

# Marion Weinreb & Associates, Inc.

Consulting Expertise in Quality Systems and GXP Compliance



Developing and implementing successful GXP quality systems and compliance strategies are what we do best. MWA affords you flexible, scalable resource options and solutions to meet your regulatory needs. Our consulting services integrate seamlessly with your operations and provide targeted, expert resources on demand.

---

Excellence in  
GXP QUALITY SYSTEMS  
and COMPLIANCE STRATEGIES

---

The pharmaceutical, medical device and biotech industries occupy a unique position in the business world. You have a special relationship with the people who use your products. It can be a life-saving relationship, where safety and efficacy depend on compliance to FDA requirements. MWA takes this responsibility seriously.

MWA shares in your commitment to quality and understands how critically important regulatory compliance is to the success of your business and to the health and safety of your customers. We stand ready to begin building a relationship with you that will address your specific regulatory requirements.

## Contact us Today

Discover the power of partnership with Marion Weinreb & Associates, Inc. and reach your compliance goals with our expert consulting support. We look forward to hearing from you.

Call 415.388.1695 or 866.497.7787 (toll-free)

Email: [info@gxpsrus.com](mailto:info@gxpsrus.com)

For more information, visit [www.gxpsrus.com](http://www.gxpsrus.com)



*MWA is a Women's Business Enterprise certified by the Women's Business Enterprise National Council—WBENC.*

[www.gxpsrus.com](http://www.gxpsrus.com)

# MWA SERVICES

## CONSULTING

Analytical/Quality Control (QC) Support  
Clinical and GCP Support  
CMC and Regulatory Affairs Support  
Compliance Audits and Assessments  
FDA Strategies  
Formulation Development  
GCP, GLP, GMP, ISO and QSR Compliance  
Manufacturing Compliance Oversight  
Manufacturing Engineering and Support  
Methods Development  
Microbiology Support  
Packaging Engineering and Validation  
Part 11 Compliance  
Pre-Approval (PAI) Auditing and Training  
Project Management  
Quality Systems/QA Development and Support  
Technical and Document Writing  
Training Programs: Standardized or Customized  
Validation: Cleaning, Equipment, Process, Software

## TRAINING

(Standardized and Customized Programs)  
Aseptic Techniques  
Effective Writing  
Equipment Qualification  
Failure Investigations  
FDA QSIT Audit Approach  
FDA Regulations (GCP, GLP and GMP)  
GMPs in Research and Development  
GMP/QSR Training  
Great Documentation Practices  
HACCP (Hazard Analysis and Critical Control Points)  
Interacting with FDA  
Internal and External Auditing Techniques  
ISO 13485:2003  
Out-of-Specification (OOS) Issues  
Overview of Methods Validation  
Packaging and Labeling GMPs  
PAI Preparation and Planning  
Part 11 Compliance  
QSIT Overview  
Technical Writing  
Validation: Key Concepts and Planning

## Expertise for the Pharmaceutical, Medical Device and Biotech Industries



Since 1995, MWA has grown into a worldwide consulting firm. With our extensive consulting capabilities and over 160 associates strategically located throughout the US, Canada and internationally, MWA can assist you in meeting your regulatory goals in pre-clinical, development or commercial operations.

MWA's expertise in GCP, GLP and GMP compliance, coupled with a hands-on approach, delivers strategies and solutions that will meet the regulatory demands of the 21<sup>st</sup> century.

We are committed to excellence in all aspects of the business and focus on establishing and maintaining strong partnerships and producing exceptional results for our clients.

Our experience ensures cost-effective and efficient service and the insight to anticipate and plan for your critical needs. We provide short and long-term consulting services like GXP audits, analytical/QC, validation, regulatory affairs support and much more.

Our creative solutions provide you with value-added options in addressing your strategic resource needs. In every case, we customize our services to the specific requirements of our clients to achieve their goals most efficiently.

