CHALLENGE
A large pharmaceutical manufacturer was transferring process technology from an existing overseas manufacturing facility to a new production site, with an aggressive timeline for completion of the new operation. To meet the timeline, the company needed to transfer specialized manufacturing process information and knowledge from the former site. Simultaneously, the company wanted to incorporate process changes to increase product quality, as well as to improve process and equipment reliability.

SOLUTION
To prepare the technology transfer plan, MPR first defined and characterized existing manufacturing processes. Next, the team identified and evaluated proposed process improvements. To document the existing process, MPR developed process flow diagrams and narrative descriptions, prepared process risk assessments, identified critical process parameters and established a basis for allowable process tolerances. MPR used the firm’s process risk analysis approach to ensure that the client resources at the new site were focused on important technical issues. This approach was implemented for each element of manufacturing operation. The risk analysis provided a qualified assessment of each operational step so that critical items became readily apparent. Resources then were prioritized to preferentially address knowledge gaps for those production areas identified.

RESULTS
The client’s senior management recognized that the risk-based approach MPR applied added value to the transfer of process technology, as well as to the evaluation of existing manufacturing operations to identify process improvements. As a result, they have adopted the MPR approach to other facility and process changes.

TIMELINE 6 Months