NexGen Inspection Readiness Index™

A Risk-Based Assessment for FDA Pre-Approval Inspection Readiness

Based on the principles of FDA Compliance Program 7346.832 and internationally recognized pharmaceutical quality standards

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Purpose

The **NexGen Inspection Readiness Index™** is a proprietary, risk-based assessment designed to help pharmaceutical and biotechnology manufacturers evaluate their organizational readiness for **FDA Pre-Approval Inspections (PAIs)** using principles consistent with **FDA Compliance Program 7346.832**.

Rather than assessing regulatory compliance alone, the Index evaluates the maturity of the **Pharmaceutical Quality System (PQS)**, manufacturing readiness, scientific process understanding, operational controls, data integrity, quality risk management, and organizational capabilities that support sustained regulatory confidence and consistent commercial manufacturing.

The assessment provides an **Inspection Readiness Score**, together with prioritized improvement opportunities across nine critical inspection readiness domains. These insights help organizations identify potential gaps, strengthen quality systems, and support continuous improvement before regulatory inspections.

The **NexGen Inspection Readiness Snapshot™** is a complimentary, high-level version of this assessment intended to provide an initial indication of organizational readiness. Organizations seeking a more comprehensive evaluation may complete the consultant-led **NexGen Inspection Readiness Index™**, which includes evidence-based assessment, weighted scoring, executive analytics, and tailored improvement recommendations.

Readiness Domains

1. Pharmaceutical Quality System

Objective

Evaluate whether the Pharmaceutical Quality System (PQS) effectively supports product lifecycle management, continual improvement, and sustained compliance.

Assessment Questions (examples)

- Quality Policy is actively supported by senior leadership.

- Quality objectives are measurable and routinely reviewed.
- Quality metrics are monitored and drive continual improvement.
- Management Reviews evaluate quality system performance.
- Knowledge Management processes capture and transfer critical knowledge.

Maximum Score: 15

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2. Commercial Manufacturing Readiness

Objective

Determine whether manufacturing operations consistently demonstrate commercial readiness.

Assessment Questions (examples)

- Manufacturing process is fully characterized.
- Critical Quality Attributes (CQAs) are identified.
- Critical Process Parameters (CPPs) are scientifically justified.
- Manufacturing variability is understood and controlled.
- Process Performance Qualification supports commercial manufacturing.

Maximum Score: 15

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3. Process Validation & Lifecycle Management

Objective

Evaluate whether validation activities support reliable commercial manufacturing.

Assessment Questions (examples)

- Stage 1 Process Design completed
- Stage 2 PPQ completed
- Stage 3 Continued Process Verification established
- Validation lifecycle documented
- Product lifecycle knowledge maintained

Maximum Score: 12

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4. Data Integrity & Digital Compliance (10 Points)

Objective

Assess whether GxP data are reliable, complete, and traceable.

Assessment Questions (examples)

- ALCOA+ principles consistently applied
- Electronic systems appropriately validated
- Audit trails routinely reviewed
- Laboratory data reliable and traceable
- Manufacturing records accurately reflect operations

Maximum Score: 12

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5. Quality Risk Management

Objective

Evaluate how risk management supports quality and operational decisions.

Assessment Questions (examples)

- Formal Quality Risk Management process implemented
- Risk assessments support decision-making
- Risks reviewed throughout product lifecycle
- Risk controls verified for effectiveness
- Are lessons learned incorporated into future projects

Maximum Score: 10

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6. Change Management & Technology Transfer (10 Points)

Objective

Assess how changes are evaluated, implemented, and monitored.

Assessment Questions (examples)

- Formal Change Control process
- Product-specific changes scientifically justified

- Technology Transfer adequately documented
- Cross-functional impact assessments performed
- Changes effectively monitored after implementation

Maximum Score: 10

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7. Investigation & CAPA Effectiveness (10 Points)

Objective

Evaluate whether quality events are effectively investigated and lead to sustainable improvements.

Assessment Questions (examples)

- Is root cause analysis effective?
- Are CAPAs implemented on time?
- Are CAPAs verified for effectiveness
- Trending performed
- Repeat deviations monitored

Maximum Score: 9

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8. Governance & Inspection Readiness

Objective

Assess leadership commitment, governance, and the organization's ability to maintain continuous inspection readiness.

Assessment Questions (examples)

- Are quality responsibilities clearly defined?
- Is executive oversight evident?
- Are mock inspections conducted?
- Are inspection action plans monitored?
- Is inspection readiness maintained throughout the year?

Maximum Score: 8

9. Inspection Readiness & Regulatory Intelligence (10 Points)

Objective

Evaluate the organization's readiness to support FDA Pre-Approval Inspections and demonstrate regulatory confidence.

Assessment Questions (examples)

- Does manufacturing reflect the approved regulatory submission?
- Is facility information current and accurate?
- Is regulatory documentation inspection-ready?
- Does Quality System have Regulatory intelligence incorporated into it?
- Is product and process knowledge readily available?
- Can the organization effectively support an FDA Pre-Approval Inspection?

Table 1: Overall Readiness Score

Score	Maturity Level	Interpretation
90–100	**Inspection Ready**	Demonstrates mature quality systems and strong organizational readiness aligned with FDA's risk-based inspection philosophy.
75–89	**Inspection Capable**	Good level of readiness with targeted opportunities to strengthen inspection confidence.
60–74	**Developing**	Key systems are established but several capability gaps should be addressed before a Pre-Approval Inspection.
Below 60	**Improvement Required**	Significant improvements are recommended to strengthen manufacturing readiness and regulatory confidence.

Want a deeper assessment? The **NexGen Inspection Readiness Index** ™ expands this Snapshot into a comprehensive consultant-led evaluation using a structured 100-question framework, weighted scoring methodology, evidence review, and an executive dashboard with prioritized improvement recommendations.

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