__ 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).

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 same rationale applies if the card access reader software is only used to restrict entrance to offices on a site.

Different situations could arise when the system is used for restricting people access to manufacturing premises. Whether the system is direct impact and needs to be qualified depends entirely upon how the system is used. If it is the intention to act on the data that are generated and managed in the system and that action supports regulatory compliance-practices, then this system is a direct impact system and would require validation.

If the electronic log entry is used to automatically block access to people who haven’t entered the aseptic area in 6 months (and thus need retraining), this would be considered a GMP-decision and thus the system would be considered direct impact.

__ If the system restricts access to specific areas based on data of the person’s training status and these data are maintained and managed by the system, this would be considered as a GMP decision and a direct impact system.

__ If it is merely a passive system that only controls access based on general HR data and does not deter who gets access based on quality or GMP training attributes, then it would be considered an indirect or no impact system, dependent on whether it interfaces a direct impact system. It would not be a direct impact systems because the data managed by the system are not used as the primary method of verification, that only trained personnel are granted access to critical processing areas; the data are Indirect or Non impact

Training Record System

