SUSTAINABILITY BY DESIGN
for Pharmaceutical Products

By Ester Lovsin Barle, Patricia (Trish) Melton, PhD, and Eamon Judge

As the pharmaceutical industry faces ever-changing global challenges and market forces, it must review and revise product design to ensure that quality products remain available in the marketplace while moving toward zero pollution for air, water, and soil. This article provides an introduction on how quality products can integrate sustainability by design.

Sustainability by design (SbD) is a framework that aims to minimize impact on the environment along the entire product life cycle. To use the SbD method, two concepts of "life cycle" need to be simultaneously considered:

1. Product sustainability-associated life cycle (Figure 1): raw materials → manufacturing → packaging → distribution → use → end of life
2. Drug development life cycle (Figure 2): early development → late development → commercial phase

SbD uses life-cycle assessment (LCA) data and eco-design principles [1] to inform and direct product decisions that minimize the environmental impact of products by reducing greenhouse gas emissions, reducing use of energy and materials, avoiding hazardous materials, generating less waste, and improving sustainability potential.

WHY IS SbD NEEDED?

Previous research analysis has shown that the emission intensity of the pharmaceutical industry is significantly higher than that of the automotive industry [2], although the figures are challenging to compare. Pharmaceutical companies want manufacturing, products, and supply chain to be sustainable to drive the high quality of products while minimizing impact to the environment. To address the environmental challenges, we need a transformational change from the way we have been operating to create a sustainable future.

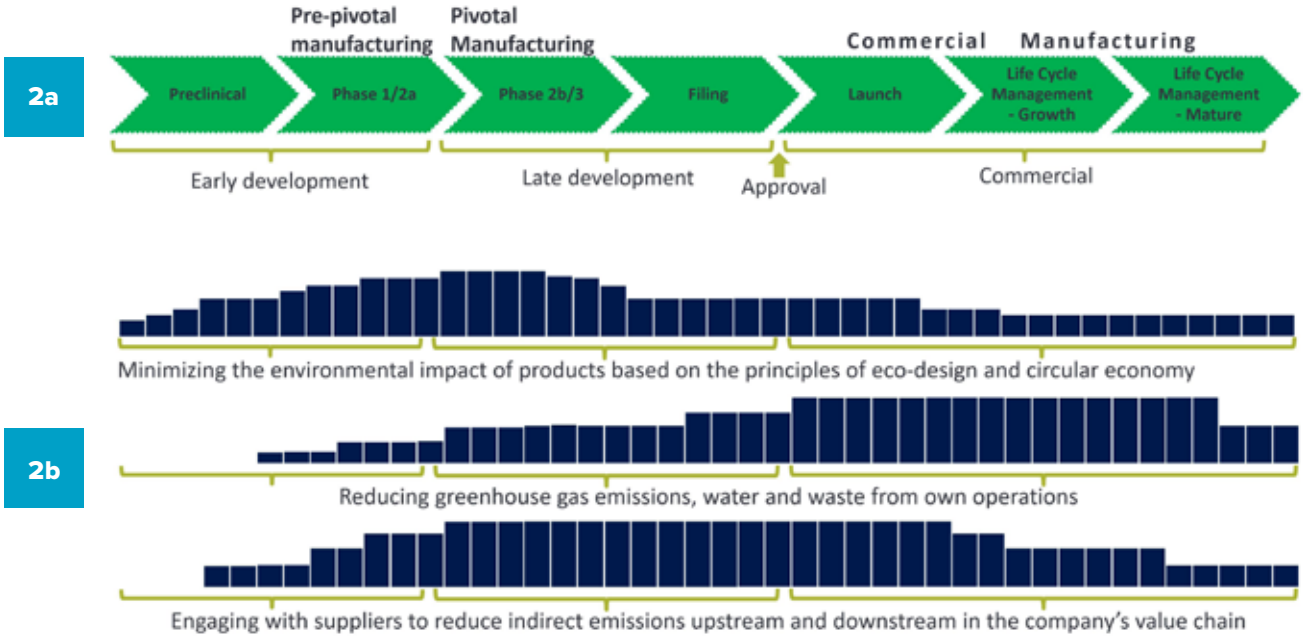
Figure 1: Product life-cycle stages as used for life-cycle thinking and assessment.



For that reason, pharmaceutical companies are rethinking how drug products are designed, manufactured, transported, administered, and disposed of across the full life cycle, including their own operations and across the value chain in healthcare systems.

The focus on the whole product life cycle aims to build in sustainability and in that regard, it is analogous to the approach taken in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline Q8 (R2): Pharmaceutical Development, which describes quality by design (QbD) for the development of pharmaceutical products [3]. QbD aims to develop quality products and processes through active management of the development knowledge to build a "design space" that uses scientific data to establish both normal operating ranges and a "control space" that supports scale-up and operation. In this way, quality is "built-in" to the product and process.

Figure 2: Pharmaceutical drug product life cycle from development through life-cycle management (Figure 2a) and relative efforts for three workstreams that deliver sustainability improvements during development stages (Figure 2b).



ICH Q8 recognizes that "quality cannot be tested into products" [3]; it needs to be a part of the development process and therefore considered at the very start of the product life cycle. To be successful, QbD requires scientific data to support knowledge of what is quality-critical and how that may change as a process is scaled up commercially. The more knowledge, the broader the design space and the more scope for operating within different parts of the design space while remaining compliant. Quality risk assessment is a vital part of this process.

It would therefore seem appropriate to take the same approach for SbD: Develop a design space that identifies those aspects of the product or process that drive environmental impacts. Conducting this evaluation during the early development phase has the potential to support "built-in" sustainability. Fundamental to this process is a strategy, integration of environmental requirements into drug development, and knowledge development management [4].

INCORPORATING SbD INTO PHARMACEUTICAL PRODUCTS

There are three synergistic workstreams that will deliver efficiency and quality requirements as intended without exceeding environmental and ecological boundaries throughout the entire life cycle.

1. Minimizing the environmental impact of products based on the principles of eco-design and circular economy
2. Reducing greenhouse gas emissions, water, and waste from the company's own operations

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3. Engaging with suppliers to reduce indirect emissions upstream and downstream in the company's value chain

The efforts required by these three workstreams are not equal and they are not equally used in all stages of the drug product life cycle. All three workstreams, however, need to be considered in the context of the materials, energy, and overall resources that are needed to bring a product to market, and through them influence resource reduction.

It has been postulated that up to 80% of a product's environmental impacts are determined at the development phase. Development is the most powerful and cost-effective point to address the resource footprint of future products [5], with early development (from preclinical to phase 2) having the most impact on possible changes, followed by late development (phase 2b to approval) [4], as seen in Figure 2. This highlights the importance of embedding sustainability in pharmaceutical research and development in line with the chemistry, manufacturing, and controls (CMC) timelines.

Table 1: Sustainability opportunities before and after regulatory approval and launch for each life-cycle stage of products. Bold = indicated activities in the stage when they are easier to influence or adopt.

Life-cycle stage	Pre-approval and launch	Post-approval and launch	Examples
Raw materials	• **Material vendor selection** • **Material use** • **Restricted substances lists**	• Material vendor selection • Material use • **Material reuse, recycling** • Updates to restricted substances lists	• Water-based synthesis instead of organic solvent [9]. • Green chemistry principles [8]. • Amendment of REACH regulation adding Triton X-100 (octyl phenol ethoxylate) to authorization list [10, 11].
Manufacturing	• **Process innovation** • **Process improvement** • **CDMO vendor selection** • **CMO vendor selection**	• CMO vendor selection • **Process optimization** • **Waste-to-energy** • **Secondary energy use** • **Renewable energy options**	• Kilogram-scale GMP manufacture of Tirzepatide using a hybrid SPPS/LPPS approach with continuous manufacturing [12]. • By closing the loop and recirculating materials, companies reduce new material demand and waste. • Use of solar farm to reduce site's carbon footprint, consequently reducing the footprint of the products manufactured at the site. • Green engineering principles [13].
Packaging and device	• **Material vendor selection** • **Material type selection** • **Packaging design** • **Reduction of packaging weight (primary, secondary, tertiary)** • **Drug delivery device design** • **Restricted substances lists** • **Recyclability and recycled content**	• Material vendor selection • Material type selection • Reduction of packaging weight (secondary, tertiary) • Updates to restricted substances lists • Recyclability and recycled content	• Thousands of the most notorious chemicals will be rapidly banned in Europe, as part of the zero-pollution goal in the EU Green Deal [14].
Distribution	• Renewable energy options • Vendor selection • **Storage conditions** • **Forecast planning**	• **Maximizing distribution routes** • **Renewable energy options** • Vendor selection	• The Science Based Targets initiative provides guidance on setting greenhouse gas reduction goals in the value chain in line with climate science. Companies are working to implement supplier engagement strategy to reach scope 3 reduction targets, which influences vendor selection [15].
Use	• **Clinical trial planning** • **Right the first time** • **Responsible use (preclinical, clinical)**	• Right the first time • **Responsible use (commercial)**	• Right-the-first-time manufacturing minimizes waste by ensuring procedures are consistently executed according to standard operating procedures [16].
End of life	• **Maximizing product lifetime (shelf-life)**	• **Packaging waste management** • **Packaging recycling** • **Pharmaceutical waste reduction (PIE)** • **Drug take-back** • **Device take-back**	• Ongoing revision of the Packaging and Packaging Waste Directive (PPWD) will seek to make all packaging recyclable by 2030 with reuse targets [17].

However, it is noteworthy to mention that while major sustainability improvements can be influences after a lead compound is identified through drug discovery and continues through all remaining stages of the drug development life cycle, the product also benefits from improvements to the facility where its manufacturing occurs. That is why synergistic efforts are needed from the manufacturing sites to reduce the energy consumption and use renewables at manufacturing facilities), as well as engage all stakeholders in the value chain.

To design a safe and environmentally sustainable chemical, material, or pharmaceutical product, principles such as green chemistry, green engineering, sustainable chemistry, circular chemistry, and safe by design have been used [6]. Recently, comprehensive sustainability improvements for newer modality have

Sustainability Definitions for the Pharmaceutical Industry

By William Whitford and Ester Lovsin Barle

While financial investment in novel therapies provides patients with new treatment options and improved quality of care, the pharmaceutical industry also recognizes its responsibility to transition toward more sustainable development, manufacturing, and stewardship of medicines throughout their life cycle.

The pharmaceutical industry commits substantial resources in new medicines and treatment options to combat a variety of illnesses and diseases affecting communities globally. This initiative's goal has always been to improve patient care and lives, but now it aims to also transition to more sustainable options, particularly the principles of a circular economy. For example, currently, every 1 kg of small molecule active ingredient can take more than 100 kg of materials to produce, requiring huge facilities for production and waste disposal, as well as long lead times [1]. Therefore, sustainability activities focus on identifying and testing alternatives to existing pharmaceutical manufacturing processes in terms of technology, ingredients, materials used, etc., while meeting patient needs as a primary goal.

Sustainability Definitions

The term *sustainability* has several distinct meanings in various contexts. The most inclusive comes from the United Nation's 2015 Sustainable Development Goal, in which 17 categories and 169 targets promote human rights and gender equality in a balance of economic, social, and environmental concerns [2]. Many have a narrower, focused view of the topic—simply envisioning the reduction of environmental impacts through use of "greener" technology.

Others adopt a more holistic view, and allow that sustainable product, process, and facility design more properly refer to creating product economies that are responsible, healthy, just, and profitable [3]. As such, the general UN definition of sustainability—"meeting the needs of the present without compromising the ability of future generations to meet their own needs"—is also the basis of approaches used in pharmaceutical applications.

In greening the arena of pharmaceuticals, we therefore look holistically at natural, human, and economic systems and seek solutions that support quality of life for all. Design decisions are evaluated against a triple-bottom-line concept that incorporates a long-term view of assessing potential effects and best practices for people (social capital), planet (natural capital), and profit (economic capital) [4]. In establishing a scope for the most important factors to consider in the corporate arena, some are defining a company's environmental, social, and governance (ESG) performance [5].

Sustainability Criteria

Environmental sustainability can be defined as responsible interaction with the environment to avoid depletion or degradation of natural resources and ecosystems and allow for long-term environmental prosperity. Organizations attribute various weight or priority to

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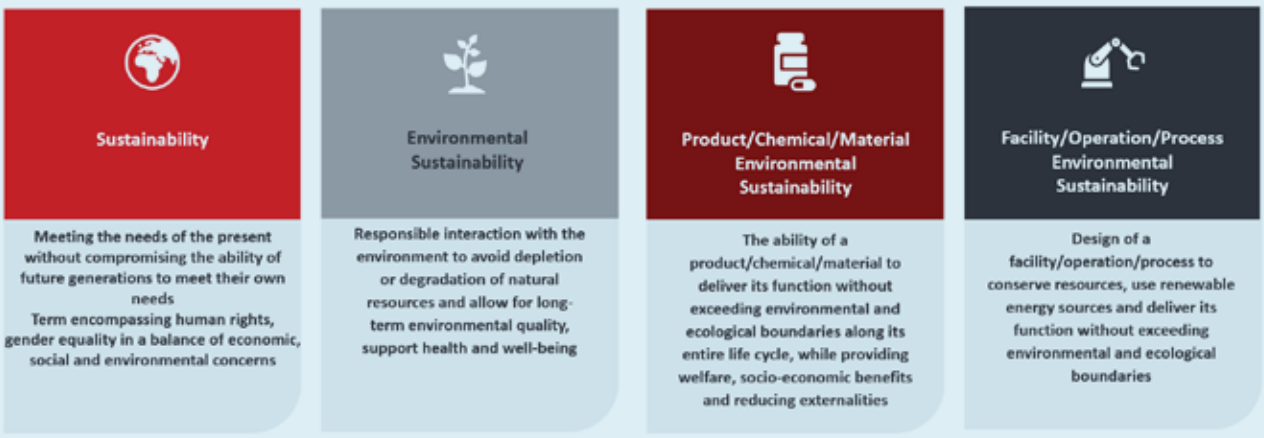
Figure 1: Definitions for sustainability concepts relevant to pharmaceuticals as integrated in the wide context of overall sustainability.



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individual environmental burden types for different, often individual, reasons. Some can maintain a differential sensitivity to particular burdens per se and impart additional weight to the consideration of those burdens.

For example, not everyone regards, a priori, the relative damage to our land, water, or air in the same way. Others can emphasize individual burdens due to local (regional setting) factors, such as water use in dry regions, or to the particular type of products, such as organic solvents in oligonucleotide production. Such ranking can also be due to special interest goals influenced by customers, regulations, or bylaws.

Consistent with the preceding general considerations, environmental sustainability in the pharmaceutical industry can be perceived from two directions: from the side of the product or operations, processes and/or facilities, both of which are required to achieve a comprehensive sustainability program. Sustainability of pharmaceutical products can be defined considering the recent JRC Technical Report (2022) [6], which has provided the following definitions for sustainable chemicals and materials:

"Sustainability could be formulated as the ability of a chemical/material to deliver its function without exceeding environmental and ecological boundaries along its entire life cycle, while providing welfare, socio-economic benefits and reducing externalities. Overall sustainability should be ensured by minimizing the environmental footprint of chemicals on climate change, resource use, ecosystems and biodiversity from a life cycle perspective."

This definition is based on criteria from the Organisation for Economic Co-operation and Development (OECD) (2004) [7] involving reducing the consumption of resources and energy and avoiding the use of dangerous substances. Additional principles refer to the following:

- Use of harmless substances or, where this is impossible, substances involving a low risk for humans and the environment, and manufacturing of products in a resource-saving manner.
- Reduction of the consumption of natural resources, which should be renewable wherever possible, and avoidance or minimization of emission and introduction of chemicals or pollutants into the environment.
- Avoidance, already at the stage of development and prior to marketing, of materials that endanger the environment and human health during their life cycle and make excessive use of the environment as a source or sink.

Sustainability in Application

The preceding sustainability criteria can also be applied to facilities, operations, and processes, prompting design that conserves natural resources, such as energy and water, and utilization of renewable energy sources within the ecological boundaries. Sustainable process or facility design requires a new way of thinking and approaches to a project: be it a new build, renovation, or operations development and maintenance.

This now includes employing critical thinking and a science-based approach to innovations and solutions. More specifically, this involves such design factors as the site, surrounding environment and community, the buildings (existing or proposed), their interiors, operations, and any ongoing maintenance processes, until the project reaches the end of its life and its parts are recycled or reused. This approach encourages an early engagement and harmonization of all stakeholders, including designers and building users in the building/process owner's purview, while establishing formalized project needs and performance targets.

Finally, the approach taken to facilities and their operation should form part of a wider program of attaining holistic sustainability goals that span across the value chain: all business operations (R&D, manufacturing and supply logistics, sales and marketing), the role of various tiers of suppliers of goods and services in the supply chain, and the end-to-end impact of medicines on the environment (covering both used and unused medicines).

The various program elements within the framework presented in Figure 1 will need collective reporting that is accurate and auditable to ensure there is no suggestion of greenwashing. Some of the many themes relevant to the general concept of sustainability will be developed elsewhere in this issue of *Pharmaceutical Engineering®*.

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been described [7] showing that assessment against the 12 principles of green chemistry [8] are relevant also for oligonucleotides, especially in the areas of waste prevention, atom efficiency, renewable feedstocks, derivatives reduction, and real-time analysis for pollution prevention.

Due to the high importance of bringing new medicines to the market while accelerating product development and lowering operational costs, many of the potential sustainability improvements identified in drug development may not be able to be implemented. Therefore, the progress of product sustainability needs to also be embedded in the product's life-cycle management from the product's first launch into the market until its final withdrawal (Figure 2).

In parallel, streamlined LCA should be applied in development phases together with qualitative measures providing products' life-cycle emissions that generate comparisons of processes and materials that help identify targeted greenhouse gas emission reduction opportunities (e.g., preferred solvents, toxic substance evaluation). Although much more complex due to regulatory restrictions, some retrofitting of existing commercial drug products with the same method will be necessary to reach ambitious environmental goals. The decision to engage in retrofitting will need to include volume of product produced, process/energy intensity, and stage of the product in life-cycle management. Inclusion of sustainability attributes and metrics in the development of stage-gating processes will assure that suitability improvements done previously are not lost.

With patient centricity and quality attributes in central focus during drug development and commercialization, distinct opportunities before and after the regulatory approval and launch of the product (Table 1) are feasible, leading to improved sustainability performance. SbD starts by intentionally designing a more sustainable process in early development. Sustainability metrics are established for each step—from scale-up and validation through to the commercialization of the final approved product—to avoid any decisions that would hinder efforts to maximize sustainability gains.

However, these decisions are always in the context of the primary goal of getting new medicines to market, particularly in considering new life-saving therapies. This undertaking demands collaborative efforts from the entire organization because many decisions—such as material use, process design, and selection of the manufacturing sites—are locked in place before launch of the product. In addition, SbD requires cross-organizational adaptation of digital tools and databases, upgrading of capabilities in the drug development and technical functions, and sustainability acumen in the entire organization. In the end, everyone in the organization can and will contribute to a particular aspect of the product life-cycle with sustainability as one of the key criteria in mind.

Another important point to achieving SbD gains is agreeing on the type of metrics to use to track the sustainability impacts. Environmental metrics (e.g., process mass intensity, atom efficiency) have been developed over the past two decades to evaluate the environmental sustainability of chemical synthesis routes of active pharmaceutical ingredients (APIs) (primary manufacturing); dosage form production (secondary manufacturing); and packaging, distribution, and logistics (end-of-life phase) [18]. Recently, within the European Green Deal, the Chemicals Strategy for Sustainability (CSS) [14] identified several interventions to reduce impacts on human health and the environment associated with chemicals and materials (including medicines), which can be applied to existing and new medicines. The European Commission (EC) thinking emphasizes framework and principles assessing environmental and ecological boundaries [6]. This puts safety and sustainability performance in combined focus,

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evaluating metrics related to chemical hazards alongside greenhouse gas, water, and waste reduction.

In the global pharmaceutical industry, there is clearly a drive to minimize the environmental impact of products and processes. SbD is a methodical, data-driven process that aligns with the principles of QbD: obtain knowledge early and robustly through consideration of how the environmental impact can be minimized, defining those parameters that are critical to sustainability and quality. To reach ambitious environmental goals, combining product and facility sustainability design internally and in the value chain is required.

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