QUALITY SYSTEMS COMPLIANCE, REMEDIATION AND AUDITING

NSF International's services in compliance and quality systems provide efficient and forward-looking compliance solutions. Our staff of former FDA and EU officials as well as industry experts allows us to combine global regulatory knowledge with industry best practices to help our clients achieve a compliant quality system that is right for their business.

We provide services to pharmaceutical, biologics and biotech companies and offer solutions tailored to your industry requirements and company-specific objectives. We ensure the quality and consistency of our solutions, by integrating senior management and employee involvement in developing practical solutions that lead to ownership and sustainability. Our systems-based approach ensures deficiencies are identified and addressed at their root cause, appropriate corrective and preventive actions are developed, and linkages between the quality subsystems are integrated to ensure sustainable and practical compliance.

We support companies' efforts to develop or enhance their quality systems, both proactively and in response to regulatory actions. We also provide auditing and assessment services to ensure companies and their suppliers are compliant, and offer practical and sustainable solutions to address your needs. Specific services include:

QUALITY SYSTEMS REMEDIATION, DEVELOPMENT AND IMPLEMENTATION

> The Quality Enhancement Program (QEP™) is NSF's approach to remediate, enhance or streamline a company's quality management systems (QMS). The program is adaptable, scalable and specifically tailored to achieve compliance with a company's specific needs and objectives. We:

- Identify deficiencies and determine their root cause
- Develop a risk-based, prioritized corrective action plan
- Create joint NSF-client teams to ensure sustainable and practical solutions

> Interim senior leadership and SME support roles

> Expertise in statistical methods and analysis: cost of quality (CoQ), sampling plans, stability models, DOE, SPC, process control, capability (CpK, PpK), root cause analysis and process optimization

> Specialized experience in clinical and bioresearch areas including BIMO, CLIA, GLP and GCP

> Coaching and mentoring for all roles and levels within your organization

> Task- and function-specific training: investigations, root cause determination, laboratory, etc.

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AUDITING AND ASSESSMENTS

- Gap assessments
- Mock FDA inspection and FDA-readiness support
- Mock European regulatory agency audits
- Data integrity audits
- Third-party audit of CMOs and suppliers: Rx pharma and OTC pharma, API, laboratory, etc.
- Due diligence assessments for large and small-scale acquisitions

REMEDIATION, COMPLIANCE AND ENFORCEMENT ACTION SUPPORT

- 483 response/remediation expertise
- Warning letter response/remediation expertise
- Consent decree (injunctions) work plan development and remediation
- Application Integrity Policy (AIP) resolution
- Corrective action plans development and execution
- DWPE import alerts/restrictions/detentions

TRAINING

- 21 CFR 210/211 cGMP for finished pharmaceuticals
- 21 CFR 600 and 610 for biologics
- PAI audit readiness
- Quality system subsystem-specific training sessions including CAPA, management review and risk management

For more information, visit our website at **www.nsf.org/info/pharmabiotech**, email **uspharma@nsf.org** or call +1 202 822 1850.

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