

New trends: Green Engineering, sustainability through a proper design

How to apply smart designs in engineering projects, to minimize run cost and maximize efficiency?

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WHITE PAPER

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ABSTRACT

In today's situation, sustainability is a more critical concept in engineering projects. Sustainability is related to the ability to meet the needs of the present without compromising the ability of future generations to meet their own needs. In other words, sustainability is about ensuring that we leave the world in a better condition than we found it.

In the design stage, where engineering starts acting, is where this concept must be kept in mind. This article unveils how and where Green Engineering plays a key role in the development of critical installations, process facilities and manufacturing plants.

Introduction

Sustainability is important in engineering projects for several reasons. First, it helps to ensure that the project is environmentally friendly. This means that the project should not have a negative impact on the environment and should ideally have a positive impact. For example, a sustainable engineering project might use renewable energy sources, or it might be designed to minimize waste and pollution.

Second, sustainability helps to ensure that the project is socially responsible. This means that it should benefit society, and not just a selected few. For example, a sustainable engineering project might be designed to minimize use of clean water, not adversely impacting the community.

Finally, sustainability helps to ensure that the project is economically viable which means that it should be financially sustainable by itself. For example, a sustainable engineering project might be designed to reduce energy costs or designed to create new jobs.

In conclusion, sustainability is a critical concept in engineering projects. It helps to ensure that the project is environmentally friendly, socially responsible, and economically viable. Incorporating sustainability into engineering projects helps to create a better world for ourselves and for future generations. Here is where Green Engineering plays a key role.

As background, and to introduce the relevance of Green Engineering in the overall picture, let us mention that the Agenda for Sustainable Development, adopted by all United Nations Member States in 2015, which defines 17 Sustainable Development Goals, to reduce the climate change effect, not exceeding some specific limits by 2030. Green Engineering acts mainly in improving 3 of the goals (the 7th – Affordable and clean energy, 11th Sustainable Development Goals and 13th – Climate Action), by introducing these features from the initial design of the project, with the objective of minimizing the overall environmental impact.

These new, or not that new, features shall be used from the beginning, with the initial design to be developed by the engineers, where they can provide the right approach, always trying to reduce the environmental impact of the facility and its operations.

Among the existing options, the features within the Green Engineering services that are going to be analyzed are the following:

- Cleanroom size reduction.
- Computational Fluid Dynamics (CFD).
- Energy saving techniques in utilities installations.
- Smart Cleanroom.
- Paperless Commissioning & Qualification and Engineering.
- Carbon footprint evaluation.

Cleanroom size reduction.

The cleanroom should contain only what is necessary, reducing its size to the minimum.

During the engineering design, there needs to be a good balance between flexibility and oversizing, developing appropriate feasibility studies and confirming as much as possible the required production equipment. The over-sizing (just in case larger machines are installed in the future .) will increase not only the initial capital investment, but also the working cost and environmental footprint, which is not good at all.

The areas should be designed in such a way that only equipment parts that must be in the cleanroom are there. For example, only the loading elements of a coater shall be placed in the cleanroom while the main part of the machine is placed outside the cleanroom in a non-classified area. This reduces cleanroom size, while simplifying maintenance operations.

Computational Fluid Dynamics (CFD).

As a general introduction, CFD analysis provides:

- A scientific approach in air-flow design to achieve maximum optimization.
- Optimized design, as CFD can reduce or eliminate the uncertainty associated with a cleanroom facility by simulating the projected design to predict or anticipate the performance.

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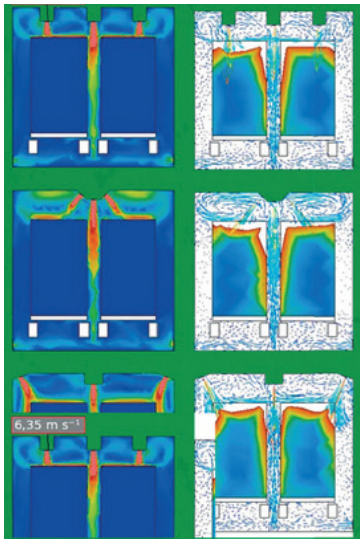
From a Green Engineering perspective, CFD can be used to optimize the air change rate in cleanrooms, as indicated in the HVAC guide from ISPE.



It can also anticipate the cleanroom recovery time, which should be 20 minutes maximum to comply with EU GMP Annex 1, concluding that less supply airflow is required to comply with airborne particles levels inside the cleanroom.

Figure 1. CFD Section views of a loaded drying chamber (Source: Telstar)

This approach will reduce the potential oversizing of the HVAC systems. And this is the reason CFD is also a Green Engineering solution.

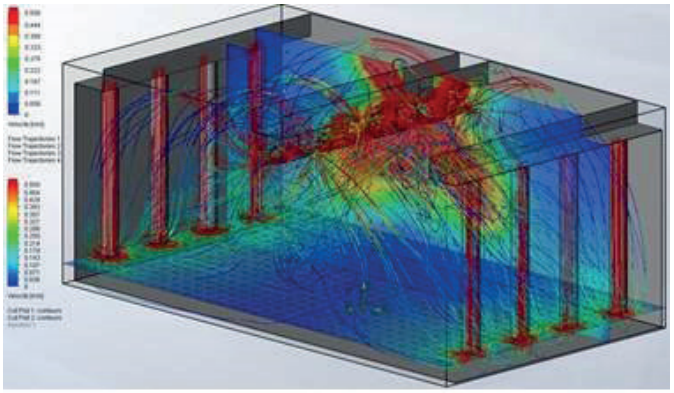


Figure 2. CFD Picture of an empty drying chamber (Source: Telstar)

Some additional advantages for the use of CFD that could be highlighted are:

- The modelling of the fluid dynamic in critical rooms (such as aseptic areas with laminar flows) allows the simulation of the airflow at Detail Engineering stages to predict the results of the smoke test if the rooms are constructed as designed.
- Points of accumulation of particles or inappropriate airflow patterns can be detected, analyzed, and corrected at design stages, ensuring that when HVAC qualification comes and smoke tests are performed, the results will be successful.
- CFD can also be used to define better the position for particle counters.
- It is also recommended in hot rooms and drying chambers (as for incubation or softgel capsule manufacturing) to predict how the chambers are going to behave, anticipating start-up and commissioning problems.
- It can be used as well to define better the position for air diffusion elements (supply and return) to avoid temperature stratification in the warehouse area.
- It also becomes useful to help define the position of the temperature sensors, either in the hot rooms, drying chambers or warehouse areas.

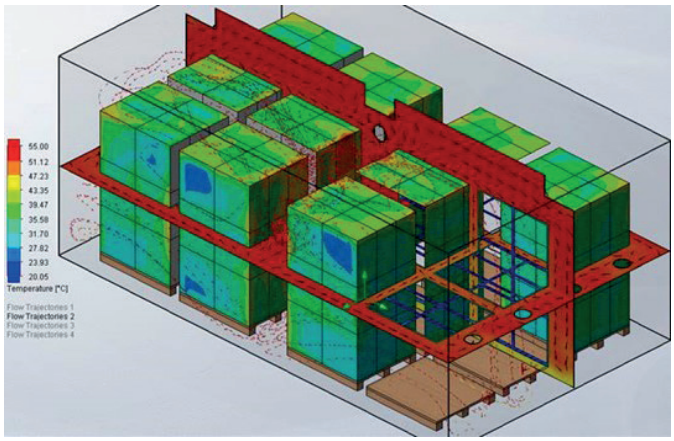


Figure 3. CFD picture of a loaded drying chamber (Source: Telstar)

It may seem that CFD is something new, but it has been an available technology for several years, even if it is not widely used in the pharmaceutical world. In some other fields it has been frequently used and it is even indicated in ISO 14644-4 (Cleanroom design), issued on Nov 23, that CFD models are a good option before going live.

Energy saving techniques in utilities installations.

This topic could be very extensive, but it is going to be limited to the energy savings associated with the selection of utilities equipment (such as steam boiler house, chillers and heat pumps, HVAC and Cold WFI generation).



Figure 4. Cleanroom HVAC and Utilities installation (Source: Telstar)

Steam boiler house

The energy losses associated to a steam boiler house can be reduced, optimizing the energy efficiency, by implementing any of the following three proposals, among others:

1. To use as feeding water for the boiler either soft water or reversed osmosis water (this reduces the boiler blowdown and boiler fuel consumption, as well as scaling).

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2. Reusing flash steam generated by a higher pressure system for use in a lower pressure system can enable considerable energy savings in addition to improving a plant's working environment by reducing vapor cloud
3. Installation of economizers at the steam boiler chimney, having two options:
   (a) To preheat the boiler feeding water or
   (b) To preheat the air for the boiler burner.

Chillers and heat pumps

In regards of chillers and heat pumps selection:

1. It is important to use refrigerants with low Global Warming Potential.
2. The equipment can be selected with partial or total heat recovery OR with direct free cooling.
3. Additionally, the equipment should be selected with high values in SCOP (Seasonal Coefficient of Performance) and/or SEER (Seasonal Energy Efficiency Ratio).

HVAC systems

Talking about energy savings techniques in HVAC systems, some of them are listed as follows:

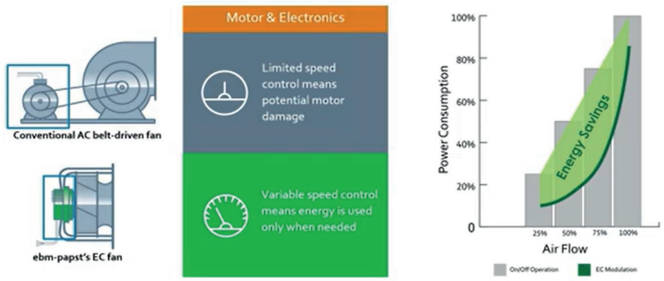

Figure 5. AC vs EC (Source: EBM-Papst)

1. Recovering the heat from the exhaust airflow (if possible) with two viable options, as an example:

   a. The exhaust coming from the air compressors is to be used to heat up adjoining rooms, such as warehouse areas.

   b. The exhaust air coming from rooms to be used to cool down (or ventilate) some hot areas.

2. Regarding AHU design, installation of heat recovery sections within the AHU to recover the heat from the exhaust air and either cool down or heat up the fresh air intake should be considered.

   It is also relevant to design AHUs with adequate Thermal Bridging factor and be proactive in selecting EC fans instead of the conventional AC fans.

3. Finally, the HVAC system for office areas is recommended to be designed with variable refrigerant Flow (VRF units) to reduce energy consumption.

Cold WFI

As an alternative for distillation, WFI can be generated as well by means of ultrafiltration membrane, reducing energy consumption. Advantages are that cold WFI is at room temperature, lower CAPEX is required, and the carbon footprint is reduced, whilst still following the current regulation.



Figure 6. WFI generation unit with membrane technology (Source: Puretech)

Smart cleanroom

The highest electricity consumption in a pharmaceutical plant is the HVAC system that feeds cleanrooms. It is so important that there is a specific regulation, ISO 14644-16, talking about cleanroom energy efficiency.

The most common way to comply with a certain grade is by 'washing' the air of that room with clean air that is moved by the Air Handling Units (AHU) into the room through filters and removed through the return ducts. This is what is known as air changes per hour. The more changes per hour in a room, the easier it is to reduce the number of particles, but at the same time, the more expensive it becomes.

When talking about clean room classification, it must be mentioned that the values of air changes per hour to comply with the room classification are based on experience, recommendations or guidance provided by several institutions, such as the FDA or ISPE.
It has been stated that air changes in classified areas should be at least 20 renovations per hour.

However, the airborne particles level is the critical parameter to be maintained within the limits defined by regulations, and not the air change rate.

Consequently, it may happen that less airflow would be enough to comply with airborne particles level. If this is achieved, the consequence will be optimized power consumption.

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The key parameters that shall be under control are:

- Particles: What define if a cleanroom complies with a certain classification.
- Pressure: That keeps the 'air barrier' between different classification cleanrooms or get the right air flow within cleanrooms.
- Temperature
- Humidity

As already mentioned, even it is not the only key parameter to be controlled, particle level is the main one and the required limits, according to EU GMP Annex 1 are:

Table 5: Maximum permitted total particle concentration for monitoring.

Grade	Maximum limits for total particle ≥ 0.5 µm/m³		Maximum limits for total particle ≥ 5 µm/m³	
	at rest	in operation	at rest	in operation
A	3 520	3 520	29	29
B	3 520	352 000	29	2 930
C	352 000	3 520 000	2 930	29 300
D	3 520 000	Not predetermined [a]	29 300	Not predetermined [a]

[a] For grade D, in operation limits are not predetermined. The manufacturer should establish in operation limits based on a risk assessment and on routine data, where applicable.

Figure 7. Maximum permitted total particle concentration for classification for monitoring (Source: Volume 4 EU Guidelines for GMP - Annex 1)

This means that a certain grade is achieved when particle levels are below the specific limit, and this is the real requirement and not the number of air changes per hour (ACH).

The Smart Cleanroom does not change the way that engineers define the design airflow for the Air Handling units. The same recommendations given by ISPE regarding ACH (as per the values indicated in the picture) are applied. Neither is changed the way temperature, relative Humidity and room differential pressure are controlled.

The differentiator factor is the inclusion of particle counters in the smart cleanroom, which is what really makes it possible to vary the supply airflow during operation, with the consequent savings in fan energy consumption.

This airflow will be variable and regulated to be within design flow and ECO minimum flow, ensuring that the 4 cleanroom key parameters are always met.

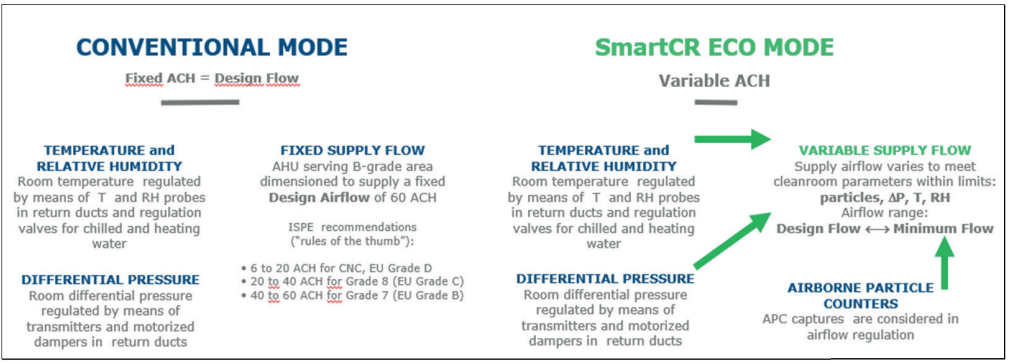

Figure 8. Smart Cleanroom ECO mode vs Conventional mode (Source: Telstar)

In the figure, the differences between conventional and smart cleanroom eco modes are shown.

Explaining the smart cleanroom functionality is set out below:

(1) Initially, the fan starts supplying a design flow, which is the fixed airflow defined for the conventional mode. At this initial stage, the cleanroom parameters are within limits.

(2) ECO mode starts gradually decreasing the AHU fan speed in controlled steps until reaching the established minimum flow unless there is a perturbation in any of the cleanroom parameters.

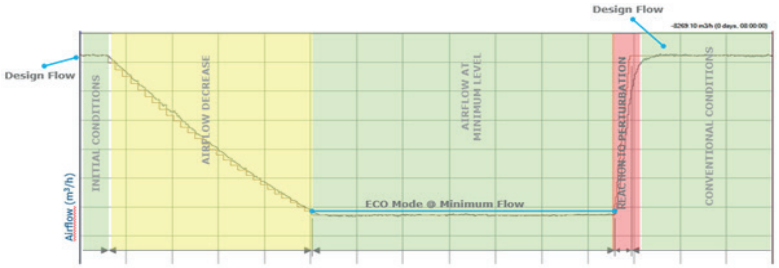

Figure 9. Graphic of the ECO mode activation and design mode recovery (Source: Telstar)

(3) Then, when working in ECO mode at minimum flow, if a perturbation drives the cleanroom out of specifications, ECO mode starts gradually increasing the AHU fan speed up to the design flow to return extremely fast within the specified limits of T, RH, DP, and maximum admissible number of particles. Once the cleanroom returns within the limits, the ECO mode starts reducing the AHU fan speed gradually again, after an established period of time. And the cycle is repeated.

The main components of the smart cleanroom system are not that different from the components of a standard installation:

- Differential pressure transmitters, temperature and relative humidity transmitters, supply air & return dampers (motorized automatically opened or closed so airflow can vary) or variable speed fans, all controlled by a PLC.

And the ones, not that standard in the past, but more present in every cleanroom.

- Airborne particle counters, isokinetic probes and centralized vacuum system.

During start-up & commissioning, the minimum airflow to guarantee T, RH, max. admissible number of particles and DP is defined.

Regarding qualification strategy, a risk analysis is performed to assess if the qualification tests must be conducted at design or at minimum flow.

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The conclusion of this risk analysis is that most of the tests (as indicated in the table) must be done at worst case scenario, which is under minimum airflow of the ECO mode. Consequently, the qualification effort required for the smart cleanroom is slightly increased.

C&Q: QUALIFICATION STRATEGY

Risk Analysis Conclusions on the standard Qualification tests:

Test	Conventional System	SCR System
HEPA Filter Integrity	Design airflow	Worst case (Design airflow)
Rooms Differential Pressure	Design airflow	Design airflow & Min. Airflow
Particle Concentration "at rest"	Design airflow	Worst case (Min. Airflow)
Air Change Rates (Informative)	Design airflow	Design airflow & Min. Airflow
Air Visualization (Smoke Test)	Design airflow	Worst case (Min. Airflow)
Recovery Time Verification	Design airflow	Worst case (Min. Airflow)
Initial Microbiology Count	Design airflow	Worst case (Min. Airflow)
Temperature & Humidity	Design airflow	Worst case (Min. Airflow)

Figure 10. Table of Qualification testing for Smart Cleanroom (Source: Telstar)

The steps that need to be followed to implement the smart cleanroom in a new project are:

- Cleanroom, HVAC and APC Basic and Detailed design
- APC Risk Analysis
- Return of Investment (ROI) study
- Proposal of Engineering services, supply and execution to develop the construction project and implementation of the SmartCR HVAC control system, including C&Q.

Regarding smart cleanroom implementation in revamped facilities, it should be developed a preliminary feasibility study, which mainly includes a previous analysis of the existing HVAC system implemented in the facility and a Site Survey to evaluate the need of hardware and software to be added or replaced.

The other 4 topics indicated are similar to those for greenfield facilities.

Smart cleanroom has shown the following energy savings compared with a conventional system:

- Reduction of up to 77% in fans electrical consumption.
- Up to 29% cost reduction in HEPA filters replacement (since the reduction in airflow means that the filters will be clogged later, filters will be lasting longer).
- Up to 54% reduction in black utilities consumption.

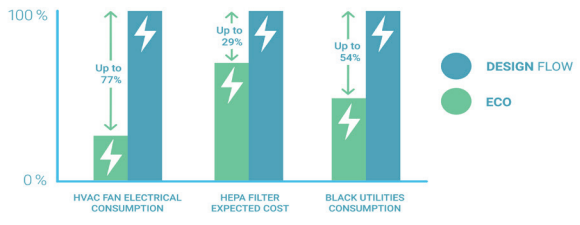

Figure 11. Smart Cleanroom consumption savings in ECO mode (Source: Telstar)

It is worth saying that the investment required for its implementation in a greenfield aseptic facility may seem not strictly significant if compared with the cost of the overall project, not even reaching the 0,5% of the global investment.

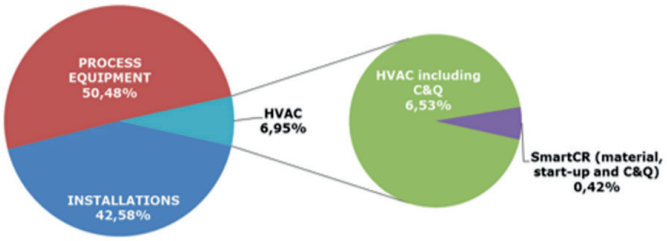

Figure 12. Smart Cleanroom investment vs total investment (Source: Telstar)

Further details about smart cleanroom can be found in the case study developed by A. Fernández on March 2020 **(https://www.telstar.com/implementation-of-the-smartcr-in-an-aseptic-processing-facility-airflow-reduction-and-energy-savings-achieved-in-hvac-compared-to-conventional-systems/**

Paperless Commissioning & Qualification and Engineering

From a commissioning & qualification (C&Q) perspective, digital smart qualification software makes project management simpler, optimizing the entire validation lifecycle, by significantly reducing the paper-intensive validation process of editing, approval, and execution.

Validation is an essential process in pharmaceutical production as it provides documented evidence that a system or process complies with GMP/FDA regulatory requirements, while endorsing the correct manufacture of products at the required quality level and with a safety guarantee. The validation lifecycle of a pharmaceutical process involves a long tedious flow of editing, approval, and execution (that consumes time and vast amounts of paper), in addition to the process of subsequent management of this documentation, its archiving and subsequent recovery, wasting human, economic and environmental resources.

The use of database applications designed for electronic and digital management optimizes the entire validation life cycle. Using such software has numerous advantages: project management, foster standardization, guarantee traceability, ensure compliance with Data Integrity concepts, provide real-time information on the status of the different documents, and allowing electronic execution and automatic generation of queries and reports on the validation status.

From an engineering point of view, BIM 360 drastically reduces the amount of paper used in a typical office, while improving overall productivity.

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When reviewing drawings, it is no longer necessary to print out copies, include the red marks and scan the file to send on to the drafters. Now it is easier to create markups with BIM 360 Docs directly on the digital drawing and report the corresponding incident to the drafting team. In the same way, approval of the drawings is done remotely and without the need to print them.

Carbon footprint evaluation

By implementing the green engineering techniques explained before, the environmental efficiency of the designed facilities will be improved, but the intention is also to provide an assessment with the quantification of the carbon footprint related to the equipment and installation designed during the engineering project development.

As background, the pharmaceutical industry is one of the largest industries that contributes to global warming through a range of sources of emissions throughout the supply chain. Just for comparison, as per published studies, it is estimated that the production of greenhouse gas emissions is 55% higher in the pharma industry than in automotive industry. It is obvious that the emissions must be managed more efficiently to get closer to the NET ZERO challenge.

Paying attention to the supply chain:

1. In the first stage (the sourcing), emissions are produced in the extraction of raw materials. Pharmaceutical companies are developing techniques to make this necessary step more sustainable and reduce emissions.
2. During the second stage, manufacturing of pharmaceuticals, for which innovative technologies (such as the ones described in this article) are being integrated to make processes greener and more efficient, including digitalization and specialist infrastructure.
3. The third step is distribution, with more companies working on a more local level, to make distribution more environmentally friendly.
4. For the product end of life, considering the energy used for the product use, the industry (and the users) is becoming more concerned about the product waste and their impact beyond the supply chain. Management strategies are being developed to reduce waste and create a more circular economy.

When talking about the impact of the pharmaceutical industry on the environment, it is vital to consider the emissions produced, as commented.

The quantification of the direct and indirect emissions of greenhouse gases is performed by following ISO 14064.

The warming impact of the different greenhouse gases emissions to measure the carbon footprint are quantified by using the same standard unit, which is carbon dioxide equivalent.

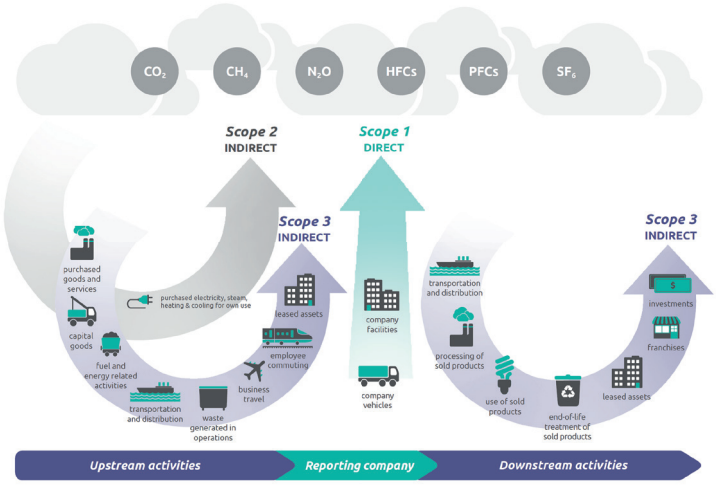

Figure 13. Overview of GHG Protocol scopes and emissions across the value chain (Source: United States Environmental Protection Agency)

Emissions are broken down into three 'scopes' and different categories, as defined in the figure 14.

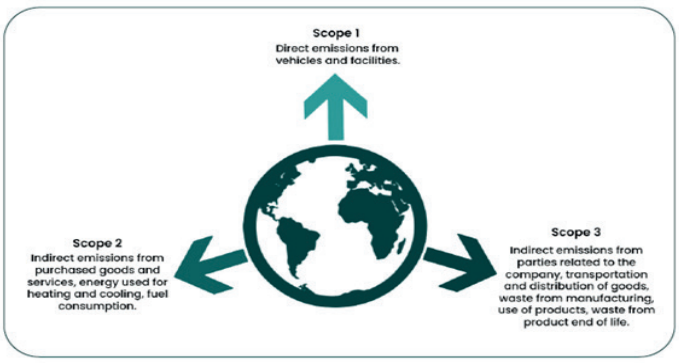

Figure 14. Direct and indirect emissions scope (Source: United States Environmental Protection Agency)

Scope 1 emissions include the direct and measurable greenhouse gas emissions a pharmaceutical company makes, such as from fuel combustion from vehicles in transporting of goods and materials.

Scope 2 emissions are more indirect, such as from using energy to heat/cool in the development stages of the value chain.

Scope 3 emissions consider the other indirect emissions associated with the pharmaceutical company. This can include all emissions the company may be indirectly responsible for, for example, those produced by the suppliers at the start of the supply chain, to those produced by customers at the other end of the chain.

Scope 1 and 2 emissions are more visible and more easily addressable. However, Scope 3 emissions are the greatest source of emissions and are also more likely to be out of a company's direct control, meaning they are harder to address in the first place.

Conclusion

From the initial design, all features described before (and the new initiatives yet to come) shall be evaluated and implemented along the execution of the engineering and construction project. This approach is perfectly applicable for either new or existing facilities, even if it makes sense to apply them from the very beginning.

By following the previous approach, each of us is giving a step into the world-wide collaboration to achieve the sustainability goals by developing smart designs in engineering projects, to minimize run cost and maximize efficiency, both outputs being positive for the day-to-day operation and for the well-being of the planet.

On the other hand, these types of considerations to be taken in the design phase are an anticipation to what may soon be a regulation to be complied (in civil part many green features are already a request in many countries).

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