PDA- PIC/S Q7 Training
September 2015

Regulatory Challenges During Inspections of API Manufacturing Sites

Matthew Davis
Senior Inspector, Manufacturing Quality Branch, TGA

Alicia Mozzachio
Director (Acting), Division of Regulations, Guidance, and Standards, FDA/CDER/OPQ

Regulatory Challenges

- Inspection Planning
  - Establishing lines of communication
  - Multiple-inspections in a single trip
  - Local and National holidays
  - Ground transport
  - Security

Regulatory Challenges

- Scope of Inspection - what's in/out
  - Current DMF / ASMF
  - Define where GMP begins (table PtII)
  - GMP evidence for intermediates
- Availability of key staff and experts
- Staff interaction with inspector
  - Prepare your staff (before, during, operators/managers)

Regulatory Challenges

- Staff interaction with inspector (cont'd)
  - Level of communication
  - Language barriers
  - Reluctance to discuss/correct inspector's observations
  - Delay/Decoy tactics
  - Refused access or restriction to certain areas

Regulatory Challenges

- Some firms do not accept joint inspections
- Announced inspections
- Disconnection between the Quality and Production Units
- Immature quality culture
- Lack of transparency during inspections
- Inconsistent information provided to regulators

Regulatory Challenges

- Deficient corrective actions; repeat deficiencies
- Inadequate or incomplete responses
- Responses without supportive evidence/data
- Drug shortages