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### Introduction

ISO 50001 is aimed at all companies with a common goal of improving energy performance through a framework of energy efficient strategies. It can be applied to all different types of company, whether large or small; and implemented in all departments, e.g. manufacturing, building management, warehouse, etc. As ISO 50001 is a worldwide standard, one strategy can be used throughout your organization.

The ISO 50001 standard does not set absolute energy performance criteria. Its objective is that you demonstrate a commitment to continual improvement of your facilities energy performance; which is defined as measurable results related to energy efficiency, energy use and energy consumption.

zenon's product family is focused on making current and future energy management improvements progressive and continuous as you move forward, using our scalable and modular philosophy.

### What do you get from ISO 50001?

Energy framework of continuous improvement

Energy management strategy

Energy efficiency

Reduced operating costs

Improved energy performance

#### zenon brings together:

Connection to multiple systems, networks and devices.

Unites your workforce, Management, Quality, Engineering, Operations, Administration.

Access information from anywhere, which is available everywhere.

Focus attention to energy efficiency.

FDA 21 CFR Part 11 compliance.



# ISO 50001 in the Pharmaceutical Industry

Visualization of all activities plays a significant role when implement the energy optimizing policy. It's crucial being able to monitor, measure and analyze energy performance.

#### Integrate existing strategies – ISO 9001 and ISO 14001

In Pharma we are one step ahead of other industries to implement ISO 50001 with its similarity to ISO 9001 & ISO 14001!

ISO 9001 has formed the backbone of pharmaceutical Quality Management, and remains a standard which is well practiced and enforced with its quality methods being integral to all operations.

ISO 50001 can be viewed as an extension to ISO 9001 and ISO 14001 methodology. Therefore, the effort when implementing ISO 50001 is relatively low when one of the above mentioned standards is already applied.

zenon's independent communication platform connects natively to existing installed equipment and systems without the need of adding or making any changes to the 3<sup>rd</sup> party system. And so without affecting their qualification or validation status, this efficient automation means significantly less time and money is tied up in validation costs, with improvements implemented in shorter time scales. When a change is clearly identified in the Energy strategy, its realization can be implemented with ease.

The reporting capabilities within the zenon product family focus the data to each key role in the Energy Management Model. Providing the global platform to display current results, record progress, efficiently communicate non-conformities and corrective or preventative actions. Aligning with a well-defined strategy it can also provide projections on future energy performance.

Pharmaceutical and other life-science industries have critical stages involved when making changes to equipment or processes. zenon easily integrates into existing systems, simple parameterization and native connectivity make obtaining data easy, and controlling changes as efficient as possible. Out-Of-The-Box modules provide efficient functionality in GMP environments.

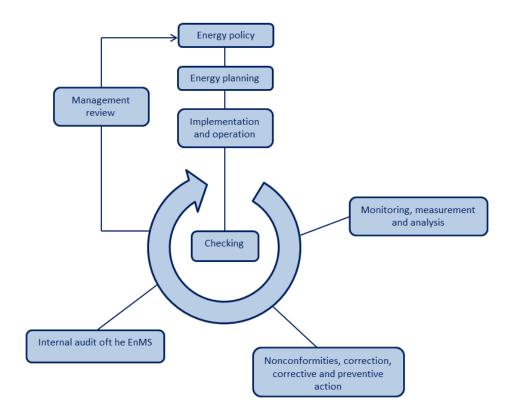


# **Creating an Energy review**

The Energy Review is a crucial stage of the Energy Management Strategy. An energy review includes an array of energy use and consumption data which must be based on direct measurement. All energy sources need to be identified collectively including electricity, gas, solar, etc.

The review should identify areas of significant energy use and consumption. It helps at this stage to employ equipment modeling to be able to form a framework reflecting the actual facility layout. The review should be transparent across the facility including equipment and machinery, also wider energy consumers such as building management, HVAC, air handling, lighting, etc.

The conclusion of the review should be a clear insight into the incoming energy supplies, and their distribution network. Furthermore it displays what individual energy consumers exist, with their consumption known. From this the performance of the facility can be assessed, energy use can be monitored by equipment, system and process; pinpointing variables that affect energy performance.





The hard results of the review provide the 'Energy Baseline', where future improvements in energy performance are measured against this baseline.

In order to sustain the continual improvement process accurately, the baseline needs to be updated when changes have taken place to processes, operating patterns or to the energy system itself. As more knowledge is gained on your operations, more details are available on energy use. Energy Performance Indicators need to be improved, and the baseline updated to monitor progress.

zenon can request information from wide ranging systems, equipment, sensors and measurement devices. It can integrate your energy activities into every corner of your infrastructure. Collating accurate data at a good resolution means clear analysis on your energy strategy.

# **Energy Performance Indictors (EnPI's)**

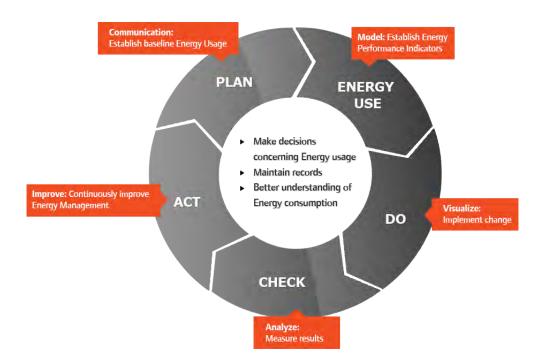
The energy review and the generation of the baseline energy performance have classified the facility under review. The baseline has catalogued measurable indicators of energy consumers, which are used constantly to monitor improvement and performance. These Energy Performance Indicators are a direct and live display relating to energy use per m² or per unit of production material. Energy PI's need to have sufficient detail to be of use.

The Energy Policy is a commitment to continual improvement in energy performance. This forms the framework which moves the facility from the energy baseline using performance indicators through continuous improvement by establishing objectives. Only by employing constant monitoring and review will performance be sustainable.

## Plan - Do - Check - Act

Similarities with existing structures in place within pharmaceutical production can be made. For example, the ISO 50001 focuses on the continual improvement process, which follows the Plan-Do-Check-Act approach. The Plan-Do-Check-Act model is similar to the 'Define Measure Analyze Improve and Control' (DMAIC) concept of 6 Sigma, which is used to improve and stabilize processes.

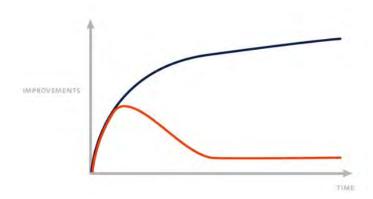




Plan-Do-Check-Act action plans hold named responsibilities and deadlines. They accurately describe what is going to happen to meet the objectives. This is a critical stage in the program, it is of extreme importance to communicate how individual efforts can affect energy consumption, and how deviations from the procedure affect achievement of the targets.

### **Constant focus**

Without constant focus and commitment, improvement programs are prone to failure. In the initial stages where the project has full focus, the improvements are clearly seen (both curves). However once the initial effort has passed, focus is generally lost, and the performance degrades (red curve). With constant monitoring the project is kept alive, allowing for organic growth (blue curve).





The ISO 50001 standard embraces the entire facility under review. To have one system at the heart of Energy Performance requires a powerful and flexible toolbox. The zenon product family provides this know-how. Its ability to obtain data from anywhere and make it available everywhere opens the door to transparent information across the facility. Bringing systems together through its extensive communication platform, then analyzing the data and presenting focused information.

Energy management is not a roulette table. A strategy based on zenon technology takes the gamble out of the continuous improvement strategy, by having continuous measurements and feedback on all your Energy Performance Indicators clearly aligns the current action plan to progressive success.