2023 PDA Pharmaceutical Microbiology Conference

Sustainable Glass Packaging and Test Reagent Use Practices that Significantly Reduce Waste

Massine Yanat, Glass Quality Engineer & Sutainability Expert, SGD Pharma; Kevin Williams, Senior Scientist, bioMérieux; Tita Tavares, Director of Consulting, Azzur Group; & Cristen Bolan, MSc, Marketing, bioMérieux.

BACKGROUND: Nine out of 10 top global pharmaceutical companies have set targets to reduce their carbon footprint. One of the main driving forces behind the pharmaceutical industry's efforts to reduce its carbon footprint is the rapidly changing regulatory environment following the Paris Agreement, ratified by 196 countries in 2015.

Additionally, reducing the carbon footprint provides a competitive market advantage in several ways, including increased investment from ESG bonds issued, reduced potential carbon taxes based on how much CO_2 is produced, fewer fines associated with excessive carbon emissions in the supply chain incurred, leading to efficiencies elsewhere in the supply chain, and an enhanced brand image in the eyes of sustainably minded consumers.

In this poster presentation, the **PDA Sustainability Steering Committee** presents decarbonization initiatives by SGD Pharma, a global leader in glass pharmaceutical packaging, that supports drug manufacturers in reducing their carbon footprint and other practices employed by suppliers like bioMérieux that support manufacturers in reducing waste and minimizing environmental impact.

DECARBONIZATION PRACTICES THAT REDUCE CARBON FOOTPRINT

The most significant part of the carbon footprint of drug manufacturers does not come from their direct operations, but instead from their indirect upstream and downstream operations, including the entire supply chain. This is why suppliers of drug manufacturers have a crucial role to play in contributing to the decarbonization efforts of the pharmaceutical industry.

In this poster, some of the decarbonization innovations and initiatives from SGD Pharma are presented. These initiatives aim to support pharmaceutical players in meeting their sustainability goals by reducing the carbon footprint linked to their indirect upstream activities.

I. Paris agreement: key points

The Paris Agreement is an international treaty adopted in December 2015 in Paris, France. Its central aim is to keep the rise in global temperature this century well below 2 degrees Celsius and to pursue efforts to limit temperature increase even further to 1.5 degrees Celsius. The agreement aims to increase the ability of countries to deal with the impacts of climate change.

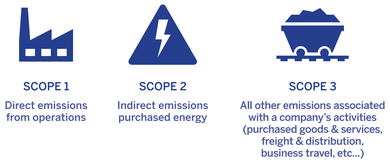


Figure 1. Carbon footprint: scope 1, 2, 3 explanations.

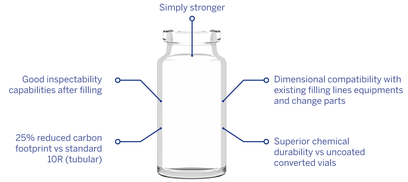
II. Weight optimization project

IDENCY – Combining the mechanical and chemical resistance of molded glass with dimensions of tubular glass to support pharma companies' reduction targets. (Figure 2.)

The rising demand for parenteral drugs, which increased by 4% in 2021 compared to 2020, has led to increased pressure on the supply chain for glass vials. At the same time, drug manufacturers are striving to reduce their carbon footprint from both their direct operations (Figure 1. scope 1 and 2) and their indirect downstream and upstream emissions (Figure 1. scope 3). To address this issue, SGD Pharma has developed IDENCY (Figure 2), a Type I borosilicate product that complements drug manufacturers' current portfolios and helps reduce their scope 3 carbon footprint.

Key benefits:

- Proven chemical durability enhancing compatibility drug/glass (high hydrolytic resistance, low extractables, no surface degradation)
- No glass delamination concerns
- Good inspectability capabilities after filling
- Can be stacked during transportation, against tubular glass. Saving costs and CO_2 emissions during transportation, due to container weight optimization.



10MR IDENCY compared with:	CO_2 emission savings
Standard ISO 10mL (molded)	-24% (Lightweighting)
Standard 10R (tubular) (1mm thick glass wall)	-25% (Production process)

Figure 2. Reduced carbon footprint impact through light weighting and due to the molded glass production process, compared to the tubular glass process.

III. Melting technology (BAT): Saint-Quentin-Lamotte – First 100% electrical furnace in Europe to serve the Pharma Industry

Furnace technology is the key factor that determines the energy consumption and CO_2 emissions of glass production, as it accounts for about 80% of the total energy demand and a significant part of the direct GHGs emissions. The furnace technology also affects the quality and performance of the glass products, especially for the pharma glass industry, which requires high-purity and high-stability glass containers for pharmaceutical applications. SGD Pharma Saint-Quentin-Lamotte is a state-of-the-art pharmaceutical glass plant for Type I molded producing 1 million bottles every day. This plant is equipped with a 100% electrical furnace since 2016, the first in Europe to serve the Pharma industry, and with an oxy-fuel furnace.

The most commonly used furnace technology in the glass industry is the end-fired or side-fired furnace, which relies on natural gas or oil as the primary fuel source for combustion. While this type of furnace has a low capital cost and a long service life, it also has a high carbon intensity and low energy efficiency.

Furnace type	Fuel	Energy efficiency	CO2 emissions	Product quality	Flexibility
End-fired or side-fired	Natural gas or oil	Low	High	Good	High
Oxy-fuel	Pure oxygen and natural gas or oil	Medium	Medium	Good	High
Electric	Electricity	High	Low	Good	Low
Hybrid	Electricity and natural gas or hydrogen	High	Low	High	High

Figure 3. The type of furnace technology used in the glass industry is important as it accounts for 80% of the total energy demand and a significant part of the direct GHGs emissions.

An alternative technology is the electric furnace. This technology uses electricity to heat the glass melt directly or indirectly through electrodes or resistance heaters. This eliminates the need for combustion, making the electric furnace cleaner and more efficient than conventional furnaces. The electric furnace technology saves 60% of the energy consumed per ton of glass produced and allows for a significant reduction in CO_2 emissions compared to a common end-fired or side-fired furnace.

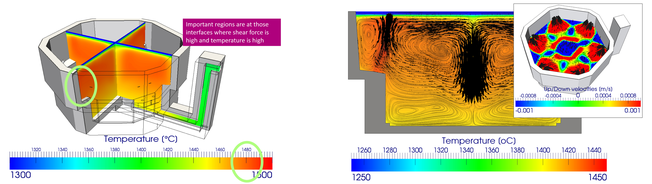


Figure 4. Important regions are at those interfaces where shear force is high and temperature is high.

REAGENT ASSAYS THAT REDUCE WASTE

A recent study[1] explored the amount of reagent wasted in endotoxin detection assays by comparing the use of LAL vs. rFC in drug product testing. RFC is a non-animal-derived synthetic reagent, whereas Limulus Amoebocyte Lysate (LAL) is a reagent harvested from horseshoe crabs (*Limulus polyphemus*).

LAL is packaged in 2.6 or 5.2mL vials (as reconstituted), and the evaluation showed less waste using rFC because it is a liquid reagent combined as enzyme, buffer, and substrate in a ratio prepared in amounts very close to whatever volume is needed, thereby reducing waste and associated cost of wasted reagent.

Figure 5 demonstrates how 4 columns of sample or 32 total wells required approximately 3.2 mL. The lowest amount of LAL that met this volume would require reconstitution of a 5.2 mL vial (or two 2.6 mL vials) and therefore would have wasted 2 mL of LAL for the test. This is a significant amount when considered on a cumulative, annual basis.

In addition to saving reagents in quality testing, the sourcing of synthetic recombinant reagents is not subject to the potential disruptions from harvesting animal-derived reagents which could become unavailable or cost prohibitive due to future supply constraints.

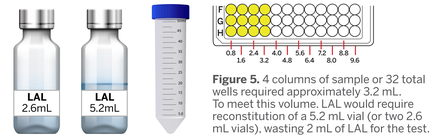


Figure 5. 4 columns of sample or 32 total wells required approximately 3.2 mL. To meet this volume, LAL would require reconstitution of a 5.2 mL vial (or two 2.6 mL vials), wasting 2 mL of LAL for the test.

In alignment with the US Pharmacopeia's efforts to "encourage smaller volumes" in quality testing,[2] bacterial endotoxin testing reagents provide an easy opportunity to meet goals associated with reducing waste, replacing animal-derived materials, and minimizing environmental impact – practices designed to support supply chain resiliency.

CONCLUSION: Pharmaceutical manufacturers are developing strategies to meet Sustainable Development Goals. The **PDA Sustainability Steering Committee** presents decarbonization initiatives by suppliers that support drug manufacturers in reducing their carbon footprint and practices employed by suppliers that support manufacturers in reducing waste and minimizing environmental impact.

References: 1. K Williams. 2023 PDA Annual Meeting, Sustainable Supply Chain Practices Ensure Supply Chain Resilience. 2. K Williams. Your Quick Guide to Better Endotoxin Testing. bioMérieux. Volume 1, p. 59. Feb. 2023.