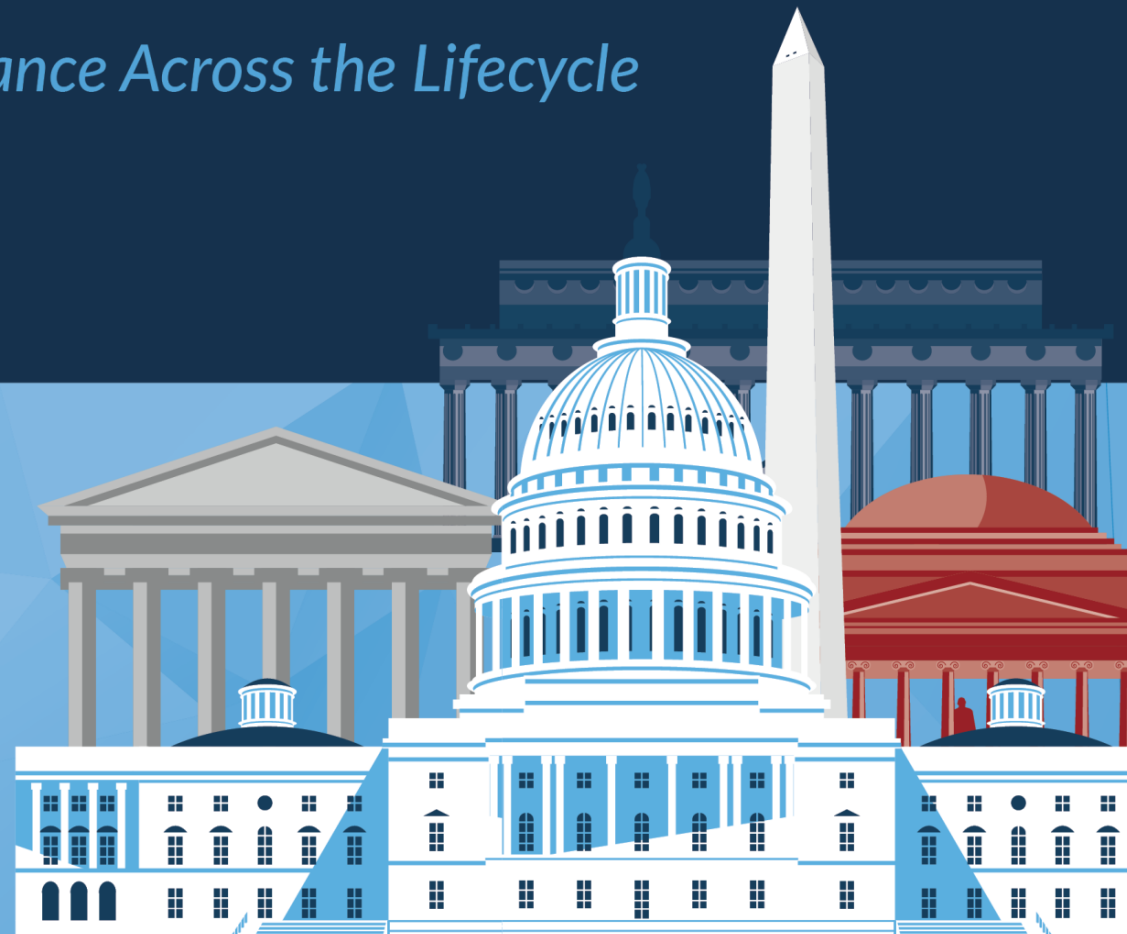
PDA Regulatory Conference 2025

Achieving CGMP Excellence: Sustainable Compliance Across the Lifecycle

08-10 September | Washington, DC



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Beyond the Bench

AI-Powered Oversight for Chem and Micro Labs

Charles Gibbons
Director, Data Governance & Data Integrity,
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Exploring AI applications in QC laboratories for enhanced decision-making and compliance

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About the Presenter

Charles Gibbons

Director, Data Governance & Data Integrity

A seasoned compliance and auditing professional with over 30 years in the pharmaceutical industry. He has led global audits across manufacturing, commercial affiliates, suppliers, and third-party sites, ensuring alignment with regulatory standards. With 21 years of leadership in digital compliance, Charles has driven the integration of technology with regulatory frameworks, enhancing innovation and risk management across global networks.

He is a founding member of the APIC/CEFIC Data Integrity Task Force and co-author of both revisions of the widely recognized APIC/CEFIC Practical Risk-Based Guide for Managing Data Integrity.

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Poll 1

- Does your company have an approved AI Strategy for QC?

Poll 2

- Is your company actively working to develop an AI Strategy for QC?

Poll 3

- Does your company have a Data Governance Policy?

AI is now a reality for the industry

GUIDANCE DOCUMENT

Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products

Draft Guidance for Industry and Other Interested Parties

JANUARY 2025

FDA; "Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products, Draft Guidance for Industry and Other Interested Parties"; January 2025; https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological.

- "This guidance provides recommendations to sponsors and other interested parties on the use of artificial intelligence (AI) to produce information or data intended to support regulatory decision-making regarding safety, effectiveness, or quality for drugs. Specifically, this guidance provides a risk-based credibility assessment framework that may be used for establishing and evaluating the credibility of an AI model for a particular context of use (COU)."

EudraLex Chapter 4 Documentation

Draft Annex 11, Computerized Systems

New Annex 22, Artificial Intelligence

European Commission; "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines"; https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en; "Stakeholders' Consultation on EudraLex Volume 4 - Good Manufacturing Practice Guidelines: Chapter 4, Annex 11 and New Annex 22"; https://health.ec.europa.eu/consultations/stakeholders-consultation-eudralex-volume-4-good-manufacturing-practice-guidelines-chapter-4-annex_en web accessed on August 28, 2025.

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AI in OOS Investigations

- Root Cause Analysis using historical data and Natural Language Processing (NLP)
  - Faster and more accurate investigations.
  - AI can rapidly analyze large volumes of laboratory and manufacturing data to identify root causes of OOS/OOT results. This reduces investigation time and improves accuracy.
- Pattern recognition in instrument logs and analyst behavior
  - Detecting subtle patterns or anomalies that humans might miss.
  - Automating data correlation across systems (e.g., LIMS, MES, QMS).
- AI-suggested CAPA based on past cases
  - Analysis of previous CAPA to determine a new CAPA.

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Data Review and Witnessing

- Automated pre-screening of lab data
  - Error Reduction: AI minimizes human errors in data interpretation.
  - Consistent Evaluation: AI applies the same criteria uniformly, ensuring consistent pre-screening across datasets.
- Early Detection of Anomalies
  - AI can flag abnormal values or patterns that may indicate issues such as contamination, equipment malfunction, or unexpected biological responses.
  - Machine learning models can forecast potential problems before they escalate.
- AI-flagged exceptions for human review
  - Identification of concerns that require human review.
- Virtual witnessing via logs, sensors, and video analysis

Chem/Micro Lab Specific Applications

- Improved Root Cause Analysis
  - Machine learning models can suggest likely causes of deviations based on historical data, helping investigators.
  - Prioritize hypotheses.
  - Avoid redundant testing.
  - Reduce human bias in decision-making.
- Chromatographic optimization, and anomaly detection
- AI-assisted colony counting and contamination detection
- Environmental monitoring trend analysis
  - Identifying trends as they emerge.

GxP Alignment and Governance

- Explainable and validated AI models
  - Documentation to support the implementation.
- Documentation of model training and performance
- Governance frameworks for ethical and compliant AI use
- By maintaining consistent, traceable, and high-quality documentation, AI can help companies:
  - Be better prepared for FDA inspections.
  - Respond quickly to regulatory queries.
  - Demonstrate robust quality systems.

Developing Staff Competencies

- AI-driven performance tracking and error analysis
- Personalized training recommendations
- Forecasting readiness for complex tasks
- AI can proactively identify trends that may lead to future OOS events by:
  - Monitoring process parameters in real time.
  - Flagging deviations before they occur.
  - Supporting preventive actions and continuous improvement.

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Streamlined Documentation

- Natural Language Processing (NLP) can:
  - Draft investigation reports.
  - Summarize findings.
  - Auto-fill regulatory forms (e.g., CAPAs, deviation reports) reducing manual effort and errors.
- Human Supervision

Safeguarding Against Data Integrity (DI) Risks

- Anomaly detection in data streams.
- NLP-based audit trail analysis.
- Digital witnessing and real-time verification.
- Enhanced Data Integrity and Compliance.
- AI tools can enforce data integrity principles by:
  - Automatically logging and timestamping actions.
  - Detecting data manipulation or inconsistencies.
  - Ensuring traceability and audit readiness.

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Networked vs. Standalone Systems

- AI can seamlessly integrate with:
  - LIMS (Laboratory Information Management Systems)
  - ELNs (Electronic Lab Notebooks)
  - QMS (Quality Management Systems)
- This ensures consistent data flow and reduces duplication of effort.
- Centralized AI for holistic oversight in networked systems.
- Edge AI for local decision support in standalone instruments.
- Periodic syncing for oversight and benchmarking.

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Define an AI Strategy & Use Case

Define Clear Objectives and Use Cases

Start by identifying where AI can add value in GMP settings:

- Predictive maintenance of equipment.
- Real-time quality control and anomaly detection.
- Automated visual inspection of injectable drugs.
- Environmental monitoring using image recognition.
- Chromatography optimization and peak integration.
- Process analytical technology (PAT) for real-time product quality prediction.
- Quality Intelligence/Quality Metrics.

Each use case should be assessed for its impact on product quality, patient safety, and data integrity.

Make the Business Case

Articulate the business case in context with the business overall AI Strategy (and Data strategy)

- Align AI strategy with broader digital transformation and sustainability goals.
- Feasibility.
- Prioritization.

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Regulators, Readiness, and Risk

Readiness: Data Governance/AI Governance, Resources & Skills, Infrastructure

- AI, Data & QMS Readiness
- Current vs. New Processes

Regulatory Engagement/Compliance and Frameworks

- Engage with Regulators in the early phases
- AI in GMP environments must comply with evolving regulatory standards
- Leverage international standards

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Regulators, Readiness, and Risk (Cont'd)

Model Risk/Risk-Based Lifecycle Management

Adopt a lifecycle approach grounded in Quality Risk Management (QRM):

- Define intended use and document it thoroughly (Question of Interest, Context of Use-FDA)
- Assess AI Model risk (Model Influence & Decision Consequence-FDA)
- Establish acceptance criteria and performance metrics (e.g., accuracy, precision)
- Ensure human-in-the-loop oversight for non-deterministic outputs.
- Apply change control for model updates and retraining.
- Monitor for model drift and validate periodically.

Ethical Considerations

- Ensure transparency and explainability of AI decisions.
- Address bias risks in training data.

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Development & Validation

Model Development

- Data preparation
- Data sets (training vs. validation)
- Data lineage

Validation, Qualification, and Data Governance/Data Integrity

Validation must ensure AI systems are:

- Fit for intended use
- Reproducible and traceable
- Data management is aligned with ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, etc.)

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AI Governance, Performance Monitoring & Continuous Improvement

Performance Monitoring

- Establish acceptance criteria and performance metrics (e.g., accuracy & precision)

AI Governance and Documentation

Ensure multidisciplinary collaboration:

- Involve QA, IT, data science, and process SMEs.
- Maintain detailed documentation of model training, testing, deployment, and performance.
- Define access controls and responsibilities clearly.

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Questions?

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Thank You!

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