

Valkit.ai Launches Valkit Greenfield for New Site Commissioning & Qualification

Paperless, AI-augmented C&Q for new sites on Valkit's pre-validated platform — all stakeholders included, delivered by Certified Greenfield Partners.

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Project-based platform brings paperless, AI-augmented C&Q to greenfield facility builds, with every stakeholder — owner, engineer, vendor, and contractor — included at no per-seat cost, delivered exclusively through Certified [Valkit](#) Greenfield Partners.



“

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Hugh Devine

Valkit.ai today announced the launch of Valkit Greenfield, a digital commissioning and qualification (C&Q) solution purpose-built for new site start-up. Greenfield runs on Valkit's pre-validated R1125 "Odin" platform and gives owner/engineering teams and all execution stakeholders a single, shared, isolated project environment to author, execute, and close out IQ/OQ/PQ — from validation plan through summary report.

Valkit Greenfield is project-based and built around unlimited collaboration. All operating companies, vendors, and contractors share one project environment with no

named seats and no access gates. Best-practice C&Q protocols are authored, version-controlled, and distributed from dedicated isolated libraries, then cloned and customised to project scope. Execution guardrails prevent skipped steps and enforce evidence capture at every test step, eliminating GDP errors at source. Deviations are logged, categorised, and resolved within the platform, with all parties notified automatically, while AI assists plan, specification, protocol, and test-case drafting — all subject to mandatory human review and e-signature. Automated risk assessments, trace matrices, and summary reports link every requirement to its test evidence end-to-end.

Customers can go live in 2–4 weeks via Express Implementation, where Valkit's onboarding team configures the project environment and trains the team to run the platform directly. For organisations that prefer to keep their teams focused on the science, Valkit Greenfield engagements can be delivered fully managed — and only Certified Valkit Greenfield Partners are authorised to deliver them. Valkit is partnered with some of the world's largest C&Q engineering firms, spanning the United States, United Kingdom, European Union, India, and Asia Pacific, with each certified partner managing every phase — planning, execution, deviation management, and sign-off — entirely within the platform.



Look for a Green Field Certified partner

Each engagement includes a complete validation package — Validation Plan (VP), Product Requirements (PRD), Functional Risk Assessment (FRA), Operational Qualification (OQ), Trace Matrix (TMX), and Validation Summary Report (VSR) — at no additional charge. Pricing is a fixed project license fee with no per-seat fees and no overage charges.

The Greenfield launch caps an extraordinary period of growth for Valkit.ai. Since beginning commercialisation in January 2025, the company surpassed 1,000 active validation projects within roughly seven months on the market, achieving ISO 27001 certification, opening a dedicated engineering centre in Barbados in late 2025, and shipping its R1125 "Odin" platform release in January 2026 — with active projects projected to exceed 2,000. Valkit Greenfield extends a portfolio that already spans computer system validation (CSV), computer software assurance (CSA), C&Q, and MSAT-led tech transfer.

"Greenfield site start-up has always been a document scramble — spreadsheets, shared drives, and PDFs moving between owners, engineers, and contractors who never share the same source of truth," said [Hugh Devine](#), CEO of Valkit.ai. "Valkit Greenfield turns that into one disciplined, project-based engagement where every stakeholder works in the same isolated environment at no per-seat cost. We've partnered with the largest C&Q engineering firms in the world to deliver it — only Certified Valkit Greenfield Partners are authorised to manage these engagements on a customer's behalf, so the rigour is consistent everywhere we operate. In barely a year of commercial availability we've gone from launch to over a thousand active validation projects and a global engineering footprint. Greenfield is the natural next step. Born in Scotland, forged in

Indiana — this is C&Q the way it should be done."

"Greenfield is delivered on our pre-validated R1125 'Odin' platform, so customers start inspection-ready from day one," said Colin Bottles, VP of Engineering at Valkit.ai. "Execution guardrails enforce evidence capture and stop steps from being skipped, automated risk assessment and trace matrices link every requirement to every test case end-to-end, and AI-augmented authoring is always backed by mandatory human review and e-signature. It's built on 21 CFR Part 11 and EU Annex 11 electronic records and signatures, role-based access control, AES-256 encryption, and a certified ISO 27001:2022 ISMS. The same engineering discipline that let us scale to over a thousand active projects underpins every Greenfield engagement."

Most customers consider Valkit to be a GAMP Category 1 or Category 3 tool. At project close, a complete, traceable qualification record set is produced, with true-copy PDF export to the customer's eQMS or legacy DVT of choice.

About Valkit.ai

Valkit.ai is a global Software-as-a-Service provider based in Indianapolis, IN, delivering digital validation software for the pharmaceutical, biotechnology, and healthcare sectors. Valkit's mission is to streamline and digitise validation, enabling life science organisations to meet their regulatory requirements. The platform supports C&Q, CSV, CSA, and tech transfer workflows on a pre-validated, ISO 27001:2022-certified foundation.

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