Line#	Review	Process	Overall Requirement	Customer responsibilities - As defined by MS in Azure GxP Guidelines	Customer Specific Requirements	GAP	GAP (IP)	GAP handled as a part of the project	Customer Process	Supplier Process	SLA	Quality Agreement	Mitigation of residual risk	Action
2	Change Management	Change Management	Valid and approved Change Management procedures are in place Covering (but not limited to): Roles and responsibilities Process for Interfacing to the Incident / Problem management Process for Change Control, hereunder patch management (including security patches of system components) and updates/upgrades Process for Change Impact Assessment Process for Testing (incl. traceability) and qualification Review and approvals Training Process for Rollback Management of controls	- Implement formal change control and deviation management processes in conjunction with validation of GxP applications. - Ensure controls are established to maintain current copies of any system documentation required to manage applicable GxP computerized systems - Ensure that appropriate logical security policies are established, and training has been documented. - Ensure that appropriate security controls are defined to govern application/system/Azure access along with permissions related to data. - Ensure appropriate system administration practices are followed for applications/systems installed within the Azure environment. - Ensure appropriate governance of system administration activities around the management of Microsoft Azure services.	N/A	Change management procedure needed for Azure platform (incl. appropriate security controls are defined to govern application/system/Azure access along with permissions related to data.	N/A	D365 Operations handbook	SOP-00515 SOP-00631	Yes Microsoft (see VA= vendor agreement) for cloud infrastructure Yes Microsoft (see VA) for D365FO	No	No	Yearly review of Microsoft certifications Regular review of incidents Ensure a Change management procedure is established to ensure alignment with Operation Handbook	Anchor regular review of change log in cloud year wheel Anchor regular review of MS change log in cloud year wheel Anchor yearly review of MS certifications in cloud year wheel Anchor regular review of incidents in cloud year wheel Ensure that "Operation handbook" is up to date Ensure a cloud policy document ('Azure Governance and Policies') is established Ensure a Change management procedure is established, including review of release notes (can be included in 'Azure Governance and Policies')
3	Configuration Management	Configuration Management	Valid and approved Configuration Management procedures are in place Covering (but not limited to): Roles and responsibilities Process for interfacing to Change Management process activities Process for baselining and reviews Process for identification of items under configuration control Blacklisting/Whitelisting aspects Inventory structure (incl. documentation format to be used) Review and approvals Maintenance (incl. how to keep information updated and ensure traceability to relevant documentation) Management of controls	- Ensure that appropriate logical security policies are established, and training has been documented. - Ensure that appropriate security controls are defined to govern application/system/Azure access along with permissions related to data. - Ensure appropriate system administration practices are followed for applications/systems installed within the Azure environment. - Ensure appropriate governance of system administration activities around the management of Microsoft Azure services. - Ensure that backup infrastructure and policies are in place and have been tested for GxP system(s) hosted the Azure environment.	N/A	Configuration management procedure is needed	N/A	D365 Operations handbook to include configuration management-link to MS documentation for configuration management	SOP-00631	Yes Microsoft (see VA) for cloud infrastructure Yes Microsoft (see VA) for D365FO	No	No	See line 2 (Residual risk already listed/handled under previous steps)	See line 2 (Actions already listed/handled under previous step) Ensure a configuration management procedure is established including review/controls (can be included in 'Azure Governance and Policies') Anchor regular review of audit trail for admin users in administration module in cloud year wheel

EPISTA LIFE SCIENCE