

The influence of qualification and validation studies on quality risk assessment

Eng. Nabil Hoseh

SAMA for Consultation, Qualification, and Calibration, Jordan

The basic rules in any good manufacturing practice (GMP) regulations specify that the pharmaceutical manufacturer must perform its activity in a manner of reducing risks to the quality of product and safety of personnel.

Qualified facility and machinery in addition to valid processes has a valuable impact on the risk regarding the processes and products. Qualification helps to build up a detailed documented picture of facility and machinery activity reliance and performance from the date of starting in the past till its current behavior now and, thus, it provides a basis for planning of corrective and preventive action what it is going to do in the future.

Regulatory inspectors, during their inspections of manufacturing sites, often spend much time examining a company's qualification, validation studies, and related documents and records.

Effective documentation of qualification and validation studies enhances the visibility of the quality assurance system. In light of above facts, the objective of such paper is to comprehensively define the impact of qualification and validation to quality risks according to GMP requirements.

GM@samacm.com