

PRESENTATION ABSTRACT

Presentation topic: GAMP5 and BAT implementation on the changes

Speaker:

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Company:

Bausch Advanced Technology, USA

Presentation abstract:

Since GAMP4, many changes have occurred in manufacturing in general, including a variety of manufacturing methods, as well as the changes in technology. This presentation will generally discuss how GAMP5 incorporates the changes that technology has made as well as several methods to encourage more supplier involvement in the writing and executions of tests that are required to verify patient safety, product quality and data integrity has been maintained for the system.

This presentation will focus on the generalities of GAMP5 and how new methods and supplier involvement can make the validation and qualification of the system more efficient and effective. It will discuss several types of testing that the supplier can be involved in, at one point or another. Such as their part in risk analysis, testing and documentation.

With this in mind, the second half of the presentation will involve the different activities or options that Bausch Advanced Technologies, Inc. can offer in order to assist the pharmaceutical companies to conform to a GAMP5 guidelines.