

# DOCUMENTATION IN PHARMACEUTICAL INDUSTRY



**Centurion**  
**UNIVERSITY**

**Record Keeping and**  
**Documentation**



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# INTRODUCTION



- ❑ A **DOCUMENT** is a piece of written, printed, or electronic matter that provides information or evidence or that serves as an official record.
- ❑ Documents should be designed, prepared, reviewed, and distributed for use per established procedures.
- ❑ **Good Documentation Practice** (GDP or GDocP), a term use in the pharmaceutical industry, is essential for the integrity of data collection and reporting for supporting development, registrations, commercialization, and life-cycle management of pharmaceutical products.





# DOCUMENTATION

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“ Documentation is any communicable material that is used to describe, explain or instruct regarding some attributes of an object, system or procedure, such as its parts, assembly, installation, maintenance and use.”

**Documentation provides Both;**



**Information** on when, where, who, why & How to Complete tasks

**Evidence** providing that the tasks have been completed as they should be.



**DOCUMENTATION** should be as detail as possible. A list of some examples (but not limited to) to be included in the document are:

- D** = Design, **Development**, deviations, dossiers and **Drug Master Files** for regulated markets, **Distribution Records** etc.
- O** = Operational procedures/techniques/methods, Out of specifications (OOS), Out of trend (OOT) etc.
- C** = Cleaning, calibration, controls, complaints, **Certificate of Analysis (CoA)** ,containers and closures, contamination and change control etc.
- U** = User requirement specifications, utilities like water systems, HVAC, etc.
- M** = Man, materials, machines, methods, maintenance, **MANUFACTURING** operations and controls, monitoring, master formula, manuals (quality, safety and environment), medical records, **Master Formula Record** etc.
- E** = Engineering control and practices, Environment control, Equipment qualification documents, **Exploratory Product Development Brief (EPDB) for Drug substance and Drug product** etc.
- N** = Non-routine activities, New products and substances etc.
- T** = Technology transfer, training, testing, Trend analysis, Technical dossiers etc.
- S** = SOPs, safety practices, sanitation, storage, self-inspection, standardization, supplier qualification, specifications and standard test procedures and **SITE MASTER FILE**.



# PHARMACEUTICAL DOCUMENTS

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Good documentation were first described by US-FDA in the form of **ALCOA** –

**A = *Attributable*** (Records and data linked to the individual or system performing the action.)

**L = *Legible*** (All data recorded must be legible (readable) and permanent)

**C = *Contemporaneous*** ( Record the result, measurement or data at the time the work is performed. )

**O = *Original*** (Source information accessible and preserved in its original form)

**A = *Accurate*** (Data are correct, truthful, complete, valid and reliable.)

**NOTE** - Proper verification of source documents to ensure data integrity, validity, and subject safety among other aspects.





# ALCOA+

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Recently ALCOA has been updated to ALCOA+ which is widely used by the WHO and FDA.

- **Complete** - All data is available, nothing has been deleted and evidence must be available in an audit trail.
- **Consistent** - Data is recorded chronologically with data and time evident again in an audit trail.
- **Enduring** - Data is accessible for an extended period of time.
- **Available** - Data is accessible over the lifetime of the product.





# DRUG SUBSTANCE

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□ **DRUG SUBSTANCE** is an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.

- ✓ Demonstration batch
- ✓ Certificate of analysis for each batch manufactured (final API and reference standards)
- ✓ BSE/TSE statements and GMP certificate
- ✓ Process development (including manufacture of demonstration batch) report
- ✓ Process safety assessment report
- ✓ cGMP campaign report
- ✓ Master and executed batch records
- ✓ Analytical test procedures, methods validation protocols and reports
- ✓ Reference standards and analytical markers characterization report
- ✓ Forced degradation study report
- ✓ Specifications for API release
- ✓ ICH stability protocol, interim and final reports
- ✓ Biweekly updates on project progress
- ✓ Documentation suitable for IMPD submission





# DRUG PRODUCT



❑ **DRUG PRODUCT** is a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

- ✓ Clinical batches supply
- ✓ Certificate of analysis and statement of cGMP compliance (per batch manufactured)
- ✓ TSE statements for excipients
- ✓ Formulation development reports
- ✓ Executed batch records for DP manufacturing
- ✓ Analytical test procedures, methods validation protocols and reports
- ✓ Specifications for DP release
- ✓ ICH stability protocol, interim and final reports
- ✓ Biweekly updates on project progress
- ✓ Documentation suitable for IMPD submission





# EXPDB DOCUMENTS



**EXPLORATORY PRODUCT DEVELOPMENT BRIEF** - Clarify preclinical and clinical approaches, as well as chemistry, manufacturing, and controls information, should be considered when planning exploratory studies in humans, including studies of closely related drugs or therapeutic biological products, under an investigational new drug (IND) application.

Information on a clinical development plan .

Chemistry, manufacturing, and controls information .

Pharmacology and toxicology information .

Previous human experience with the investigational candidate or related compounds.

Other.



## ➤ CLINICAL INFORMATION

- ✓ Introductory statement and general investigational plan
- ✓ Types of studies



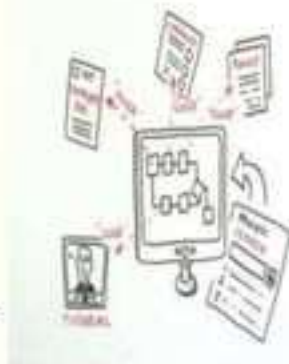
## ➤ CHEMISTRY, MANUFACTURING, AND CONTROLS INFORMATION

- ✓ General information for the candidate product
- ✓ Analytical characterization of candidate product



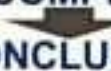
## ➤ SAFETY PROGRAM DESIGNS

- ✓ Clinical studies of pharmacokinetics or imaging
- ✓ Clinical trials to study pharmacologically relevant doses
- ✓ Clinical studies of MOAs related to efficacy




## ➤ GLP COMPLIANCE

## ➤ CONCLUSION



# Types of documents



- Commitment document: Relationship between industry and the regulatory authorities.
- Directive document : Relationship between management and employee.
- Record document : Relationship between the employee and the work they perform.





*Thank You*

