

\_\_ The system manages records that support the process of annual reviews or batch yield calculations.

\_\_ The system manages data that is used to create labels that identify a drug substance, intermediate, commercial product, clinical material or drug product.

\_\_ Data from the system are part of the batch record or used to support lot release.  
The system generates, stores or transmits data used to support quality decisions related to product quality;

**Examples:**

\_\_ Evaluation of acceptance/rejection of raw materials, in-process materials or final products (e.g. laboratory test result values).

\_\_ The system is used in demonstrating compliance with a registered process. The term “registered process” refers to documents filed with regulatory agencies (e.g. an artwork system storing the sizes and colors of packaging material).

\_\_ The system generates, stores or transmits product status (e.g. released versus quarantined).

**Figure: [Flowchart on approach to System Level Impact Assessment](#)**

Based on the flowchart, a system is categorized as “Direct Impact System” when it manages Direct Impact Data. On the other hand, a system is categorized as “Indirect Impact System” when it manages Indirect/Non Impact Data and interfaces with a Direct Impact System. A No Impact System is determined as a system that manages Indirect/Non Impact Data and does not interface with a Direct Impact System.

This type of evaluation may seem obvious for systems with clear boundaries and one way of intended use, like a LIMS (Laboratory Information Management System) system managing data that will lead to decisions to accept or reject product based on lab results. But in some cases, the answer requires some thinking as the classification depends on how the system actually is used.

Therefore, the documentation of narrative rationales for the Y/N decisions of the system level impact assessment is essential.

Below are some examples of information systems that often raise questions in determining the direct, indirect or no impact.

**Card Access Reader Software**

The system used at a center location to restrict access to people entering offices would not be considered as a Direct Impact system. Where people in the building work with compliance-supporting information systems, access to these systems is restricted with logical security. The