FEDERCHIMICA
ASCHIMFARMA
Associazione nazionale produttori principi attivi
e intermedi per l'industria farmaceutica

Introduction to the theme: Data Integrity a logical outcome of Good Documentation rules

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WORKSHOP

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Data Integrity: reliability, quality and competitiveness factors of API manufacturers

Data Integrity: fattore di affidabilità, qualità e competitività del produttore di API

GRUPPO DI STUDIO ASCHIMFARMA: "DATA INTEGRITY"

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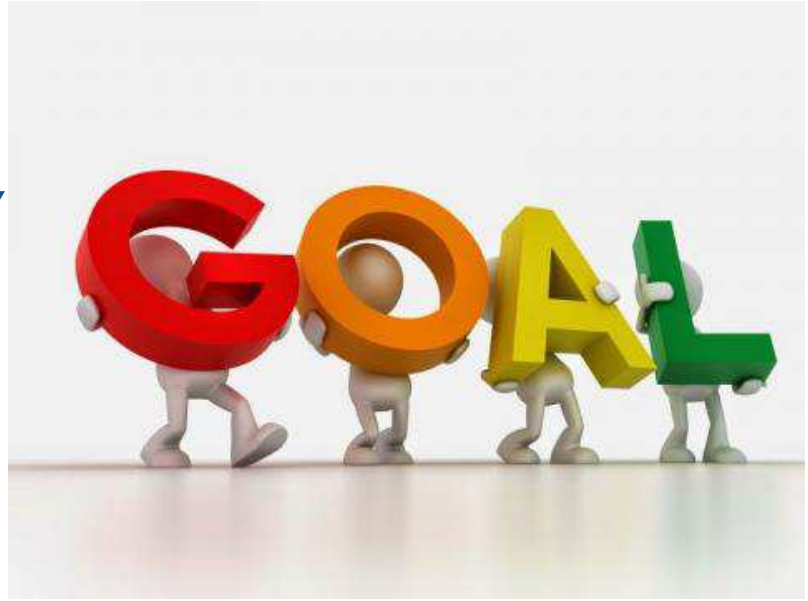
DATA INTEGRITY



The data integrity has to be considered as an intrinsic and fundamental aspect in a Quality System, being the target to guarantee that the active substances to be marketed are in compliance to the required quality and with the filed documentation.

INVESTIGATION BY AUTHORITIES

Proper data management is therefore considered by the Authorities as a key element of the Pharmaceutical Quality System to ensure the required quality of active ingredients and medicines. As such, it has become subject to careful investigation during AIFA's and FDA's inspection activities, but generally by all Regulatory Authorities

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DATA INTEGRITY COMPLIANCE

- essential part of Quality System
- a way to be excellent
- a way to be competitive

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GOOD DOCUMENTATION PRACTICES

- ✓ EudraLex The Rules Governing Medicinal Products in the European Union Volume 4 Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Part I: Basis requirements for medicinal products, Chapter 4: Documentation
- ✓ EudraLex The Rules Governing Medicinal Products in the European Union Volume 4 Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Part II: Basis requirements for active substances used as starting materials, Chapter 6: Documentation
- ✓ GMP regulations for drugs (21 CFR Parts 211)

WHY GDocP?

The soul of documentation is, naturally, the written word. What happens when something that happened is not actually written down? It is a work of no practical use, because apart from those that carried out the particular undocumented task; no one else is aware of it. And even when the people who did that task or were witness to it are prone to have their own interpretation and perception of what was done. This is why proof in the form of writing is the most important element of Good Documentation Practices.

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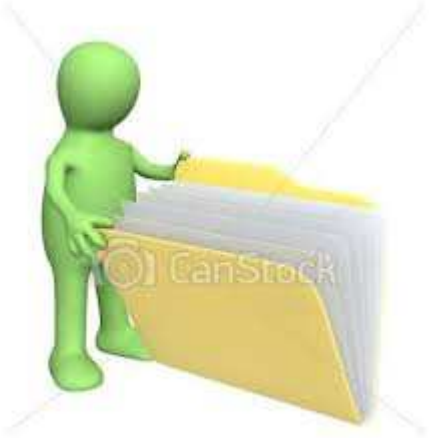
GOOD DOCUMENTATION PRACTICES

Documents governing the relationship between Industry and Regulatory Authorities → SMF

Documents governing the relationship between the Management and Employes → SOPs

Documents governing the relationship between the employes and the work they do → Batch Records, logbooks



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Good Documentation Practices

- Ensures reliable and consistent transfer of information
- Indispensable to produce quality results
- Helps to maintain traceability and accuracy
- Guarantees trasparency agaist fraud and dishonesty

Good Documentation Practices

- Paper based systems
- Computerized based systems
- Hybryd systems

GOOD PRACTICES FOR DATA MANAGEMENT AND INTEGRITY IN REGULATED GMP/GDP ENVIRONMENTS, AUG. 2016, PIC/S

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DEFICIENCIES TO GDocP

CRITICAL

"A critical deficiency is a practice or process that has produced, or leads to a significant risk of producing either a product which is harmful to the human or veterinary patient or a product which could result in a harmful residue in a food producing animal. A critical deficiency also occurs when it is observed that the manufacturer has engaged in fraud, misrepresentation or falsification of products or data".

DEFICIENCIES TO GDocP

Data integrity deficiencies can also relate to:

- Data integrity failure resulting from bad practice,
- Opportunity for failure (without evidence of actual failure) due to absence of the required data control measures.

Impact to product with risk to patient health CRITICAL DEFICIENCY	Impact to product with no risk to patient health MAJOR DEFICIENCY
No impact to product; evidence of widespread failure: MAJOR DEFICIENCY	No impact to product; limited evidence of failure: OTHER DEFICIENCY

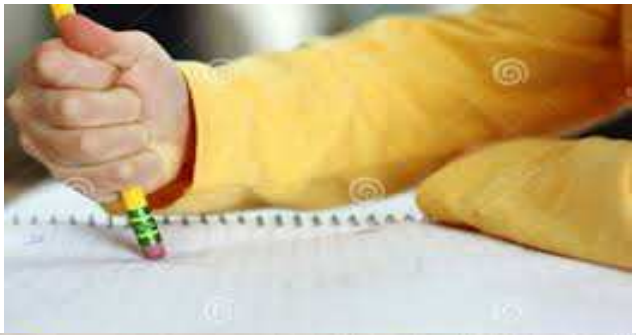
AS PER GMP REQUIREMENTS

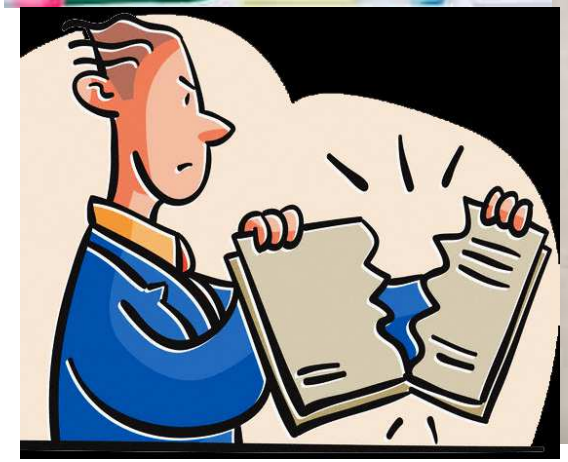
If it is not written down, then it did not happen

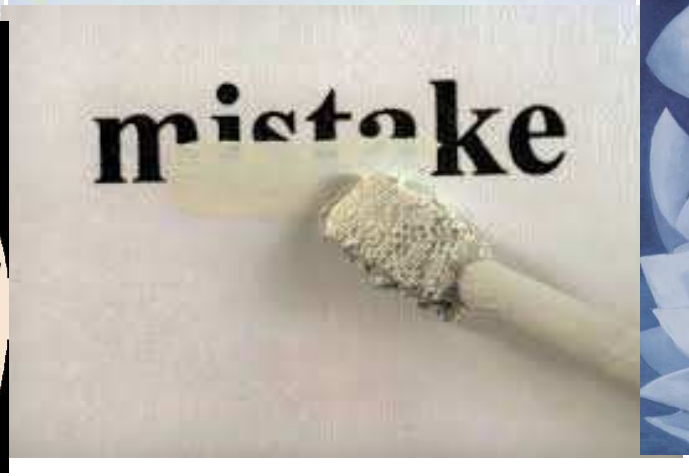
AS PER DATA INTEGRITY REQUIREMENTS

ensuring the integrity and completeness of such data

GDocP in brief







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DATA INTEGRITY AS LOGICAL OUTCOME OF GDocP COMPLIANCE