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Short Communication

An Overview on Trustworthy Computer Systems

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DESCRIPTION

Our previous study describes the concept of trustworthy computer systems in a medicinal manufacturing environment within the scope of the referenced competent authority. As a result of the relevance of the data during the drug development, the concepts explained in the original article can be implemented in the drugs development environment.

Drug development stages and activities

The drug development process has several key objectives that guide its stages and activities.

Safety and tolerability: The primary objective of drug development is to ensure that new drugs are safe for human use.

Efficacy: Drug development aims to demonstrate that the new drugs effectively treat or prevent the targeted disease or condition.

Pharmacokinetics and pharmacodynamics: Drug development seeks to understand how drugs are absorbed, distributed, metabolized, and excreted (pharmacokinetics) within the body.

Selectivity and specificity: Ideally, new drugs should specifically target the disease-causing process while minimizing effects on healthy tissues.

Dosing and administration: Determining the appropriate dosage and dosage regimen is critical.

Quality and manufacturing: Throughout the development process, there is a focus on maintaining consistent quality and ensuring the drugs can be reliably manufactured commercially.

All the above drugs development stages/activities require data transformed into information. The integrity of the data is the first step in obtaining reliable data to be transformed into information. With the current emphasis on data reliability to ensure the integrity of electronic records (e-records), the computer system managing these e-records must be, at the same time, trustworthy [1-3].

What is a trustworthy computer system?

Trustworthy computer systems consist of computer infrastructure, applications, and procedures that are reasonably suited to performing their intended functions; provide a reasonably reliable level of availability, reliability and correct operation; are reasonably secure from intrusion, misuse and adhere to generally accepted security principles.

Here are the key points from the article on trustworthy computer systems in regulated environments, including drugs development:

- Trustworthy computer systems are critical for ensuring the integrity of e-records. They must be suited to their intended use, reliable, secure, and adhere to security principles.
- Requirements and guidelines for trustworthy systems come from regulations like FDA 21 CFR Part 11, EU Annex 11, WHO, PIC/S, and so on. These cover system suitability, reliability, security, change control, and more.
- Some computer verification must exist in the drugs development process. Verifying computer systems is important to ensure they meet specifications and operate as intended. Risk assessments should inform verification scope and activities.
- Procedural controls for operation, maintenance, security, change control, training, and so on. Are essential for maintaining trustworthy systems.
- Security practices like access controls, audit trails, and user account management are key for applications and infrastructure. Systems should adhere to accepted security principles.
- Cloud environments don't change the requirements for trustworthy systems that handle regulated activities. The responsibility lies with the regulated user. Precise requirements, supplier selection, contracts, and oversight are essential.
- Regulations worldwide align on principles for trustworthy computer systems in regulated environments. Following international guidelines helps ensure compliant systems.
- The objectives of the drug development process revolve around ensuring the safety, efficacy, quality, and appropriate use of new drugs, with the ultimate goal of benefiting patients and addressing unmet medical needs [4,5].

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CONCLUSION

The drug development process is lengthy, often taking over a decade and requiring significant financial investment. During the drug development process, it is necessary to have reliable information to decide on time if any of the key objectives that guide drugs development stages and activities are not still need to be. To obtain reliable data is necessary that the computer systems managing drug development-related e-records are trustworthy.

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