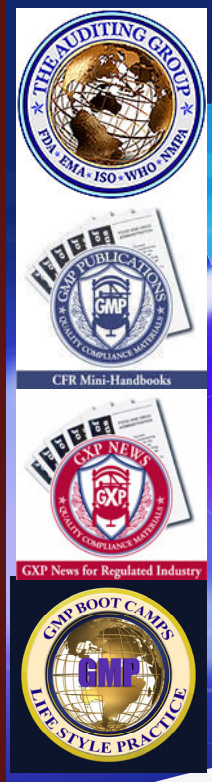
THE AUDITING GROUP

GMP Publications & GMP Boot Camps

Reinforcing GMP Lifestyles through
Training, Audit and Regulatory Guidance



- GXP Global Auditing
- Site Gap Analysis
- SME Consulting
- GXP and ISO Training
- Site Remediation
- FDA Readiness
- Mock Audits
- Turnkey QMS

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U.S Food and Drug Administration · European Medicines Agency · Santé Canada Health Canada · World Health Organization · CFDA China Food and Drug Administration · ISO · MHRA

GXP AUDITS AND REMEDIATION

- GMP AUDITING—MOCK AUDITING
- PHARMACEUTICAL, BIOTECHNOLOGY AUDITS
- MEDICAL DEVICE QSR AUDITS — ISO 13485:2016
- DIETARY SUPPLEMENTS
- COSMETICS & THERAPEUTIC PRODUCTS
- LABORATORY—GLP/GCLP—GMP & CLINICAL
- **VENDORS, SUPPLIERS QUALIFICATIONS**
- CMOs, CDMOs, CAOs, CPOs
- ENGINEERING AND FACILITIES QUALIFICATIONS
- TRAINING - ON-SITE AND REMOTE
- ISO PREPARATION & MOCK AUDIT
- CLINICAL AUDITS—SITE AUDITS
- REMEDIATION, VALIDATION & GAP ANALYSIS
- 21 CFR PART 11 COMPLIANCE
- ACQUISITIONS & BUSINESS VENTURE AUDITS
- FOLLOW UP FDA 483 AUDITS
- VALIDATION AUDITS:
  - PROCESS,
  - FACILITIES,
  - EQUIPMENT
  - PROCESS

GLOBAL SUPPORT

- **US Title 21 FDA, DEA, CDC, CDER, CBER, CDRH**
- EU GMPs, EU MDR
- Canadian GMPs
- China NMPA
- WHO and ISO Standards
- OECD, ICH, CE MARK

GMP/GXP AUDITING SERVICES

HELPING COMPANIES MEET AND EXCEED COMPLIANCE REQUIREMENTS THROUGH AUDIT.

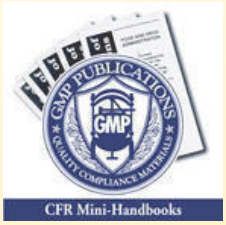
Since 1999, The Auditing Group's global presence, has been providing GXP Auditing SMEs supporting regulatory Agencies world-wide.

- United States and Canada
- China, Asian Countries, and India
- South and Central America, and Mexico
- Australia and the Pacific Rim

GMP, GXP & QSR, Device Training

Provides extensive on-site and remote Training programs for the regulated industry.

GMP Publications provide the handbooks, GMP Boot Camps provides the training!



- Good Manufacturing Practice Training
- Medical Device 820 QSR & ISO 13485
- Good Laboratory Practice (GLP, CGLP)
- Dietary Supplements & Cosmetics

More training at www.gmpbootcamps.com

Remediation & CAPA Management

Strict adherence to Gantt driven GPM is essential to ensure all tasks are completed in accordance with formal written procedures and attention to meeting timelines. All TAG SMEs have the Experience, Education, and Training to ensure that your remediation efforts meet Agency requirements.

- FDA 483 and Warning Letter Remediation
- Procedure Development and Implementation
- Validation Services
- Training Services
- Quality Management Systems Implementation
- GMP Design / Build Engineering and Analysis
- As-Built Drawing Management Services