Good Documentation Practice (GDocP): Global Regulatory Foundations and Best Practices

A Comprehensive Introduction

AGENDA

Presentation overview and learning journey.

01	**Introduction & Importance of GDocP**	Why documentation practice is critical to data integrity, patient safety, and regulatory compliance.
02	**Regulatory Framework Overview**	Key global guidelines: ICH, FDA, EMA, PIC/S, and WHO regulatory hierarchy.
03	**Core Principles of GDocP**	The ALCOA+ framework: Attributable, Legible, Contemporaneous, Original, Accurate, and more.
04	**Documentation Types & Quality Requirements**	Batch records, SOPs, protocols, change control, training records, and electronic audit trails.
05	**Compliance Examples, Timeline & Best Practices**	Do's and don'ts, regulatory milestones, implementation guidance, and summary Q&A.

WHY IT MATTERS

Good documentation

is the backbone of quality.

Good Documentation Practice (GDocP) ensures data integrity, traceability, and regulatory compliance across every stage of the product lifecycle. It is the foundation for GMP, GCP, and GLP systems — protecting patients, supporting audits, and sustaining license to operate in every market we serve.

I
Data Integrity
Ensures records are accurate, complete, and traceable throughout the entire product and process lifecycle.

II
Patient Safety
Supports product quality decisions that directly protect patients and end users from documentation-related failures.

III
Audit Readiness
Maintains inspection-ready documentation at all times, enabling swift and confident responses to regulatory audits.

REGULATORY FRAMEWORK

Global Regulatory Framework Overview.

Good Documentation Practice is governed by a hierarchy of international and regional guidelines. Understanding the sources — from ICH and WHO at the global level to FDA, EMA, and PIC/S at the regional level — is essential for achieving and sustaining compliance across all markets.

I
ICH & WHO
Global standards: ICH Q7 (GMP for APIs) and WHO Technical Report Series establish the international baseline for documentation requirements.

II
FDA & EMA
Regional regulations: FDA 21 CFR Part 11 (electronic records), FDA GMP regulations, and EMA GMP Annex 11 define binding requirements for their respective jurisdictions.

III
PIC/S & Company SOPs
Industry best practices: PIC/S PI 007-1 harmonizes GDocP across member authorities. Company SOPs translate these requirements into site-level quality systems.

KEY REFERENCES

Key Regulatory Guideline References.

01	**ICH Q7: GMP for Active Pharmaceutical Ingredients**	Section 6 establishes documentation requirements for API manufacturing, including batch records, SOPs, and laboratory controls.
02	**FDA 21 CFR Part 11: Electronic Records & Signatures**	Defines criteria for electronic records and signatures to be considered trustworthy, reliable, and equivalent to paper records.
03	**PIC/S PI 007-1: Good Documentation Practices**	Dedicated GDocP guidance covering ALCOA principles, error correction, and documentation standards for GMP environments.
04	**EMA GMP Annex 11: Computerised Systems**	Addresses validation, data integrity, audit trails, and electronic signatures for computerised systems in GMP-regulated environments.
05	**WHO TRS 1010: GMP Guidance**	WHO Technical Report Series No. 1010 provides internationally recognised GMP standards including documentation and data integrity requirements.

REGULATORY HIERARCHY VISUAL

From global standards to company practice — how requirements cascade.

LEVEL 01
Global Standards
ICH guidelines (Q7, Q9, Q10) and WHO Technical Report Series establish the international baseline for GDocP and GMP.

LEVEL 02
Regional Regulations
FDA (21 CFR Parts 11, 210, 211) and EMA GMP Annexes translate global principles into enforceable regional requirements.

LEVEL 03
Industry Best Practices
PIC/S PI 007-1 and industry guidance harmonize expectations across participating authorities and sectors.

LEVEL 04
Company SOPs
Internal SOPs, quality systems, and controlled documents operationalize all higher-level requirements at the site level.

CORE PRINCIPLES OF GDOCP

Six principles for trustworthy records.

01 **Attributable**
Every entry must be traceable to the individual who performed the action — identified by name, signature, or unique login.

02 **Legible**
Records must be clear, readable, and permanent — written in durable ink or captured in a validated electronic system.

03 **Contemporaneous**
Document activities at the time they occur — never in advance or from memory after the fact.

04 **Original**
Retain the first-captured record. Copies must be verified, and the original preserved as the authoritative source.

05 **Accurate & Complete**
All data must be correct, truthful, and fully recorded — with no omissions. Together, these six principles underpin data integrity and regulatory confidence.

GDOCP PRINCIPLES EXPLAINED

The ALCOA Principles in Practice.

Each GDocP principle translates into a specific, actionable documentation behavior. Together, they form the foundation of data integrity and regulatory compliance across all life-sciences operations globally.

16 **Attributable**
Every entry must be traceable to the person who made it. Sign and date all records at the time of creation. Use unique identifiers and never share login credentials or signatures.

Legible & Original
Legible: All entries must be clear, permanent, and readable throughout the document's retention period. Original: Record data directly — never transcribe from scraps or unofficial notes.

Contemporaneous, Accurate & Complete
Contemporaneous: Record data at the time of the activity — no backdating. Accurate: Entries must reflect true observations. Complete: No blank fields; use N/A where not applicable.

Compliant documentation in practice.

A well-maintained record is the cornerstone of regulatory compliance. Compliant documentation is clear, complete, and traceable — enabling auditors, inspectors, and colleagues to reconstruct every action taken without ambiguity.

I **Dated and Signed**
Every entry must include the date of recording and the author's handwritten or approved electronic signature in ink.

II **Approved Templates**
Records must be completed on controlled, version-approved forms and logbooks to ensure consistency and traceability.

III **Legible and Complete**
Entries must be written clearly in permanent ink with no blank fields — all required data points captured at the time of activity.

NON-COMPLIANT DOCUMENTATION

Examples: Non-Compliant Documentation

The following examples illustrate common documentation failures observed during regulatory inspections. Each error undermines data integrity and traceability, and may result in audit findings, product recalls, or regulatory sanctions.

01 **Unsigned Corrections**
Text crossed out without a single-line strike-through, date, reason, or signature. Use of correction fluid (white-out) to conceal original entries is strictly prohibited.

02 **Illegible Entries**
Handwritten data that cannot be read or interpreted unambiguously. Illegible records cannot be verified during audits and compromise traceability and data integrity.

03 **Missing Dates or Initials**
Entries lacking a date, time, or author initials cannot be attributed to a specific person or moment. Uncontrolled or unapproved form versions further invalidate the record.

DOCUMENTATION TYPES IN LIFE SCIENCES

Key Records Across Life-Sciences Operations

01 **Batch Records**
Comprehensive records documenting each step of manufacturing, including materials, equipment, and in-process controls for every production batch.

02 **Standard Operating Procedures (SOPs)**
Approved written instructions describing routine operations, processes, and quality activities to ensure consistency and compliance across sites.

03 **Protocols and Reports**
Validation protocols, study plans, and corresponding reports that document objectives, methods, results, and conclusions for regulated activities.

04 **Change Control Forms**
Formal documentation for proposing, evaluating, approving, and implementing changes to processes, systems, or materials within the quality system.

05 **Training Records**
Records evidencing staff qualification, SOP training completion, and competency assessments required to demonstrate regulatory readiness.

TIMELINE

Regulatory Timeline: Evolution of GDocP.

16	**1970s — GMP Inception**	WHO and FDA establish foundational GMP regulations, introducing formal documentation requirements for pharmaceutical manufacturing and quality control.
02	**1990s — ICH Guideline Development**	ICH launches harmonized guidelines (Q7, Q9, Q10), aligning documentation standards across the US, EU, and Japan for APIs and finished products.
03	**1997 — FDA 21 CFR Part 11**	FDA issues 21 CFR Part 11, establishing requirements for electronic records and electronic signatures, extending GDocP into digital environments.
04	**2000s–2010s — EMA Annex 11 Updates**	EMA revises GMP Annex 11 (2011) to address computerized systems, audit trails, and data integrity, reinforcing electronic documentation compliance across the EU.
05	**2010s–Present — PIC/S Revisions and ALCOA+**	PIC/S updates PI 007-6 and member agencies reinforce ALCOA+ data integrity principles, driving global harmonization of GDocP expectations through today.

QMS INTEGRATION

GDocP and Quality Management System Integration.

PILLAR 01

CAPA

GDocP records provide the documented evidence required to initiate, track, and close corrective and preventive actions effectively.

PILLAR 02

Change Control

Accurate documentation ensures all changes to processes, systems, and materials are reviewed, approved, and traceable.

PILLAR 03

Risk Management

Complete and reliable records support risk assessments, hazard identification, and mitigation documentation across the product lifecycle.

PILLAR 04

Continuous Improvement

Training records, deviation logs, and audit findings feed back into the QMS to drive ongoing improvement and sustained compliance.

REFERENCES

Reference Documents and Sources (1)

01 **ICH Q7: Good Manufacturing Practice for Active Pharmaceutical Ingredients**
International Council for Harmonisation. ICH Q7: GMP Guide for APIs, Section 6 — Documentation. Geneva: ICH; 2000. Available at: ich.org/products/guidelines/quality/q7

02 **ICH Q9 and Q10: Quality Risk Management and Pharmaceutical Quality System**
ICH Q9: Quality Risk Management (2005); ICH Q10: Pharmaceutical Quality System (2008). Geneva: ICH. Available at: ich.org/products/guidelines/quality

03 **FDA 21 CFR Part 11: Electronic Records and Electronic Signatures**
U.S. Food and Drug Administration. 21 CFR Part 11: Electronic Records; Electronic Signatures. Washington, DC: FDA. Available at: ecfr.gov/current/title-21/chapter-I/part-11

04 **FDA 21 CFR Parts 210 and 211: Current Good Manufacturing Practice**
U.S. FDA. 21 CFR Part 210: cGMP in Manufacturing; 21 CFR Part 211: cGMP for Finished Pharmaceuticals. Available at: ecfr.gov/current/title-21/chapter-I/part-210 and /part-211

05 **PIC/S PI 007-1: Good Practices for Documentation**
Pharmaceutical Inspection Co-operation Scheme. PI 007-1: Recommendations on Validation Master Plan, Installation and Operational Qualification, Non-Sterile Process Validation, and Cleaning Validation. Geneva: PIC/S. Available at: picscheme.org

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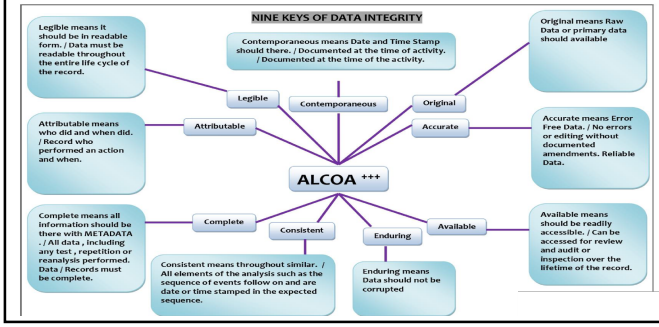
Reference Documents and Sources (2)

01 **EMA GMP Annex 11: Computerised Systems**
European Medicines Agency. Annex 11 to the EU GMP Guidelines — requirements for computerised systems including audit trails and electronic signatures.

02 **EMA GMP Annex 15: Qualification and Validation**
European Medicines Agency. Annex 15 to the EU GMP Guidelines — qualification, validation, and documentation requirements for life-sciences processes.

03 **WHO Technical Report Series No. 1010**
World Health Organization. TRS No. 1010, Annex 4 — WHO good manufacturing practices: guidelines on validation (2019). Includes GDocP requirements.

04 **Industry Whitepapers and Best-Practice Guides**
ISPE GAMP 5 (2nd ed.); PDA Technical Reports on data integrity; IPEC-PQG GMP Guide; recognized GDocP best-practice publications from industry associations.



THANK YOU

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