



Letter from the Partners

Fundamental to XL Construction's ability to execute cGMP projects is our commitment to technical training for all employees, including superintendents, project engineers, and project managers. Everyone benefits. Our customers gain access to expertise that is not common in the industry, including cGMP, constructability review, value engineering, and properly managing turnover packages for biopharmaceutical cGMP projects. And our employees appreciate our commitment to their career advancement, which has contributed to a very high employee retention rate. We have also found that our training program is a powerful recruiting tool for attracting the best and brightest.

Staff technical training at XL Construction includes formal and informal programs, conducted by members of our firm as well as industry-leading consultants. Just in the last quarter, formal training courses have included *Design-Build vs. Design-Assist, MEP Fundamentals, Exterior Skin Systems*, and *Earthwork and Grading Pre-Task*. Informal training is provided on job sites. For example,

staff members assigned to other projects tour cGMP job sites so they can observe construction processes and learn what factors led to construction decisions.

XL Construction's commitment to technical training ultimately creates benefits for our clients' customers. Our staff's familiarity with cGMP can help expedite FDA approval for new manufacturing facilities, accelerating the availability of new treatments for the people who need them.

Sincerely,
Eric Raff, Dave Beck, and Mario Wijtman

featured project photography
Image Center Photographic Design/Marco Zecchin

Recently Awarded Projects

Abbott Vascular. Demolition and rebuild for executive suites.

Challenger School. A new 7,000 s.f. classroom building.

John Muir Health. New 60,000 s.f. medical office building.

Kaiser Permanente. Oakland Hospital door replacement project.

Star One Credit Union. A 6,300 s.f. new credit union branch.

Palo Alto Medical Foundation. Interior improvements to two floors of an existing medical office building in Fremont.

Palo Alto Medical Foundation. Lee Building. Renovations to two floors of an occupied medical office building.

Posiflex Technologies. Improvements for offices and light laboratory spaces.

St. John the Baptist Episcopal Church. A new church facility in Aptos.

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Featured Project

To accommodate projected growth and manufacture its individualized lymphoma treatments, Genitope Corporation needed new headquarters, R&D and manufacturing facilities. The buildings would need to comply with current Good Manufacturing Practices (cGMP). Read how XL Construction planned and managed the 220,000 square-foot project.

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cGMP: There is No Substitute for Experience

In the marathon process of securing FDA-approval, expertise in key components of this process is essential. XL Construction focuses on helping its clients achieve compliance with current Good Manufacturing Practice (cGMP), a critical part of the FDA-approval process. Mitigating client risk with its extensive experience, XL continually demonstrates its cGMP knowledge throughout projects for Allergan, Alza, Genentech, Genitope, Gilead, Medarex and Novartis. XL brings value to all aspects of cGMP protocol, from working in aseptic environments to assisting with systems validation and also provides its clients with customer-specific training, personalized MEP solutions, and tailored project management.

Expertise with Aseptic Environments
In cGMP projects, different areas of the facilities

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need to comply with various ISO requirements for air cleanliness and room finishes. For example, XL Construction built Genitope's aseptic manufacturing fill area with Class 10,000 air (ISO 7), installing hoods that met Class 1,000 (ISO 5) requirements. XL Construction also has experience managing the installation of reverse osmosis/deionization (RO/DI) and water-for-injection (WFI) water purification systems.

Validation Assistance

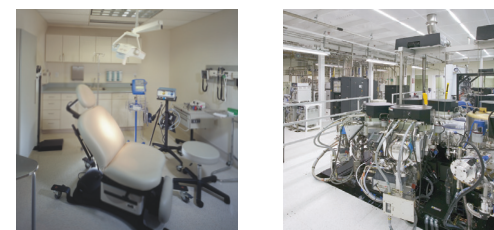
Before manufacturing can begin, one aspect the FDA confirms is that the proper validation has occurred, including installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ). For clients whose internal validation departments want assistance, XL Construction develops a turnover package matrix that identifies the critical systems to be validated, such as HVAC, building control systems, water systems, and others. "We provide the matrix to all subcontractors so that they thoroughly understand the required documentation and testing," says Alan Laurlund, project executive. "Our employees and subcontractors check off each requirement as it is met, sparing our clients the time and money it would take to make corrections during the validation process."

Customer-specific Training

To efficiently train craftspeople on cGMP and Good Documentation Practices (GDP) for each client's specific requirements, XL Construction has created customized online training modules for workers to complete before they begin work on the jobsite. "Online training enables us to keep our foreman and superintendents focused on quality and schedule – not classroom instruction," says Laurlund.

Personalized MEP Solutions

In addition to the one-time goal of securing FDA approval, XL Construction considers the ongoing goal of facility maintainability. In some cases, XL Construction creates 3D models of congested spaces in order to design efficient ductwork and



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catwalks for maintenance staff. XL Construction's Mechanical, Electrical, and Plumbing and Process Piping (MEP) staff coordinates systems with accessible valves and dampers, for easier maintenance.

Tailored Project Management

Every cGMP project is different, and XL Construction communicates closely with all trades as well as the client during the project life cycle. "Good collaboration during the critical time of coordination helps us help our clients receive FDA approval," Laurlund concludes.



Featured Project

Genitope Corporation is a biotechnology company focused on the research and development of novel immunotherapies for the treatment of cancer. Its lead product candidate is currently in Phase 3 FDA trials for the treatment of follicular non-Hodgkin's lymphoma.

The company planned a new headquarters in Fremont, California, with two structures totaling 220,000 square feet. Among the construction challenges would be converting an existing two-story office structure to a state-of-the-art, 108,000 square feet manufacturing space that complied with stringent cGMP and aseptic re-

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quirements for water quality, air classification, room pressure, and more.

Genitope turned to XL Construction because of its staff's experience with other cGMP manufacturing facilities. At the outset of the project, XL Construction helped identify the documents and procedures required for validation and developed an online training course for workers to ensure that they understood the project's cGMP requirements and Good Documentation Practices (GDP).

XL Construction completed the office and R&D building in July 2006, just nine months after construction began. The manufacturing facility, built concurrently, was complete in November 2006. Within four weeks of completion, XL Construction provided Genitope with a complete turnover package documenting that all cGMP requirements had been met, helping to expedite the validation process.