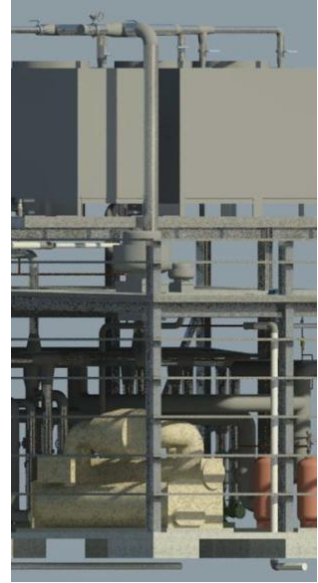


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## *We make the Difference*

**For over 50 years**, CMA Architects & Engineers has provided design and constructing management services to most pharmaceutical manufacturing companies established in Puerto Rico.

From designing their original facilities, as well as providing services while in operation, CMA has been supporting the industry with quality solutions for today's requirements.





## Expertise

Through the years, CMA Architects and Engineers LLP has developed facilities that meet global regulations, with special focus on Current Good Manufacturing Practice regulations enforced by the US Food and Drug Administration (cGMPs). CGMPs provide for systems that **assure appropriate design, monitoring, and control** of manufacturing processes and facilities.

With five decades of pharmaceutical manufacturing design and construction support under its belt, CMA has a highly experienced workforce knowledgeable in global regulations such as: cGMP, FDA, ISO and PIC/S.



## Our Commitment

### Confidentiality

We honor our clients, thus any information shared with our company - from general information to specific details regarding manufacturing and operation - we treat them with the importance it deserves.

Throughout the years, CMA Architects and Engineers have worked hand in hand with leading industry names to enhance their manufacturing and processes. To do this, privileged information has to be shared. CMA provides confidentiality throughout the process by implementing client specific security measures regarding data sharing and distribution through limited access digital media management.





## **Services**

*Your one-stop shop for global regulation  
design, permitting, construction management  
and project administration*

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## Manufacturing Facilities

From the macro to the micro, we can assist you to achieve the results you need.

If you are aiming towards designing a large scale facility, a specific modifications all the way to an existing production room, or a more specific look into cGMP compliance, we have the expertise to add value to your project.

Single product suites or adaptable multi-product manufacturing centers require special considerations to remain operational for a long period of time.

Lean manufacturing trends must keep the working environment safe for the operators, while allowing for fast project execution and cost savings.

Listening, understanding and documenting the needs of client's is one of our tools for successful project delivery. Quality control through the design process is another reason why our clients trust us and help us develop long lasting working relationships.





## Laboratories

The **current trends** in laboratory design consider flexible facilities that can adapt with the fast pace changing business. Lounge meeting areas promote synergy and idea sharing. Bench areas can be shared. More and more lab processes need to be documented and analyzed in computer stations which can be accommodated in an office environment.

Centralizing lab functions used by multiple lab operations can allow for shared spaces and equipment improving operational efficiency. Typically segregated areas can appear as a unified space by strategically using glazing as transparent partitions.

We have experience designing Chemical, Micro-Biology, R&D, Quality Control, and High Hazard Laboratories. We look at people and material flows to achieve efficient laboratory arrangements.

Using a sustainable design approach help clients manage energy, control operational costs and reduce the environmental impact while complying with cGMP and safety regulations.

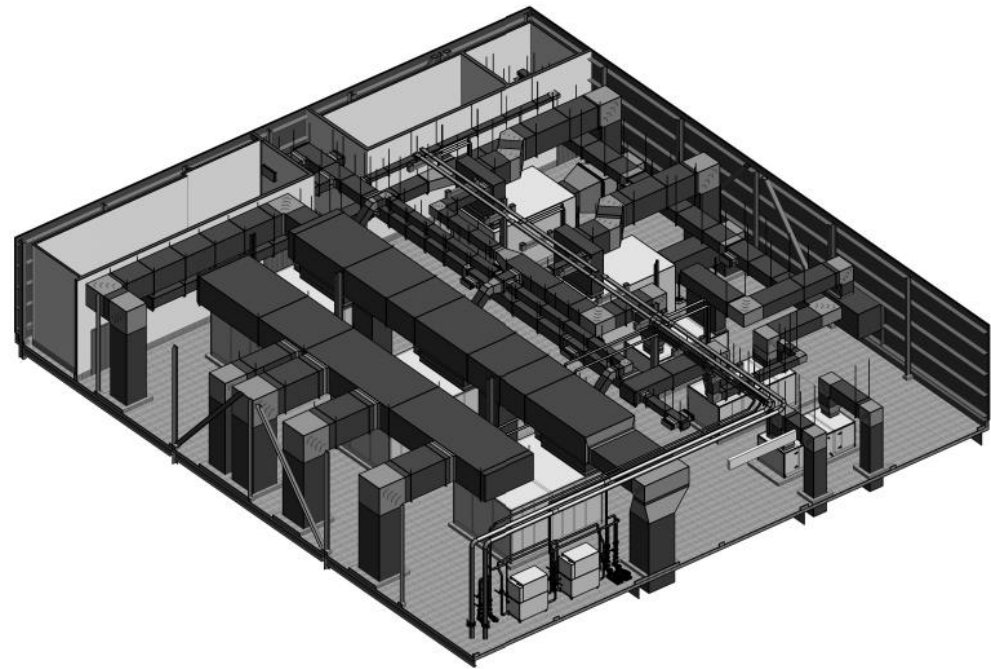
## Centralized Utility Centers

Centralized utility centers allow for cost effective energy management. Furthermore, the waste product of a system can be reused to reduce energy and operational costs.

CMA Architects and Engineers have work together with our clients to update utilities to achieve higher levels of safety, comfort and efficiency that result in operational savings.

Among the services we offer are:

- Energy Audits
- HVAC Systems Optimization
- LEED (*Leadership in Energy and Environmental Design of the US Green Building Council*)





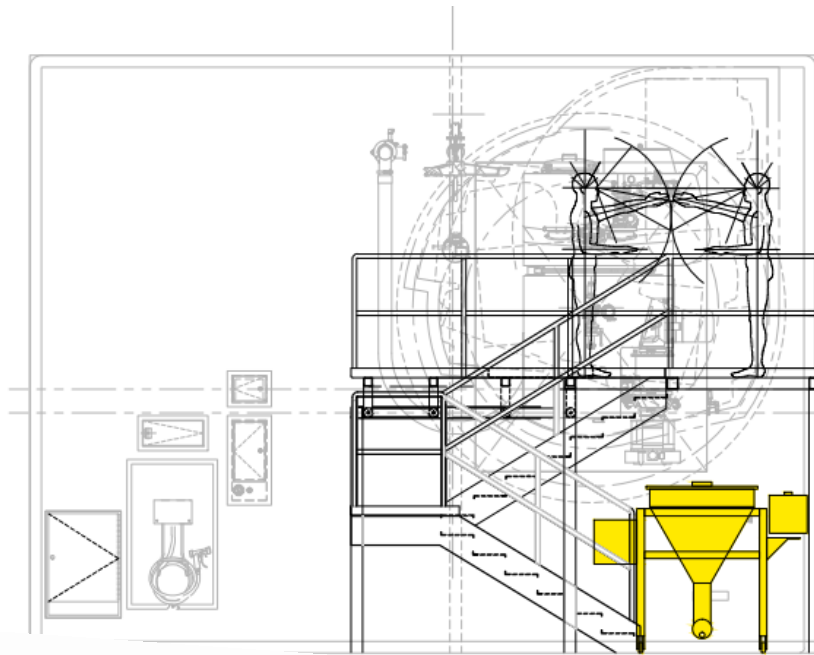
## Clean Rooms

Clean Rooms require a tight level of environmental conditions control, whether it's temperature, humidity, particulates or hazardous materials.

Clean Room designers must maintain cleanliness of the air. This can be achieved by recirculation through HEPA filtration avoiding to throw away energy associated with one-pass air systems. Rooms configuration and location of diffuser and air returns are critical to achieve a proper sweep of air.

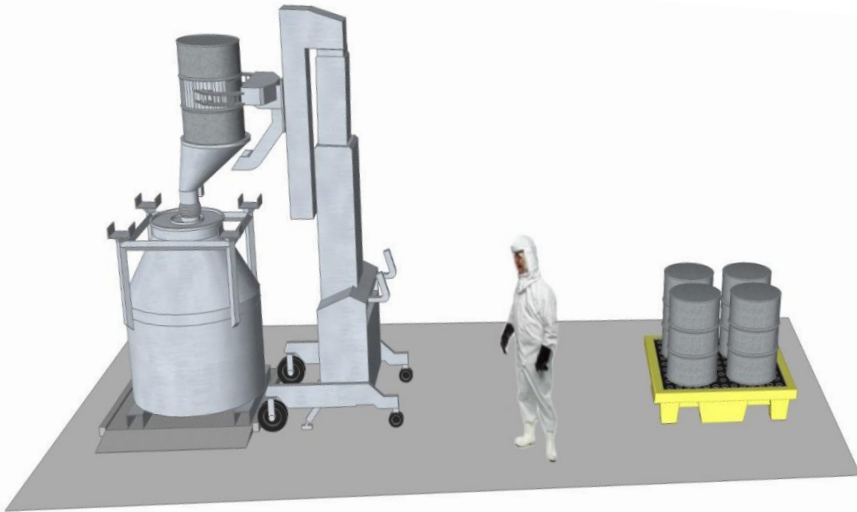
The correct classification of clean Rooms will define how many air changes per minute are required, filter coverage %, CFM per SF, and air returns location and quantity. It will also determine architectural considerations such as ceiling type and material, light fixtures type, wall system type and finish material, and flooring and wall base type and material. Clean Room must be designed with cleanable surfaces that do not stain with the chemicals and materials that will be handled in the room. Horizontal surfaces should be avoided at all time to reduce opportunities for particles to accumulate.





## Other Specialties

- cGMP Upgrades
- Technology Transfer Project
- Pilot Plants
- Quality by Design
- Modular Construction
- Packaging Facilities
- Controlled Warehouses
- Ergonomic Evaluations
- General Arrangement Drawings

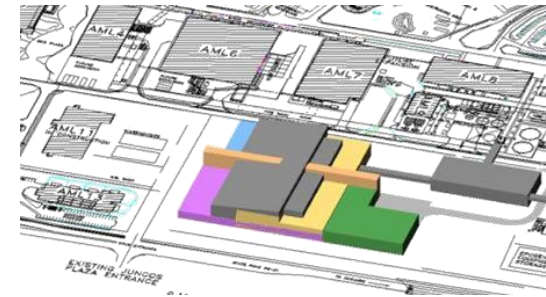
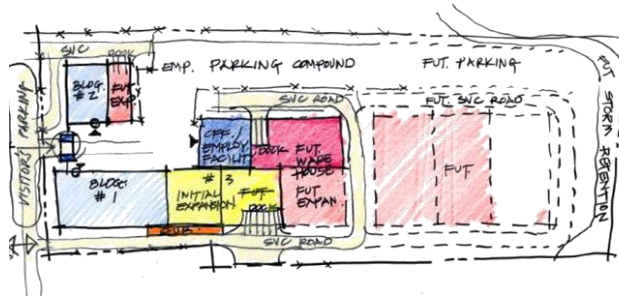


## Master Planning

The primary benefit of a Master Plan (MP) is that it offers a 'big picture' view of the facility goals, thereby setting out a clear, logical vision for the future that stakeholders can understand, feel involved in and work towards.

A MP creates a flexible, client-owned strategic development framework for the short, medium or long term. The MP flexible 'live document' can be easily adapted to meet changing market requirements for new and/or value-added initiatives.

Working in close collaboration with all stakeholders, a MP takes account of key issues such as site location, infrastructure and expandability. Topics covered in a MP can include energy conservation, building location and lay-out as well as production processes, good manufacturing practices (GMP), material flow, warehousing and personnel requirements to create a number of low risk yet innovative concept options for the client, the best of which is then selected as the way forward for the company.





*CMA's 7 Steps of Strategic Master planning*

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## *Support & Assistance*

In addition to design services to the pharmaceutical and manufacturing industry, we also provide our clients with the alternative to help with the **permits** acquisition. Sample of permits we work with for our clients are:

- Environmental Impact Assessment
- Land Use Consultations
- Air Emissions
- Solid Waste
- Earth Extraction
- Tree Pruning, Cutting and Removal
- Wastewater and Storm Water NPDES
- US Army Corps of engineers Joint Permit
- Construction
- Use Permits
- SHPO & ICP Consultations
- Federal Endorsements



## ***Representative Projects***

Excellence through value services and  
commitment to our clients

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## Medical Facility Expansion Ponce, PR

Zimmer had to double their production capacity without affecting on-going operations. CMA designed and provided construction support services for a 100,000 SF expansion for the manufacturing of orthopedic implants and surgical products considering current and future production needs such as utilities capacity and parking for employees.

Zimmer again contracted CMA for the design of modular cleanroom modules and the improvements to a Oil Reclaim Area. CMA helped Zimmer developed a conceptual master plan for the optimization of the original facility, identifying future growth opportunities, aesthetical building exterior improvements and reorganizing site internal traffic and access.



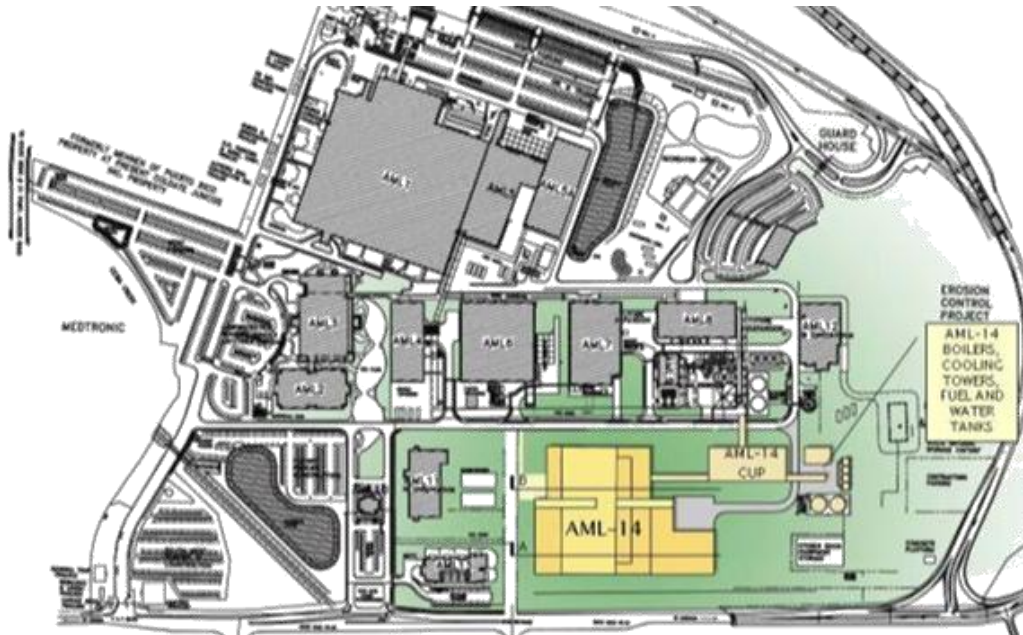


*Capacity Expansion Master Plan*

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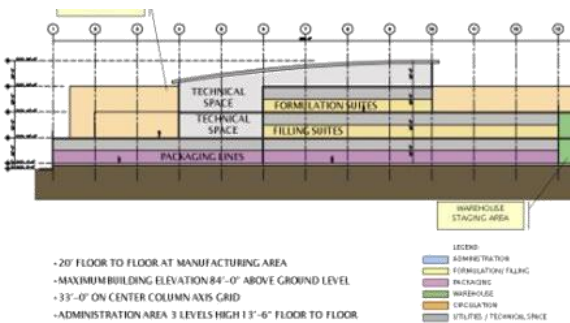


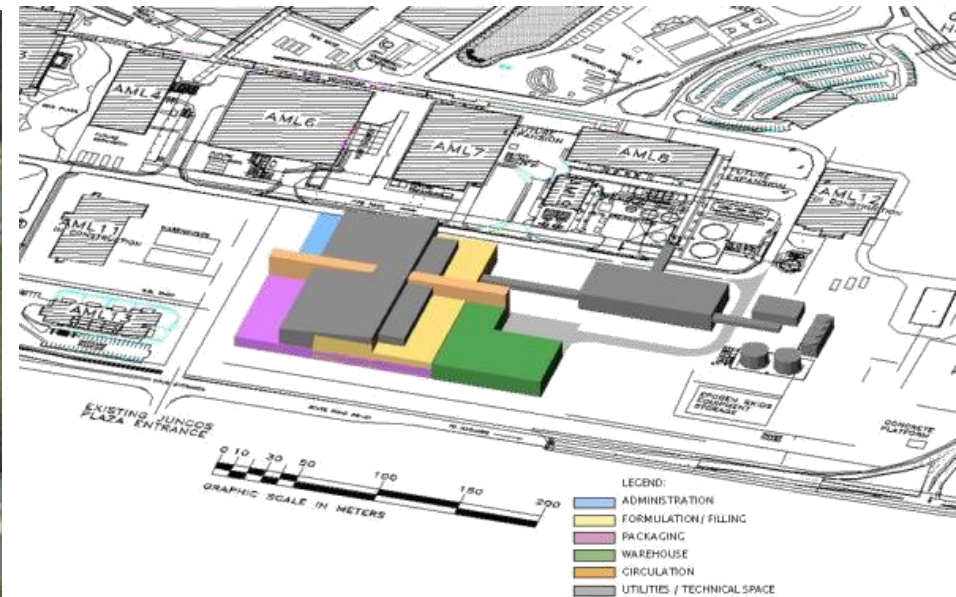
## Bioprocess Expansion Master Plan Juncos, PR



Amgen had an ambitious plan to add a new state of the art Bioprocessing facility at their existing facility in Juncos, PR. CMA worked with Foster Wheeler to develop a conceptual master plan. The master plan consisted of manufacturing facilities for formulation, filling suites for vials and pre-filled syringes.

All necessary utilities, buffer warehouse, administrative and support spaces for the manufacturing area were to be provided as well to serve the facility in support buildings all connected by a utilities spines and corridor. The support facilities included an Administration Offices Building with offices, cafeteria and laboratories, Service Building, Central Utility Plant Building and Emergency Power Building.



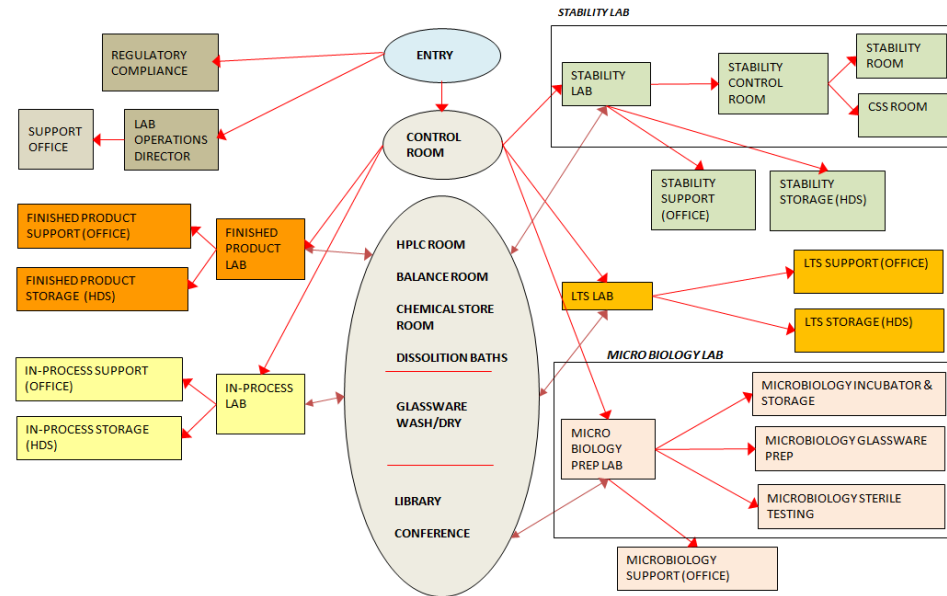


## Amgen Bioprocess Expansion Master Plan

## Chemical & Microbiology Lab Confidential Client, PR

The Client needed to accommodate a complex laboratory program in a reduced site. Spatial Relationship Diagrams were used to develop a functional floor plan maximizing available space and optimizing operations. Materials and People flows were analyzed to reduce travel distances and ensure lab operators safety and product quality assurance.

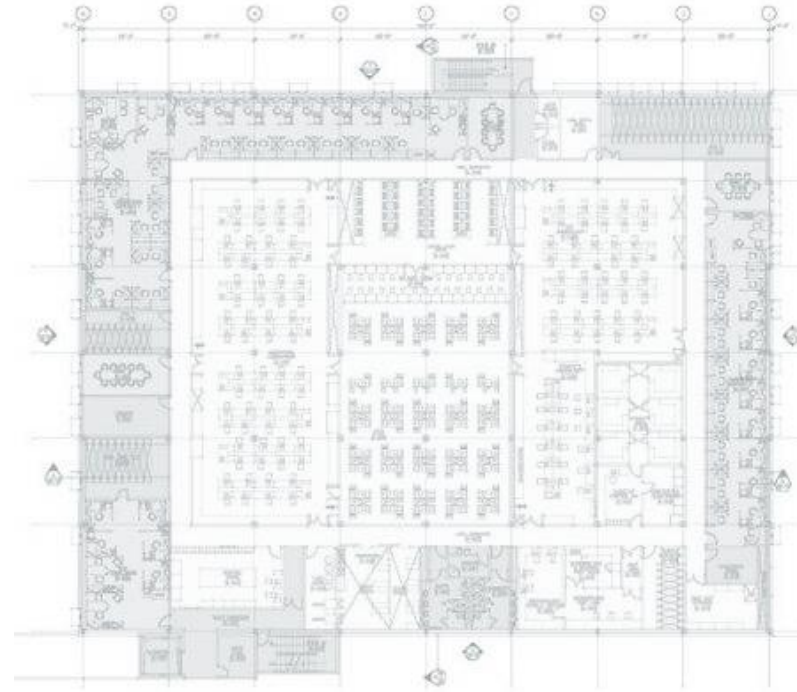
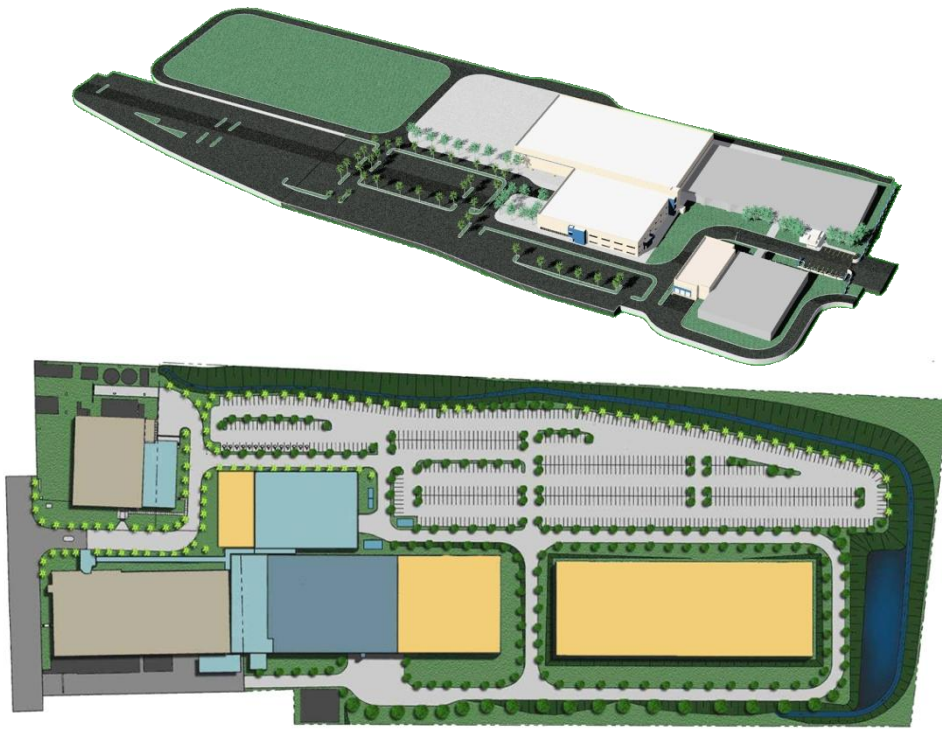
Controlled areas shared by different labs were centralized and documentation and support areas were accommodated in the perimeter of the building.



### Services

Architecture  
Structural,  
Civil,  
Mechanical and Electrical engineering

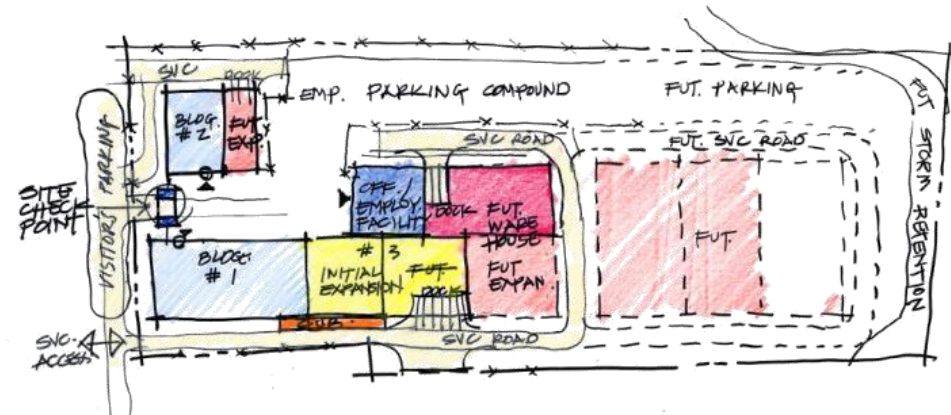




*Chemical & Microbiology Laboratory*

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## Capacity Expansion Master Plan Humacao, PR

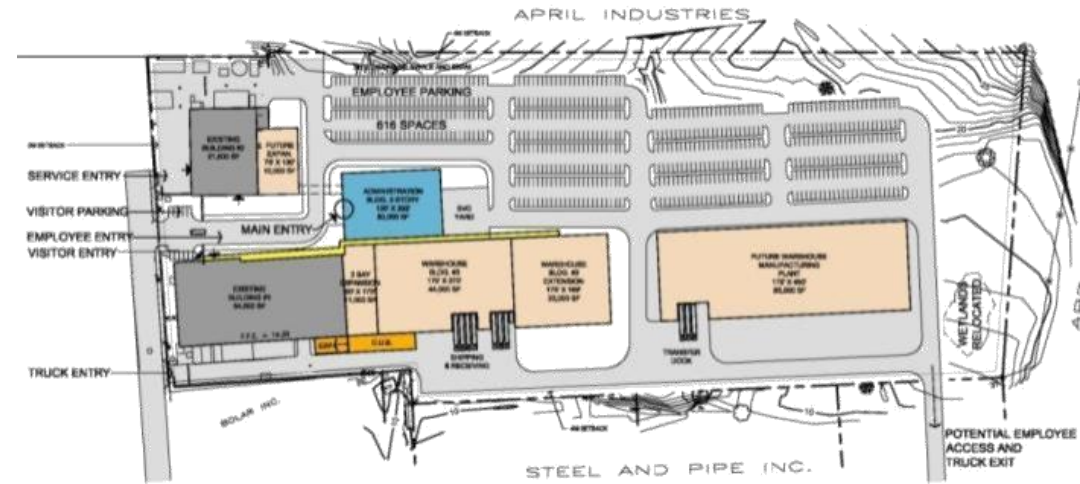
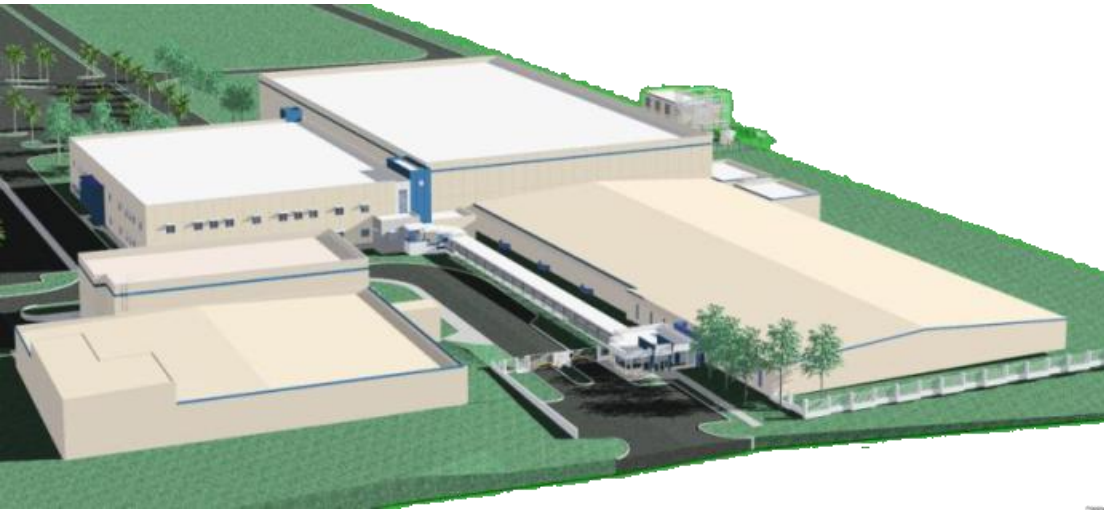


CMA developed a Site Master Plan for 21 acres with the adjacent existing 7 acres for a combined manufacturing site, incorporating existing facilities, Buildings 1 and 2, and projected future requirements for a 3X increase in production.

Program included: a new manufacturing building, a new administration, cafeteria and laboratories building, a new warehouse and a new utilities yard.

CMA performed site traffic studies, site access evaluations, materials, personnel and waste flow diagrams, functional bubble diagrams, utilities capacity studies etc.





*Capacity Expansion Master Plan*

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## Training & Development Complex Mayaguez, PR

The Bioprocess Development and Training Complex was a joint effort between Puerto Rico's Industrial Development Company (PRIDCO), the University of Puerto Rico and the Puerto Rico Science, Technology and Research Institute Trust, to improve the Island's potential in biotechnology and bioprocess manufacturing, education and research.

### Focus:

- Promote interaction between academia and industry.
- Provide the grounds for investigative communication.
- Strengthen Puerto Rico's capacity research, development, manufacturing and bioprocess engineering.

### Features:

- 30,000 square feet facilities
- \$19M investment
- 10,000 square feet of research and development laboratories
- conference room
- lecture room
- training laboratory
- amphitheater with a capacity of 150 people

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## Training & Development Complex

The project's design organized the program into two distinct wings joint together by a common walkway: the manufacturing-research wing and the education-training wing. Common areas, such as cafeteria, sitting areas and conference rooms were located in between these two wings to provide the means through which users of both wings could share information and experiences, in both formal and casual settings.





## **Sample Clients**

*Quality services that help maintain the  
excellence for which our clients are recognized*

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## Our Clients

CMA's history of long-term relationships with the industry's leading companies reflects the level of its expertise and the quality of its work.



Bristol-Myers Squibb

**AMGEN**



**JANSSEN ORTHO LLC**



*Lilly*

**Medtronic**

**Baxter**

*Johnson & Johnson*

**PRPharmaceuticals, Inc.**  
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**BAIRD**

**abbvie**



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