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Business Central GxP Validation – Practical Checklist

This checklist is designed for companies in regulated industries (life sciences, pharma, medtech, food) using or planning to implement Microsoft Dynamics 365 Business Central.
It combines a regulatory compliance self-assessment with practical guidance on how Business Central can help meet GxP, 21 CFR Part 11, and EU GMP Annex 11 requirements.

Checklist Step	What We Deliver	Why It Matters (Term Definition)	Status	How Business Central Supports
Plan & Scope	Validation Plan (VMP), supplier assessment, environment strategy	**CSV** – Documented proof the system is fit for use & compliant.	☐	Define intended use in VMP; configure cloud/SaaS environments per compliance plan.
Define URS	User Requirements Specification linked to risks/regulations	**URS** – System "must-have" requirements tied to GxP and risk.	☐	Map BC modules (Finance, Warehouse, Manufacturing) to regulated processes.
FS/DS	Functional & Design Specifications for BC configuration & integrations	**FS/DS** – Blueprint of how BC meets URS.	☐	Document BC setup: dimensions, workflows, permissions, integrations (LIMS/QMS/WMS).
Part 11 / Annex 11 Assessment	Control mapping for electronic records, signatures, data integrity	**21 CFR Part 11 / Annex 11** – Secure, trustworthy system con-	☐	Assess BC workflows for e-signature needs, audit logs, record protection.
IQ	Installation Qualification evidence	**IQ** – Proof BC is installed/configured correctly.	☐	Document tenant provisioning, backups, security roles, version numbers.
OQ	Operational Qualification tests	**OQ** – Verify controls work in practice.	☐	Test BC role-based permissions, audit log entries, time stamps, data exports.
PQ	Performance Qualification scenarios	**PQ** – Confirm BC works for daily regulated operations.	☐	Simulate end-to-end BC transactions: batch/lot, CoA, quality holds, release to ship.
Traceability Matrix	URS → FS/DS → IQ/OQ/PQ → evidence mapping	**Traceability Matrix** – Ensures nothing is missed in validation.	☐	Link BC test evidence to requirements via validation repository or SharePoint.
Audit Trails	Verify change tracking for GxP records	**Audit Trail** – Secure log of changes.	☐	Use BC Change Log to track modifications with user/-date/time.
Access Control	Roles, permissions, segregation of duties	**Access Control** – Limit system access to authorised users.	☐	Configure BC permission sets, restrict sensitive functions, enforce strong passwords.
Electronic Signatures	Secure, unique, linked to record	**Electronic Signature** – Legal digital approval.	☐	Implement BC approval workflows with user authentication.
Data Integrity (ALCOA+)	Ensure Attributable, Legible, etc.	**ALCOA+** – Core data integrity principle.	☐	Enforce BC mandatory fields, validation rules, and log retention policies.
Backup/Restore	Test backup and recovery	**Backup & DR** – Protect against data loss.	☐	Use Microsoft cloud backup/restore features, test recovery to sandbox.
Interfaces	Validate system connections	**Interface Validation** – Ensure data stays accurate across systems.	☐	Configure BC API integrations with retries, error logs, and reconciliation reports.
SOP Set	SOPs for user management, change control, incident handling, review	**SOP** – Written instructions for consistent operation.	☐	Link BC processes to SOP steps (e.g., "how to change a role" in BC).
Training Records	Proof of staff training	**Training Compliance** – Regulators require proof of competence.	☐	Record BC user training completions in LMS or attach certificates in BC.
Validation Summary Report	Fit-for-use sign-off	**VSR** – Formal compliance decision.	☐	Include BC configuration screenshots, executed test logs, and sign-offs.
Change Control & Periodic Review	Procedures for updates/re-validation	**Change Control** – Keep system compliant after changes.	☐	Track BC updates via release notes, re-test affected processes, log in change tracker.

Business Central GxP Validation – Glossary of Terms

GxP
An umbrella for "Good x Practice" regulations in life sciences and adjacent industries (e.g., GMP – Good Manufacturing Practice, GDP – Good Distribution Practice, GLP – Good Laboratory Practice). Focus: patient/consumer safety, product quality, and data integrity.

21 CFR Part 11
US FDA regulation that defines the requirements for electronic records and electronic signatures in "closed systems" (controlled user access). Covers secure user authentication, audit trails, e-signatures, record retention, and backups.

EU GMP Annex 11
European guideline for computerised systems used in GMP-regulated environments. Covers lifecycle validation, data integrity, security, change control, periodic review, and supplier assessment.

CSV (Computer System Validation)
A documented, risk-based process that provides objective evidence that a system consistently performs as intended and complies with relevant regulations.

URS (User Requirements Specification)
A document listing everything the system must do to meet business, regulatory, and quality needs. Forms the foundation for design and testing.

FS (Functional Specification)
Details how the system will meet the URS from a functional perspective (features, workflows, modules).

DS (Design Specification)
Technical description of how the system is configured or developed to meet requirements (e.g., architecture, integrations, security setup).

IQ (Installation Qualification)
Evidence that the system and its environment have been installed correctly according to specifications and vendor guidance.

OQ (Operational Qualification)
Testing to confirm the system functions as intended, particularly the compliance-related controls (e.g., audit trails, permissions, e-signatures).

PQ (Performance Qualification)
End-to-end process testing with real-world scenarios and representative data to prove the system supports actual business operations.

Traceability Matrix
A mapping that links every requirement (URS) to its corresponding design and test evidence, ensuring nothing is missed in validation.

Audit Trail
A secure, time-stamped record of changes to regulated data, capturing who made the change, when, and what was changed.

Access Control
The system's ability to restrict user access to only what's necessary for their role, enforcing segregation of duties.

Electronic Signature
A unique digital identifier for a user that securely links their approval or review to a record, with legal standing equivalent to a handwritten signature.

Data Integrity (ALCOA+)
Principles ensuring data is Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available.

Backup & Disaster Recovery (DR)
Processes and tools to safeguard data, restore it when needed, and maintain operations after failures.

Interface Validation
Testing and verification that data exchanged between systems (e.g., BC and LIMS/QMS/WMS) is accurate, complete, and handled properly in case of errors.

SOP (Standard Operating Procedure)
A written instruction describing how to perform a task consistently and in compliance with regulations.

Training Compliance
Evidence that all relevant staff have been trained to operate the system and follow SOPs.

Validation Summary Report (VSR)
A formal document summarising validation results, with a decision on whether the system is fit for regulated use.

Change Control
A controlled process for evaluating, approving, implementing, and documenting changes to the system to ensure ongoing compliance.

Periodic Review
Regularly scheduled evaluation of the system and its controls to ensure it continues to meet requirements.