

Facility Design Review Services

Strategic Design Consulting & Review for FDA-Regulated Packaging & Manufacturing Facilities

Design Compliance Experts

cGMP Consulting offers decades of experience providing engineering and regulatory guidance during the facility design phase. We help integrate compliance requirements directly into the facility layout and infrastructure to comply with cGMP expectations for packaging and manufacturing. This requires careful integration of process flow, cleanroom design, monitoring systems, and qualification strategies.

Proven Approach

Regulatory Strategy & Qualification Planning

- Identification of Critical Aspects (CAs) and Critical Design Elements (CDEs)
- Development of a Design Qualification (DQ) report framework
- Guidance on commissioning and qualification planning
- Review of system classifications and risk assessments

Facility & Product Handling Review

- Assessment of wall, floor and ceiling finishes for cleanability
- Guidance on temperature and humidity control ranges
- Optimization of material and personnel flow
- Recommendations for ceiling and utility chase configurations
- Guidance on personnel gowning requirements

Laboratory & Cleanroom Design

- Utility layout optimization
- Protection of sensitive detector electronics
- Appropriate ISO classifications and airflow design

Environmental Monitoring & Control

- Environmental monitoring strategies for viable and non-viable particulates
- Cleaning program strategies for ISO and non-sterile areas
- Best practices for pest control
- Selection of cleaning chemicals

Tangible Results

- ✓ cGMP-aligned facility design principles
- ✓ Efficient personnel and material flow
- ✓ Appropriate contamination control strategies
- ✓ Integrated environmental monitoring programs
- ✓ Infrastructure for safe material handling
- ✓ Path toward commissioning and qualification

Industries Served

- Pharmaceuticals
- Radiopharmaceuticals
- Biologics & Biotechnology
- Pharmaceutical APIs
- Non-sterile bulk APIs
- CBD
- Dietary Supplements
- Cosmetics

Notable Clients

