IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY
Unlimited Validation Knowledge Awaits...
UBM A division of UBM Americas
Published on *IVT Network* (http://www.ivtnetwork.com)

# Understanding the FDA Data Integrity Guidance

By **Ivan Soto Apr 23, 2019 8:03 am PDT**

**INTRODUCTION**

In 2016 the FDA issued their first data integrity guidance document to compliment the expectations already defined in the predicate rule requirements.

One of the main drivers for the initial guidance was the fact that over the past decade, the agency uncovered situations in which drug quality data and information wasnot accurate - and even compromised.

Data integrity issues can mask problems and failures which can be a result of deceptive practices such as data falsification. They are normally a result of inadequate processes, procedures and systems which are supposed to ensure reliable and accurate data. The FDA considers any gap in data integrity as a risk to patient safety.

The latest data integrity guidance is part of the FDA's approach to ensure the integrity of data. The FDA also uses inspections to uncover data integrity problems. Historically, the FDA pre-approval inspection process is used to help ensure the integrity of data. In addition to the pre-approval inspections, the FDA also conducts thorough assessments of applications prior to approval, in which the industry submits information about changes to their manufacturing processes.

This new guidance is an update to the 2016 draft guidance. The new guidance covers the design, operation, and monitoring of systems and controls to maintain data integrity. The FDA revised this guidance to address industry comments requesting additional details about data integrity. The revised guidance document is intended to help the industry address identified data integrity lapses, implement best practices to address gaps that can create risks to data integrity, and ensure consistent awareness and commitment to ensuring data integrity.

This article will discuss the revised guidance document and provide ideas for the implementation of the current FDA data integrity requirements.