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# **EU GMP Annex 22 – AI in Regulated Manufacturing and Business Central**

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EU GMP Annex 22 is the European regulatory framework governing the use of artificial intelligence and machine learning in pharmaceutical and medical device manufacturing. Published in draft form in 2025 and progressing toward mandatory adoption, it introduces new requirements for regulated organisations deploying AI systems – including AI features embedded in ERP platforms like Business Central.

Annex 22 applies to AI and ML systems used in GxP-relevant processes: quality control, batch release, process monitoring, deviation detection, and predictive maintenance. It does not apply to all AI use – only to systems where AI outputs influence GxP decisions or records.

For Business Central users, the relevant question is whether AI features in use produce outputs that affect regulated data or regulated decision-making. If yes, Annex 22 applies to those specific features.

## Six core requirement categories

**Data governance:** training data must be documented, its source and quality controlled, and its relevance to the intended use demonstrated.

**Model validation:** AI models must be validated before GxP deployment, using a defined approach proportionate to the risk of the intended use.

**Transparency and explainability:** regulated organisations must be able to explain AI decisions affecting GxP outcomes. Black-box models without explainability mechanisms are not acceptable in high-risk GxP applications.

**Human oversight:** Annex 22 explicitly requires human oversight of AI outputs in GxP-relevant processes. Automated AI decisions affecting batch release, quality status, or regulatory records without human review are not compliant.

**Continuous monitoring:** AI model performance must be monitored in production. Model drift must be detected and managed.

**Change control:** changes to AI models, training data, or integration architecture follow documented change control procedures.

## Practical implications for Business Central users

Most BC implementations in regulated manufacturing use AI features at the periphery of GxP processes – demand forecasting, purchasing suggestions, cash flow prediction. These typically do not meet the Annex 22 threshold because they do not directly influence GxP records or decisions.

As AI capabilities expand within BC through Microsoft Copilot features that can interact with inventory, quality, and production records, the boundary between AI-assisted and AI-influenced GxP decisions is narrowing. Organisations should conduct an Annex 22 scoping assessment now, before AI features are deployed in production. The scoping assessment answers: which AI features are in use or planned, do any produce outputs that influence GxP records or decisions, and if yes, what validation and oversight measures are in place.