Computer System Validation & Data Integrity

By **Eileen Cortes May 30, 2018 9:27 am PDT**

For all the professionals in the Pharmaceutical and Biotech industries this is a daily and common topic, almost like the morning traffic report. But, how do we get to that “route” that is going to provide a smooth ride to our final destination and in this case to a Mature Data Integrity state?

It all starts with your Quality Culture within the Organization. There are common elements that are embedded to the business culture and leadership and those get translated into the company’s behaviors. When I speak of Data Integrity, I always start with this note as we can excel in our technical and validation approaches, but if the values and business culture don’t support awareness on the topic, transparency, right and prompt communication, and mechanisms to report issues; data integrity events are going to be observed on a frequent basis. As ISPE GAMP Guide: “Records and Data Integrity” mentions; “People, Process and Technology are interconnected and is the responsibility of the Data Governance and Senior Leadership to design an effective framework within the business”. But, enough of ethics and philosophy, let’s get to the Tech stuff.

One of the best processes that can support a reliable Data Integrity Program is your Computer System Validation approach. But, how do we get there? Simple. The idea concentrates in how the ALCOA+ concept (Attributable, Legible, Contemporaneous, Original and Accurate; plus, Complete, Consistent, Enduring and Available) is integrated into the Computer System Validation Lifecycle and what elements are critical for its successful implementation. Something like the “12 Steps of AA” but in the Technology space, and concentrated into 4 Steps: