

Laboratorios Farmacéuticos ROVI S.A.



Thanks to the implementation of ISO 50001 Laboratorios Farmacéuticos ROVI saved more than 3,363 tCO2.

Case Study Snapshot	
Industry	Pharmaceuticals
Product/Service	Active Ingredients and Research and Development of Medicines and Health Products.
Location	Granada / Spain
Energy performance improvement percentage (over the improvement period)	2020: Electricity (2.9%), Natural Gas (0.4%) 2021: Electricity (2.1%), Natural Gas (8.5%)
Total energy cost savings (over the improvement period)	38,160.13 \$USD
Cost to implement Energy Management System (EnMS)	21,500 \$USD
Total energy savings (over the improvement period)	2,138.43 GJ
Total CO₂-e emission reduction (over the improvement period)	3,363 tCO2

Organization Profile / Business Case

In Laboratorios Farmacéuticos ROVI S.A. Granada we work for the well-being of society and to improve the quality of life and patient care, promoting human health through the research and manufacturing, marketing and distribution of medicines and other healthcare products.

We have a firm and constant commitment to environmental protection, which forms part of our day-to-day activity. Our environmental strategy is based principally on implementing energy efficient solutions, managing natural resources rationally and recycling the waste we produce.

Laboratorios Farmacéuticos ROVI S.A. Granada is committed to a responsible use of energy in its production of active ingredients and research and development into medicine and other health products in order to reduce greenhouse gases and other negative impacts on the environment, as outlined in the “Policy against climate change” from the ROVI group. Laboratorios Farmacéuticos ROVI S.A. Granada is aligned with the general policy of the ROVI group, which works with the objective of reducing the environmental impact, and thanks to its "Avoid, Reduce and Compensate" strategy, it has achieved CO2 emission neutrality. Offsetting emissions through financing high environmental impact projects in 2021 has been key to achieving these goals. Visual example:

<https://www.youtube.com/watch?v=QPzpnxEVLOA>

Energy consumption, as part of the production process at Laboratorios Farmacéuticos ROVI S.A. Granada, constitutes one of links necessary to undertake its activity.

The acquisition of energy efficient products and services, designing and improving the energy performance and an energy management system based on the Plan-Do-Verify-Act (PDVA) continual improvement cycle, are parts of our regular practices in the organization.

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In addition, promoting a correct usage and consumption of energy and sharing these principles across all levels and with all employees, by means of continual training and awareness-raising, is part of our company culture.

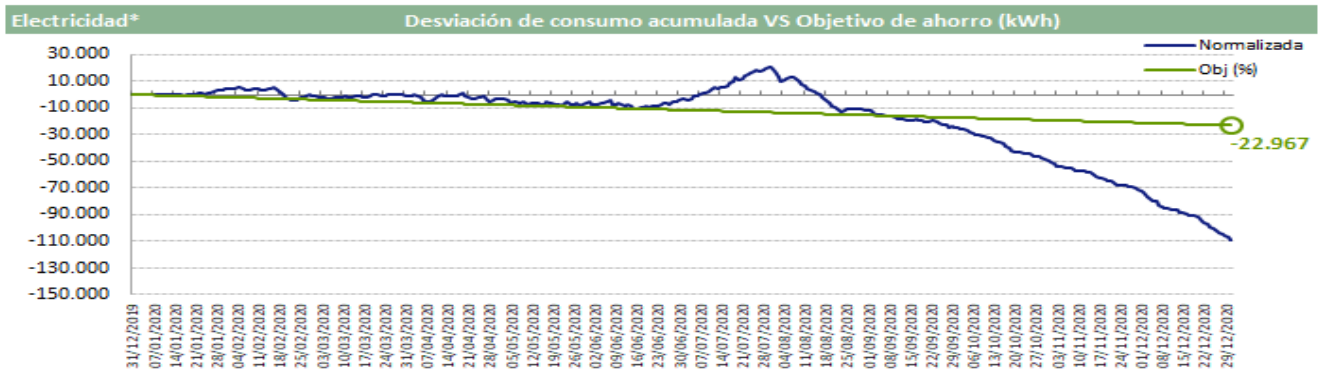
Business Benefits

Energy Performance Improvement 2020: The baseline calculation is done through statistical regression analysis including the relevant variables that affect energy consumption. Energy performance is measured by comparing actual consumption with the calculated baseline and with the savings target proposed in each case.

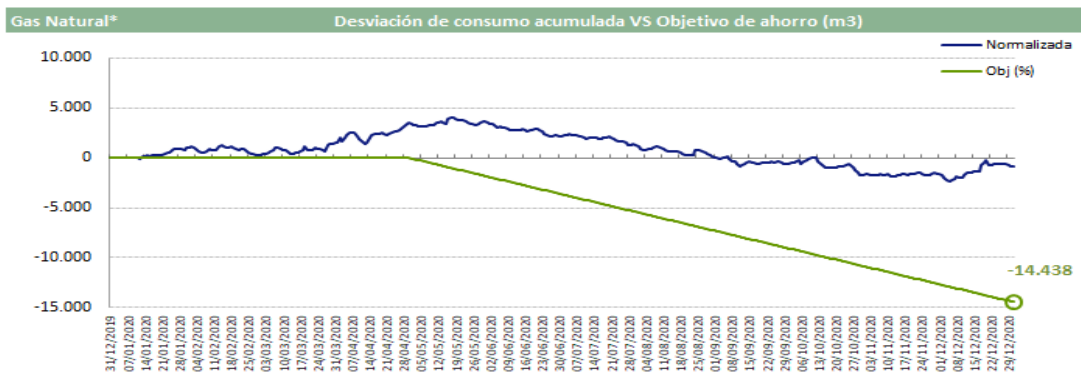
The variables analyzed for baseline have been: Freeze drying hours, Work calendar, Heating degree days, Cooling degree days, Cooling process phases, Sanitizations, Sterilization and uses of GVL, Thermal oxidation reactor.

Energy performance indicators 2020:

- 1- ELECTRICITY: Blue line → Actual accumulated consumption / Green line → Objective



- 2- NATURAL GAS: Blue line → Actual accumulated consumption / Green line → Objective
In 2020, energy performance of natural gas is improved but the objective is not achieved due to a failure of a conductivity meter in the boilers, of the traps in the steam line and of a valve in the clean steam line



Energy performance report 2020:

INFORME DE DESEMPEÑO ENERGÉTICO. REGRESIÓN											
Fecha:	31/12/2020										
SERVICIO	OBJETIVO		REAL	AHORROS						CO2	
	Ahorro 2020	Consumo út. 7 días	út. 7 días	2020		últimos 28 días		últimos 7 días			2020
Electricidad*	22.967 kWh	44.213 kWh	35.119 kWh	-2,9%	-108558 kWh	-€ 9.622	-16,6%	-31833 kWh	-21,4%	-9534 kWh	1.057 t
Gas Natural*	14.438 m3	3.951 m3	4.070 m3	-0,4%	-914 m3	-€ 337	7,1%	1122 m3	-6,7%	-294 m3	371 t
TOTAL				-1,4%		-€ 8.051					1.676 t

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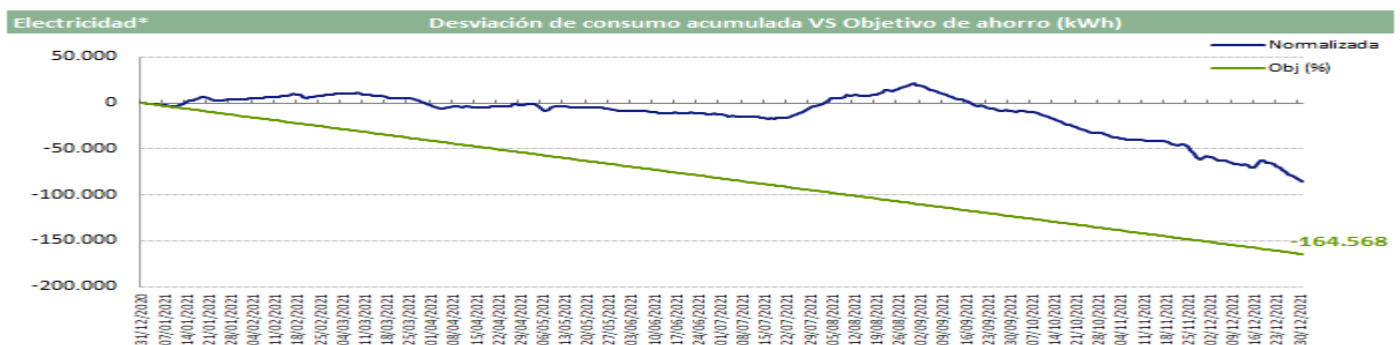
In this figure three different colors are shown: the red tabs show those periods in which there is no improvement in energy performance, the yellow tabs show those periods in which there is improvement in energy performance, but the objectives are not achieved, and the green tabs show those periods in which energy performance is improved and objectives are also achieved.

Energy Performance Improvement 2021:

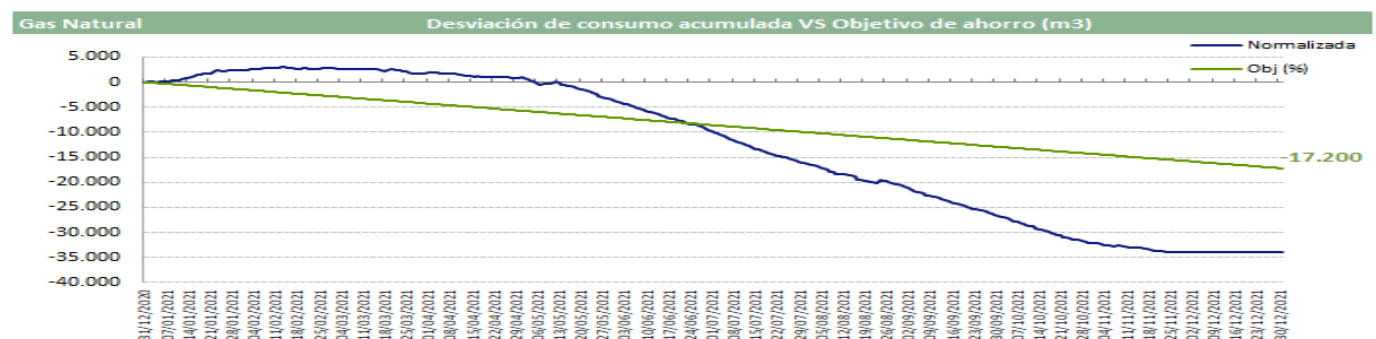
The baseline calculation is done through statistical regression analysis. Energy performance is measured by comparing actual consumption with the calculated baseline and with the savings target proposed in each case. The variables analyzed for baseline have been: Freeze drying hours, Work calendar, Heating degree days, Cooling degree days, Cooling process phases, Sanitizations, Sterilization and uses of GVL, Thermal oxidation reactor

Energy performance indicators 2021:

- 1- ELECTRICITY: Blue line → Actual accumulated consumption / Green line → Objective
In 2021, energy performance of electricity is improved but the objective is not achieved due to a some changes in the quality of the compressed air generated at the plant. To adapt it to the production needs of Moderna's vaccine



- 1- NATURAL GAS: Blue line → Actual accumulated consumption / Green line → Objective



These graphs represent the objectives that are calculated through the implementation of energy efficiency measures. These measures are collected in a table that is constantly updated and where ideas for improving energy performance are described.

Energy performance report 2021:

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INFORME DE DESEMPEÑO ENERGÉTICO. REGRESIÓN

Fecha: 31/12/2021

SERVICIO	OBJETIVO		REAL	AHORROS						CO2	
	Ahorro 2021	Consumo últ. 7 días	últ. 7 días	2021		últimos 28 días		últimos 7 días		2021	
Electricidad*	164.568 kWh	64.166 kWh	53.120 kWh	-2,1%	-84909 kWh	-€ 12.382	-7,4%	-25374 kWh	-21,1%	-14202 kWh	1.153 t
Gas Natural	17.200 m3	7.836 m3	8.166 m3	-8,5%	-33883 m3	-€ 13.929	0,0%	0 m3	0,0%	0 m3	682 t
TOTAL				-4,7%		-€ 30.049					2.011 t

In this figure two different colors are shown: the yellow tabs show those periods in which there is an improvement in energy performance, but the objectives are not achieved, and the green tabs show those periods in which energy performance is improved and the objectives are also achieved.

NON-ENERGY BENEFITS: Through the implementation of the EnMS we obtain the following non-energy benefits: Optimization of existing resources, Efficient use of workspace, Increased worker safety, Improvement of the maintenance of equipment and facilities, reinforces teamwork, Plant technology improvement, improves knowledge of the organization's activities, Promotes the search for new investments. Since Laboratorios Farmacéuticos ROVI has begun to build its relationships with suppliers based on ISO 50001, products and equipment are acquired that contribute to improving the organization's energy performance.

COSTS: Internal/External staff time to develop, implement, and maintain EnMS → Greater than 1 year // Overall energy cost savings → 38,160.13 \$USD // Percent of overall cost savings that was due to operational savings → less than 25 %

Plan

Since 2015, Laboratorios Farmacéuticos ROVI has worked on the analysis of the plant's energy consumption and on the development of trends that allow responsible energy consumption and improvement of the operation of equipment and facilities, as well as their maintenance.

When new ISO 50001 was published in 2018, work began under its recommendations, and after reporting to senior management the opportunities detected in the PESTLE and SWOT analyses carried out, the economic benefits derived from the implementation of energy efficiency measures, benefits not energy such as social prestige, improvement of the corporate image in the eyes of customers and investors, and benefits for the environment and the fight against climate change.

The commitment of senior management is achieved by signing and publishing the energy policy according to ISO 50001 of Laboratorios Farmacéuticos ROVI S.A. Granada. This signature is achieved after explaining to senior management all the economic and environmental benefits that are obtained after the implementation of the EnMS (Investments with great profitability, savings derived from lower energy consumption, improvement of the corporate social image...)

After the commitment of the senior management, the economic financing, and the reserve of resources for the EnMS is decided at each annual management review meeting, where all those factors that will have an impact on the EnMS are considered, such as: Policy Energy, energy performance indicators, objectives, goals, energy saving opportunities, audits, improvement opportunities, risks, non-conformities, legal requirements.

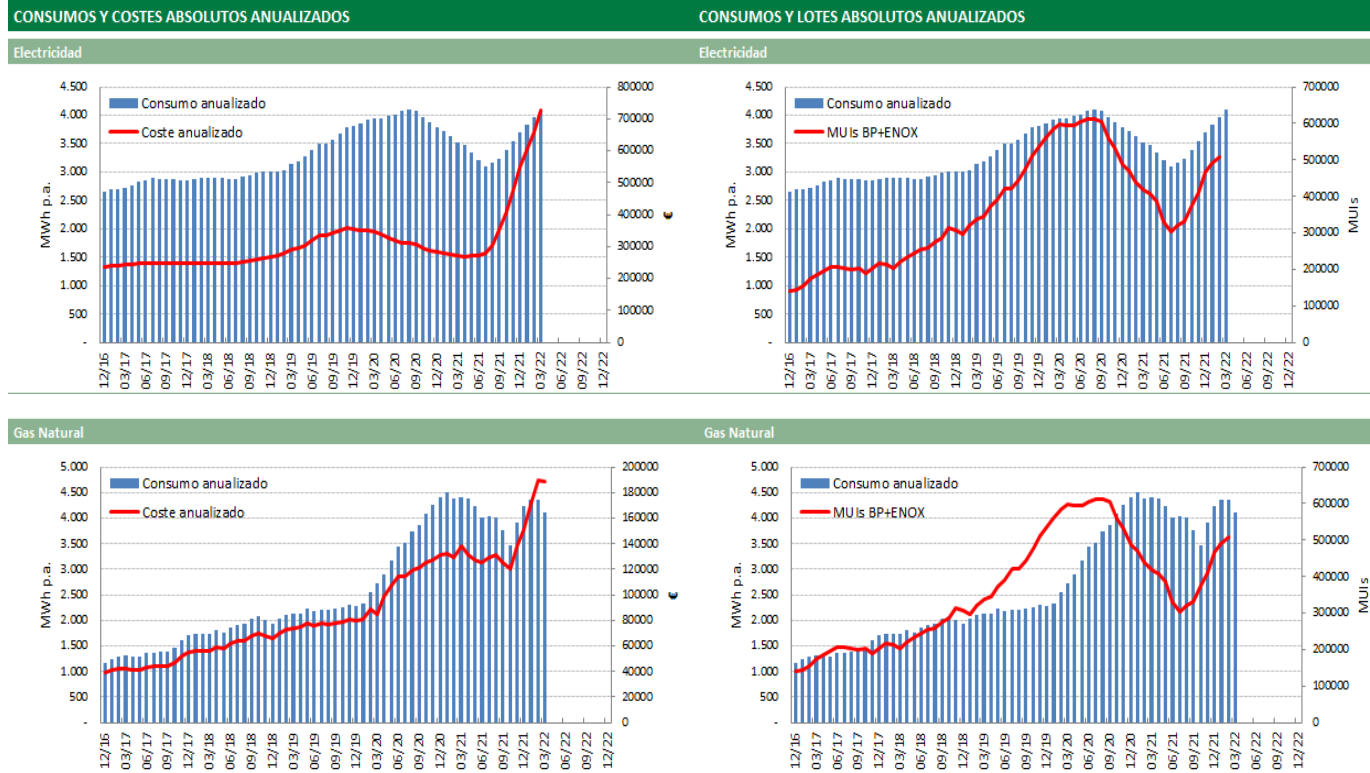
DATA ANALYSIS TO IMPROVE ENERGY PERFORMANCE.

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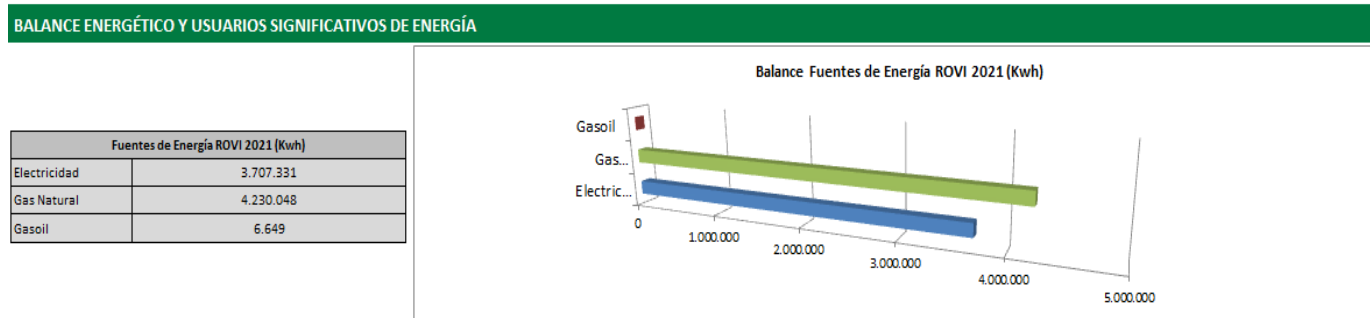
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1. Analysis of annual historical energy consumption, energy cost and manufacturing.



1. Analysis of energy sources, energy balance and significant energy users



The EnMS focuses its efforts and resources on the continuous improvement of the energy performance of those energy consumers that exceed 4% of the organization's total consumption (significant energy users).

These SEUs are obtained after carrying out an energy inventory and analysing consumption.

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Electricidad

USE = Consumo > 4 %

		BALANCE 2021			USOS SIGNIFICATIVOS DE ENERGÍA				
Área	Proceso Productivo / Equipo	%	Consumo	ud	¿Tiene línea base?	¿Es un USE?	¿Está medido?	¿Cuáles son las variables?	¿Quién influye?
Producción	Línea A	0,1%	3.412 kWh		No	No	No	Volumen de producción	Producción
	Línea B	0,2%	6.625 kWh		No	No	No	Volumen de producción	Producción
	Línea C	0,2%	5.759 kWh		No	No	No	Volumen de producción	Producción
	Filtros Secadores	0,7%	26.875 kWh		No	No	No	Volumen de producción	Producción
	Centrifugación	1,3%	48.018 kWh		No	No	No	Volumen de producción	Producción
	Liofilización	17,0%	629.608 kWh		Si	Si	Si	Volumen de producción Fabricados / Averías / Mtos	Producción
	Dispensing SA	0,0%	895 kWh		No	No	No	Volumen de producción	Producción
	Dispensing MP	0,0%	805 kWh		No	No	No	Volumen de producción	Producción
	Parque de Tanques	0,4%	13.683 kWh		No	No	No	Volumen de producción	Producción / Mantenimiento / Ocupantes
	Almacén Moderna	0,0%	557 kWh		No	No	No	Volumen de producción	Producción / QC
Utilities	Aire Comprimido	6,1%	227.765 kWh		No	Si	Si	Volumen de producción / Calendario	Producción / Mantenimiento
	Condensadores Evaporativos	3,7%	135.342 kWh		No	No	No	Volumen de producción / Calendario/CDD	Producción / Mantenimiento
	Calderas	0,4%	14.366 kWh		No	No	No	Calendario/HDD	Producción / Mto. / Ocupantes
	Calefacción	0,5%	19.710 kWh		No	No	No	HDD / Ocupación	Mantenimiento
	Agua Caliente Sanitaria (ACS)	0,2%	6.213 kWh		No	No	No	Ocupación/HDD	Ocupantes
	Enfriadoras	20,9%	773.634 kWh		Si	Si	Si	Volumen de producción / CDD	Producción / Mantenimiento / Ocupantes
	Ajibe PCI	0,0%	317 kWh		No	No	No	Calendario	Mantenimiento
	Sala Hídrica	1,4%	52.560 kWh		No	No	No	Ocupación / Volumen de producción / Calendario	Producción / Mantenimiento / Ocupantes
	Agua Purificada	10,0%	371.307 kWh		No	Si	No	Volumen de producción	Producción / Mantenimiento
	COVs	0,5%	17.520 kWh		No	No	No	Volumen de producción	Producción / Mantenimiento
	Vertidos	0,0%	1.722 kWh		No	No	No	Volumen de producción / Ocupación	Producción / Mantenimiento / Ocupantes
	Climatización	13,7%	507.243 kWh		No	Si	No	Calendario	Producción / Ocupantes / QA
	RTO	4,7%	173.407 kWh		No	Si	Si	Volumen de producción	Producción / Mantenimiento
Iluminación	Iluminación	5,5%	5,5%	204.100 kWh	No	Si	No	Ocupación	Ocupantes
I+D	I+D	1,2%	1,2%	44.373 kWh	No	No	No	Calendario / Ocupación	Ocupantes
Laboratorios	Laboratorios	1,1%	1,1%	40.026 kWh	No	No	No	Calendario / Ocupación / Volumen de producción	Producción / Ocupantes
Oficinas	Oficinas	1,5%	1,5%	54.685 kWh	No	No	No	Calendario / Ocupación	Ocupantes
Resto	Resto	0,4%	0,4%	13.020 kWh	No	No	No	--	--

Gas natural

USE = Consumo > 4 %

		BALANCE 2021			USOS SIGNIFICATIVOS DE ENERGÍA				
Área	Equipo	%	Consumo	ud	¿Tiene línea base?	¿Es un USE?	¿Está medido?	¿Cuáles son las variables?	¿Quién influye?
Utilities	Calderas	51,3%	2.169.999,74 kWh		No	Si	Si	CDD / HDD / Volumen de producción / Ocupación	Producción / Ocupantes
	GVL	9,9%	420.000 kWh		No	Si	No	Volumen de producción	Producción
	Plantas de Agua	14,2%	600.000 kWh		No	Si	No	HDD / Volumen de producción	Producción
	Termostatación Reactores	5,9%	250.000 kWh		No	Si	No	HDD / Volumen de producción	Producción
	ACS	8,3%	350.000 kWh		No	Si	No	HDD / Ocupación / Calendario	Ocupantes
	Climatización	13,0%	550.000 kWh		No	Si	No	HDD / Ocupación / Calendario	Ocupantes
	Resto	0,0%	0 kWh		No	No	No	n/a	n/a
	RTO	48,7%	2.060.048,26 kWh		No	Si	Si	Volumen de producción	Producción / Mantenimiento
TOTAL GAS NATURAL		100%	4.230.048 kWh						
TOTAL USES		100%	4.230.048 kWh						
TOTAL OTROS		0%	0 kWh						

In the tables all the energy-consuming equipment of the plant is represented, that is, an inventory and energy balance of the plant. Equipment that exceeds a consumption greater than 4% of the total energy source is identified as significant energy use.

Do, Check, and Act

To engage employees in energy management, we created awareness campaigns that are shared by mail and in the canteen's TV. For example: <https://www.youtube.com/watch?v=dqBWvUdf1ag>, <https://www.youtube.com/watch?v=VRGrb5hHp5M>

Next, in the following excel table, we have identified more than 100 variables (relevant and non-relevant) that help us to determine the baseline and the energy performance indicators. In this table, we define the frequency of data sampling and where they are collected:

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Medida	Energía	Clase	Instrumentación existente	Ud	Tipo de lectura	Frecuencia de datos	Sistema de recogida	Frecuencia de actualización de IDens	Frecuencia de seguimiento	Fecha último seguimiento	Tolerancia
Total Electricidad	Electricidad	Consumo (Total)	Medidor de compañía	kWh	Automática	15 minutos	Automática (DEXCell)	Semanal	n/a	n/a	n/a
Total Gas Natural	Gas Natural	Consumo (Total)	Medidor de compañía	m3	Automática	15 minutos	Automática (DEXCell)	Semanal	n/a	n/a	n/a
Total Agua	Agua	Consumo (Total)	Contador de agua	m3	Automática	15 minutos	Automática (DEXCell)	Semanal	n/a	n/a	n/a
Compresor Atlas	Electricidad	Consumo (USE)	Medidor de electricidad	kWh	Automática	15 minutos	Automática (DEXCell)	n/a	Bienal		5% de la medida
Compresor Ingersoll	Electricidad	Consumo (USE)	Medidor de electricidad	kWh	Automática	15 minutos	Automática (DEXCell)	n/a	Bienal		5% de la medida
Liofilizador LLF-LF1	Electricidad	Consumo (USE)	Medidor de electricidad	kWh	Automática	15 minutos	Automática (DEXCell)	n/a	Bienal	24/03/201	5% de la medida
Liofilizador LLF-LF2	Electricidad	Consumo (USE)	Medidor de electricidad	kWh	Automática	15 minutos	Automática (DEXCell)	n/a	Bienal	17/10/2021	5% de la medida
Liofilizador LLF-LF3	Electricidad	Consumo (USE)	Medidor de electricidad	kWh	Automática	15 minutos	Automática (DEXCell)	n/a	Bienal	16/04/2021	5% de la medida

This image represents some examples of all the variables that are used to determine the baseline and performance indicators, as well as their collection frequencies and the data collection system.

When there is a continued worsening of the energy performance of any indicator, we carry out an investigation and it is collected in the following table. Thanks to the energy performance indicators, we can detect deviations of energy consumption and react.

The objective is to detect unexpected energy consumption in time:

Fecha de ident.	Fecha Desviación	Fuente	USE	Origen	Desviación	Responsable	Investigación	
115	27/12/2021	17/12/2021	Electricidad	LLF-LF2	Francisco Ortiz	Uso no planificado del Liofilizador	Francisco Ortiz	Avería compresor . Se sustituye y se comprueba funcionamiento. MC-0177-21
116	01/02/2022	01/02/2022	Electricidad	Moderna	Francisco Ortiz	Se produce un aumento del indicador de electricidad	Francisco Ortiz	Posibles desviaciones en los consumos estimados de moderna con respecto al real. Verificar con nuevo contador a instalar
117	07/02/2022	07/02/2022	Electricidad	LLF-LF4	Francisco Ortiz	Uso no planificado del Liofilizador	Francisco Ortiz	Sustitución separador de aceite compresores nº 4 y 5 + prueba de funcionamiento. MC-0027-22
118	11/02/2022	28/01/2022	Electricidad	LLF-LF4	Francisco Ortiz	Se produce un aumento del indicador de electricidad	Francisco Ortiz	Montaje bomba de fluido y prueba de funcionamiento. MC-0004-22

This image shows some examples of studies that have been carried out on consumption deviations. These deviations occur if there has been a worsening of the energy performance during the last 7 days and at the same time during the last 28 days (identified with the red color in the energy performance report table) or if there has been an improvement of the energy performance greater than 10% in the last 7 days and in the last 28 days (green color in the energy performance report table). Critical operating parameters have been established for each of the significant energy uses, all defined in the following table:

USE	Documento	Código Formulario QA	Código Ficha Mto. Preventivo	Frecuencia de revisión	¿Quién debe ser informado?	¿Quién debe ser informado de desviaciones?
Liofilización	Revisión semanal de los liofilizadores y sistema de descongelación	FM-104	Prev 16.S	Semanal	Responsable de Mantenimiento	Gestor energético
Aire Comprimido	Revisión diaria sala ACO y compresores ACO de reserva	FM-102	Prev 04.D	Diaria	Responsable de Mantenimiento	Gestor energético
Condensadores Evaporativos	Revisión diaria condensadores evaporativos	FM-115	Prev 07.D	Diaria	Responsable de Mantenimiento	Gestor energético
	Revisión semestral de los condensadores evaporativos	FM-131	Prev 07.SM	Semestral	Responsable de Mantenimiento	Gestor energético
Enfriadoras	Revisión anual enfriadora utilidades 1 LAE-ENF4	FM-140	Prev 20.A	Annual	Responsable de Mantenimiento	Gestor energético
	Revisión semanal enfriadora utilidades 1 LAE-ENF4	FM-108	Prev 20.S	Semanal	Responsable de Mantenimiento	Gestor energético
	Revisión mensual de las enfriadoras de proceso 1, 2 y 3	FM-125	Prev 39.M	Mensual	Responsable de Mantenimiento	Gestor energético
	Revisión trimestral de las enfriadoras de proceso 1, 2 y 3	FM-146	Prev 39.T	Trimestral	Responsable de Mantenimiento	Gestor energético
Agua Purificada LAP-AP1	Registro de datos y revisión diaria planta de agua purificada LAP-AP1	FM-077	Prev 06.D	Diaria	Responsable de Mantenimiento	Gestor energético
	Revisión mensual planta de agua purificada LAP-AP1	FM-089	Prev 06.M	Mensual	Responsable de Mantenimiento	Gestor energético
Agua Purificada LAP-AP2	Registro de datos y revisión diaria planta de agua purificada LAP-AP2	FM-046	PREV49	Diaria	Responsable de Mantenimiento	Gestor energético
	Revisión mensual planta de agua purificada LAP-AP2	FM-113	Prev 49.M	Mensual	Responsable de Mantenimiento	Gestor energético
Climatización	Revisión anual UTA's y secadora	FM-141	Prev 25.A	Annual	Responsable de Mantenimiento	Gestor energético
	Revisión mensual UTA's y secadora	FM-097	Prev 25.M	Mensual	Responsable de Mantenimiento	Gestor energético
	Revisión anual extractores UTA's	FM-142	Prev 26.A	Annual	Responsable de Mantenimiento	Gestor energético
	Revisión mensual extractores UTA's	FM-009	Prev 26.M	Mensual	Responsable de Mantenimiento	Gestor energético

This image is a representation of the table in which all the critical operating parameters defined for the SEUs are collected. The name of the form to be completed and the frequency of data collection and verification are also

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indicated.

New projects are approached from the perspective of energy efficiency. Each member of the organization that may have an impact on energy performance is included in a training plan defined in the EnMS.

There is an audit plan, also defined in the EnMS where the external and internal audits are planned.

The organization's purchases are also made taking into account energy efficiency factors. Suppliers are aware of the organization's commitment to the responsible use of energy that Laboratorios ROVI wants to make at all levels.

Transparency

As a sign of Laboratorios Farmacéuticos ROVI S.A. Granada commitment to the EnMS, the ISO 50001:2018 certificate and the energy policy of ROVI have been published on the website. Link: <https://www.rovi.org/es/accionistas-inversores/esg>

<p>Certificado ISO 5001:2018 Laboratorios Farmacéuticos ROVI S.A. Planta de Granada</p> <p>Certificado de Laboratorios Farmacéuticos ROVI S.A. Planta de Granada</p>	<p>Política Energética de Laboratorios Farmacéuticos ROVI S.A. Planta de Granada</p>	<p>Política de Sostenibilidad</p> <p>Política de sostenibilidad en materia medioambiental y social aprobada por el Consejo de...</p>	<p>Política integrada de gestión</p> <p>Principios para la gestión ambiental y de seguridad y de salud laboral que alcance a...</p>
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As part of this transparency, there is communication within the boundaries of Laboratorios Farmacéuticos ROVI S.A. Granada about the EnMs, the energy policy, ideas for improvement, energy performance and awareness campaigns: <https://videoenplay.com/login/assets/uploads/ge6i6-sabiasqueeficenergetgranada.mp4>

What We Can Do Differently

If we were to start over with EnMS implementation, the first thing I would do would be to devote more resources to explaining the real benefits of EnMS through communication and awareness campaigns at all levels of the organization. With greater involvement of all the people who are part of the organization, the implementation would have improved even more since they would understand the importance of their actions in the performance of the EnMS.

We would also have improved the implementation of the EnMS if we had created synergies with industries in the sector where we could have shared our ideas to move towards the same point, which is the improvement of energy performance, having national and international forums/meetings related to energy efficiency, publish on social networks, such as LinkedIn, the achievements obtained after the implementation of energy efficiency measures to obtain feedback from other colleagues. Regarding the use of alternative tools to those used in the installation of the EnMS, I would use a new tool that facilitates the management of all the documentation that is generated in the EnMS.

In conclusion, the most important thing about this Energy Management system is how integrated it is in the organization's day-to-day activities. Today, if we think of ROVI Granada Pharmaceutical Laboratories, we think of energy efficiency. The EnMS is not an independent system. For Laboratorios Farmacéuticos ROVI to exist, the EnMS must exist. This is the most important value and in turn the most difficult to achieve.

“Laboratorios Farmacéuticos ROVI has managed to breathe energy management.” Francisco José Ortiz, energy manager.



The Energy Management Leadership Awards is an international competition that recognizes leading organizations for sharing high-quality, replicable descriptions of their ISO 50001 implementation and certification experiences. The Clean Energy Ministerial (CEM) began offering these Awards in 2016. For more information, please visit www.cleanenergyministerial.org/EMAwards.