Pharmaceutical Manufacturing Facility Requires Fast-Track Construction and Production with 100% FDA Compliance

A manufacturer of high-quality pharmaceutical eyewash solutions needed to establish new systems to ensure consistent satisfaction of Food and Drug Administration (FDA) standards. The speed, accuracy and 100% reliability of these systems are essential.

Main Objective
The project goal was to meet the customer’s rigorous construction schedule of more than 1,600 input/output monitoring points, including HVAC, process and batch control. The customer uses a combination of stainless steel portable vessels and stationary tanks for batching more than 100 different types of eyewash and saline solutions. Because of the sensitive nature of these solutions, extra care must be taken to ensure the cleanliness of the vessels and the entire processing facility. Approximately 150 valves control the different substances that must be piped into each tank according to tight FDA specifications.

The manufacturing facility requested that MAVERICK Technologies provide installation services for electrical conduits for process and Ethernet backbone communications. The customer also required pneumatic sensing lines accompanied with the provision of the FDA-required instrumentation and PLC-based control panels. Engineering and drawings were to be provided by the owner based on an 80 percent completion factor.

Customer Results
The PLC system was tested by the client for factory acceptance, before delivery. This testing revealed inaccuracies in panel and field design. Working within a tight schedule before delivery and execution, the MAVERICK engineers redlined the panel drawings and modified panel designs to reflect a working system. The client was pleased that MAVERICK had the expertise to assist in this arena.

Once the engineering was completed and the panels were delivered, the project proceeded by the installation task and met the schedule and project requirements for an on-time and successful project.

Application Description
- To meet FDA standards, the PLC-based control system monitored the quality of the batch control, bottle filling and packaging of the different eyewash solutions.
- PLC programs were created to facilitate the accurate batching and filling of these intricate systems. The amount and orientation of each of the different eyewashes must be accurately measured, dispensed and labeled.
- HVAC, humidity and temperature controls are essential for a class 10 cleanroom environment; these delicate processes require state-of-the-art design and implementation for a fungus- and bacteria-free laboratory.
- To fully utilize the PLC that MAVERICK supplied, supported by the client’s software, it had to be professionally installed and accurately tested to the FDA standards, with trace documentation provided to the owner and the FDA at the time of validation.