

Impact Assessment for Validation

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“How far should we validate?”, is a very common question in a biopharmaceutical manufacturing environment. During the development of a project or a VMP (Validation Master Plan), the answer(s) to that question may have a tremendous impact on regulatory compliance or project/validation costs. Without proper planning, an organization may spend a tremendous amount of money and resources for validating or qualifying unimportant or non-critical systems or components in a facility.

In March 2005, I had an opportunity and honor to be one of the instructors for an IVT (Institute of Validation Technology) class in Alexandria, Virginia on several interesting topics about “Commissioning and Qualification”. One of the objectives of this class was to promote the use of ISPE’s Baseline Pharmaceutical Engineering Guides. The “Commissioning and Qualification” topic, which I presented, was in Volume 5 of the Pharmaceutical Engineering Guide for New and Renovated Facilities, first Edition, March 2001.

During my IVT presentation, the Impact Assessment subject (Section 3 in Volume 5 of the Guide) generated a lot of interest for the students in the class. From that experience, I would like to share some of the key concepts, which might help answer that question in the beginning of this article.

Impact Assessment is a process by which the impact of a system on product quality is evaluated, and the critical components within those systems are identified. This step should be carried out in the early stage of a project, or a validation program, by those with the appropriate skills and experience to make a proper and cost effective decision. Typical stakeholders may include user representatives, process experts, relevant engineering disciplines, validation manager and QA representatives.

Those systems having a direct impact on product quality are subject to Qualification Practices (such as IQs, OQs, PQs, etc.) in addition to Good Engineering Practices (GEP). “Indirect Impact” or “No Impact” systems are designed, installed, and commissioned according to GEP only. *The Impact Assessment process allows appropriate effort and focus to be concentrated on the quality impacting systems and components.*

As shown in Figure 1 illustrating the Relationship between Systems and Components, only critical components in direct impact systems require qualifications. Components deemed non-critical may be managed within GEP alone. The “arrow” in Figure 1 means “Design for Impact” to minimize the scope of systems or components subject to qualification practices and focus on the components presenting a risk to product quality. The main concept here is to qualify only the components that have a direct impact on product quality resulting in a cost effective validation program.

An example from the guide may help explain this concept ----

Example: A control valve for chilled water distribution to a heat exchanger serving a WFI distribution loop.

This valve is controlled and adjusted based on the temperature of a transmitter on a sub-loop to a WFI system. The recorded temperatures are used to support WFI quality-related decisions. In this example, the temperature transmitter is a critical component since it has a direct impact on product quality. In contrast, the control valve on the chilled water distribution system is not a critical component as the temperature transmitter can detect a problem with the WFI system temperature, which deemed critical to the product quality. Therefore, the control valve can be managed by GEP alone.

By now, I hope that you may have learned something new or reinforced what you have already known from this article. For more information, you may refer to the ISPE Baseline Guide book.

