

Decide where it runs. Name who runs each part.

For IT, quality, validation and procurement teams choosing between hosted and on-premises deployment, and planning qualification, change control and recovery.



Name an owner for every tier

Hosting, patching, backups, identity, validation.

Restore it before you rely on it

A tested restore beats a backup policy.

Validate your intended use

Your quality team decides, whatever the deployment.

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Who this is for

IT and infrastructure leads, validation and quality owners, procurement and security reviewers at regulated and non-regulated manufacturers.

Important. This guide helps you plan. It is not a contract, a statement of work or legal advice, and it does not change any term. Your Order and the current V5 Commercial Terms, EULA and S.G. Systems SLA govern. No deployment option is presented as required by any regulator.

How to use it. Fill in the ownership table on page 4 with your vendor, adapt the test matrix on page 11, and settle page 12 before the Order.

1 • OPTIONS

Three options, one decision

V5 Ultimate runs as Cloud, Private Cloud or On-Premises. Your Order states which; there is no default.

	CLOUD	PRIVATE CLOUD	ON-PREMISES
What it is	Shared hosted service	Your own isolated instance and database, hosted by S.G. Systems	Installed on infrastructure you or your contractor operate
Where	United States (Oregon, Iowa)	Same platform as Cloud	Your data centre or cloud account
Region choice	None today	None today	Yours
Plan	All plans	Per Order	Enterprise

Questions that usually decide it

QUESTION	ASK	OK
Data location	Does a policy require data in a place you control?	☐
Network	Must the system work inside a segregated plant network?	☐
Operating capacity	Can your team patch, back up, monitor and restore 24/7?	☐
Release timing	Do you need to choose when releases go in?	☐
Integrations	Which systems must it reach, and from where?	☐

On-Premises moves work to you. Choose it for a real requirement, not by default.

2 • OWNERSHIP

Who runs what

Agree this table in writing before the Order. Blank cells are risks.

TIER	CLOUD	PRIVATE CLOUD	ON-PREMISES
Hosting and infrastructure	S.G. Systems	S.G. Systems	You / contractor
Application and database operation	S.G. Systems	S.G. Systems	You
OS and database patching	S.G. Systems	S.G. Systems	You
Backups and disaster recovery	S.G. Systems (per SLA)	S.G. Systems (per SLA)	You design, run and test
Encryption keys at rest	Ask in writing	Ask in writing	You manage
Monitoring and alerting	S.G. Systems	S.G. Systems	You
Identity provider (SAML, Enterprise)	You	You	You
When releases go in	S.G. Systems schedule, with notice	S.G. Systems schedule, with notice	You decide
Intended-use validation	Your quality team	Your quality team	Your quality team
Software defects and support	S.G. Systems	S.G. Systems	S.G. Systems, remote

Uptime, backups, RPO/RTO and service credits in the S.G. Systems SLA apply only to Cloud and Private Cloud. For On-Premises they are yours to design and prove.

3 · A COMMON CONFUSION

Your cloud account vs Private Cloud

"Private cloud" means different things to different people. Here it has one meaning.

Private Cloud. Hosted and operated by S.G. Systems on the same platform and by the same operator as Cloud, with a separate isolated application instance and database for you.

Your own cloud account. A tenancy or subscription you control is treated as **On-Premises**: you run security, patching, backups and recovery, even though it's in a public cloud.

QUESTION	PRIVATE CLOUD	YOUR CLOUD ACCOUNT (ON-PREMISES)
Who holds admin access to the hosts?	S.G. Systems	You
Who pays the cloud bill?	Per Order	You
Who restores after a failure?	S.G. Systems, per SLA	You
Can we pick the region?	Not today	Yes, your account
Who applies releases?	S.G. Systems, with notice	You, when you decide

Write the label in the Order. Ambiguity here becomes a dispute after the first outage.

4 • DESIGN

Topology, sizing and identity

The published On-Premises specification gives planning starting points. Each site's design is confirmed in writing during project design.

PATTERN	SHAPE	TYPICAL FIT
Linux VM or server	App and PostgreSQL on Linux hosts; on Windows Server sites a Linux guest VM	Single site
Container host	One Linux host running containers	Pilot, validation, sandbox
Container orchestration	Cluster, database separate	Multi-site or high availability
Hybrid	Site app near devices, data in your cloud	Only with link-loss behaviour designed

TIER (PLANNING)	USERS	VCPU	RAM	STORAGE YR 1
Small	≤ 25	4	16 GB	200 GB SSD
Medium	25–100	8	32 GB	500 GB SSD
Large	100–300	16	64 GB	1 TB NVMe

Identity. SAML SSO with providers such as Okta, Microsoft Entra ID and Google Workspace (Enterprise). SCIM provisioning is coming soon, not available today.

Network. HTTPS inbound; app to database internally; optional outbound to identity, mail and integrations; devices on the same segment or through your gateway.

Integrations, AI and air-gapped limits

Every integration is a network path someone must allow, monitor and re-test after change.

INTEGRATION	DIRECTION	ASK
ERP connector	Outbound to your ERP	Where does the connector run? Dry-run before go-live
REST API and webhooks	In and out	Who owns credentials and rotation?
EDI / GS1-128 labels	Partners and printers	Which partners, which paths?
Devices (SICS, Modbus TCP, OPC-UA, MQTT, ZPL)	Plant network	Segment or gateway; tested per device
AI features	Outbound to a configured provider	Available on your deployment? Which provider?
Email notifications	Your mail relay	Relay owner and allow-list

Air-gapped. Available as an On-Premises option. Some analytics features may be unavailable without outbound connectivity. Confirm each feature you need during scoping; don't assume full parity.

AI providers. AI features need configured provider access. In a closed network that may not be possible; agree which features you'll run without.

Backup, restore and monitoring

For On-Premises these are yours. For hosted options, ask for evidence rather than assuming.

QUESTION	ON-PREMISES: YOU DECIDE	HOSTED: ASK S.G. SYSTEMS
How often are backups taken?	Full plus log archiving, your schedule	Current policy summary (shared on request)
Where are copies kept?	Storage you control	Independent copies: Google Cloud Storage, US multi-region
Recovery objectives	Set per site, proven by restore	As stated in the SLA for hosted services
Last restore test	Into a separate database, records and audit trail compared	Latest recovery-check evidence, under NDA
Who is woken at 03:00?	Your on-call	S.G. Systems Severity 1 process
Monitoring	Your log platform, health checks	What you'll be told, and when

A tested application restore is not a full disaster-recovery plan. Plan for site loss, people, credentials, identity provider, network and devices too.

Restore drill (On-Premises). Restore into a separate database at go-live and at regular intervals; compare record counts, a sample of records and the audit trail; sign the result.

7 • VALIDATION

Intended use and validation context

Whatever the deployment, your quality team owns intended-use validation, testing, approval, release and change control.

ACTIVITY	WHAT IT SHOWS	WHO	V5 SUPPORT
Intended-use statement	What the system is for and not for	Your quality team	—
IQ: installation qualification	Installed as specified	Your team (On-Prem install)	Enterprise only
OQ: operational qualification	Functions work as specified in your configuration	Your team	Enterprise only
PQ: performance qualification	Works in your real process	Your team	Your procedure
UAT	Your users accept your workflows	Your users	Your procedure

Independent assessment. V5 Ultimate 5.10 has an independent assessment available on request under confidentiality. It is supporting evidence, not approval, and does not validate your instance.

Medical-device production and QMS software. FDA's Computer Software Assurance guidance (final, 3 Feb 2026) gives non-binding, risk-based recommendations for that software. It is not a universal rule for every sector or an approval route.

Other markets and sectors have their own expectations; apply those that fit your products and sites.

Change control for releases

On-Premises, you decide when a release goes in, so you can test it first. Write the path down.

STEP	WHO DECIDES	EVIDENCE
1 Release notes reviewed	IT + quality	Impact assessment
2 Installed in test / validation environment	IT	Install record
3 Risk-based testing of affected functions	Quality	Test results
4 Change record approved	Quality	Signed change record
5 Production update scheduled	Operations + IT	Downtime notice
6 Post-update checks	IT + key users	Smoke test, restore point

Emergency patches come with recommended deployment guidance. Agree a fast path in advance.

Falling behind is a risk. Plan regular updates; old releases accumulate untested change.

9 · PROVING IT

RFP and acceptance test matrix

#	TEST	EXPECTED	PASS	BY
1	Hosts meet agreed sizing	Spec sheet signed		
2	Services start, health checks pass	All green		
3	SSO sign-in via your identity provider	Signed in; local fallback per policy		
4	Operator sign-in on a shop-floor device	Kiosk works on plant network		
5	One scale, scanner, printer per line	Live checks recorded		
6	End-to-end e-signature on a representative record	Signature and audit entry		
7	Backup to your storage, encrypted	Backup verified		
8	Restore into a separate database	Records and audit trail match		
9	Outbound blocked (if air-gapped)	Listed features unavailable, rest work		
10	Release applied in test first	Change record approved		

AREA	WHAT TO SEE DEMONSTRATED	SYSTEM A	SYSTEM B
Ownership	Page 4 agreed in writing	_____	_____
Recovery	Restore demonstrated	_____	_____
Change	Release path written	_____	_____
Constraints	Air-gap and AI limits listed	_____	_____
Total (0–3 each)		_____	_____

Contracts and support

Commitments come only from your Order and the current documents. This page points to them; it doesn't paraphrase them.

DOCUMENT	COVERS	LINK
V5 Commercial Terms	Commercial relationship with the Seller	v5ultimate.com/legal/commercial-terms
SG Systems EULA	Licence, use and IP	v5ultimate.com/legal/eula
S.G. Systems SLA	Support and service levels	v5ultimate.com/legal/sla
Your Order	Deployment option, scope, fees, services	Signed with you

Support. For critical (Severity 1) issues, a person from S.G. Systems responds within 2 hours, 24/7/365, for every supported deployment, including On-Premises. A response time is when a person starts work, not a fix time. Contact support@sgsystemsglobal.com.

Orders that accepted MSA V1.24 keep its terms. Older documents that cite it, including earlier on-premises material, do not set terms for new Orders.

11 • NEXT STEPS

First month and sources

WEEK	DO	EVIDENCE
1	Requirements and ownership table (page 4)	Signed table
2	Topology and sizing confirmed in project design	Design record
3	Install in validation environment; tests 1–8	Matrix rows signed
4	Change path and restore drill; plan production	Change SOP, restore record

Sources explain buyer questions; they are not V5 compliance claims. Reviewed 2 October 2026.

Guidance (medical-device production and QMS software)

- **FDA Computer Software Assurance guidance page (3 Feb 2026)** — www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-management-system-software
- **FDA CSA guidance PDF** — www.fda.gov/media/188844/download

V5 (current terms and technical reference)

- **S.G. Systems SLA** — v5ultimate.com/legal/sla
- **V5 Commercial Terms** — v5ultimate.com/legal/commercial-terms
- **SG Systems EULA** — v5ultimate.com/legal/eula
- **On-Premises specification (technical topology only)** — v5ultimate.com/resources/on-prem-specification
- **Security & Trust** — v5ultimate.com/security

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