## Potential Use of Specialists — An Emerging Team Approach

#### Manufacturing Science

- Process understanding and risk mitigation strategies.
- Facilitate the introduction of new manufacturing technologies in the pharmaceutical industry (continuous improvement).

#### Warning Letter Review

- Input to improve consistency and utilize science-based risk management.
- Feedback to improve science and regulatory policies.

## **Specialists**

- •Bringing all available scientific expertise to bear on critical FDA processes
- •CBER/CDER/CVM Review Scientists
- •Expertise within ORA
- •Other identified expertise within FDA: Center research scientists, non-review experts (e.g., compliance experts), or other technical expertise within the Centers and ORA (e.g., National Drug Experts).

### Application Review

- Identification of process critical control points and assessment of controls for mitigating risk of poor quality.
- Improve scientific basis of setting specifications.
- Communicating this information with inspection staff and develop a more risk-based approach for inspections.

#### Pharmaceutical Inspectorate

Specialized team for drug manufacturing inspections

#### Technical Issues Resolution

Rapid, objective resolution of scientific and technical questions and issues arising from inspections

# Inspections: Pre-approval, Biennial, "For Cause"

Based on risk assessment relating to:

- product complexity
- process understanding
- manufacturing capability