

Advisory Committee for Pharmaceutical Science
April 13, 2004
PAT
Rapid Microbiology Methods Update
Background

Rapid Microbiology Methods (RMM) came under the umbrella of the PAT initiative during an ACPS PAT subcommittee meeting in Oct 2002. Several presentations were made regarding the advantages of using RMM for the pharmaceutical manufacturing process. Discussion by the participants in the subcommittee meeting also supported the inclusion of RMM as part of PAT.

Since a key component of PAT is technical training for review and inspection personnel, a rapid microbiology training session was organized. In July 2003 selected FDA personnel from CDER, ORA, CBER and CVM met in Rockville for a one day training session on RMM. The training session started with an overview of available RMM technologies. A detailed look at two RMM technologies was provided by the vendors of these test methods. A pharmaceutical company presented their experiences with validation of a RMM. Finally a discussion of RMM took place among the FDA personnel present at the training session.

To conform to the PAT regulatory model, a RMM review and inspection team, consisting of personnel from ORA and CDER, was formed to deal with PAT RMM submissions. The RMM team has already handled the regulatory approval process for a RMM product release test. The RMM team met on several occasions prior to the inspection to discuss the proposed RMM and the inspection process. Issues of potential concern to the team members were discussed and decisions were made as to the appropriate method(s) to deal with these issues. The inspection went smoothly and no problems were found.