What is GxP?

GxP is a collection of quality guidelines and regulations created to ensure that bio/pharmaceutical products are safe, meet their intended use, and adhere to quality processes during manufacturing, control, storage, and distribution.

GxP was established by the Food and Drug Administration (FDA) and encompasses different standards recognized as:

G – stands for “Good”

P – stands for “Practice”

x – variable depending on the application. It can be M for “Manufacturing”, C for “Clinical”, L for “Laboratory”, S for “Storage”, D for “Distribution”, R for “Review”, etc.
GxP ensures that regulated organizations comply with specific and secure manufacturing and storage processes and procedures which determine effective research standards for non-clinical laboratory trials and safe human-subject clinical trials. GxP’s guidelines focus on:

- **Traceability**: the ability to reconstruct the development history of a drug or medical device.
- **Accountability**: the ability to resolve who has contributed what to the development and when.
- **Data Integrity (DI)**: the reliability of data generated by the system. DI could be determined by the following activities:
  - Identifying the data generated by the system during critical processes (data flow diagram)
  - Defining the DI requirements (e.g. ALCOA data attributes) during the lifecycle of data
  - Identifying the risks and mitigation strategies (e.g. technical or procedural controls) to avoid DI breaches.

**Who is impacted by GxP?**

Regulated industries including food, pharma, medical devices, and cosmetics are impacted by GxP. GxP guidelines and regulations are global; some of the popular regulators include FDA in the US, TGA in Australia, and HS-SC in Canada. GxP includes varied regulation sets, but the most common are GCP, GLP, and GMP:

- **GCP (Good Clinical Practice)**
  GCP is an international quality standard that is provided by the International Conference on Harmonisation (ICH), an international body that defines standards which governments can transpose into regulations for clinical trials involving human subjects. It controls experimentation on humans done for the sake of advancement in medical sciences and serves as a quality benchmark as well as a moderator that keeps such experimentation in check.

- **GLP (Good Laboratory Practice)**
  GLP is the non-clinical counterpart for GCP. These guidelines apply to non-clinical studies conducted for the assessment of the safety or efficacy of chemicals (including pharmaceuticals) to humans, animals, and the environment.

- **GMP (Good Manufacturing Practice)**
  GMP consolidates the practices required to conform to the guidelines recommended by agencies that control authorization and licensing for the manufacture and sale of food, drug, and active pharmaceutical products. These guidelines provide minimum requirements that a pharmaceutical or a food product manufacturer must meet to ensure that the products are of high quality and do not pose a risk to the consumer or public.

Good manufacturing practices, along with good laboratory practices and good clinical practices are overseen by regulatory agencies in the United States, Canada, Europe, China, and other countries. The most common GMP guidance documents are:

- **EU Good Manufacturing Practice (GMP) Guidelines**, Volume 4
- **US FDA current Good Manufacturing Practice (cGMP) guidelines**: 21 CFR Part 11, 210, 211, and 820
ClearDATA Advantage
ClearDATA Compliance & Security Monitoring Dashboard

With healthcare transformation moving at a rapid pace, compliance and security monitoring across the healthcare enterprise is a major HIT challenge.

ClearDATA Compliance and Security Dashboard simplifies adherence to administrative, physical and technical safeguards. Our Dashboard is mapped directly to HIPAA and FDA and GDPR guidelines.* It can be enabled across different cloud environments and easily monitor thousands of components, providing unique individual asset scorecards as well as a wide variety of additional reports.

*coming soon

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**Key Scorecard Metrics & Features**

- **Encryption Verification**: Validate that your storage medium is successfully encrypted to ensure compliance for FDA – 21 CFR Part 11.30.

- **Login & Log Monitoring**: Quickly identify and mitigate the risk of unauthorized system access to ensure compliance for FDA -- 21 CFR Part 11.10(g).

- **Log Retention**: Securely retain six-years of access logs with automated validation to ensure compliance for FDA – 21 CFR Part 11.10(e).

- **Patch Level Reporting**: Receive notifications when new patches become available and quickly track previous updates to ensure compliance for FDA – 21 CFR Part 820.30(i).

- **Backup Validation**: Monitor and validate backups to ensure they were successful. Receive real-time notifications in the event of a failure to ensure compliance for FDA -- 21 CFR Part 11.10(e).

- **Virus Scan/Intrusion Detection Status**: Monitor and validate that a daily vulnerability scan has been performed on each asset to ensure compliance with FDA – 21 CFR Part 11.10(h).
# GxP Readiness Checklist

Partner with a healthcare expert/managed service provider to address the following items:

1. Define Quality System Regulation (QSR) gaps
2. If applicable, discuss how to perform a Computer System Validation (CSV)
3. Ensure that the following controls and procedures are implemented:
   - Backup and Recovery
   - Contingency Plan
   - Disaster Recovery
   - Change Control Management
   - Configuration Management
   - Error Handling
   - Maintenance and Support
   - Corrective Measures
   - System Access

Prepare for your GxP Validation Process:

1. Decide which GxP guidelines apply to you
2. Decide how your technology maps to GxP guidelines
3. Define User Requirements
   - What are your user needs?
4. Functional Specifications
   - What will be automated?
5. Solution Analysis
   - Validation of your system
6. Build and Construction
   - System detailed design specifications
   - System test procedures
   - Quality review
### 7. Implementation

- Preparation
- Data Migration (legacy systems)
- Production
- Roles and Responsibilities

### 8. Establish change control process

- Establish change control logs
- Establish patch/upgrade logs

### 9. Access Control System

### 10. Configuration Management

- Establish change control logs

### Prepare for your GxP Validation Process (continued):

### 11. Audit Trails

- Secure, computer-generated and time-stamped

### 12. Archive/Backup/Recovery

- Availability and Continuity Plan
- Accurate and complete records
- Ability to retrieve records
- Backup Restoration Protocols

### 13. Security Controls

- Encryption (rest and transit)
- Network encryption
- Intrusion detection
- Virus scanning

### 14. Quality System Gaps

- Security and Compliance Audit Process