

Microbiology lab remediation and process improvement

PHARMACEUTICAL
INDUSTRY



Client ► The vaccine manufacturing facility of a major global pharmaceutical company

Problem ► Significant pressure was being placed on an aging microbiology laboratory because of a number of factors: the upcoming launch of a major new product, the need to qualify / validate new equipment and procedures, and the recent loss of several of the more senior / experienced analysts and supervisors. The situation was further compounded by an increase in laboratory investigations and growing concerns about lab efficiency / productivity in light of the current challenges.

Approach ► A Tunnell cross-functional team of microbiologists and process / organizational improvement SMEs worked in partnership with senior management and staff to quickly assess the current state and capabilities of the facility. This entailed: (1) identification of opportunities for near-term improvement, (2) development of prioritized remediation plans, and (3) implementation of the highest-return corrective actions that were needed. Included in this was an analysis of:

- Test methods
- Current and upcoming workload
- Laboratory workflow
- Consolidation of efforts/activities
- Analytical results and quality documentation
- Suitability of current equipment / facilities.
- Staffing, staff competencies, training, and work assignments (supervisory and technical)

Results ► Several critical issues were quickly identified and addressed in partnership with the client regarding: (1) modifications to workflow, (2) centralization / consolidation of equipment and facilities, and (3) improved training for staff (both supervisory and technical). These actions resulted in a marked improvement in throughput (30 – 40 percent), significant decrease in investigations, and visible increase in morale and self confidence within the laboratory.