The Auditing Group

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The Auditing Group

- GxP AUDITING SERVICES
  - Mock FDA Audits
  - GMP / API Audits
  - GLP Audits
  - GCP / Site Audits
  - IT & Electronic Systems Audits
  - Validation Audits
- REMEDIATION SERVICES
- TRAINING – GMP GLP GCP
- VALIDATION
- CAPA MANAGEMENT
- QUALITY ASSURANCE

The Auditing Group

Audit Services

- ***GMP – Good Manufacturing Practice***
  - *US Parts 210/211 & Predicate Rules*
  - *Vendors & Suppliers,*
  - *API – Starting Materials Manufacturer*
  - *EU/EMeA, Canadian & WHO GMPs,*
  - *Facility &Site Audits,*
  - *Mock FDA, WHO, EMeA Audits,*
  - *Department & Internal Systems,*
  - *Documentation audits,*
  - *'For-cause' – 'Due Diligence' audits.*
  - *Standard Operating Procedures,*
  - *Validation & Qualifications*
  - *Good Documentation Practice Audits*
  - *Good Auditing Practices*
  - *Quality Assurance / Quality Control*
  - *CAPA, Recall & Complaint Systems*
  - *Quality Assurance – Quality Control*
  - *Employee Training &Qualification*

- ***GCP – Good Clinical Practice Audits,***
  - *CROs*
  - *Data Management*
  - *Laboratory Support*
  - *Investigator Sites*
  - *Database Audits*
  - *Filing Audits - IND, NDA, PMA/510k,& BLA*
  - *Drug Supply Management Audits*
  - *Training & Support Audits*

- ***GLP – Good Laboratory Practice***
  - *21 CFR Part 58 GLP*
  - *US Title 42 FDA Part 493 GLP*
  - *OECD, ISO, 17025,*
  - *EMeA/ICH, Canadian Health*
  - *Tox/Non-Tox Clinical Support,*
  - *Method / Equipment Validation,*
  - *LIMS, Data Transfer, Systems & Software Compliance*
  - *Animal Tagging & Process Systems*
  - *Deviations, OOS, CAPA Audits*
  - *Calibration, Maintenance & Engineering*

- ***Systems & Part 11 Compliance***
  - *Systems Audits*
  - *Software & Part 11 Audits*
  - *Good Programming Practices*
  - *EDC – SAS – Clinical Data Management Systems – ASPs, ISPs, & Data Houses*
  - *Validation Audits*
  - *Systems & Validation Audits*

- ***JCAHO Compliance***
  - *Hospital Mock Audits*
  - *Pharmacy Audits*
  - *Training / Educational Service*

The Auditing Group

Professional Consulting / Expert Implementation Assistance

- GMP, GLP, GCP, QSM Site Readiness Preparations – New & Existing Facilities
- Standard Operating Procedure & Quality Manual Development
- CAPA Management Services – From Remediation to Resolution
- Validation Consulting & Audit Services, Development & Execution
  - Process,
  - Systems,
  - Software,
  - Equipment, &
  - Facilities
- Documentation Development
- Engineering & Design Specifications Consulting Services
- Quality Assurance Department Development
- Education & Training Services
  - On-site 21 CFR Part 11 Training Seminars
  - On-site 21 CFR Part 820 Training Seminars
  - GMP 21 CFR Parts 210/211 Training Seminars
  - GMP API Training Seminars
  - GCP & GLP Training Seminars

The Auditing Group… Where Experience Counts

TAG was founded and incorporated in 2003 by John Cuspilich, President, along with a small group of industry-known, experienced GxP Auditors. Today we are a global network of experienced Auditors and Quality Assurance professionals.

The Latest Regulatory Updates & News

The Auditing Group & GMP Publications

The Auditing Group works closely with the leading regulations distributor, GMP Publications, as the Quality Auditing Group for review and qualifications of the Federal Regulations for the US FDA. So we bring real-time regulatory FDA, WHO & EMA updates to our projects, our Auditors, and to our clients.

GXP News

The Auditing Group publishes the weekly GXP News e-newsletter to over 150,000 subscribers, updating the industry with what is new within the FDA divisions, CDER, CBER and CDRH along with all of the changes to the Federal Regulations every week.

CAPA Management
A Practical Full-Service Solution

The Auditing Group supports the CAPA Manager service and CAPA Manager Software (SaaS) with our own CAPA Oversight and Management Engineers and Quality Assurance Subject Matter Experts.

Efficient…Practical…Cost-Effective!

We provide the option for you to outsource all, or part, of your CAPA Management program. From remediation to resolution through interactive weekly meetings and reporting tools using the FDA 21 CFR Part 11 Compliant Software solution.

You can find more info at www.capamanager.com

Your Quality Compliance Partner

The Auditing Group, Inc. (TAG) has extensive experience within the FDA, European, & International regulated industries working under the various standards (cGMP, cGCP, cGLP, Systems) with **one goal:**

to provide reliable Auditing, Remediation, Validation, Consulting, Training, and Quality Assurance services that efficiently provide the assistance our clients need to be compliant and to succeed.

With a company history of more than 11 years of regulated pharmaceutical industry experience, TAG provides the hands-on knowledge, industry experience and FDA insight that your company needs…

when you need it!