

Managing Data Across Multiple Sites, Locations, and Regions with Sievers* DataShare Elite Software

Industry Challenges

Pharmaceutical and biopharmaceutical manufacturers across the globe are increasingly tasked to improve productivity without sacrificing quality. At the same time, budget pressures and resource consolidation continue to intensify, forcing manufacturers to do more with less in a highly regulated environment.

Faced with these demanding pressures, manufacturers turn to technologies and solutions to help improve productivity and increase efficiency. When it comes up to compliance monitoring of ultrapure water (UPW) and validating or verifying results, choosing the right tools is key. Software is one tool that should be carefully considered to make sure all data integrity and 21 CFR Part 11 requirements are met.

Solution

Sievers DataShare Elite software offers a central repository that allows the management of data from multiple Sievers Total Organic Carbon (TOC) Analyzers. The intuitive software allows you to make faster, more informed, and actionable decisions for your process. Additionally, the software meets 21 CFR Part 11 compliance and follows ALCOA+ principles to ensure you are maintaining data integrity.

The amount of data generated between the various analyzers can be overwhelming if not managed correctly. For this reason, DataShare Elite software allows users to assign Sievers TOC analyzers to specific regions, sites, and locations to quickly identify where the data is coming from and make quick actionable decisions with traceability.

How DataShare Elite works

The data imported off each analyzer into the software is tracked in the “Management” tab of the software. This tab has four sections in total: Regions, Sites, Locations, and Analyzers **(Figure 1)**.



Figure 1: Management Tab

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“Regions” are generally separated by the physical geography or functional area they represent (**Figure 2**). They should be specific and recognizable for operators of the software.

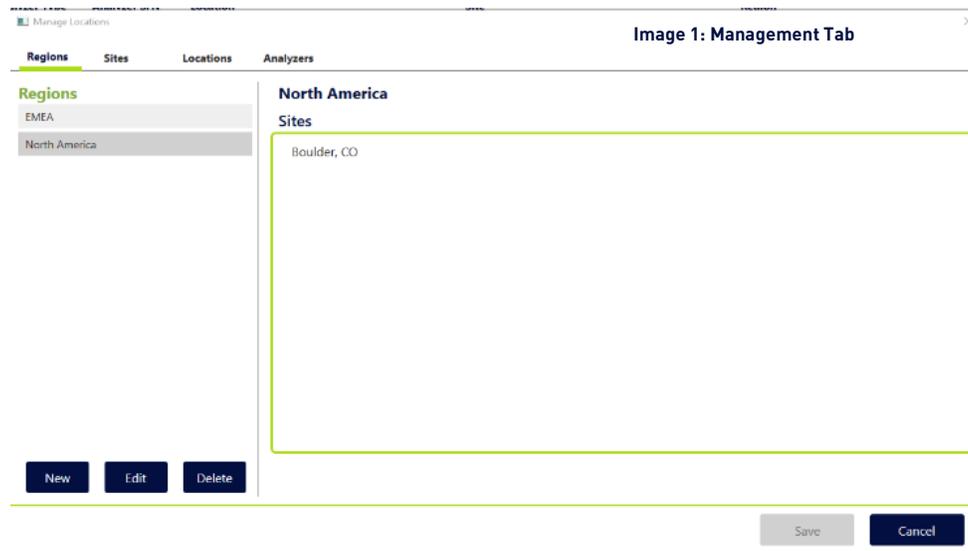


Figure 2: Regions

“Sites” are specific buildings or geographical locations that identify specific business units within a defined region (**Figure 3**).

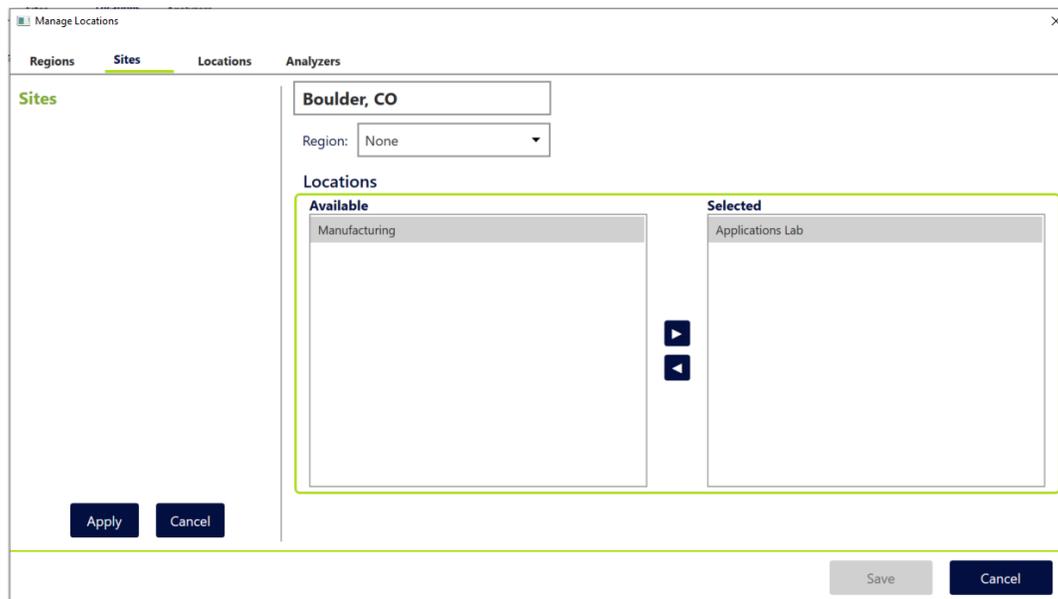


Figure 3: Sites

“Locations” can be used to identify the point within the site that the TOC analyzer is being used (**Figure 4**). Because DataShare Elite bridges the gap between facilities and labs, it is important to correctly identify where the specific analyzer is measuring the TOC, Conductivity, and Temperature.

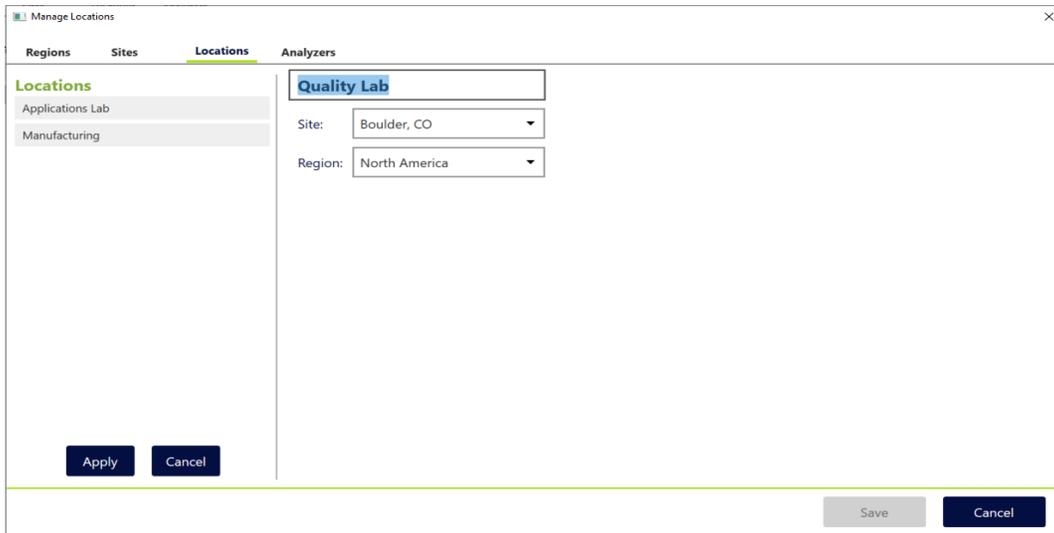


Figure 4: Locations

The “Analyzers” section allows you to name the specific TOC instrument within that location if there are multiple analyzers (**Figure 5**). This give operators the ability to identify the system by a name, serial number, and model of analyzer.

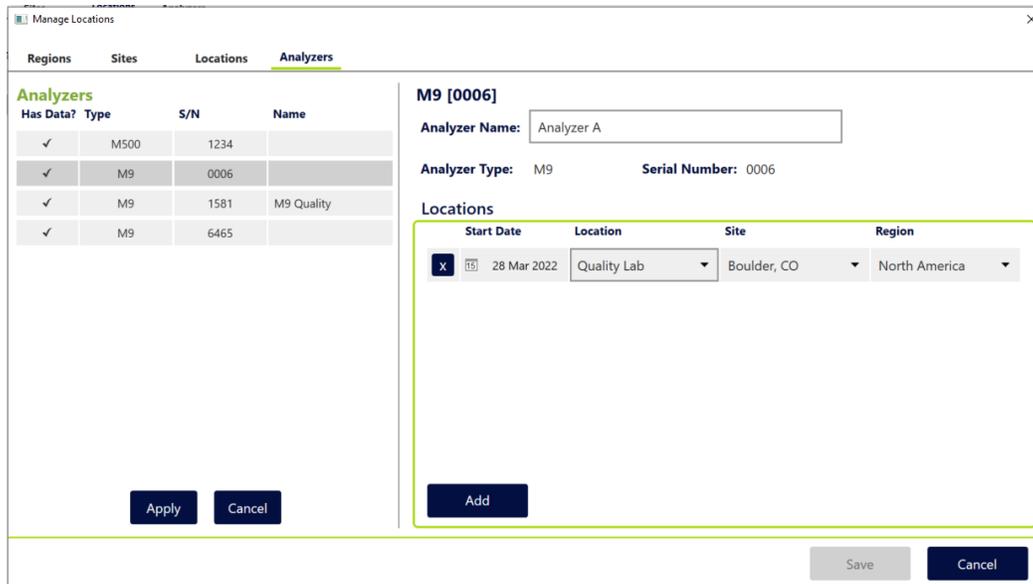


Figure 5: Analyzers

How to begin configuring the software for data management

Starting with the region is the easiest way to begin the process. Identify the major regions you would like to aggregate and enter them into the system by pressing “Add” to the analyzer management section. This will launch a new window that facilitates the management of all sections.

Select the “Regions” section then press the new button on the bottom left of the window. Enter in the name of each region that was identified. Each time select “Apply”.

The process is repeated for the “Sites” and “Locations” sections. When finished you can apply the associated location with its respective site and region.

As data is imported into the DataShare Elite software, the analyzer information will be displayed in the “Analyzer” section. The analyzer information can also be manually added to this section prior to import. It is important to correctly identify the model and serial number of the analyzer if using the manual method.

Once the analyzers have been added to this section, they may be applied to the locations by selecting the appropriate analyzer and pressing “Edit”. In the “Locations” section, press the “Add” button and use the location drop down to correctly identify the specific location. The site and region should automatically populate with the correct values if previously associated.

Conclusion

DataShare Elite software is a revolutionary tool that brings quality into all aspects of the pharmaceutical and biopharmaceutical manufacturing process. Understanding where the data is coming from ensures operators can make quick actionable decisions based on real time data. Using a centralized repository that meets 21 CFR Part 11 and is guided by ALCOA+ principles, the software allows any user to effectively manage data across multiple sites increasing productivity and data integrity.