



*Clinical Quality Assurance Experts
for the US and Asia Pacific*

Our Mission: To provide our clients with objective Clinical Quality Assurance (QA) oversight as it relates to the conduct of clinical research and clinical laboratory accreditation. Our clinical QA services are driven by ethics and competency which is supported by our comprehensive understanding of regulatory requirements and industry standards. We strive to ensure that our services exceed industry expectations which, in turn, ensures our client's success.

Who We Are: CliniQAL, Inc. (*Klini - Kwal*) is a network of seasoned industry professionals with international and US clinical research and clinical laboratory expertise. We provide consulting services to include: quality auditing, QA infrastructure development, training and clinical laboratory accreditation services. Our efforts are focused on the US and Asia Pacific markets.

What We Do:

Primary Services

- **Quality Auditing** – *Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and Good Clinical Laboratory Practice (GCLP) (i.e., Sponsor, Clinical Site, Vendor/Contractor, For Cause Investigations, Prequalification Audits, Electronic Systems Evaluation).*
- **QA Infrastructure Development**
- **Training** – *in support of GCP and clinical laboratory activities.*
- **Clinical Laboratory Accreditation Services** – *we specialize in international and US College of American Pathologist (CAP) accreditation.*
- **Prequalification audits and Preparation Service** – *review quality systems in lieu of regulatory and/or notified body inspections/audits.*

Secondary Services

- **Good Manufacturing Practice (GMP)** – *quality auditing, training and systems / infrastructure development.*
- **Regulatory Affairs** – *regulatory document review, preparations and submissions.*

Our Website: www.cliniQAL.net

The CliniQAL, Inc. website provides our visitors with content which is designed to aid clinical research and clinical laboratory professionals in the United States and Asia Pacific.

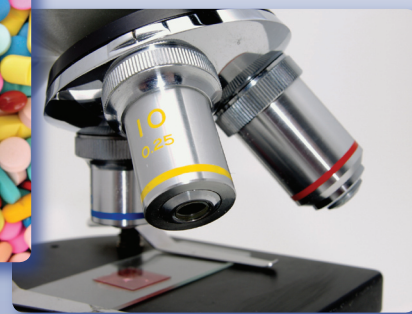
The following information and services will be available and updated on a regular basis:

- The website can be viewed in multiple language formats.
- Links to applicable country specific regulatory agencies, ministries of health and other government and notified body web sites.
- U.S. and Asia Pacific regulatory information – *helpful information for those that wish to conduct clinical research in Asia to include: country specific regulatory agency names and contacts, country specific requirements for the conduct of clinical research, estimated times of approval for conduct of clinical studies and product approval.*
- Forum / Blog
- Ask the Expert – *contact the President of CliniQAL, Inc. for expert advice or join the forum to post and discuss relative issues with other industry professionals.*



Tobin C. Guarnacci
Founder, President and Principal Consultant

Tobin brings 20 years of relative experience to the field of Quality Assurance (QA) related to clinical studies of biologics, drugs and medical devices.



Summary of Experience

- Former Consumer Safety Officer with US FDA
- Over fourteen (14) years of international and domestic QA and quality auditing experience related to GCP, GMP and clinical laboratory auditing and accreditation.
- Nine (9) years of management and project management expertise related to GCP and GLCP (e.g. Clinical and Clinical Laboratory QA infrastructure development and maintenance).
- Seven (7) years experience as a clinical microbiologist.
- Tobin spent 8 years in Thailand supporting the QA process as it related to US sponsored HIV and Dengue Hemorrhagic Fever vaccine trials and has extensive experience conducting GMP, GCP, GCLP (to include CAP and CLIA) auditing and/or infrastructure development in Australia, Brazil, Germany, Japan, Thailand and the USA.
- Tobin was responsible for securing the first College of American Pathologist (CAP) international accreditation (with distinction) for three clinical laboratories in South East Asia (Thailand).

For additional information please contact us at: 4104 24th Street, Suite 711 San Francisco, CA 94114 USA

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