Validation Requirements for Building Automation Systems

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BAS Network Considerations

There are several options for creating BAS network architecture to accommodate both validated and non-validated systems. Many companies combine validated and non-validated systems on the same BAS network and separate operator access via logical security. As an alternative, some companies place validated systems on dedicated network controllers that connect to a common BAS network. Still others provide physically separated architecture for validated and non-validated BAS networks. Determining which option is best for you depends on the maintenance needs of your networks and the capabilities and GMP training of your operations staff.

Common networks allow a single BAS operations staff to manage and maintain both validated and non-validated systems. It also simplifies the use of the system by placing all related control and information of indirect systems into the same graphical user interface as the direct systems. With a common network it is relatively easy to determine cause and effect and to design maintenance and operations procedures accordingly. However, when utilizing this common network approach special attention must be given to modifications made to both validated systems and non-validated systems tied to this network.

Segregated networks require either dual operating staffs or a single staff managing dual graphical user interfaces for multiple networks. One benefit to segregated networks is that they separate changes made to non-critical systems from those made to the validated system, simplifying qualification maintenance and documentation. Often times HVAC Utility system and support equipment is not considered direct impact and may then be controlled under separate management systems, GMP and non-GMP. However, segregated networks may make it very difficult to operate the facility, since data you need to make decisions on the GMP side may be lost on the non-GMP side. Each approach should be weighed against your operating staff capabilities, legacy system installations, and the complexity of qualification efforts for your sites.

Just as with other aspects of FDA compliance, proper project planning is essential to the success of a BAS validation effort. Detailed project planning, system design and development, and system testing are all crucial to ensuring that validated systems function as intended. Early in the project design be sure to consider the concept of “designed for impact.” When making decisions with respect to the impact of system operation, the number of direct impact systems can be reduced and qualification steps optimized if you design with the facility lifecycle in mind. Proper operation and monitoring of the systems by trained personnel and an on-going preventative maintenance program incorporating Standard Operating Procedures will ensure the systems continue to function consistently and reliably.

Benefits Beyond Compliance

Although FDA Title 21, CFR Part 11 had created an immediate need for updating the processes addressing compliant and validated systems, it also created an opportunity for the pharmaceutical, bio-tech and medical device industries to further improve performance. The impact on BAS installations and operations is particularly positive. BAS suppliers are responding to customer needs by producing more complete and usable environmental packages. The new BAS packages combined with the focus on validation are assisting companies in meeting their overall business goals. If properly planned and executed, a BAS validation effort can result in consistent practices and procedures that produce a quality product, decrease process downtime, and ultimately reduce production costs.

References:

About the Author
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Step 1: Determine Your Company’s Interpretation of FDA Code

Interpretation of FDA Code should be outlined in your company’s master validation plan. An effective plan will discuss FDA Code application and provide direction and response to activities across the company including research, pilot production, manufacturing, stability, warehousing, distribution, and Administration/Support spaces. Many companies look to the International Society of Pharmaceutical Engineer’s (ISPE) “Baseline Pharmaceutical Engineering Guide, Volume 5 Commissioning and Qualification” for further interpretation of FDA Code. The guide serves as an excellent basis for evaluating systems and practices against FDA Code.

Step 2: Identify Environmental Impact to Product or Employees

Environmental impact can be broken down into two aspects, product quality and employee safety. The first step in evaluating whether a system requires qualification in addition to commissioning is to determine the impact that space environmental conditions have on product consistency and quality. The Baseline Guide on commissioning and qualification outlines a process for identifying environmental conditions with “direct impact,” “indirect impact,” or “no impact” on the product. In essence, the process evaluates the Basis of Design conditions for a product or research against the building and control components, and controlled deliverables. Before impact assessments are assigned it is key that system boundaries define the granularity of what makes up a system and how its boundaries are defined. The FDA has issued 483’s where system boundaries have been exaggerated down to the point of components. The boundary must define a logical system as defined against its ultimate deliverable.

The diagram on the next page provides an example of an application of a system boundary for an environmental control system for a critical space.

In the example, temperature, humidity, and differential pressure are all considered “critical components” as they relate to the product delivered from this space. The boundary will determine our approach for design and qualification based on the presence or absence of critical components. In this example our system would be classified as “Direct Impact” and qualification will be required.

The best way to select optimum system boundaries for HVAC systems is to start with an airflow diagram of the space involved. The diagram should include the air distribution systems from fresh air to controlled space to exhaust. Look at all the logical equipment associated with this grouping and determine your smallest boundary based on the process involved, the interrelationships of equipment and logical maintenance approach. This may allow you to select the Air Handling unit, terminal units and space, and exhaust systems as three distinct boundaries or it may also point you to considering them as one boundary. Now look to the Utilities that serve these systems and select boundaries at this level of the facility. Keep in mind that smaller systems are generally easier to validate and maintain; however, components are not systems. Also remember that a system with even one “critical component” will be considered a “Direct” impact system and require qualification.

Selection of system boundaries will impact how you design, validate and operate your facility so keeping the lifecycle of the space in mind during this definition will optimize

The recent U.S. Food and Drug Administration (FDA) Final Guidance Document, which describes current thinking on Title 21, CFR Part 11 (electronic records/electronic signatures), has highlighted the requirement for clear, documented assessments of all systems serving the pharmaceutical, bio-tech and medical device facility spaces. The rationale used to assess these systems, and documentation of that rationale, is key to communicat- ing and defending your implementation.

One specific challenge facing the industry is determining how to apply FDA Codes for validation to building automation systems (BAS) for HVAC, Security, and Fire/Life Safety. Although it may seem like a daunting task, developing a validation plan that documents the process used for determining which portions of the BAS require commissioning and qualification testing — as opposed to commissioning only— is actually fairly straightforward. To distinguish whether a system requires qualification, you must simply evaluate it against three factors: 1) environmental impact (risk) to the product and employees, 2) interpretation of the FDA codes (Predicate rule), and 3) your company’s internal policies regarding information technology (IT), security, safety, quality assurance (QA) or other mission-critical functions.

References:
Internal Company Policies must also be considered when Installation Detail Design. Step 3: Evaluate Internal Company Policies

- **Qualification Requirement**
- **Performance**
- **Good Manufacturing Practices**

In our example, we identify Temperature, Humidity, and Differential Pressure as Critical components to this process. Since these components are included in the system boundary this system is considered a "Direct" system and will require qualification.

Notes:
1. In our example we identify Temperature, Humidity, and Differential Pressure as Critical components to this process. Since these components are included in the system boundary, this system is considered a "Direct" system and will require qualification.
2. Classification of each system boundary requires examining critical HVAC Sub Systems and parameters within the boundary for any product impact. If a critical HVAC parameter (critical component) is not included in the system boundary, this system is considered a "Indirect" system and will not require qualification.
3. The Overall Boundary shows the components of HVAC that deliver control, and monitoring of the critical HVAC parameters in this building space. The Overall Boundary is Direct Impact if a critical HVAC parameter is included in the defined boundary, Indirect Impact if not. Only the devices measuring critical HVAC parameters are Critical Components; everything else is a Non-Critical Component. Other systems boundaries associated with this building space will be evaluated for Direct, Indirect or No Impact based on their own product influence. (Note: Identifiers: LIMS, Process, BMS network architecture, etc.).

The process below the dotted line in the lower right quadrant represents the plan, design, build and qualification steps required for cGMP of critical systems. The process is known in the Life Sciences Industry as the Validation "V" and is the foundation of the FDA’s expectations of how manufacturers build and operate facilities and systems that have an impact on product quality. Activities in the lower right quadrant must involve your Quality Assurance (QA) department and key technical experts for approval and signoff at each step in the process. All actions performed in the quadrant must be documented, organized, and maintained throughout the lifecycle of your facility and must be performed by operators with specific training. This documentation is what protects your operation in event of an audit by the FDA.

The primary difference between the commissioning and the qualification processes is, for qualification, the addition of procedures and formal approval/testing/signoff by your QA department as required for the cGMP systems. As a final step in the evaluation, it is recommended that you create a rationale document that 1) defines your assignment of systems boundaries, 2) provides the definition of "direct," "indirect," and "no impact" systems, and 3) documents what qualification or commissioning steps are applied to each. Defining in detail the procedures for qualification and commissioning efforts will help you to standardize and understand the use, delivery, and approval requirements for both efforts.

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**BMS / HVAC Boundary example**

- This is a general example of applying boundaries to critical HVAC systems and parameters for HVAC. You must determine how to apply this to your specific situation.
- The Overall Boundary shows the components of HVAC that deliver control, and monitoring of the critical HVAC parameters in the GMP area. The overall HVAC system may be broken into sub-systems for the purpose of improving maintenance or qualification. However, be careful to set your boundary limits tight enough to include a true system, for example pushing a boundary limit around an HEPA filter bank alone would be inappropriate in most cases since that component does not constitute a logical delivery system.
- Establishing an Overall Boundary involves identifying critical HVAC parameters (critical components), then everything inside the Overall HVAC Boundary is Direct Impact; if not, then what is inside the boundary is Indirect or No-Impact. Only the devices measuring critical HVAC parameters are Critical Components, everything else is a Non-Critical Component. Other systems boundaries associated with this building space will be evaluated for Direct, Indirect or No Impact based on their own product influence. (ie. Utilities, Lifts, Process, BMS network architectures, etc.).

After you complete your systems and component assessments, you may want to revisit system boundaries to assure your logic still holds. It is absolutely critical to document your rationale for determining each system boundary. Take advantage of your good work here by documenting this process so that it is available if it is ever needed in defense of your facility validation planning.

In addition to evaluating the impact of systems on product quality, you must consider the potential impact of systems on employee safety. Any component of the BAS that assists in protecting employees from risks such as contamination or exposure will be advanced through the qualification process.

**Step 3: Evaluate Internal Company Policies**

Internal Company Policies must also be considered when determining which systems require qualification or other higher-level testing in addition to commissioning. Because these policies can touch many aspects of system application, care must be taken to obtain a clear understanding of the requirements. Typically, policies around security, IT, maintenance procedures, and QA reporting have the greatest impact on your BAS validation plan. For example, if your IT department has a written policy that all computer systems require qualification, then every computer, whether cGMP or not, must be qualified unless a written rationale indicating otherwise is approved by IT and QA.

**Final Analysis: Good Engineering Practices vs. Good Manufacturing Practices**

Once you have evaluated each system against the three criteria outlined above, you can determine whether they require commissioning or qualification or commissioning only. The diagram below helps to identify the difference between the two.

The horizontal dotted line represents a transition from non-critical above, to critical, or Good Manufacturing Practices (cGMP) systems below. The upper left quadrant specifies a process involving Good Engineering Practices for the design, build, and commission phases of facility development. Facility systems that fall in this quadrant are built to specifications and requirements defined by general building practices and building codes. BAS systems that are covered here could include those handling administrative spaces, cafeteria and some central plant utility equipment.

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