



An Introduction to Compliance & Data Integrity

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* في الشركات الصيدلانية تزايد الاهتمام بـ Compliance & data integrity في آخر السنوات
 كدورات تدريبية وورشات عمل ، و يوجد دورات مدفوعة
 في هاد المجال ، كتب الشركات من زمان مبيعة Compliance من خلال guideline



The pharmaceutical industry is one of the most highly regulated sectors globally.

لأنه attached مع صحة الإنسان



Our primary focus is on ensuring the quality, safety, and efficacy of medicines that impact human health.

* لأنهم نفسهم بصحة الإنسان ، ويكونون هاد تكون عالية quality ، تبرزت عليها efficacy عالية ، safety عالية



Compliance with regulations and maintaining data integrity are fundamental to achieving these goals. Think of them as the cornerstones of trust in the medicines we provide.

الارتباط بين الامانة والصحة ، efficacy employee efficacy and safety

* الفرق بين Compliance with regulations and maintaining data integrity
 - following less formal ، تكون غير رسمية
 - following with official ، تكون رسمية
 * غرضها مع law ، غرضها مع official ، غرضها مع personal

Compliance



3

What is Compliance? (The 'Following the Rules' Concept)

- Compliance simply means adhering to the rules, regulations, guidelines, and standards set by various authorities. (FDA, EMA, CH).
- These rules are established by regulatory bodies like the FDA, EMA, and local health authorities.
- The purpose of compliance is to ensure:
 - Patient safety is paramount. highest of superior importance
 - Product quality is consistently maintained.
 - Ethical practices are followed throughout the lifecycle of a medicine.
- Analogy: Imagine a sports game – there are rules to ensure fair play and safety. Pharmaceutical compliance serves a similar purpose for medicines.

Areas of Pharmaceutical Compliance

* تمتد المفاهيم إلى عدة مجالات

❑ Compliance extends across various aspects of the pharmaceutical industry:

- **Good Manufacturing Practices (GMP)**: Ensuring medicines are consistently produced and controlled according to quality standards.

- **Good Clinical Practices (GCP)**: Ensuring ethical and scientific integrity in clinical trials.

- **Good Laboratory Practices (GLP)**: Ensuring quality and validity in non-clinical studies.

- **Good Distribution Practices (GDP)**: Ensuring the quality and integrity of medicines throughout the supply chain.

- **Pharmacovigilance**: Monitoring the safety of medicines after they are on the market.

analysis setting

تكون مضبوطة

سلامة الامداد

5

Example of Compliance - GMP in Manufacturing

Scenario: Manufacturing a batch of tablets for blood pressure.

➤ **GMP Compliance in Action:**

① **Cleanliness**: The facility and equipment must be meticulously cleaned and sanitized to prevent contamination.

accurate cleaning for cross-contamination

② **Documentation**: Every step of the manufacturing process must be documented accurately and completely.

③ **Personnel Training**: Staff must be trained on procedures and hygiene practices.

④ **Equipment Calibration**: Measuring equipment must be regularly calibrated for accuracy.

جزء مهم كمنهج GMP

➤ **Non-compliance Example**: Falsifying a cleaning log, potentially exposing the next batch to residues.

* يتبع خطأ cross-contamination

ممن الراديا يكون سجل مضبوط

٥

Example of Compliance - GCP in Clinical Trials

Scenario: Testing a new vaccine for its effectiveness and safety in human volunteers.

➤ GCP Compliance in Action:

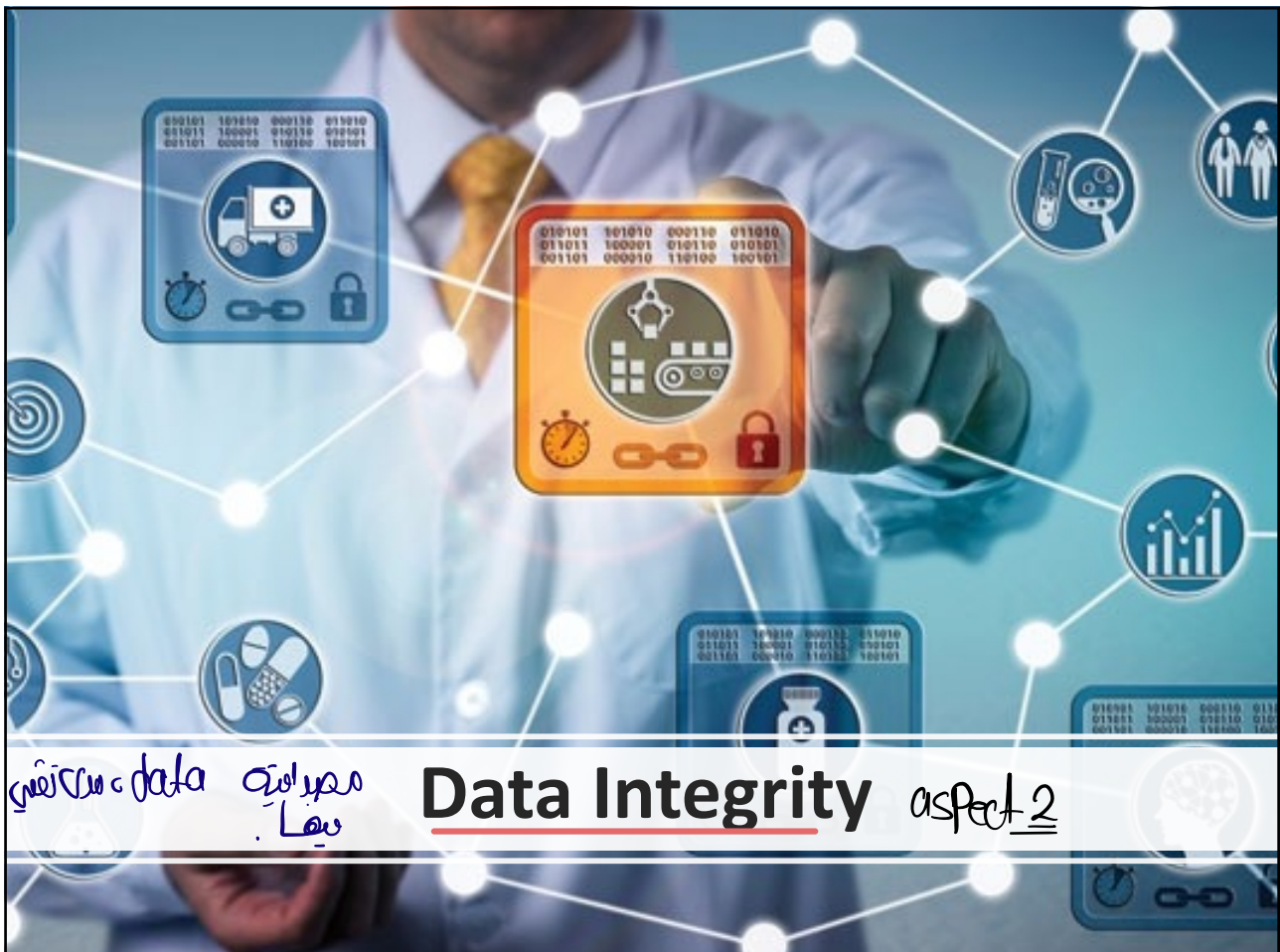
- ① - Informed Consent: Volunteers must be fully informed before agreeing to participate.
- ② - Data Privacy: Patient data must be kept confidential and secure.
- ③ - Adverse Event Reporting: Promptly report and investigate adverse effects.
- ④ - Protocol Adherence: Follow the pre-defined study plan meticulously. "Very Precisely"

- **Non-compliance Example:** Enrolling a patient who doesn't meet inclusion criteria, skewing results.

healthy volunteer (18-40y)

دخول لشخص في 18 ← برأسه

7



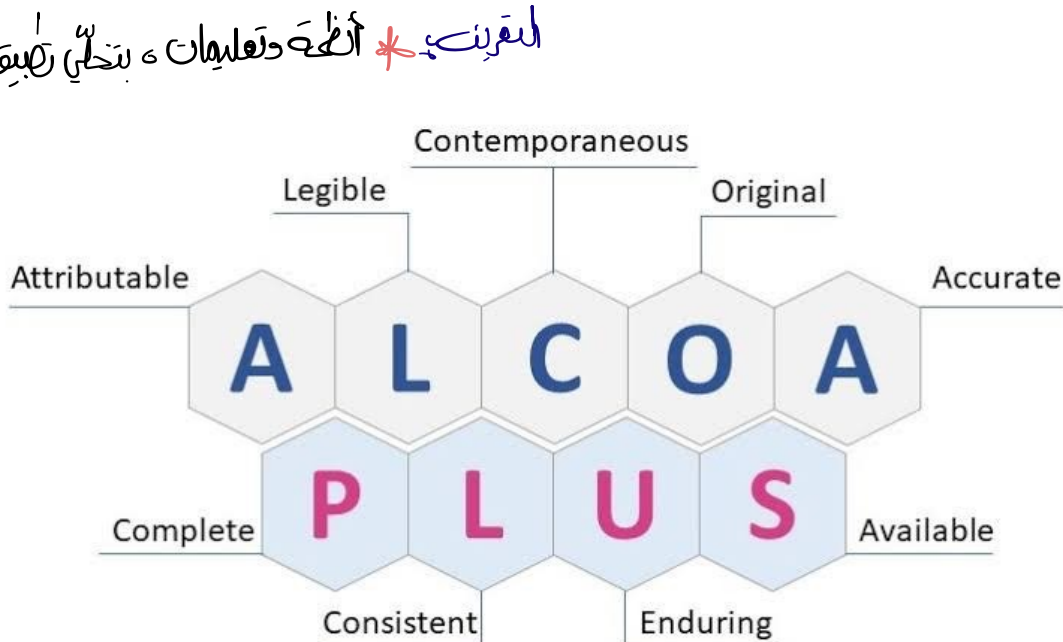
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What is Data Integrity? (The 'Trustworthy Information' Concept)

- Data Integrity refers to the completeness, consistency, accuracy, trustworthiness, and reliability of data throughout its entire lifecycle.
- It ensures:
 - Accurate decision-making regarding product quality and safety.
 - Demonstrating compliance to regulatory authorities.
 - Ensuring reliability of research findings.
- Analogy: Think of financial records. If incorrect or tampered with, the entire financial picture is unreliable. Data integrity applies this principle to pharmaceutical information.

9

The ALCOA(+C) Principles of Data Integrity



10

What is ALCOA (+C) stands for

- **A** → **Attributable**, ^{مقتب} ^{إلى أصل السيرة}
- **L** → **Legible**, ^{مفروق} ^{لغير أقرانه}
- **C** → **Contemporaneous**, ^{مفعول على الوقت} ^{ما يعتمد على الزمان}
- **O** → **Original and** ^{أصلية} ^{أصلية نسخة} ^{مصدقة على الأصل}
- **A** → **Accurate**, ^{الدقة} ^{مطابقان دقيقة} ^{مستطاب}
- **(+C)** → **Complete, Consistent, Enduring, and Available.** ^{تامة} ^{دائم}

11

The ALCOA(+C) Principles of Data Integrity

1) **Attributable:**

All generated data must be traceable to the applicable instrument and the person who generated the data. The date and time of the collection or generation of data should also be recorded. For example, A correction in the record should be initialed and dated to show when and who made the correction.

the record should be initiated and dated to show when and with whom the correction was made. **اساتذت کرامہ نظام ماہیت سے لیا گیا ہے**
یہ سب ذیل کلیہ عام اشاعت و اشاعت واضح ہو
مفتوح کیس سے لیں ہوگی

2) **Legible (Readable):** لما كتبت هذا البريد.

Data should be easy to understand, recorded permanently, and preserved in its original form. There should be no overwriting, All the corrections need to be clearly written with proper justification. For example, when making corrections to a record, it should be struck using a single line, to ensure the data is legible.

لا تتركوا الدنيا
لنفسه وحده
تسوء بالوقت ، التارخ

(initialed)
SA

12

The ALCOA(+C) Principles of Data Integrity

3) Contemporaneous (Online Record):

Contemporaneous means data should be recorded at the time work is performed. Date and time entries should follow in chronological order.

Data should never be backdated.

4) Original:

Source data or Primary is a medium in which the data point is recorded for the first time. This could be an approved form or protocol or a dedicated notebook.

5) Accurate (Error Free):

To achieve accurate data, the data should be error-free, complete, truthful and it should reflect the observation made. If any correction is made to the data, it should record that who has made the corrected and when it is made.

13

(+C) includes:

• Available:

The data or information must be able to be accessed at any time during the defined retention period.

• Enduring:

The data or information must be maintained, intact, and accessible throughout their defined retention period.

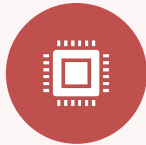
• Consistent:

The data are presented, recorded, dated, or time-stamped in the expected and defined sequence..

• Complete:

Information that is critical to recreating and understanding an event. This would include any repeat or reanalysis performed on a laboratory test sample.

In the era of information revolution, the Data integrity is very crucial for every validation process in every manufacturing industry. Data integrity allows manufacturers to review their in-process loss, quality errors, cost efficiency and future plans.



ALCOA+ is a quite good framework to ensure data security and data integrity with less efforts. If the data is available easily and complete in nature that helps to make corrective action plans for past discrepancies.

* RCA يسهل انماثل
 انك تعمل على
 صحتك

meeting Regulatory

Example of Data Integrity - Lab Analysis

- Scenario: A technician tests a raw material sample in a quality control lab.

Data Integrity in Action:

- Record exact weight immediately after weighing, including date, time, and initials.
- Results are accurately and legibly recorded in the designated system.
- Errors corrected by a single line cross-out, initialed, and dated.

- Data Integrity Breach:** Recording results from memory later, leading to inaccuracies.

Example of Data Integrity - Manufacturing Batch Record

- Scenario: Documenting steps in manufacturing a batch of cream.

- Data Integrity in Action:**

① - Document each step in real-time with operator's signature and timestamp. *done by, checked by...*

② - If deviations occur, they are documented and investigated.

- Data Integrity Breach:** Supervisors instruct workers to sign off on steps not actually completed, creating false records.

emulsion
لو صار عليك الشئ بالتفصيل والتبويب
والخطوات تفعل خطوات جديدة

توقيع
تزدبر عن المطلوب

17

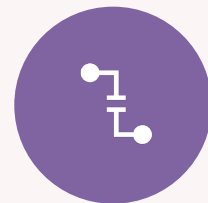
The Link Between Compliance and Data Integrity



DATA INTEGRITY IS
ESSENTIAL FOR
DEMONSTRATING
COMPLIANCE.
with rules.



REGULATORS RELY ON
ACCURATE AND
RELIABLE DATA TO
ASSESS ADHERENCE
TO REGULATIONS.



WITHOUT DATA
INTEGRITY, PROVING
ADHERENCE TO
PROCESSES AND
QUALITY STANDARDS
IS IMPOSSIBLE.

Think of it this way: Compliance is the set of rules, and data integrity is the evidence you followed those rules.

الرابط بينهم

18

Why are Compliance and Data Integrity Important?

➤ **Compliance and Data Integrity ensure:** *تبعات Data-integrity*

- Patient Safety: Safe and effective medicines.
- Product Quality: Consistent manufacturing and control.
- Legal and Ethical Obligations: Meeting regulatory requirements.
- *تأثير* Public Trust: Confidence in medicines.
- Avoiding Regulatory Action: Preventing fines, recalls, or license suspension.
- Business Reputation: Preserving trust and brand image.

الشركة

19

Consequences of Non-Compliance and Data Integrity Issues

data integrity and non-compliance تبعات

Legal and Regulatory Consequences:

- Civil penalties, lawsuits, and injunctions against production or marketing.
- Warning Letters from Regulatory Agencies.
- Risk of product recalls and stringent regulatory oversight.

Operational and Supply Chain Disruption:

- Costs of addressing regulatory issues and implementing corrective measures.
- Long-term supply chain impacts and loss of market share.

Loss of Public Trust:

- Credibility of companies and involved regulators questioned.
- Diminished trust in pharmaceutical products and processes.

Significant Financial Penalties

Suspension of Licenses.

Potential Harm to Patients.

Reputational Damage.

20

Example of a Compliance Issue - Failure to Follow SOPs

- **Scenario:** SOP outlines steps for cleaning equipment between products.
- **Non-Compliance:** Skipping a crucial cleaning step to save time.
* مسأله کاره
- **Consequences:** Cross-contamination of next product, potentially causing adverse effects in patients.

21

Example of a Data Integrity Issue - Backdating Records

- **Scenario:** Laboratory analyst realizes a test wasn't performed on time.
* كان لازم يعمل التحليل Stress على العينات اليوم لكنه شغلهم بعد بكرة بس سجلهم بتاريخ اليوم
- **Data Integrity Breach:** Backdating the record to make it appear performed within the timeframe.
مصادقة بتأريخ القرار الغاي
- **Consequences:** Mask potential delay, impacting product quality and Compromising data integrity.

* المعلومات التي تلعب من الحصة من دقيقة
ممكن أعطى لها القيمة راسية، لكن في الحقيقة
هذه ناجحة القس صحيح

22

Building a Culture of Compliance and Data Integrity

A strong organizational culture requires:



23

21 CFR: The Foundation for Data Integrity in Pharma

Guidance for Industry

Part 11, Electronic Records;
Electronic Signatures — Scope
and Application

* 21 CFR: لغير بقاءة منتجات
Part 11: لغير بالمنتجات
الميدانية

24

* لانه مرنا في عصر التكنولوجيا، كل شيء يتحول الى Automated

What is 21 CFR Part 11?

- This specific part of the Code of Federal Regulations addresses the **use of electronic records and electronic signatures** within FDA-regulated industries, including pharmaceuticals.
- It sets forth the criteria under which electronic records and electronic signatures are considered **trustworthy, reliable, and equivalent to paper records and handwritten signatures**. (data integrity) to ↑ electronic records as reliable

Why was Part 11 Created?

- With the increasing reliance on computer systems, the FDA recognized the need to establish regulations for managing data and signatures in the **digital environment**.
- Part 11 ensures that electronic records are as **accurate, reliable, and secure** as traditional paper records, maintaining data integrity in a digital context.

Key Goal: To ensure the trustworthiness and reliability of electronic data and signatures used in pharmaceutical activities subject to FDA regulations.

25

21 CFR: The Regulatory Compass for Data Integrity

- The Code of Federal Regulations (CFR), Title 21, outlines the fundamental requirements for data integrity and record-keeping in the pharmaceutical industry. It's not just a suggestion; it's the law.
- **Why is 21 CFR Important?**
 - Provides the legal framework for ensuring the safety, efficacy, and quality of drug products. electronic record and data integrity
 - Mandates rigorous controls over data and records to prevent fraud, errors, and omissions. data controls
 - Enables regulatory agencies like the FDA to effectively oversee and inspect pharmaceutical operations.
- **Focus:** Maintaining trust in the reliability and accuracy of data submitted to regulatory bodies and used for critical decision-making.

CFR Part 11: Embracing Electronic Records and Signatures

- **Focus on Electronic Systems:** Part 11 addresses the use of electronic records and electronic signatures, which are now prevalent in the pharmaceutical industry.
- **Key Requirements of Part 11:**
 - **System Validation:** Ensuring that computer systems perform as intended and are fit for their intended use.
 - **Audit Trails:** Secure, computer-generated, time-stamped electronic records that allow for reconstruction of the course of events relating to the creation, modification, or deletion of an electronic record.
 - **Data Security:** Implementing controls to protect the integrity, authenticity, and confidentiality of electronic records.
 - **Electronic Signatures:** Ensuring that electronic signatures are equivalent to handwritten signatures, attributable, and secure.
- **Impact:** Part 11 enables the use of efficient electronic systems while ensuring data integrity is maintained in the digital environment.

27

How 21 CFR translates to daily practices

- **Detailed Documentation:** Precisely recording all actions, observations, and deviations at the time they occur, adhering to ALCOA principles.
- **Controlled Access:** Limiting access to systems and records to authorized personnel to prevent unauthorized changes.
- **Regular Backups:** Establishing procedures for backing up electronic data to prevent data loss.
- **Periodic Reviews:** Conducting regular reviews of records and systems to ensure compliance with 21 CFR requirements.
- **Training:** Ensuring that personnel are adequately trained on 21 CFR requirements and data integrity principles.

28

Key Takeaways

- Compliance means adhering to regulations.
- Data Integrity ensures trustworthy, accurate, and complete information.
- Both are fundamental to patient safety and product quality.
- As future pharmacists, uphold these principles.

Compliance & Data integrity:

تتمتع بها ممارسها.

مبدأها في الصناعة

في كل مرحلة من مراحلها، تأخذ على محمل الجد.

29

لا تتسرع في اتخاذكم
التوقيع مباداة، المستحيل

اللهم لك الحمد أن علمنا ما جعلنا في رحمتك
ووفيتك بارك لنا أيضا وهبتنا وأهدانا أن
نعمل صالح ترضاه



Rand Noel Habbak

Thank you