How to validate a new lyophilizer SCADA supervision and its connection to the network

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ABSTRACT

Lyophilizers are used in pharmaceutical industry to dry heat sensitive products. This is a large and expensive equipment that is not easily replaced. It is then useful to upgrade some parts of the equipment as its SCADA supervision and connect it to the critical network of the company. The validation strategy will follow the V-cycle approach.

1 INTRODUCTION

A lyophilizer is used when a pharmaceutical drug needs to be dried for different reasons as an increased stability (shelf life). The principle is based on water sublimation by decreasing the pressure inside the chamber, the boiling temperature is then lower than in normal conditions (atmospheric pressure and ambient temperature). This method is very useful for heat sensitive pharmaceuticals products.

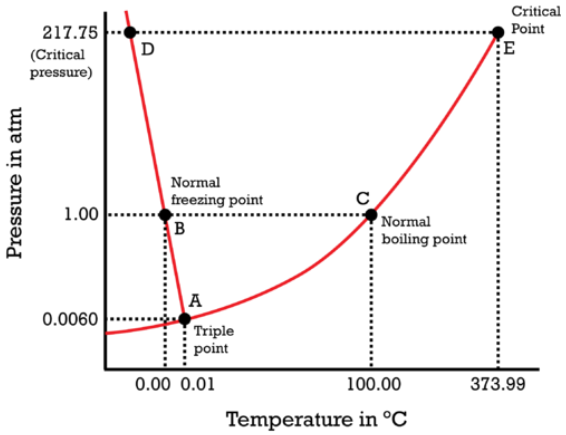

FIGURE 1: PHASE DIAGRAM FOR WATER[1]

As this equipment is large and expensive, it is not easily replaced. After some time, it is sometimes useful to upgrade some parts of the system to comply with new regulations rules for example. If it has not been done previously, it is useful to connect the lyophilizer to the network to store and make the raw data and the batch reports available for every needed person.

The purpose of this document is to present the validation strategy for a lyophilizer SCADA supervision upgrade and its connection to the network.

[1] https://courses.lumenlearning.com/cheminter/chapter/phase-diagram-for-water/

1.1 CURRENT CONFIGURATION

In our case study the lyophilizer works stand alone, the configuration is shown hereafter:

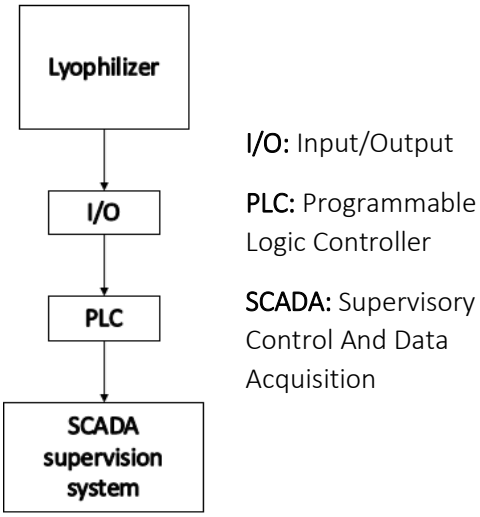

FIGURE 2: CURRENT CONFIGURATION

1.2 NEW CONFIGURATION

As explained above, the lyophilizer will be connected to the network and the SCADA supervision system will be replaced. The changes are shown in green in the scheme below:

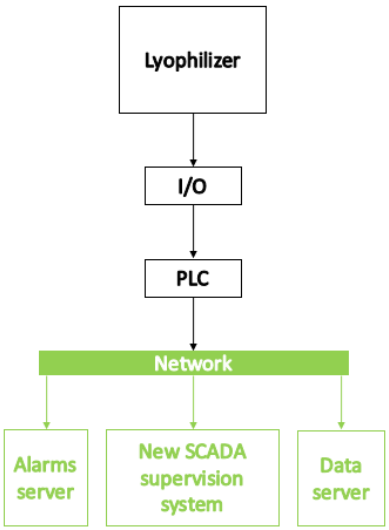

FIGURE 3: NEW CONFIGURATION

2 VALIDATION STRATEGY

The validation strategy will follow the "V-cycle" approach. That means that the installation qualification (IQ) will correspond to the design specifications and the operational qualification (OQ) will correspond to the functional specifications. Considering that:

- no modifications are made in the PLC programing (processes cycles are managed by the PLC),
- the equivalence between the recipes recorded in the new and the old supervision system will be demonstrated,
- the correct execution of the sequence of processes will be demonstrated,

the performance qualification is not needed.

3 INSTALLATION QUALIFICATION

Before starting the implementation of any changes, the availability of **backups** for the old SCADA supervision system, the data server and the alarm server must be checked. They will ensure the possibility to restore the system in its current configuration in case of problems and the traceability in case of audit. In the same time, the **installation of new components** can be checked to verify if they are correctly installed, identified and wired.

The **software and hardware configuration** will then be verified to confirm the compliance of the new system with the software and the hardware design specifications. This is an important point because it will assure the compatibility of the new SCADA computer and software with the network.

Before connecting the new SCADA supervision to the **network** it must be configured to allow

communication. The points hereafter must be checked:

- IP addresses and subnet masks creation for the PLC and the new SCADA supervision,
- Gateway creation, if applicable, for the PLC and the new SCADA supervision,
- Vlan (local virtual network) and switch configuration,
- update of the Access Control List.

As the lyophilizer parameters and alarms will be recorded respectively in the data and the alarms servers, **new tags** must be created and checked for each parameter and alarm.

The last point to check is the update of the following **documentation**:

- Logbooks,
- IT specifications (ITS),
- Procedures: they must be effective before the end of the qualification.

4 OPERATIONAL QUALIFICATION

The first step of the OQ consists in the **shutdown and restart verification** to assure that the SCADA supervision is not corrupted and restarts without any errors after a shutdown. Then the **communication** between the network, the PLC and the new SCADA must be verified. It will demonstrate the ability of the system to report all communication loss thanks to the watchdog software for both new elements added on the network.

The next step is the verification of the **user access and security**. This means that for each user group, the permissions must be checked. For example, a basic user (operator, technician, …) cannot have the same accesses than the system administrator (which must be defined in the software design specifications). After that, the **password protection** is checked according to specifications defined in the software design specifications. For an easy use, the user groups of the SCADA supervision system can be associated to the user groups already defined in the Domain Controller so this association must be verified.

For the **system check against user error**, all parameters will be verified for their availability (selection boxes, empty fields). Numerical parameters with defined ranges must be checked as follows:

- Try to set a value above the input range. This must be impossible and the value should not be stored in the system,
- Try to set a value below the input range. This must be impossible and the value should not be stored in the system,
- A value inside the input range can be entered and should be stored in the system.

The "**recipes and parameters**" test must be performed to verify:

- That all parameters can be modified and that all these modifications are recorded when saved,
- That all parameters are correctly recorded for each recipe in the new SCADA system and that their values are correct. This test is important to demonstrate the equivalence between the recipes recorded in the old supervision and in the new one.

The **Audit Trail and user log** verification ensure the correct traceability and recording of the modifications; and the recording of the user logs in the user log file. For the audit trail verification, all parameters modified and saved during the test "Recipes and parameters" must be recorded in the audit trail.

The correct recording of the **processes and alarms messages** in the system screen must be verified as well as the effectiveness of their visual/audible indicators.

According to the P&ID (for the schematics) and to the software design specifications, the **screen layouts** must be checked.

Once all previous tests have been performed, a **functional test** for each process must be performed to demonstrate that the associated recipe is correctly followed during cycle execution.

At this step of the validation, the right **recording of data and alarms** in the servers must be verified:

- For the data, each tag must be present in the server and their values must vary over time. The tag must correspond to the incoming data from the lyophilizer,
- For the alarms, each one must be recorded in the server and the description must be the same than on the SCADA supervision.

As the communication between the alarm server and the alarm reporting system has been already validated during their own validation, it is not needed to test it.

The last point of this validation is the verification that **backups** are available for the new configuration system.

5 CONCLUSION

As it is difficult and expensive to replace a lyophilizer, sometimes some parts need to be upgraded. In this case, a new SCADA supervision has been installed and connected to the company critical network. The "V-cycle" approach is interesting for this validation because it allows to check if the new system complies with the software and hardware design specifications.

6 AUTHOR

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