



AUDIT & INSPECTION PREPAREDNESS

Why Choose NPG?

Ensuring regulatory inspection is crucial for pharmaceutical and medical device organizations. Being well-prepared streamlines inspections and ensures compliance. However, organizations often delay preparation until they file a marketing application, posing challenges throughout the process.

Network Partners Group presents a pragmatic approach that enables our clients to preemptively avoid the last-minute rush of trying to prepare for an audit or inspection.

NPG will enhance your inspection readiness through a comprehensive approach built on four key elements:

- Robust inspection strategy
- Effective corporate governance
- Reliable metrics
- Efficient tools and systems

With their proven efficacy, these elements form the backbone of our approach, ensuring our clients are well-prepared for audits and inspections.

Services at a Glance

- Performing audits and mock inspections
- Tactical support during audits and inspections
- Educating employees on audit and inspection preparedness
- Drafting responses to audit and inspection observations
- Managing observations from root cause analysis to post-closure monitoring

1. Educate

- Conduct an audit/inspection readiness training workshop
- Educate the audit team on effective communication with auditors

2. Assess

- Perform mock audits
- Assess processes and systems for compliance with regulatory requirements
- Identify and report gaps and observations
- Review SOPs for regulatory compliance

3. Review

- Assess the identified gaps and observations to validate the significance
- Identify and address risks once confirmed
- Evaluate and close out ongoing CAPAS

4. Rectify

- Conduct a repeat mock audit to ensure all issues are addressed and resolved
- Resolve the identified gaps and observations

5. Sustain

- Continue educating the organization on updated regulatory requirements
- Stress the critical importance of always maintaining a state of readiness for audits and inspections
- Develop presentations for future audits and inspections

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