related Experience

Ampio Pharmaceuticals Production and Office Facility
Englewood, Colorado

About the Project

Design and construction of a 19,000-SF pharmaceutical production facility, which included cleanrooms, laboratories, warehouse and office space for a proprietary biopharmaceutical company specializing in anti-inflammatory treatments. GBA provided complete architectural, structural, mechanical, electrical and controls design services; equipment procurement; and construction management.

Project Elements:
- Modular cleanroom for aseptic processing
- Utility design for pure steam, water for injection, compressed air, nitrogen, argon and central vacuum system
- HVAC design for the manufacturing facility (ISO 8 thru ISO 5), laboratories, and office/warehouse areas
- Class A corporate headquarters (office design)
- Equipment procurement including specifications, obtaining quotes, bid tab, recommendations, and FAT/SAT attendance for manufacturing equipment including:
  - Autoclave
  - VHP chamber
  - Vial Filler with RABS
  - Custom fluid removal machine
  - Pure steam generator
  - Water for injection skid
  - Laboratory equipment
  - Modular cleanroom
- Owner’s Representative services including project management, procedure (SOP) authoring, validation protocol generation and execution
- Full-time construction manager on site to represent the Owner during construction

Owner Contact
Ampio Pharmaceuticals
373 Inverness Parkway
Englewood, Colorado 80112
Holli Cherevka
720.437.6500
hcherevka@ampiopharma.com

Facility Size
19,000-SF

Completion
2014

Construction Cost
$3.7 million
About the Project

In 2012, GBA was selected to provide project management and process engineering services as part of a $120 million multi-product manufacturing facility improvement. Portions of the scope completed by our team included:

**Process Design**
- Process Water Systems
- Deionized
- USP Purified Water
- CIP systems
- Process Chilled Glycol Systems
- Clean, Dry, Compressed Air
- Flammable Product Processing
- Compounding Tank Equipment/Skid Design
- P&ID Development

**Consideration for Hazardous Materials**
- Design included closed mixing operation utilizing flammable liquids
- Code compliant strategies for risk management and to address use of a control area to avoid Group H occupancy classification, fire separation, classified electrics, ventilation, and vapor detection

**Equipment Procurement**
- Equipment URSs, specifications and bid packages

**Process Automation and Controls**
- System architecture design
- Software selection
- Integration

**Commissioning of Equipment**
- Preparation of System Commissioning Plans
- Execution of System Commissioning Protocols
- Verification and test forms
- Coordination of delivery, installation, inspection and functional/run testing of equipment
- Process automation / commissioning
- Commissioning turnover package assembly

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**Owner Contact**
Promega Corporation
2800 Woods Hollow Road
Madison, WI 53711
John Koehler
Project Engineer
608.250.9647

**Facility Size**
272,000-SF

**Completion Date**
2014

**Total Construction**
$120 million
HACH, Laboratory Expansion
Loveland, Colorado

About the Project

HACH selected GBA to provide full design services for their new 100,000-SF R&D facility. The building will sit adjacent to their existing facility in Loveland and will support their engineering teams in research and development for their comprised of laboratories, BSL2 space, machine shop, optics labs, a 10 meter EMC test chamber, offices, conference rooms, and customer experience spaces.

GBA participated in Kaizen meetings with HACH personnel to better understand HACH’s needs. A unique design element of the project included creating space for the Obeya rooms where during the design development stage, all individuals involved in managerial planning meet in a great room to speed communication and decision making.

GBA provided full design services including civil, architectural, structural, mechanical, electrical, plumbing, fire protection and laboratory planning.

“Everyone is really excited to see our new R&D building go up. We think GBA did a great job of putting our vision for the facility, especially the Obeya rooms, into the design” Karin Bogren – Director of R&D programs, Hach

Owner Contact
HACH Company
5600 Lindbergh Dr
Loveland, CO 80538
Karin Bogren
Director of R&D Programs
970.663.1377 X 2592

Facility Size
104,000-SF

Construction Cost
$22.3 million

Estimated Completion
July 2017
JACOB VESTAL
Design Architect

Jake brings five years of experience working within the Life Sciences studio at GBA. He relocated to the Broomfield, Colorado office in 2015. His responsibilities include facility design, both new construction and renovations, for the pharmaceutical and industrial/warehouse sectors. He excels at coordinating with multiple design disciplines and is proficient in Revit and AutoCAD. His relevant experience includes:

Sandoz, Maintenance Parts Storage, Broomfield, CO – Project architect for the development of a plan to consolidate the storage of maintenance spare parts into a newly renovated area in the finished goods warehouse. Responsibilities included: general project management including owner meetings, field surveys, coordination with storage consultant, design of new spare parts area, and drafting of construction documents.

Sandoz, Packaging Fit and Finish, Broomfield, CO – Project architect responsible for creating a fit and finish report for the packaging area at Sandoz’s Broomfield, Colorado facility. Report included documentation of existing finishes, gap analysis, and finish recommendations.

Hospira, a Pfizer Company, Lyophilization Conceptual Design Services, McPherson, KS and Nationwide – Design architect providing conceptual design and cost estimates for increased aseptic fill capacity and Lyophilization capacity at Hospira/Pfizer sites both nationally and internationally. Layouts included stand-alone facilities, plant renovations and plant expansions. Provided multiple conceptual design reports for the following sites: McPherson, KS; Rocky Mount, NC; Australia; Spain; Japan; and Croatia.


Hach Corporation, New R&D Laboratory Expansion, Loveland, CO – Project architect for the new research and development facility. Project included the Obeya room concept, a new 10 meter EMC chamber, large machine shop, optics laboratories and chemistry laboratories.

Hospira, a Pfizer Company, M22 Vial Filling Line, McPherson, KS – Design architect providing design services of this wash, filling and packaging suite. Space functions included an ISO 5/7 filling suite, ISO 8 washing station, ISO 8 accumulation and packaging area, personnel and material airlocks, control rooms and mechanical mezzanine. A notable feature in the M22 project is a custom designed hepa cart docking/product transfer station. CFD modeling was successfully utilized to pre-determine air flow around the docking station and throughout the ISO 5/7 filling area.

Hospira, a Pfizer Company, EPO Building Expansion, McPherson, KS – Design architect of a new 26,300-SF space for packaging and cold storage of a biological product. Design included renovation to an existing building, which included a new API freezer room, tank storage area, and product packaging. The expansion also included a walkway to connect the new building to the existing structure.
JOE WINSLOW, CPIP
Project Manager

For the last 24 years, Joe has focused specifically on the pharmaceutical environment where he has held responsibilities for master planning, project management, facility layout, process and equipment engineering and manufacturing layout. Joe brings a unique perspective to the team by drawing on more than 15 years of industry experience while working directly for owners in various leadership positions overseeing facilities operations and logistics. He understands the plant lifecycle and various regulations including FDA and EU cGMP. This extensive experience in operations and quality will guide the GBA team during the project’s duration. His relevant experience includes:

PHARMACEUTICAL

Terumo BCT, Cleanroom Upgrades, Lakewood, CO – Project manager responsible for consulting on the modification of the HVAC system in the L100 clean room in building A10. The current system is designed for static pressure control and the change will allow dynamic pressure control. The purpose of the project is to allow the cleanroom to continue to operate if one of the nine air handlers has any unplanned downtime or needs scheduled maintenance.

Hach Corporation, New R&D Laboratory Expansion, Loveland, CO – Project manager for the design of a new electronics manufacturer research and design facility. Project included the Obeya room concept, a new 10 meter EC chamber, large machine shop, optics laboratories and chemistry laboratories.

ZS Pharma, Conceptual Design of a Manufacturing Facility, Denver, CO – Project manager leading conceptual design and site investigation services for the development of a preliminary floor plan for a new manufacturing facility. This project included a site search, municipal incentive research, and conceptual design for a new API facility slated to produced 100’s of tons of material per year.

Ampio Office, Cleanroom and Production Facility, Englewood, CO – Project manager, construction administrator and process engineer for a 19,000-SF aseptic production facility involving clean rooms, laboratories, warehouse and office space. GBA acted essentially as the Ampio Engineering department for the duration of the project and held such diverse roles as manufacturing equipment specification/procurement, writing SOP’s, detailed facility design, construction administration, equipment installation, commissioning and validation.

Colorado State University, New cGMP Building, Fort Collins, CO – Provided overall guidance, oversight and review during construction and qualification of new $18 million building project to ensure regulatory compliance.
KELSEY TARLETSKY, PE  
Mechanical Engineer

Kelsey is a mechanical designer who joined GBA in 2012. She works closely with project leadership to keep projects on-track and within budget. Her expertise includes designing HVAC systems and process utilities for filling suites, compounding areas, solutions areas, lyophilizers, packaging rooms, temperature controlled warehouses, security vaults, aseptic clean rooms, gowning suites, and stopper processors. Her experience includes:

PHARMACEUTICAL

**13605 - GCON, AveXis Phase 2 Pods, Libertyville, IL** – Providing design documents for GCON modular PODs for the expanded AveXis gene therapy production. Responsible for providing mechanical design documents to be issued for fabrication of the PODs as well as permitting.

**13592 - Hospira, a Pfizer Company, UV Water Treatment, McPherson, KS** – Mechanical design engineer of a new water treatment system on the City Water line serving the McPherson facility. Scope of work included the design of a UV system with a water filter system as well as associated piping and valves.

**13517 – Hospira, H3 Pilot Plant Conceptual Design, Lake Forest, IL** - Mechanical designer responsible for mechanical layouts, equipment list, utility analysis, and phasing plans.

**13511 - Cambrex, Pilot Plant Expansion, Glycol Skid Design, Charles City, IA** – Mechanical designer for portion of plant expansion project, scope of work included sizing and specify the individual components for a tempered glycol skid to be used during production processes. The component design and specifications included instruments, pumps, control valves, piping and all required accessories for the skid.

**13494 - Hospira, a Pfizer Company, M23 Vial Filling Line EPCM, McPherson, KS** – Mechanical designer for conceptual and final design layouts. Completed mechanical and process utility system designs, and laminar flow hood system designs for the aseptic filling suite. Was also responsible for a variety of project management tasks such as client and vendor coordination, assisting in facility and equipment layouts, as well as CR & Validation engineering support.

**13463 – AveXis, Libertyville Plant, Libertyville, IL** - Provided mechanical design for the renovation of an existing 80,000-SF precast warehouse type building for use in clinical scale gene therapy process. Work includes BSL2 labs in prefabricated cleanroom PODs, coordination with city and state regulators for code compliance.

**13402 - PBI-Gordon, New Third Street Herbicide Facility, Kansas City, KS** – Mechanical designer for a new 40,000-SF chemical manufacturing facility. Responsibilities included: assisting with conceptual floorplan layouts.