

I N T R O D U C I N G



A I C O M P L I A N C E C E N T E R
O F E X C E L L E N C E

New |
QACV Consulting
AI Program
Development





New!

AI Compliance Center of Excellence

What is **AI** CCoE



Machine Learning-enabled Medical Devices (MLMDs), including Good Machine Learning Practice (GMLP) for Medical Devices: Guiding Principles



Artificial Intelligence (AI) Usage in Drug & Biological Product Development & Manufacturing Processes

Gain insights into the current and emerging regulatory requirements, learn best practices for validating machine learning algorithms, data governance, case studies, specialty trainings and more.



Services included:

- **TRAININGS:** Strategic training, to help understand the emerging regulatory expectations
 - Historical context to explain the “Why?” behind regulatory requirements
 - Tactical training with introduction to AI/ML and the appropriate compliance controls specifics for Quality and Compliance experts
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- **AUDITS:** Performed for companies that are using AI/ML vendors
 - Targeted specifically for vendors who develop or use AI/ML
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- **SYSTEMS/ SOPS:** Align AI/ML development into current best practices
 - Avoid a force-fit of AI/ML development into inadequate systems
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- **SUBMISSIONS:** Built for companies that need clear guidance on how to properly position and document AI/ML systems within medical device and pharmaceutical filings
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- **EXPERT ADVICE:** Consultation for companies that require practical, experience-based guidance to implement compliant and scalable AI/ML governance models



AI COMPLIANCE CENTER OF EXCELLENCE



AI/ML Compliance Assessments, including Vendor Audits, and AI/ML Validation Support

- Dataset Governance
- Documentation of Algorithm Development
- Validation of Algorithms
- Gap Assessments, and Remediation
- Audits of AI/ML Software vendors



Training in AI/ML Regulatory Compliance

- Training Programs and Courses
- Tactical Training: What to do?
- Strategic Training: Why ?
- Ethical AI and Transparency



GxP Services

- Development and Review of AI/ML Regulatory Submissions
- Regulatory Agencies Inspection Preparation, including Mocking Inspections

AI Compliance Corner Access

- Case studies
 - Monthly meetings
 - Articles
 - Evaluations
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REGISTER TODAY

Access exclusive
content on AI/ML
and our New AI
Compliance Services



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