



THE KNOWLOGY

Knowledge driven Quality Assurance

QUALITY ASSURANCE SERVICES;
UK, EUROPE and BEYOND



Introduction

The Knowlogy Group was founded to provide a different Quality Assurance consultancy, with a key value of sharing knowledge through all its services.

We are committed to providing Quality Assurance services and consultancy to organisations so that they can continue with pioneering research and growth. That's why we offer a range of services which can be tailored to your organisation - so you can benefit from world-leading knowledge, without a high cost.



Benefits of working with The Knowlogy

We provide solutions not problems, by working with you to ensure we provide timely and practical support and advice.

Increase Understanding

Organisations can save time and resources with our collaborative approach we don't just perform the audit or complete the project. We will provide coaching so that our knowledge is passed on.

Maintain Compliance

With an understanding of why and how, organisations can ensure that they remain compliant with industry standards and regulations, reducing the risk of fines, penalties, and other legal consequences.

Enhanced Decision-making

With gained knowledge from working with The Knowlogy personnel will be able to make informed decisions by application of the regulations to individual situations.

Improved Reputation

Staying compliant with industry regulations enhances an organisation's reputation, instilling confidence in stakeholders, investors, and customers.

Scalable services

Our services grow with you, to provide the optimum package of solutions according to the maturity of your quality system and personnel knowledge.



SERVICES

Good Laboratory Practice

Our GLP team has a wealth of experience in diverse organisations applying the principles of Good Laboratory in unique situations, including medical devices, and academic research *in vivo* and *in vitro*.

We can provide support to your internal audit team, act as your QA manager and have successfully implemented quality management systems from nothing to become members of the national GLP monitoring programme.

If you're interested in our services, please don't hesitate to contact us.

Our team would be happy to discuss your needs and provide a customised solution for your organisation.

GLP Service

Facility Audits

Study Audits

- Critical or in-process phase audits
- Study plan audits
- Data audits
- Report audits
- Procedure/process audits

Document reviews

Archive audits

Qualification or requalification audits

Subcontractor and vendor inspections

Quality System development and deployment

Quality System Assessment / Gap Assessment

Regulatory Inspection Readiness

Mock Inspections

QA Manager

Expert advisory support for internal audit teams & Test Facility Management

SERVICES

Good Clinical Practice – for laboratories

Otherwise known as Good Clinical Laboratory Practice (GCLP).

The GLP team also provides services for laboratories analysing samples from clinical trials for safety parameters, small and large molecules, biomarker and other speciality bioanalysis.

GCLP Services

Facility audits

Study Audits

- Analytical plan audits
- Data audits
- Procedure/process audits
- Report audits

Mock inspections

Document reviews

Archive audits

Qualification or requalification audits

Subcontractor and vendor inspections

Quality System development and deployment

Quality System Assessment / Gap Analysis

Inspection Readiness

QA Manager

Expert advisory support for internal audit teams/Laboratory Management

SERVICES

Good Practice for Computer Systems Compliance

The Knowlogy provides computer system validation audits, 21CFR11 compliance reviews and can conduct complete computer system validation services with our specialist Computer System Validation expert.

We are often called to support small organisations with limited IT support for validation of laboratory analytical instrumentation to specialist equipment such as CT, digital x-rays.

Our range of Computer System Compliance services includes:

Computer System compliance auditing

- System-specific computer system validation audits
- Data centers
- Backup and data recovery
- Business continuity and disaster recovery
- IT Security
- Computerised System Development Life Cycle (SDLC) Process Audits

Computer System Compliance (CSC) Consulting

21 CFR 11 Compliance Gap assessment

Development and deployment of Computer System Validation processes tailored to your systems

Conduct and completion of Computer System Validation

SERVICES

Good Clinical Practice

Our capabilities for Good Clinical Practice is expanding and we currently support qualification or requalification audits for many services.

Good Clinical Practice (GCP) is essential which is why our services ensure that the data collected during your trials is accurate, complete, and verifiable. Overall, we aim to ensure that your clinical trials are conducted according to the highest ethical and scientific standards.

Good Clinical Practice services

Phase I units

Central Laboratory Services

Archive facilities

Imaging facilities

Data management

- Database audits
- Data management System Audits



SERVICES

For Sponsors

The Knowlogy can support the completion of your pre-clinical and clinical vendor qualification or requalification audit program.

Our services can ensure pre-clinical research meets the required quality standards and regulatory guidelines. Also, to help sponsors navigate the complex pre-clinical research process and support them in achieving their research goals.

For Sponsors services

Pre-clinical Contract Research Organisations

Bioanalytical Laboratories

Formulation development and analysis

Specialist histological techniques

Toxicokinetic and Pharmacokinetic analysis

ISO10993 – biocompatibility of Medical Devices

Statistical Analysis

Phase I units

Pharmacy



SERVICES

ISO Standards

In a world driven by quality and excellence, organisations seeking to enhance their reputation, foster customer trust, and gain a competitive edge must prioritise the implementation of international standards.

That's why The Knowledge offers a comprehensive range of auditing, consultancy and training services for ISO 9001, ISO 17025, and ISO 15189 to equip your team with the knowledge and skills to excel in these standards – to help you achieve and maintain compliance, enhance your processes, and gain a competitive edge.

ISO 9001

Streamline Your Quality Management

Improvement Opportunities: Our in-depth audits go beyond simple compliance checks, identifying areas for improvement and streamlining your Quality Management System (QMS) for optimal efficiency.

Drive Continuous Excellence: Leverage audit findings to implement effective improvement strategies, fostering a culture of quality and innovation throughout your organization.

Proactive Risk Management: Mitigate potential risks impacting your QMS and operational integrity with our thorough risk assessment and mitigation strategies.

ISO 17025

Elevate Your Laboratory Competence

Laboratory Competence: Aim to ensure your laboratory meets the highest international standards of testing and calibration with our technical competence assessments.

Accurate Results: Assure the integrity of your results through audits that focus on equipment calibration, maintenance, and adherence to documented procedures.

Foster Transparency and Accountability: Achieve complete traceability and accountability with documented procedures and records that meet ISO 17025 requirements.

ISO 15189

Ensuring Excellence in Medical Testing

Prioritise Patient-Centric Care: Our audits emphasize a patient-centric approach, ensuring your medical testing practices deliver the highest standards of quality, accuracy, and patient safety.

Validated Personnel Competency: Verify the qualifications and skills of your medical staff through detailed audits, guaranteeing reliable and accurate testing results.

Optimise Healthcare Quality: Integrate ISO 15189 principles into your healthcare processes, promoting a culture of quality and safety while meeting all regulatory requirements.



SERVICES Training

Having a knowledgeable and well-trained team is vital, which is why we offer a range of training services to stay up-to-date on the latest regulatory requirements and best practices.

Our training services can be provided at your chosen location or remotely. Uniquely, we work with you to understand your objectives and desired outcomes of the training, to ensure our courses meet your specific needs.

We provide learning over a wide range of subjects

Good Research Practice

Good Laboratory Practice

Good Clinical Practice for Laboratories

Computer System Validation

Using Risk as part of the Quality Assurance Programme

Data Integrity

Periodic Regulatory Refresher

Specific to the roles of attendees

Support personnel

Scientific / Study personnel

Study Directors / Principal Investigators /
Analytical Project Managers

Test Facility Management / Laboratory
Management / Management

Archivist

Sponsors



SERVICES

Consultancy

Navigate the intricate regulatory landscape of the research and life sciences industries while maintaining the highest standards of quality and compliance.

Grant Application Support

Funding Identification: Specialised in identifying tailored grant opportunities for life science research and development.

Proposal Precision: Provides nuanced support in crafting grant proposals, ensuring alignment with unique research and life science funder requirements.

Regulatory Compliance: Ensures grant applications adhere to your sector-specific regulations and ethical guidelines.

Software Qualification

Validation Protocols: Development and execution of validation protocols for life science research software, covering functionalities and compliance with record-keeping regulations.

Regulatory Documentation: Assistance in creating regulatory documentation tailored to your projects, ensuring adherence to stringent regulatory requirements.

On-Demand Support – Hourly/Daily Fees

The Knowlogy offers on-demand support with flexible engagement models tailored to the unique demands of life science projects. This allows organizations to access expertise for short-term initiatives, such as clinical trials, data analysis, or research collaborations.

Independent Audits

Internal Audits

Risk Assessment

Comprehensive risk assessments focus on potential risks in experimental design, data collection, and analysis for research protocols.

Compliance Check

Evaluation of internal processes ensures alignment with rigorous life science standards (GLP, GCP) to enhance research outcomes' integrity.

Vendors/Suppliers Audits

Quality Control

Audit services extend to assessing the quality control measures of life science suppliers for critical materials, equipment, and reagents.

Biosecurity Assurance

Audits of external partners mitigate biosecurity risks associated with the procurement of biological materials.

Expert Regulations and Standards Advice

Regulatory Landscape Monitoring: Remain current with dynamic regulatory changes in biosafety, bioethics, and data protection for the life science sector.

Customised Compliance Guidance: Specialised advice on how regulatory changes impact sectors specific operations, providing strategies for compliance with standards.



SERVICES

Mentoring and Coaching

At The Knowlogy, we believe that mentoring and coaching are highly effective ways to help individuals and organisations grow and succeed.

They can offer a wide range of benefits to individuals and organisations, from structured guidance and support to help individuals develop specific skills to achieving short-term goals. Also, to offer long-term career guidance for helping individuals navigate complex professional challenges. By providing both immediate support and long-term career development, our tailored solutions can meet your unique needs and requirements.

That's why we offer a flexible service for areas such as auditing, business leadership and strategy, sales growth, marketing, and operations. We work with you to understand your unique needs and provide tailored guidance and support to help you achieve your full potential and long-term success.

The benefits of our mentoring and coaching services include:

Comprehensive approach to personal and professional development

Structured guidance for immediate support and long-term career development

Tailored solutions that meet unique needs and requirements

Access to diverse perspectives and best practices

Improve performance, job satisfaction, and career advancement

If you're interested in our services, please don't hesitate to contact us. We would be happy to discuss your needs and provide a customised solution for your organisation.

Why The Knowlogy Group?

Experienced International Consultants

Our team is comprised of experienced international consultants with a wealth of knowledge and expertise in the life sciences industry. We have worked with clients across the globe and have a deep understanding of the regulatory landscape and best practices in the industry.

Customised Solutions

At The Knowlogy Group, we understand that every organisation is unique, with its own set of challenges and requirements. That's why we offer customised solutions tailored to meet your specific needs and objectives.

On-demand Services

Our services are available on-demand, meaning you can access our expertise and support whenever you need it. Whether you require ad hoc support or ongoing consultancy, our team is available to provide the guidance and assistance you need.

Comprehensive Services

We offer a wide range of services, including auditing, computer system validation, training, QA support, quality systems, inspection readiness, and mentoring. This means you can rely on us to provide a comprehensive solution for all of your life sciences industry needs.

Our Promise

THE KNOWLOGY will never offer a one-size fits all solution. We are highly agile, so we can deliver a complete, end-to-end service, tailor a suite of services, or deliver an individual service to a specific need. But whatever our way of working, it will always be driven by a single, unifying ambition to provide value for our client's investment by ensuring knowledge is shared.

Take control of your learning and development with The Knowlogy Group.





About the Founder

Cate Ovington

Cate Ovington, the visionary behind The Knowlogy Group, recognised that traditional scientific research training was too regimented and still stuck in the classroom.

Also, that mentoring and other support services were not flexible enough to provide timely and effective results. So, in 2020 Cate founded The Knowlogy Group, a company that is revolutionising the way scientists learn about quality, regulations, and standards.



Cate's career in the regulatory industry started in the Quality Control laboratory for a veterinary pharmaceutical manufacturer, before moving into quality assurance in 2000. Cate has worked in quality assurance R&D for diverse organisations; small, medium and global contract research organisations (CROs), academia, medical device R&D and start-up biotechs.

As a seasoned coach and mentor, Cate is committed to helping individuals and organisations achieve their goals through a focus on personal and professional development. She is an active member of several industry organisations, including the memberships of Research Quality Assurance (RQA) and Society of Quality Assurance (SQA), Regulatory Affairs Professionals Society and the Institute of Directors.

Cate has over 20-years in Good Laboratory Practice, Good Clinical Practice specialising with laboratories, Computer Systems Validation, UK Human Tissue Act, and ISO9001, ISO17025, ISO15189, ISO13485 standards as an auditor internal and external and implementing systems.

Cate is also a member of the Research Quality Association (where she serves on the Northern Regional Forum Committee and the GLP Committee) and is the Principal Tutor for QA for GLP Course and a Tutor on The Auditing Course. QA for GLP, and the Society for Quality Assurance, from whom she has been certified as a Registered Quality Assurance Professional in GLP (RQAP-GLP). Cate is also a qualified ISO 9001 Lead Assessor and an internal auditor for ISO 17025.



THE KNOWLOGY

At The Knowlogy Group, we're flipping the script on scientific research training by offering a fresh approach to learning about quality, regulations, and standards.

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We take a personalised approach to our services, working closely with you to understand your unique needs and requirements. Our goal is to build long-term relationships with our clients and to help them achieve their goals and objectives.

theknowlogy.com

