TRUSTED PARTNER IN

EVERY STEP OF THE DEVELOPMENT & PRODUCT LIFECYCLE

QualiZen™

Pharma Services

Where Science Meets Speed Taking Your Molecule To Market Seamlessly

About QualiZen Pharma Services

QualiZen Pharma Services is an independent global pharma services provider built on integrity, transparency, and innovation. With over 50 years of cumulative team experience, we deliver end-to-end solutions across the pharmaceutical journey - from clinical drug development and GCP audits to regulatory dossier support, product artwork creation and Cosmetic formulation development.

More than a service provider, QualiZen is your trusted partner, empowering pharma companies to navigate complex compliance challenges and accelerate their drug development and product lifecycle success.

Mission :

To accelerate pharmaceutical innovation by delivering expert clinical development, regulatory compliance, auditing, and product lifecycle services. We uphold uncompromising quality, integrity, and client-focused solutions across global markets.

Vision :

To be the most trusted global partner delivering science driven, patient-focused, and regulatory-compliant solutions.

Integrity | *Transparency* | *Excellence*

Innovation | *Collaboration*

Decoding QualiZen

QualiZen = Quality + Zen

Quality : Compliance, Integrity, Global Standards

Zen : Balance, Harmony, Seamless Execution

Q	QUALITY
U	UNDERSTANDING
A	ASSURANCE
L	LEADERSHIP
I	INTEGRITY
Z	ZEST
E	EXCELLENCE
N	NAVIGATION

Quality & Compliance Consulting

Consulting Scope :

- GMP, GCP, GLP, GDP audits and assessments
- Regulatory gap analysis and remediation plans
- Quality Management System (QMS) development and enhancement
- Compliance assessment and mock inspections
- Computer System Validation (CSV) strategy and implementation
- Data integrity evaluation and governance
- Inspection readiness support and CAPA guidance

Key Highlights :

- Independent, science-driven compliance advisory
- Ensures alignment with global regulations (FDA, EMA, MHRA, WHO etc.)
- Risk-based and inspection-ready solutions

Clinical & Preclinical Consulting

Consulting Scope :

- Independent GCP monitoring and oversight
- Phase I–IV clinical trial management support
- Clinical trial audit and inspection support
- Clinical quality management system advisory
- Pharmacovigilance (PV) safety monitoring and signal detection
- Preclinical study oversight and GLP compliance consulting
- Inspection readiness support and CAPA guidance
- Medical and PV writing services (protocols, IBs, CSRs)

Key Highlights :

- Ensures subject safety and data reliability
- Supports audit and regulatory inspection readiness
- Independent advisory on clinical trial governance

Manufacturing & Validation Consulting

Consulting Scope :

- Technology transfer planning and execution advisory
- Facility design consultation (Greenfield & Brownfield projects)
- Equipment and utility qualification strategy (IQ/OQ/PQ)
- Process and cleaning validation consulting
- Computerized system validation (CSV) advisory
- Cleaning and process risk assessment (FMEA)
- Audit and remediation support

Key Highlights :

- Focus on GMP-compliant, scalable manufacturing processes
- Supports inspection readiness and regulatory compliance
- Risk-based approach for validation and operational efficiency

Training & Documentation Consulting

Consulting Scope :

- GxP training programs (GMP, GCP, GLP, GDP, CSV, Data Integrity)
- Classroom and on-the-job training (OJT)
- SOP development, review, and harmonization
- GxP documentation development and control
- Inspection readiness consulting and mock audits
- eQMS selection, implementation, and validation support

Key Highlights :

- Builds sustainable quality culture
- Improves operational compliance and staff competence
- Aligns documentation and training with regulatory expectations

Toxicological & Environmental Health (EHS) Consulting

Consulting Scope :

- Permitted Daily Exposure (PDE) report preparation
- Health-Based Exposure Limit (HBEL) calculation and documentation
- Occupational Exposure Limit (OEL) assessment
- Environmental risk assessment (ERA) and documentation
- EHS risk assessment and audits
- Qualification of cleaning limits based on PDE/HBEL
- Environmental monitoring program design and documentation

Key Highlights :

- Supports cleaning validation, cross-contamination control, and toxicology compliance
- Aligns with EMA, ICH, ISPE, and global health authority expectations
- Independent, science-based advisory for EHS programs

Regulatory Affairs Consulting

Consulting Scope :

- Global regulatory strategy development (US, EU, UK, APAC, ROW)
- Regulatory submissions consulting: IND, CTA, NDA, ANDA, BLA, MAA
- eCTD dossier compilation, publishing, and quality review
- Lifecycle management advisory: post-approval changes, labeling updates
- Regulatory intelligence and impact assessment
- Health authority query response strategy
- Regulatory inspection preparedness support

Key Highlights :

- Helps clients navigate complex global regulations
- Ensures regulatory compliance throughout product lifecycle
- Supports accelerated approvals and risk mitigation

Artwork & Labelling

Cosmetic Development

Artwork & Labeling Services

- Regulatory-Compliant Labelling
- Artwork Creation & Design
- Technical Artwork (Barcodes, Aerialization, Braille)
- Change Management
- Global Packaging Lifecycle Management

Cosmetic Development

- Formulation R&D
- Regulatory & Compliance Support
- Manufacturing Services
- Packaging & Artwork
- Logistics & Global Delivery
- Specialty Cosmetics (Cosmeceuticals, Clean Beauty, Men's Care, Baby Care)

Experience

- 300+ Global GxP Audits & Assessments
- 100+ Phase I–IV Clinical Trials Supported
- 500+ BA/BE Studies Successfully Overseen
- 100+ IQ/OQ/PQ Qualifications Executed
- 35+ Process & Cleaning Validation Programs
- 500+ SOPs Developed, Reviewed & Harmonized
- 100+ GxP Training Programs Delivered
- 400+ PDE/HBEL & Toxicological Risk Assessments
- 30+ Global Regulatory Submissions
  (IND, NDA, ANDA, BLA, CTA)
- 100+ Health Authority Query Responses Managed
- 25+ Inspection Readiness & Mock Inspection Programs
- 500+ Artworks Created
  100+ E-commerce Packaging Designs
- 50+ Years of Cumulative Team Expertise In
  Clinical Drug Development And Global Pharma Services

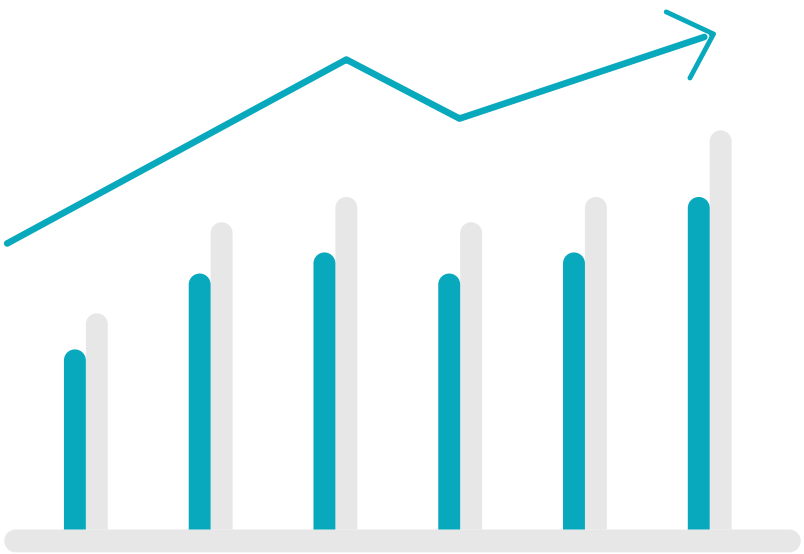
Global Reach

Why Choose QualiZen Pharma Services

- Over 50 Years Of Cumulative Team Experience In Pharma Services
- Customized, Cost-ef ective Solutions Tailored To Client Needs
- High-quality Audit Reports And Structured, SOP-Driven Service Delivery
- Advanced Regulatory And Technical Expertise Across Global Markets
- Global Footprint Spanning Major Pharma Hubs Worldwide
- Commitment To Integrity, Transparency, And Client-centric Partnership

Impact Statement

“Empowering your pharmaceutical journey with seamless clinical development, rigorous regulatory compliance, expert audits, innovative product artwork, and specialized cosmetic formulation - delivering quality and speed from molecule to market.”



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