

Top management is responsible for ensuring appropriate implementation of GMP

REVIEW

- ▶ Evaluation
- ▶ Compliance
- ▶ Adjustment
- ▶ Improvement

COMMIT

- ▶ Policy
- ▶ Strategic Plan
- ▶ Excipient Grade
- ▶ Industry Alignment

Roles and Responsibilities for GMPs and Patient Safety

PROVIDE

- ▶ People
- ▶ Equipment
- ▶ Testing
- ▶ Materials

LEAD

- ▶ Certification
- ▶ Involvement
- ▶ Improvement
- ▶ Accountability

- Risks of Non-Compliance

- ▶ Recalls
- ▶ Reputation
- ▶ Regulatory Action
- ▶ Criminal Penalties
- ▶ Drug Efficacy
- ▶ Patient Harm
- ▶ Inspection Observations
- ▶ FDA Warning Letters

+ Rewards of GMP

- ▶ Financial
- ▶ Sustainability
- ▶ Public Image
- ▶ Growth
- ▶ Industry Leadership
- ▶ Regulatory Acceptance

