THE KNOWLOGY

Knowledge driven Quality Assurance

QUALITY ASSURANCE SERVICES; UK, EUROPE and BEYOND

Supporting

Academic Institutions
NHS
Not-For-Profit's
BioTech Start-Up's
Pharmaceutical
Contract Research Laboratories

Members

RQA

Society of Quality Assurance
HOME TO THE WORLD'S BEST QA PROFESSIONALS

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

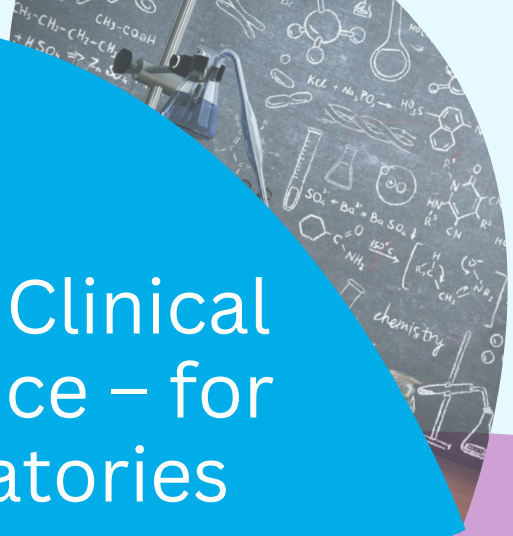
Quality System Assessment / Gap Assessment

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

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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 CRF 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

THE KNOWLOGY

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

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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 Knowlogy 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

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.

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.

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.

Our Clients

Therini Bio

DANISH QUALITY ASSURANCE GROUP

ACM GLOBAL LABORATORIES

APIS APPLIED INSECT SCIENCE

TBRC

University of BRISTOL

SARTORIUS

SELDEN

Animal & Plant Health Agency

Thank you again for providing other GLP guidance and recommendations outside the scope of this audit over the two days – the team and I found the conversations very useful.

QA Manager, Contract Research Organisation

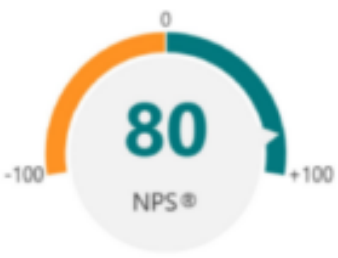
Lovely Knowledgeable approach and style, clearly a depth of experience that could be mined.

Training Course Attendee

Cate is amazing, a lot of knowledge, lot of anecdotes during presentations, very comfortable speaking in front of audience, and very helpful and interactive way during exercises

Training Course Attendee

Training course ratings



Meet our Team

Cate Ovington

Founder & Managing Director
Cate is a seasoned quality assurance professional with over 20 years of experience in the regulatory industry. She has worked in a variety of organisations, including contract research organisations, academia, medical device R&D, and start-up biotechs.

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 R&D for diverse organisations; from small to global CROs, Universities, medical device research and training facility, and a consultancy group, before starting a new venture at the beginning of 2021, with The Knowlogy.

With over 20 years in Good Laboratory Practice, Good Clinical Practice specialising with laboratories, Computer Systems Validation, UK Human Tissue Act, and ISO Standards as an auditor, internal and external, quality site lead and implementing quality management systems.

She is a member of the Research Quality Association (where she serves on the Northern Regional Forum Committee and the GLP Committee) and the Society for Quality Assurance, from whom she has been certified as a Registered Quality Assurance Professional in GLP (RQAP-GLP). She is a qualified ISO 9001:2015 Lead Assessor and ISO 17025.

Outside of work, Cate is a keen campanologist and cyclist. She is also a charity trustee and on committees managing events to support local causes.

Meet our Team

Stuart Ovington

Company Director
Stuart brings a wealth of experience in implementing processes for business and building teams, with over 30 years of experience in business leadership.

A seasoned and strategic business leader with an extensive background in delivering remarkable results across diverse sectors such as warehouse racking, marine, wholesale, safety equipment, and retail. Stuart's career is marked by a strong track record in formulating and executing strategic plans, driving business transformations, achieving significant sales growth, and leading team development.

Recent achievements have involved a 46% sales increase within two years, along with significant market share expansion for an industrial company and for another, streamlining operations from the merger of two companies while launching new revenue-generating innovations.

Stuart is very active in community support and through the Help To Grow Scheme where he volunteers` as a business mentor.

Education and Training:

- MBA, Sheffield Hallam Business School (2002)
- Cranfield General Management Program
- NEBOSH with credit
- ILM7 Coach and Mentor Trained

Meet our Team

Elaine McLachlan

Quality Consultant
Specializing in ISO Standards ISO9001, ISO7025, and ISO15189, Elaine international experience also brings a unique global perspective and communication skill to help our diverse clientele.

Elaine has broad experience across quality assurance, especially Quality Management Systems (QMS), having worked as a quality assurance supervisor at a leading global genomic service provider. With a bachelor's degree in Biomedical Sciences and a Master's degree in Genomic Medicine.

Elaine started her career as a Molecular Biology scientist at a genomic service provider and soon took responsibility in the laboratory as part of the management team. Leading the design, documentation and implementation of the Quality Management System (QMS) in the laboratory, to comply with the requirements of ISO 17025:2017, the Human Tissue Act (HT Act), and GCLP.

Trained as an internal auditor and actively involved in assessments and third-party audits as a technical representative, Elaine has led the way in continuous improvement of the QMS within organisations. Elaine has also won multiple awards throughout her career, including a Professionalism Award and New Star Award, and with a passion for helping customers from different backgrounds and providing a service which adds value to their work and business.

Elaine is a keen musician, a singer and a pianist, passionate about classical music and musical theatre.

Meet our Team

Joe Turton

CSV Specialist
Over 12 years experience as a GxP Consultant and CSV Specialist with a proven track record in computerised system validation, compliance, and auditing.

Joe is a dynamic professional with over a decade of expertise in the regulatory industry. Joe embarked on his professional journey as an Apprentice Laboratory Technician, quickly gaining recognition as the "Chemical Sciences" Apprentice of the Year by the Royal Society of Chemistry. His academic pursuits led him to earn a BSc in Environmental Science from The Open University.

Professionally, Joe has managed complex projects, laboratories and facilities within a CRO; during this role, he led advancements in Computerised Systems Validation and Data Integrity.

His tenure at the CRO included a role as a Support Systems Developer, which saw him spearhead the development and support of web applications and databases, enhancing operational efficiency and system reliability. As a QA Manager and CSV Specialist for The Knowlogy, Joe provided consultancy and auditing and improved CSV processes for our clients.

Beyond the professional realm, Joe's passion for 3D printing marries technology with creativity to produce intricate designs and prototypes.

THE KNOWLOGY

At The Knowlogy 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.

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