

Joseph Yammine

Founder & Managing Director



Nationality: Lebanese

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Languages: Proficient in English, French and Arabic

Membership: SQA, RQA, SOFAQ and LSQSH (Lebanese Society of Quality in Healthcare)

Membership: ChairPerson Educational Committee – Society of Quality Assurance, SQA (USA)

AREAS OF EXPERTISE

• GCP, GLP, GMP, GSDP, PV	• Total QMS Management
• CAPAs Management	• Risk Management Strategies
• Project Management	• Process Re-Engineering
• Vendors / Suppliers Management	• Healthcare Compliance
• ISO 13485 & MDSAP: Medical Devices	• Internal Audit / Reporting
• ISO 9001:2015	• ISO 17025: Calibration Laboratories
• ISO 22716: Cosmetics	• Product, Area and System Audit
• 21 CFR Part 11, 312, 314, Etc.	• Data Management / Statistics
• Management Reviews	• KPIs / Metrics Management
• Regulatory Compliance & Responses	• Staff Development
• Root Causes Analysis	• Lean Manufacturing
• ISO 14644: Cleanrooms & associated controls	• ISO 14971: Risk Management Medical

PROFESSIONAL SUMMARY

Process & Quality Engineer possessing large expertise in the Quality Management Systems, Auditing, Consultancy, Organizational design and restructuring, compliance, process re-engineering, working with a diversified portfolio of clients within Europe, Middle East, Gulf and Africa

With my varied experience in several industries, starting by the Healthcare, Logistics, Quality and Education and covering different geographical areas, my professional objective is to assist small to large organizations in designing their systems and structure, so they may be able to transform and upgrade their business.

ACADEMIC QUALIFICATIONS

- **Master in Process and Quality Engineering (Field: Quality, Security & Environment)**

Université Technologique de Compiègne – FRANCE (2007 – 2009)

- **Master's in physical chemistry (Field: Nanotechnology)**
Université Denis-Diderot (Paris VII) – FRANCE (2006 – 2007)

- **BSc Chemistry**
Université Saint Joseph (USJ) – LEBANON (2003 – 2006)

- **International Certified Professional Manager – ICPM (2014 – 2015)**
Institute of Certified Professional Managers – UNITED KINGDOM (Online)

PROFESSIONAL EXPERIENCE

Jan 2018 – Present

Senior Consultant and Trainer

ProKai FZco (Managing Director – Founder) – Dubai, UAE

- Conducts / Supervises GxP / PV / 21 CFR audits successfully from beginning to end from Phase Ia to IV.
- Identifies / communicates issues raised, offering recommended solutions relevant to business and risk
- Supervises and trains auditors assigned to engagements providing guidance and overall review of deliverables from beginning to the end
- Ensures audit conclusions are based on a complete understanding of the process, circumstances, and risk analysis, continuous improvement
- Develops audit programs and testing procedures relevant to risk and test objectives.
- Oversees group of Auditors and coach them during audit cycle
- Develops audit plans, audit flows and interacts with clients / sponsors
- Train junior auditors and do co-audits when required / compliance audits & inspections
- Freelancer trainer on Quality Topics (i.e. GCP, GSDP, GLP, 21 CFR, CAPAs, Auditing, etc.)
- Assisting clients to be ready for Inspection, Qualifications, SOPs Development, etc.
- Human Resources Consultancy (Strategy, Recruitment, Training & Development)
- HQ Compliance Audits (i.e. Events, Samples Management, Promotional Material, Marketing Activities)

June 2013 – December 2017

Senior Quality Auditor – Head of Quality Unit

Quality Systems International (QSI) – Beirut, Lebanon

- Conducts / Supervises GxP audits successfully from beginning to end
- Supervises junior auditors assigned to engagements providing guidance
- Ensures audit conclusions are based on a complete understanding of the process, circumstances
- Develops audit programs and testing procedures relevant to risk and test objectives.
- Obtains and reviews evidence ensuring audit conclusions are well-documented
- Ensures adherence at all times to all applicable department and professional standards
- Communicates with clients / sponsors to guarantee successful conduction of projects
- Provides Training programs to Healthcare Institutions and related to GCP, GMP, GLP, PV, Quality and ISO Requirements
- Participates in the development / update of Procedures & Checklists related to QSI services
- HQ Compliance Audits (i.e. Events, Samples Management, Promotional Material, Marketing Activities)

June 2008 – June 2013

Quality Engineer / Management Representative

Algorithm Pharmaceuticals – Beirut, Lebanon

- Ensures maintenance of all Quality Management System
- Assists in the implementation of the Company processes, defining and approving indicators.
- Conducts Audits according to the Company Audit Plan and with Support of Quality Manager (QM)
- Conducts Audits according to the GLP, GMP for the Laboratories, Warehouses and Hospitals
- Leads Internal Auditors; from Preparation to Conduction, Reporting, Closure, Documentation of Audits
- Manages the Management Reviews Meetings (Agenda, MOM, Follow-up, CAPAs, etc.)
- Manages the External Audits and assists QM (preparation, assistance, closure of findings, etc.)
- Helps employees in all ISO 9001:2008, GxP and 21 CFR related topics
- Plan, conduct & coordinate Internal Audits in direct compliance to the ISO 9001:2008, cGMP, GLP, GDP and GSP standards and guidelines
- Communicate audits findings to management during Management Reviews
- Implement documentation systems to assure comprehensiveness & provide a solid basis to demonstrate that
- the company's business conduct is ethical/legal
- Review audit results, implement & monitor corrective policies and procedures
- HQ Compliance Audits (i.e. Events, Samples Management, Promotional Material, Marketing Activities)
- Management of Healthcare Compliance Unit, Monitoring, SOPs / Policies Development, Etc.

SUMMARY OF CONSULTANCY EXPERIENCE

Indicators	Numbers
# of Years as Auditor	16 years
# of Completed Audits	> 400 audits (Current Average: 2 days on-site or remote audit / visit)
# of Completed Consultancy Projects	> 45 Projects
Distribution of Audits	25% GLP (Vendor, Therapeutic Area, Clinical) 25% GMP / GDP (Finished Products, API, Sterile, Vaccine, etc.) 30% GCP (Site Investigator, CROs, Data Management, Statistics, Medical Writing, Investigator Files, Pharmacies) 15% PV / 21 CFR (PV Affiliates, Distributors, QMS, Systems Validation, etc.) 5% ISO (9001, 14001, 13485, 17024, 14971, 30001) + Compliance
Main Countries	Lebanon, Egypt, Jordan, Turkey, UAE, Greece, Georgia, Zimbabwe, Uganda, Iran Algeria, Tunisia, Qatar, Oman, KSA, Mali, Nigeria, South Africa, New Zealand France, Belgium, Germany, United Kingdom, Serbia, Finland, Lithuania, Romania, Cyprus, Denmark, Hungary, Italy and USA

TRAININGS & DEVELOPMENT

- ▶ Nov 2022 Conference of RQA – GDP and GMP
- ▶ Oct 2022 Data Integrity and Computer System Validation
- ▶ Nov 2021 Conference of RQA – GCP and Data Integrity
- ▶ Feb 2020 GMP Auditing (Excipients, APIs, Packaging Material)
- ▶ Apr 2019 Design of PV QMS
- ▶ Jan 2019 ISO 9001:2015 – TUV Certification
- ▶ Dec 2018 PV Auditing Principles & Tools
- ▶ Nov 2018 Conference of RQA – GMP
- ▶ Nov 2018 Conference of RQA – Data Integrity & PV
- ▶ Apr 2018 GMP Part I: Audit Practices & CAPAs Management
- ▶ Feb 2018 Refresher on Quality in Warehouses - Healthcare
- ▶ Jan 2018 Quality Auditing Principles in Healthcare
- ▶ Dec 2017 ISO 17025: Laboratory
- ▶ Nov 2017 Conference of RQA-UK – Section PV
- ▶ May 2017 Advanced Project Management
- ▶ Mar 2018 ISO 13485 and MDSAP
- ▶ Jan 2017 Process Re-Engineering
- ▶ Nov 2016 Conference of RQA-UK – Section GLP and GCP
- ▶ May 2016 Initiation to Project Management
- ▶ May 2016 Clinical Data Management and Data Privacy
- ▶ March 2016 Pharmacovigilance workshop on signal detection and ICSR
- ▶ March 2016 Risk Management Plans in PV
- ▶ Dec 2015 “Sensibilisation suivant la norme en ISO 9001:2015”
- ▶ Nov 2015 Conference of RQA-UK – Section GLP and cGMP
- ▶ May 2015 New Perspectives of Quality in Clinical Research
- ▶ Jan 2015 Pharmaco-Vigilance Audit and Inspection / PSUR
- ▶ Jan 2015 Management & Reporting Of ICSRs
- ▶ Jan 2015 Ethics, Data Protection and Confidentiality in Clinical Research
- ▶ Dec 2014 “Personal Development” Training & Workshop
- ▶ Dec 2014 “Audit Techniques & Etiquette” Training
- ▶ Sep 2014 GPvP – Drug Safety / Device Safety
- ▶ Aug 2014 Training program on GLP and GCP
- ▶ Mar 2014 “Caring for Customers”
- ▶ Feb 2013 Compliance Systems, Monitoring and Evaluation
- ▶ Mar 2013 Training program for Project Management Professional (PMP)

- ▶ Jan 2013
- ▶ Jan 2013

Introduction to PV – Arab and EU Regulations & Guidelines
 Training program on GLP, GMP and GDP

SUMMARY OF TRAINING EXPERIENCE

Indicators	Numbers
# of Years as Trainer	11 years
# of Completed Trainings)	> 120 trainings
# of Covered Clients	> 35 Clients
# of Total Learners	> 2,100 Learners
Main Countries	Lebanon, Egypt, Jordan, Turkey, UAE, Iran, Algeria, Qatar

SPEECHES & DELIVERED TRAININGS

- 2019** GMP, GDP and ISO Sessions
- 2018** Lecturer in "Biomarketing Course"
Université Saint Joseph – Lebanon
- 2018** Introduction to GMP
ClinGroup Holding Client – MENA
- 2018** Good Storage & Distribution Practices
ClinGroup Holding Client – MENA
- 2017** Quality in Good Clinical Practices
ClinGroup Holding Client – MENA
- 2017** HR Mapping, Recruitment and Performance Evaluation
- 2017** Trainer on KPIs and QIPs
ClinGroup Holding Client – MENA
- 2016** Lecturer in "Biomarketing Course"
Université Saint Joseph – Lebanon
- 2012 – 2016** Trainer on Quality Management Systems & Best Practices
ISO Standards, GCP, GMP, GSP, GDP, Etc.
ClinGroup Holding Clients – MENA
- 2013 – 2016** Trainer on Business Development Plans & Business Plans Trainer on
Marketing Tactics, Strategies and Sales Approaches Trainer on Job Profiles,
Job Competencies & Interview Hints
Trainer on Performance Management, Employees Schemes & Benefits
ClinGroup Holding Clients – MENA
- 2014 & 2015** Speaker at the Annual Conference of 'Quality in Physical Therapy'
Order of Lebanese Physical Therapy (OPTL) – Lebanon
- 2014 & 2015** Trainer on 'Management & Capacity Building of NGOs'
Ministry of Social Affairs – Lebanon
- 2015** Trainer on Basics of Business Development
ClinGroup Holding – Lebanon
- 2014** Trainer on Project Management
ClinGroup Holding – Lebanon
- 2014** Speaker on 'Quality in Clinical Research'
Lebanese Advanced Association for Sciences (LAAS) – Lebanon
- 2014** Trainer on Business Communication Skills & Business Etiquette
ClinGroup Holding – Lebanon
- 2013 & 2014** Trainer on 'Standards of Physical Therapy'
Order of Physical Therapy (OPTL) – Lebanon
- 2011 – 2013** Trainer on Pharmaceutical Code of Ethics &
Business Conduct Quality in Healthcare
(GMP, ISO and Local Regulations) *Algorithm
Pharma – Lebanon*

REFERENCES & CLIENTS PORTFOLIO

Available upon request (separate documents)