



AdvaMed

Advanced Medical Technology Association

MDUFMA Stakeholders Meeting – Qualitative Performance Goals

November 17, 2005

Patricia B. Shrader

BD



Qualitative Performance Goals Overview

- FDA is meeting many of the explicit performance goals for MDUFMA
- Concerns continue over qualitative goals, including:
 - Scheduling of meetings
 - Modular PMA review
 - Pre-approval GMP audits
 - Bundling



AdvaMed

Advanced Medical Technology Association

CDRH 2006 Priorities

- “Remarkable” performance record in FY05
- Center-wide culture that emphasizes coordination and accountability
- Continued improvement in review times is a goal.



Scheduling of Meetings

- FDA and industry agree that use of informal and formal meetings is critical to ensure high application quality.
- Yet, AdvaMed members indicate that scheduling of meetings is becoming more and more a concern.
- Improvements in scheduling will be needed to assure performance goals can be met.



PMA Modular Review

- Modular PMA program is important to industry and can yield benefits for FDA
- FDA perspective on modular PMAs is mixed
- To be effective program, modules need to be closed in a timely fashion – 90 days; questions by day 75
- Specific goals for modular PMAs should be an element of MDUFMA reauthorization



- Good in concept; concerns about actual performance
- Example: Anti-microbial susceptibility tests
 - FDA guidance states that one submission required per drug, can cover gram + and -.
 - Actual decision is made on case-by-case basis.
 - May require large numbers of 510(k) submissions and extraordinary costs.



GMP Pre-Approval Inspection

- Coordination in timing of pre-approval inspections key in overall PMA review times.
- Sponsors need to incorporate this in project planning and be prepared for inspection.
- “Noise level” around this issue is reduced; quantitative measures important for true MDUFMA performance assessment