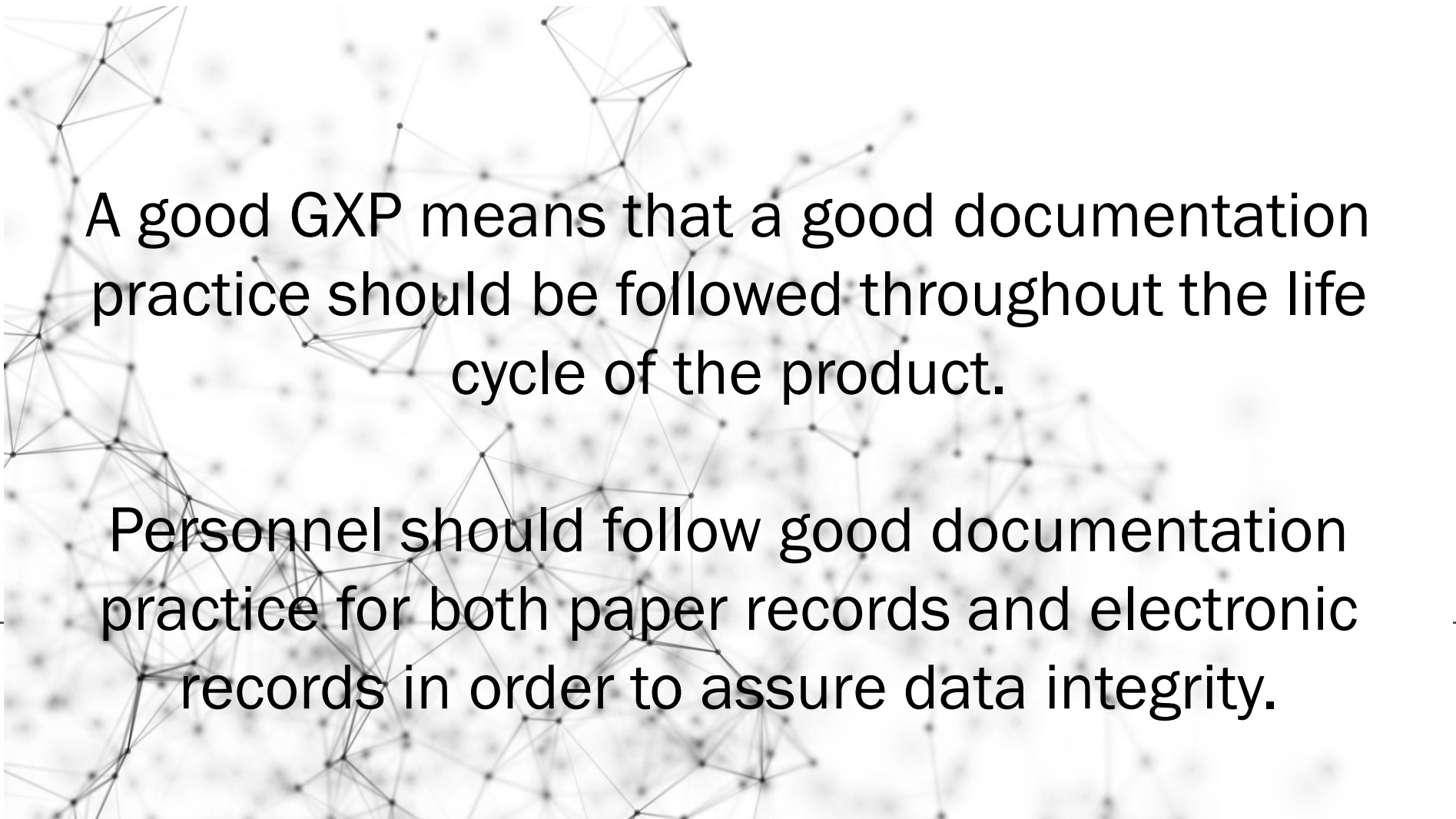




ALCOA++

PRESENTED BY cGALP



A good GXP means that a good documentation practice should be followed throughout the life cycle of the product.

Personnel should follow good documentation practice for both paper records and electronic records in order to assure data integrity.

ALCOA++ principles

A commonly used acronym for “attributable, legible, contemporaneous, original and accurate”, which puts additional emphasis on the attributes of being complete, consistent, enduring and available – implicit basic ALCOA principles

Attributable

Attributable means information is captured in the record so that it is uniquely identified as executed by the originator of the data (e.g. a person or a computer system).

Legible

Legible refer to the requirements that data are readable, understandable, and allow a clear picture of the sequencing of steps or events in the record so that all GXP activities conducted can be fully reconstructed by the people reviewing these records at any point during the records retention period set by the applicable GXP.

Contemporaneous

Contemporaneous data are data recorded at the time they are generated or observed.

Original

Original data include the first or source capture of data or information and all subsequent data required to fully reconstruct the conduct of the GXP activity.

The GXP requirements for original data include the following:

- original data should be reviewed;
- original data and/or true and verified copies that preserve the content and meaning of the original data should be retained;
- as such, original records should be complete, enduring and readily

Accurate

The term “accurate” means data are correct, truthful, complete, valid and reliable.

Complete

The record needs to be complete, and it must include all descriptions, metadata and associated information necessary to reconstruct the record.

Consistent

Records need to be consistent, both internally, within its immediate set, and with regards to the larger body of information.

Enduring

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

Available

Records need to be available when needed.



Thank you