Nimble Design Philosophy Enables Completion of CDMO’s Greenfield Facility Expansion In Record Time

As businesses must stay nimble to adjust to changing requirements, facility design and construction are becoming more nimble as well. Rather than the traditional approach of doing the design first and construction second, a more cost-effective and efficient method has emerged that takes on each aspect of the project in parallel – with designers staying several steps ahead of their construction colleagues.

This novel way of working allowed Grand River Aseptic Manufacturing, Inc. (“GRAM”) to take on a two-year greenfield expansion project that increased the pharmaceutical manufacturing company’s capacity four times over. The ambitious undertaking was made easier with the assistance of innovative designers and engineers from CRB.

GRAM is a parenteral contract development and manufacturing organization, founded in 2010. The company was born through the acquisition of assets of a joint venture between the Van Andel Institute and Grand Valley State University, to provide outsourced sterile parenteral manufacturing for the life sciences industry.

Today, GRAM employs more than 200 employees in Grand Rapids, MI, with nearly 100,000 square feet of Current Good Manufacturing Practice (cGMP) space. The company provides a range of fill and finish needs, from early clinical trial fills through commercialization. GRAM’s facilities support pharmaceutical development, cGMP manufacturing, analytical testing, and regulatory filing.
GRAM’s rapid growth led to its facility expansion that incorporated modern features and state-of-the-art equipment. According to John Wichelt, VP, Client Pharmaceutical Services, “GRAM had reached maximum capacity at our current facilities. We needed more capacity for large scale, commercial products to support growing demand and to benefit our clients. We continue to see opportunities in the injectable market – it is an exciting time here at GRAM!”

The search was on to find a suitable design/build partner.

**The Search for One Solution**

GRAM interviewed three different Architecture and Engineering firms before settling on CRB, according to Steve Nole, VP, Operations at GRAM. “CRB fit our project scope, from our aggressive timeline and goal of creating a facility that is flexible to fit our needs for years to come,” Nole explained. “We wanted to use local resources as much as possible and continue working with the local contractors that we have established relationships with. CRB has completed multiple construction projects in the West Michigan area which allowed GRAM to leverage additional relationships with skilled trades in the local area.”

As important as the local connection was, it was CRB’s design-build philosophy that cemented their relationship with GRAM. John Wichelt, VP, Client Pharmaceutical Services, had some previous experience with CRB’s services from past projects. Both he and Nole resonated with CRB’s ONEsolution™ design-build philosophy.

“The design-build philosophy allows for the design to be completed in phases, to enable construction to begin as soon as possible, while still designing certain phases of the facility,” Wichelt noted. “This efficient process allowed GRAM to save months on our project schedule.”

CRB’s ONEsolution methodology integrates planning, design, and construction into a structured, measurable, and efficient approach to achieve clients’ project objectives. The company provides clients with a single, accountable, and collaborative entity to execute architecture, engineering, procurement, construction, safety, quality, regulatory inspection, commissioning, and project management.
“CRB designed and managed the construction of the facility,” Wichelt explained. “They also worked closely with GRAM to ensure that the process equipment vendors were supported with the necessary utilities and startup operations. The level of service from the construction management side is exceptional, and the CRB group integrates well into a full team concept, from engineering design through to construction,” Wichelt said.

Site Selection and Design Considerations

The scope of the greenfield facility expansion was vast, comprising a two-story building, fill line, and all support equipment, as well as a QC laboratory on the second floor of the building. Technology is state of the art, which includes a fully integrated, high-speed Bausch+Ströbel filling line, SKAN isolators, and IMA Lyophilizer auto-loader.

Of course, a project of this size is not without its challenges. Among the most important considerations for the expansion was appropriate site selection in Grand Rapids located near GRAM’s other facilities. Once a suitable location was identified, the first course of action was to stabilize the soil for facility construction.

While every construction project in the Grand Rapids area takes soil stabilization into account, it was particularly important for an operation that required accurate fill processes.

“As an aseptic filling manufacturer, it’s critical for GRAM to have accurate product fill,” explained Melinda Smith, Pharmaceutical Specialist at CRB. “A design that would limit vibration and provide the best possible isolation – especially in the weigh cells where the product is actually filled – was of paramount importance to GRAM.”

GRAM produces life-saving products in vials, and it is imperative the building be constructed on stable ground to ensure there would not be any movement of the structure. The team worked diligently to create a feasible and comprehensive mitigation plan that would ensure a solid, stable foundation that would still not be prohibitively expensive.

Designers also had to accommodate the unusual shape of the available property, explained Mike Hinkamp, CRB’s project manager on the GRAM expansion. “The project demanded a completely custom facility design, to make the best use of the location and be acceptable for local setback and other regulatory requirements,” he said. Because one of GRAM’s key objectives was increased capacity, CRB’s design maximized the building’s footprint, in spite of site constraints. “There’s still room for additional capacity that hasn’t been committed to yet,” Hinkamp noted.
Another consideration came in the inter-relationship of the grounds and the facility itself. “We were given the challenge to build a facility that was open all the way around, that still provides access to the parking lot to bring in additional heavy equipment GRAM may need in the future,” Smith explained.

Given some of the foundation limitations that are not uncommon for Grand Rapids construction projects, this was an interesting design puzzle, Smith acknowledged. But, she noted, “we were able to give them the most flexibility possible for their future plans.”

The ONEsolution approach enabled the CRB team to meet these challenges while staying on time and on budget. As Hinkamp explained, “We do constant checks and balances along the way, staying nimble throughout to maintain budget and scheduling controls. We don’t get to do a lot of sitting back. Our experience allows us to make decisions along the way and keep those controls in check.”

### Flexibility and Modernization

Now, two years later, GRAM’s greenfield expansion is allowing the company to increase capacity by at least four times its previous levels.

For Steve Nole, this affords GRAM benefits on two fronts: Flexibility and modernization. “We have the flexibility to service multiple customers: Biologics, small molecule, suspension products, aseptic formulations, lyophilized and liquid products in vials or syringes,” Nole explained.

And as regulatory agencies scrutinize legacy or aging facilities, GRAM has the modernization required to ensure thoroughly successful regulatory inspections, adding to their immaculate track record of zero 483s on their last two inspections.

“A well-designed, modern facility employs separation of critical areas from the surrounding environment and contamination risks. It also utilizes automation and advanced aseptic manufacturing practices to reduce human interventions to assure that drug product of the highest quality is consistently produced,” said Nole. “That is fundamental to our business, and that is what CRB has helped us achieve.”

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