



Quality Systems International

We Deliver Quality

In Healthcare, Education & Social Quality . Integrity . Excellence

1 Introduction



QSI is the first and only, French established expertise in Quality Systems providing expertise in **GxP** & **e-Health Solutions** for Pharmaceutical, Bio-Pharmaceutical, Clinical Research organizations & Medical Device industry.

Capabilities

- 8 Years of experience with over 300 audits and training accounts.
- Coverage of over 50 countries
- Over 500 highly local qualified auditors and trainers in health standards and development covering EMEA countries

2 Mission & Vision



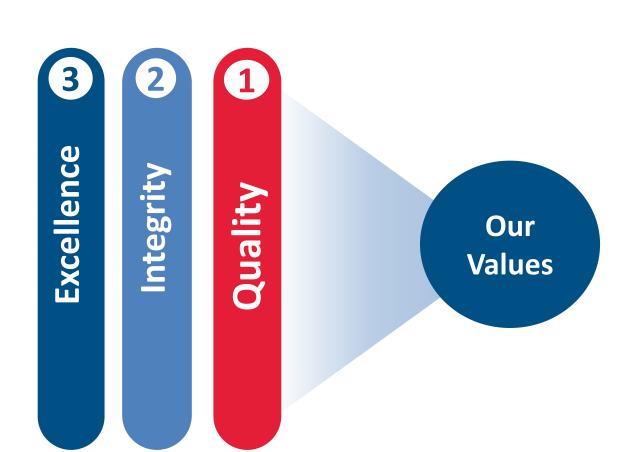
rision

Become a Leader in our industry, a major player in each of our market segments and key geographical market

Mission

Your effective and efficient quality system is our business; We support your company in building effective systems to achieve the highest quality & safety compliance by providing Auditing, Accreditations, Certifications, Coaching, & Gap Analysis Services.





4 QSI Board

Co-chair: Dr Nadia Cheaib

PharmD, PhDc, MSc, DVP France

Founder & Chairwoman ClinGroup

President of Healthcare Commission-Egypt French Chamber

President BOT Hope MCF Foundation

Forbes Most Impactful MEA Women 2014-2018

World Healthcare Congress 100 MEA healthcare leaders



Over 10 years of experience in Auditing, Coaching & Training in Healthcare & Food Safety Sectors and holding Master Degree in Quality Management.

Jessy is the Business Unit Manager of QSI & ClinAcademy, the French-Lebanese QA Consultancy Company delivering High quality Audits / Consultancy & Accredited Training Programs.



Over 25 years of experience in Auditing & Training in Quality Management. Georges is the General Manager of AB Certification France in charge of the development of the organization in France and on an international basis.

Georges is member of AFNOR normalization in several commission for developing ISO and French standards.



Business Unit Manager: Mrs. Jessy Tannous

Partner & Board Member: Dr. Georges Abi Rached





In addition to e-Health Solutions, QSI provides a wide range of services







Computer System Validation

- End to End Computer System
 Validation Services
- 21 CFR Part 11 Analysis & System Remediation
- Quality Assurance Review
- Computer System Validation Audits

10 GMP- EU Coaching



We provide a wide range of services to Pharmaceuticals Factories

QUALIFICATION

- ☐ Design qualifications
- ☐ Installation qualifications
- Operational qualifications
- ☐ Performance qualifications
- Maintenance qualifications
- ☐ HEPA filter integrity test
- ☐ Microbiological air sampling
- ☐ Particle counting
- ☐ Surface cleanliness
- ☐ Visualization of air flow patterns
- ☐ Pressure controls
- ☐ Air velocity air flow
- ☐ Air change rate
- ☐ Sound level control

REAL TIME MONITORING

- Online particle counter
- Design of online monitoring system
- ☐ Supply and installation of online monitoring systems.
- ☐ Validation of monitoring system
- ☐ Supply of portable particle counters.
- ☐ Calibration of online and portable particle counters

AUDIT

GMP

cGMP

EU-GMP





11 Plutus

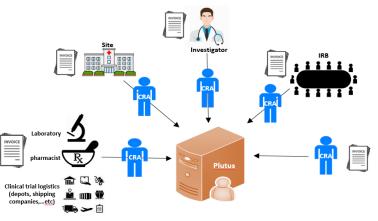




Automate Today Site payments easily

Solution Benefits

- Business Intelligence Fair Market Value
- Advanced analytics & accurate Financial insight
- Financial Transparency & Invoice reconciliation
- Quality Control by 3rd Party
- Consultancy services: Site budget setting, site negotiation & agreement
- Minimum sponsor involvement with maximum control



System Benefits

- Flexibility in Integration with any Data source (EDC, Oracle, SAP, CTMS)
- Ease of Payments and budget tracking
- User friendly Interface
- Payment Promptness & Security
- E-Invoice / Request for payment submission
- Financial and study Reports and Analysis Dashboards



12 GxP Audit Library



Benefits of joining QSI Audit Library

Reduce number of **Audits**

Reduce **costs and time** associated with hosting audits

Minimize the time spent of completing the **CAPA**. Only one **CAPA** required.

Ready Audit report

Quick access by your customers to a **cost- effective** report of sites.

Ideal for customers who purchase **small amounts** of product

Improve your supply chain

Provide you with high quality of ICH Q7 GMP & EU GMP compliance, which is accepted globally

No Customers refused entry due to limited audit dates availability from your Site.

You will have your company profile and web address on website in Audit Report Library

13 Target Clients?





QSI-Paris has Offices in the below countries: Headquarters: Paris – Beirut – Cairo



* Other regions than the territory of QSI are covered through the same auditors who re-allocate based on project / company requirements and needs

Contact us

Headquarters:

France, Paris Lebanon, Beirut Egypt, Cairo

Offices:

UAE, Abu Dhabi Egypt, Cairo





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