

CASE STUDY

Biotech Plant Acquisition - Transition & Integration

Manufacturing Plant Acquisition – Transition / Integration

Situation, Goals, & Business Drivers

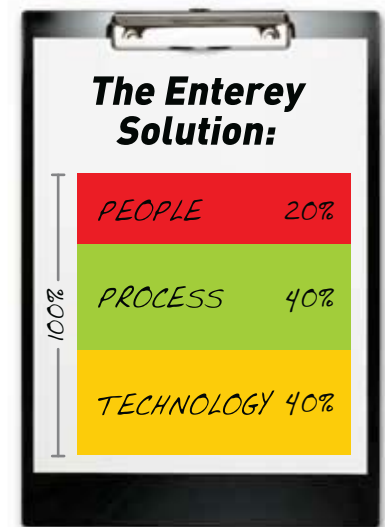
A leading biotech manufacturer acquired a large biotech manufacturing plant nearing construction completion. The company needed to integrate the new site and employees into its operations to address significant demand concerns. Aggressive deadlines were set to ensure the new plant was producing marketable product within the targeted timeframe.

Actions Taken

As part of an overall program, focus areas were determined and specific project plans were defined for overall integration. Decisions were made about the systems and processes the new site would adopt, integrate with, or keep unchanged. Enterey provided project management support to 3 key business areas.

Results Achieved

Transition of the new site was completed on schedule. The new site integrated with corporate and had established plans to complete integration of all business areas. The success of the transition allowed the site to focus intently on the transfer of new product technology into the facility.



CASE STUDY

Biotech Plant Acquisition - Transition & Integration

Manufacturing Plant Acquisition Integration

Situation, Goals, & Business Drivers

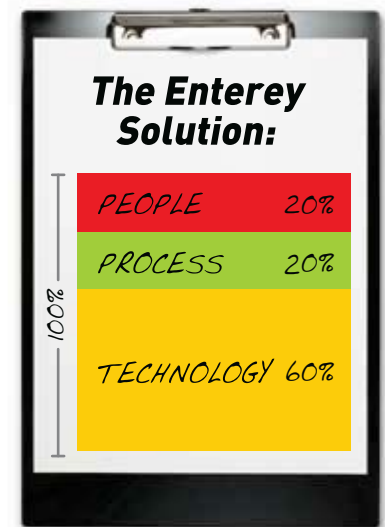
A global pharmaceutical manufacturer acquired a large biotech site and marketed product from another global pharmaceutical manufacturer. The company needed to integrate the new site and employees into its operations and ensure the company seamlessly continued manufacture of its newly acquired product as well as four contracted products.

Actions Taken

Project plans were put in place and key milestones determined. "Day 1 Critical" items were determined and tracked to ensure a successful cut over. Processes and systems to be used after cutover were determined and appropriate procedures put in place. Enterey provided project management support to the Quality and Quality Systems business areas.

Results Achieved

The site integrated into the new company and appropriate processes were identified to be integrated Post Day 1. All site personnel were made aware of provisions in key Quality Agreements and operations of all products continued with no unplanned interruption of service.



CASE STUDY

Major Biotech Manufacturer

Quality & Manufacturing Business Process Improvement Program

Situation, Goals, & Business Drivers

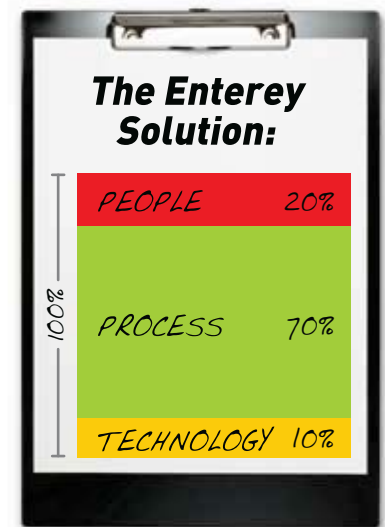
A major biotech manufacturer was anticipating rapid growth of operations and had plans to move to a significantly larger facility. In order to achieve the scale necessary to operate the new facility, the company knew they must improve existing business processes and eliminate inefficiencies.

Actions Taken

Company Leadership defined corporate goals as guidance for the project team. Through a series of facilitated sessions, projects were identified and grouped into phases to allow the company to achieve the necessary process improvement in alignment with the facility construction timeline. A Program Management Office was created to establish governance and organization to all projects.

Results Achieved

Fifteen projects were kicked off during the 1st phase of the project. The PMO monitored progress and issues of each project and regularly reported status to the Steering Committee. Over \$2M of efficiencies were identified during the first phase of the program.



CASE STUDY

Major Biotech Manufacturer

Headcount Optimization

Situation, Goals, & Business Drivers

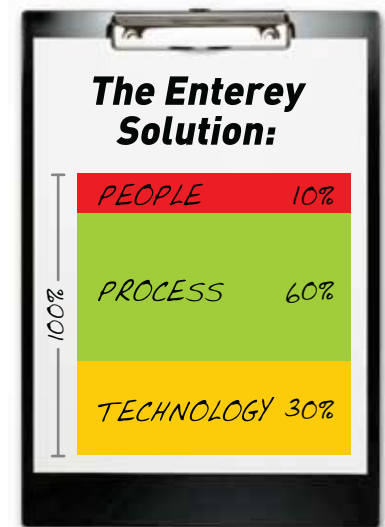
Identify proposed headcount targets and required efficiencies at specified run-rate targets to support a 50% reduction in cost per gram by year end 2009. Department management was to be engaged in the overall process and implementation of the plan.

Actions Taken

We assisted our client in determining the optimal org structure at specified run rates and benchmarked data against other sites. Required efficiencies to enable headcount reduction with increased span of control were determined. A matrix model of run rates and headcount by department was developed.

Results Achieved

Headcount targets were identified to reach improved operational performance goals with no impact to business operations. Opportunities for staff to improve and build skill sets were increased, and opportunities for displaced employees were identified.



CASE STUDY

Inspection Readiness - Major Biotech Company

Inspection Readiness for Facility Startup

Situation, Goals, & Business Drivers

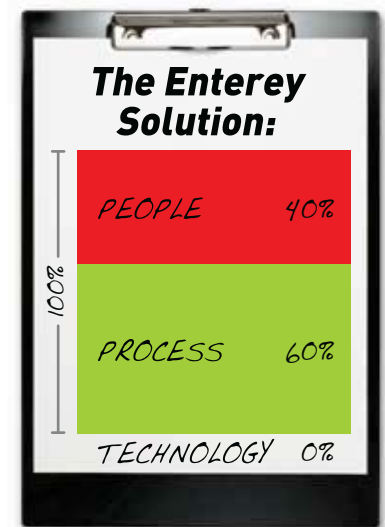
With construction and plant commissioning complete, a leading biotech manufacturer set timelines to license its new facility and to pass all required inspections – State, FDA, and EMEA Pre Approval Inspections.

Actions Taken

A gap analysis was performed, and action plans were developed to remediate or defend the identified gaps in the plant's Quality System. Enterey provided project management support to the 14 departments throughout the plant and to the Director of Quality Assurance. In addition, Enterey provided the communication updates to Corporate Compliance and the GMP Core Team. Enterey also supported the staff during the inspections with defense strategies, documentation and final inspection room prep.

Results Achieved

The facility was licensed per plan. The State, FDA and EMEA inspections were successful. There were no FDA observations. Observations issued by the State and EMEA were minor, and action plans to correct were implemented.



CASE STUDY

Clinical Plant Start-up and Technology Transfer

Project Management – Plant Startup

Situation, Goals, & Business Drivers

A leading biotech manufacturer acquired a clinical plant to meet three key business drivers:

Enable the “go fast” methodology for process development and reduce the average timeline from 22 months to under 12 months.

Expand clinical capacity so no project waited more than 2 months for a production slot.

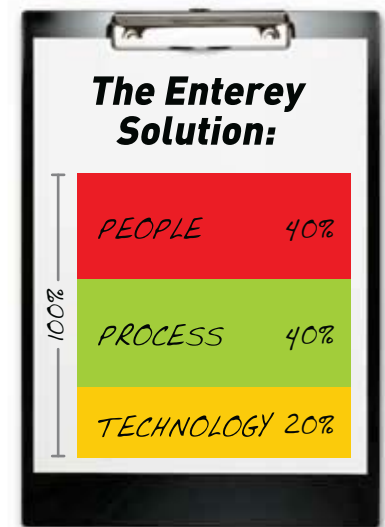
Allow the expansion of company pipeline for new molecular entities.

Actions Taken

Corporate developed the overall project goals to align with corporate goals which included reduced project budget, timeline and startup team. A multi-dimensional startup team was created and was held accountable to meet project objectives and define the timing of first production run.

Results Achieved

Project met all project milestones, budget and workforce constraints. Plant delivered the company’s first ever 100% successful clinical run while attaining one of the highest product yields, enabling the expansion of clinical trials.



CASE STUDY

Commercial Plant Start-up & Technology Transfer

Tech Transfer including Plant Startup

Situation, Goals & Business Drivers

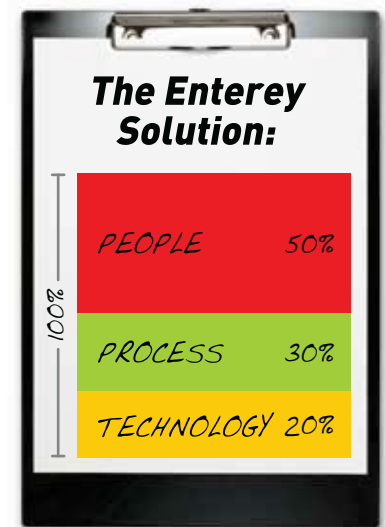
A leading biotech manufacturer acquired a large biotech manufacturing plant nearing construction completion. Plans for the acquired plant included manufacturing startup and technology transfer of a leading commercial bio-oncology therapeutic antibody for regulatory approval within two years.

Actions Taken

Project plans were created to include completion of the construction phase of the plant, manufacturing startup and transfer of the antibody. Key milestones were set, project teams developed, and communication plans defined. Enterey provided project management support for the lead project manager of the receiving plant reporting into the site leadership team, and for site preparation for regulatory inspections by the State, FDA, and EMEA.

Results Achieved

Construction, plant commissioning, and commercial product manufacturing activities completed on time, leading to successful State, FDA, and EMEA approvals within the initial project timeline.





CASE STUDY

Class A Certification – Biotech Manufacturer

Project Management - Business Improvement Program

Situation, Goals, & Business Drivers

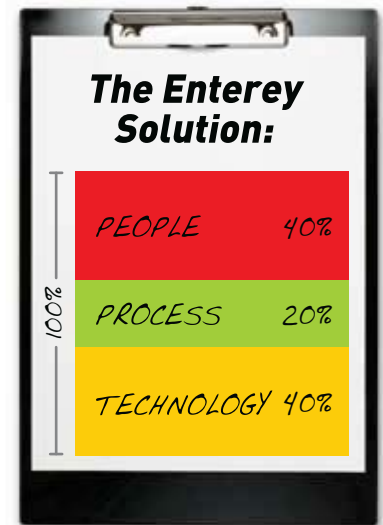
A leading biotech manufacturer expanded their existing business improvement program to attain Class A certification. The program included 3 key projects; Class A certification, SAP implementation and Lean initiative. Completion of the program would allow our client to ensure planned and predictable performance.

Actions Taken

Corporate goals were developed and used as input to the overall project timing. The site was held accountable to assess readiness and meet project objectives. Project teams were formed with defined goals, standard methodology, and reporting requirements.

Results Achieved

Project is currently ongoing and to date has successfully met all project milestones, including Class B attainment by Oliver Wight. Process improvements to date have yielded significant labor and raw materials savings. Key savings areas included material prep and site-wide metric reporting.



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