WHY CLIENTS INVOLVE W2 EARLY

Cleanroom projects can become difficult and costly when GMP expectations are addressed too late. W2 provides independent challenge and expert GMP advice before layouts are fixed and become difficult to change.

Independent, practical, inspection-aware

We connect facility design, contamination control, qualification planning and operational GMP requirements so project teams can make better decisions earlier.

LET'S DISCUSS YOUR CLEANROOM PROJECT

Whether you are planning a new facility, reviewing a design, preparing for qualification or strengthening an existing GMP operation, W2 can provide structured, independent support.

CLEANROOM DESIGN INPUT

Layout, zoning, flows, pressure cascades and GMP design challenge.

QUALIFICATION READINESS

URS devleopment, Design Qualification (DQ), validation planning and evidence mapping.

OPERATIONAL GMP SUPPORT

Compliance remediation, SOP and PQS improvements, deviation review, root cause, CAPA and inspection-readiness support.

Consultant outputs are provided for client review through the client's own Quality system and governance routes.

CONTACT OUR TEAM

www.w2cleanrooms.com
info@w2cleanrooms.com
+44 7840 292981
+44 7874 156824

W2 Cleanroom Consulting

INDEPENDENT GMP CLEANROOM AND COMPLIANCE CONSULTANCY

Design review, CCS development, validation, remediation and inspection-readiness support for regulated cleanroom projects.

GMP CLEANROOM SUPPORT

THE PROBLEM WE SOLVE

Cleanroom projects often run into difficulty at the interfaces between design intent, operational use, contamination control, validation stages and Quality approval.

W2 helps project teams identify these risks earlier, reducing the likelihood of costly facility redesign, qualification delays and inspection-readiness gaps.

WHO WE SUPPORT

- Pharmaceutical manufacturers
- NHS aseptic services
- Sterile manufacturing facilities
- Radiopharmacy and ATMP aseptic environments
- Cleanroom refurbishments and facility upgrades
- Support for project, estates and validation teams

WHAT W2 PROVIDES

CLEANROOM DESIGN REVIEW

Layouts, zoning, flows, pressure cascades, contamination control and GMP design.

URS AND DQ SUPPORT

User requirement specification, DQ execution and regulatory compliant evidence packs.

CONTAMINATION CONTROL STRATEGY

CCS input linked to facility design, EM, cleaning, utilities and operational controls, and process risk assessment.

VALIDATION AND QUALIFICATION PLANNING

DQ, IQ, OQ and PQ protocols and execution, validation planning and risk assessment input.

REMEDIATION AND INSPECTION READINESS

Gap analysis, CAPA challenge, remediation planning and inspection preparation.

OPERATIONAL GMP SUPPORT

SOPs, PQS improvement, deviation review, root cause, CAPA and training support.

Selected project experience

Guy's and St Thomas' NHS Foundation Trust
URS gap analysis and GMP design review support, including input into RIBA Stage 3 and 4 redesign, Design Qualification execution and operational-readiness planning.

North Cumbria Integrated Care NHS Foundation Trust
URS gap analysis and specialist GMP design review support, including input into RIBA Stage 2, 3 and 4 design, DQ protocol generation and execution and operational-readiness planning.

The Christie NHS Foundation Trust
Aseptic service improvement, GMP remediation, staff mentoring and project support.

Savills
Pharmaceutical cleanroom project support for a major global pharmaceutical manufacturing site, delivered through an established estates and project-management partner under extreme time constraints.

Project references are included as experience context only. No endorsement, accreditation or approval by any named organisation is implied.