Company Profile

ClinVigilant

Experience The Innovation

ABOUT OUR COMPANY

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2006

GSC TECHNOLOGIES

GSC Technologies is a trusted IT Consulting and Implementation Partner based in London, UK. Since 2006, we have been providing state-of-the-art products and services in the field of Information Technology.

2017

QSCIENCE CONSULTANCY

QSC is the most promising consultancy company in pharmaceuticals & biotechnology industry.

2019

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ClinVigilant is a joint venture of GSC Technologies and Q Science Consultancy (QSC) which comes with potential combination of Information technology and technical expertise in clinical research / Pharmaceutical industry

- The establishment of the company is inspired by Quality with science. With footprints in UK and Ahmedabad, India provides us with the ability of delivering cost-effective solutions at a high development pace..
- We have full-fledged R&D facilities that enable us in meeting our client expectations in implementing the ever-changing technologies
- We solve organisation's most complex operative and business challenges and help them implement robust and agile business and enterprise software solutions.
- Our expert consultants and developers help in implementing complex business and enterprise solutions with our in-depth in wide range of industries
- We work with you to understand your business goals and define the necessary roadmap of changes required in your industry either by implementing new solutions or transforming existing processes and legacy.

WHAT WE OFFER

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01

eClinical Suite

Our solutions are beyond anything that many clients have never seen before which helps them to fully digitalise the clinical trials and BA/BE studies

02

eClinical Consulting

Our principles of Lean & Six Sigma resulting in transparency, simplification, digitalisation and compliant systems enhancing the business revenue.

03

eClinical Best Practice Implementation

Identification of Gaps and redundant Processes, simplified process, Interfacing and Automation

OUR APPROCH

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ZERO TOLERANCE ON QUALITY

Our promise is to deliver the best quality of data.

TIMELY DELIVERABLES

We take pride for delivering the services before the deadline

ETHICAL PRACTICE

Proven records for following highest ethical standards

COST EFFECTIVE MODEL

Providing customised model suits for the project

OUR eClinical SUITE : KEY BENEFIT

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- Developed by the industry domain experts
- Complete Configurable System
- CDASH-CDISC Based Platform
- Single Place for Phases I - IV of Studies
- Scalable Platform with Cloud & On-prem Solution
- Third Party Integration
- Complaint ICH-GCP, GDPR & 21 CFR Part 11

OUR eClinical - CORE SOLUTION

WE HAVE PROFESSIONAL AND COMPETENCE IN OUR SOLUTION

INTERFACE
IWRS/IMP/ Pathology Interface

BARCODE base auto entry & verification

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REGISTRATION & SCREENING

Volunteer Database, General/ Project Specific screening, Biometric and photograph identification, Easy database filtration, management reports, version controlling, Review cycle

CDISC/CDASH-SDTM compliant e-CRF Designing & CDM

Standard Library, easy designing and programming tool, version controlling, medical coding, data review cycle, inbuilt standard reports

PHARMACY MANAGEMENT & EDC

Handling, Tracking & Accountability of IMP, Randomization integration, Dispensing, Handling of BA/BE studies, Barcode based data entry, scheduling of events, review cycle, standard library (protocol & SOP driven), inbuilt standard reports.

SAMPLE MANAGEMENT & DOSSIER MANAGEMENT

Barcode based Handling, Tracking & Accountability of Samples and regulatory compliant CRF and related data export with bookmarking, margins, TOC etc.

LABORATARY INFORMATION MANAGEMENT SYSTEM

Machine Interface, Batch request, approval, data review and acceptance and standard reports.

LEARNING MANAGEMENT SYSTEM

Training Matrix, training document management, scheduling, assessment, training gap assessment, certificates, etc

QUALITY MANAGEMENT SYSTEM

Document control, change management, vendor management, incidence management, SOP management

E-ARCHIVAL SYSTEM

Request, handle and tracking of archival and retrieval, location and re-location of the data and easy to track the expiry of the data, inbuilt reports etc

OUR eClinical CONSULTING SERVICE

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Centralised Solution

CDISC-CDASH/SDTM Data Management platform for BA/BE and multicentric trial (EDC and eCRF)

Advisory & Auditing

We provides Process Transition Support,SOP Management,GAP Assessment,GxP Training

Validation Service

Computer System Validation, Spreadsheet Validation, PLC Validation as per GAMP5 & 21 CFR part 11

Clinical Trial Operation

Our expert team provide medical writing services, Biostatistics and Programming, Medical Writing

Regulatory Advice

Our expert SME provides pre-inspection audit, regulatory query responses, clinical trial data audit, site selection and management

Complete Digitalisation

We provide single solution for end to end processes for easy interfacing with medical devices and smooth compliant data flow

CDM & Statistical Services

Scientific Data Management of clinical trials from database setup through lock. Statistical analysis with compliant output

IT Advisory

Helping you to shape your organisation for Change Management, Big Data Management, IT Auditing and Validation

OUR EXPERIENCE

Our team has extensive experience in Therapeutic area, Handling Regulatory Submission and Inspection

109
Clinical Trials - Data Management

109
Regulatory Submission

45
Regulatory Inspection

WHY CHOOSE US

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01

Quality & Regulatory Expert

Global Brand strong in IT solution and clinical research / Pharmaceutical industry

02

CRO Domain Expert

Identifies relevant challenges at various steps of the clinical trial operations programme

03

Technology Expert

Solve organisation's most complex operative and business challenges and help them implement robust and agile business and enterprise software solutions.

WHAT WE HAVE FOR YOU?

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DISCOVERY PHASE

Initiate the project plan, business requirement documentation

IMPLEMENTATION

Configure and customize the business process as per business requirement

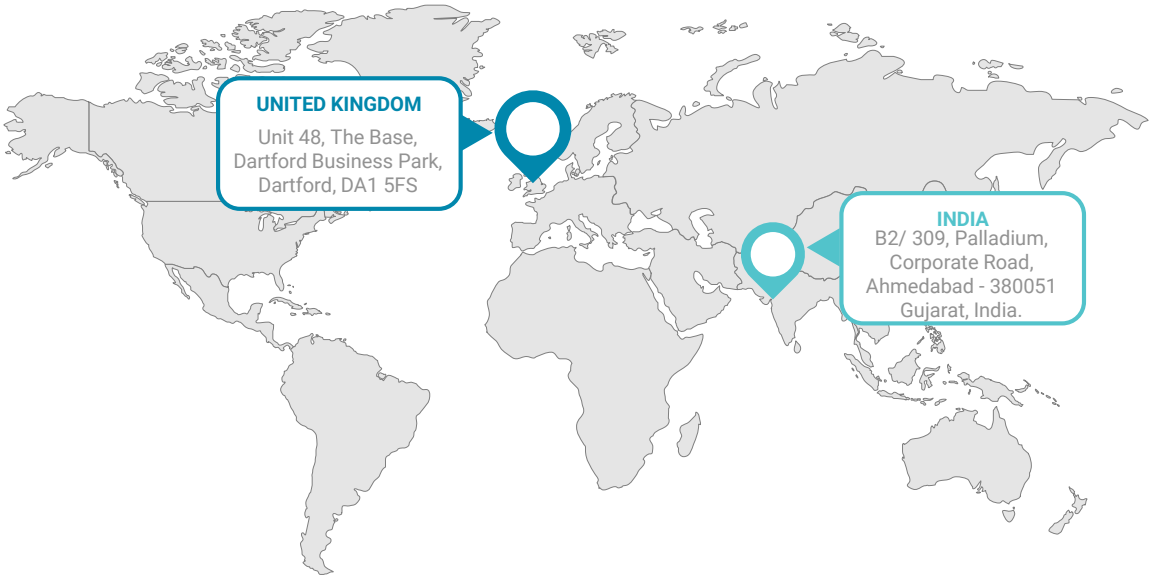
SUPPORT

Pre and Post Go Live support, stabilization of system, incident management and manage change request

PROJECT MANAGEMENT

Manage project plan, reports to stakeholder on weekly basis on status of the project, Project Governance

OUR LOCATION



QUESTIONS