Third-Party Audits for Ensuring Pharmaceutical Quality Across the Supply Chain

A Legislative Brief Presentation

Executive Summary

- Ensuring pharmaceutical safety is a public health priority
- Global supply chains are increasingly complex
- Rx-360 provides independent third-party audits
- Enhances transparency, compliance, and efficiency

The Challenge: Supply Chain Risk

- Highly global, multi-tier supply chains
- Involves APIs, suppliers, manufacturers, logistics
- Regulators cannot inspect all entities
- Manufacturers face duplication and inefficiency

Sampling of Facts

- Substandard and falsified medical products affect people all around the world.
- At least 1 in 10 medicines in low- and middle-income countries are substandard or falsified.
- Countries spend an estimated US$30.5 billion per year on substandard and falsified medical products.
- Substandard and falsified medical products are often sold online or in informal markets.

  World Health Organization | December 3, 2024

- There were 6,424 pharmaceutical crime incidents in CY 2024.

  The Pharmaceutical Security Institute

- Fifteen percent of active drug shortages are controlled substances. Patients with chronic pain or ADHD may struggle to fill monthly prescriptions. Health systems may struggle to obtain sufficient supplies needed for surgeries and procedures.

  American Society of Health-System Pharmacists | March 2026

Role of Rx-360

- Nonprofit licensable audit platform
- Provides standardized global supplier audits
- Supports compliance and transparency

Key Risks

- Contamination or adulteration
- Inconsistent quality standards
- Limited upstream availability
- Resource constraints and theft risks

All of these harm patients

Independent Oversight

- Objective, unbiased audits
- Eliminates conflicts of interest
- Supports accurate risk identification

Standardization & Coverage

- Consistent audit frameworks
- Improves comparability
- Expands global oversight
- Strengthens supply chain integrity

Efficiency Gains

- Reduces redundant audits
- Lowers supplier burden
- Focus resources on high-risk areas

Risk Prevention

- Identifies recurring issues
- Detects emerging trends
- Supports proactive safety approach

Preventing Unfair Practices

- Separates auditing from commercial pressure
- Reduces imbalanced negotiations
- Encourages transparency

Why Legislative Recognition Matters

- Enhances regulatory efficiency
- Promotes global quality standards
- Strengthens supply chain resilience
- Supports fair supplier relationships

Policy Considerations

- Encourage third-party audits
- Recognize audits in FDA frameworks
- Support standardization and data sharing
- Ensure ethical use of audit findings

Conclusion

- Third-party audits are essential to quality systems
- Improve safety and transparency
- Strengthen resilience and collaboration
- Scalable solution for patient safety

Learn More & Contact

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