SUStainability

Concerning Single-Use Systems and the Environment

by William Whitford and Mark A. Petrich

BioProcess International eBook Series 2018

GREENER PRODUCTS AND SOLUTIONS

MilliporeSigma

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A REVOLUTIONARY WAY TO RECYCLE MIXED-WASTE BIOHAZARDOUS PLASTIC

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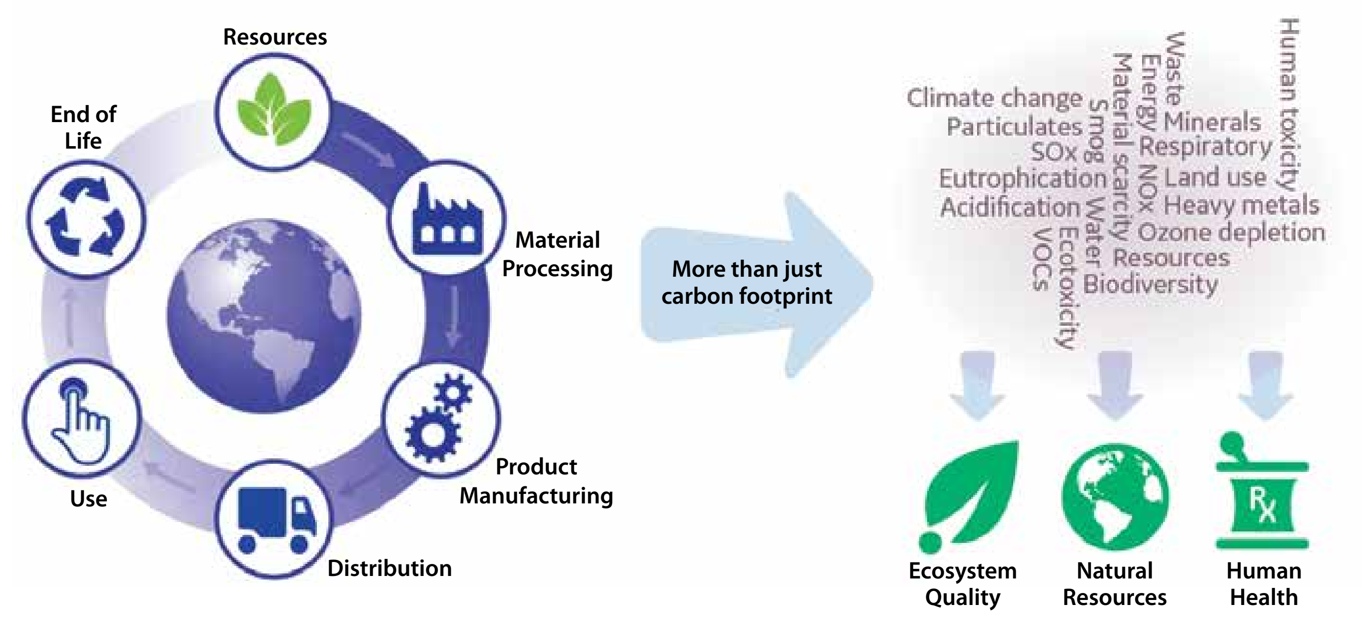
Disposable materials have been used in many aspects of biomanufacturing since muromonab was first launched in 1986. Single-use stirred-tank bioreactors first became commercially available from HyClone in 2004 (**1**). Despite their demonstrated value to bioprocessing, disposable materials remain the subject of wide-ranging differences of opinion. Discussions of any technology are healthy and important for identifying areas for improvement, but some hearsay and bold propositions made regarding single-use components and the environment are not always helpful. Sustainability is an important and much-publicized topic, and among both lay people and industrial decision-makers is a tendency to automatically equate "disposable" or "plastic" with an environmental liability. Because so many scientists and engineers are involved in biotechnology, we are hopeful that a true technical analysis of sustainability and single-use systems (SUS) for bioprocessing — thus, *SUStainability* — will get a fair hearing. This is important because the results of such analysis contradict popular opinion. SUS do provide an environmental advantage over traditional durable manufacturing facilities.

No one wants to live with air quality like that of Los Angeles in the 1970s or water quality as in the Hudson River of the same era. So why do biotech professionals resist an opportunity to deploy technology that yields both quality and business benefits while providing for reduced environmental impact? First, although most people sincerely wish to reduce "pollution" and "environmental stress," confusion comes when they consider how many distinct types of pollution and stress apply. Whether intuitively or through some study, most individuals tend to focus on some specific particular environmental concern(s) rather than looking at a holistic picture of "sustainability." Some people are most concerned about landfill use, others are passionate about plastics pollution in the ocean, others are seriously afraid of the consequences of carbon in the atmosphere, and so on. Anthony Noce (vice president of EHS management systems at Tetra Tech) recently remarked, "Unfortunately, green chemistry means different things to different people. I have rarely found it a good thing when different people use the same term to mean different things" (**2**). But it's not as though the issue hasn't been reviewed at length (**3**). The true science of the matter is often surprising — even counterintuitive.

You might recall the frustration of shoppers who were relieved to be saving trees by using plastic bags at the supermarket, only to be saddened shortly thereafter to discover that plastic bags presented their own problems. In biomanufacturing, it's possible to grasp at a quick solution to one environmental stress only to discover that the cure for that may in fact be no better than the disease. For example: If you're most concerned about landfill use and plastics in the ocean, then shipping a used mixing bag to a modern waste-to-power facility may seem to be a wonderful solution. However, if you're also concerned about carbon released into the atmosphere, the amount of fuel burned by shipping a bag hundreds or thousands of miles to such a facility could appear to override any benefit gained by its use in energy production. "Well," you

Figure 1: Schematic diagram of the product life cycle (LEFT) and impacts evaluated in life cycle assessment (LCA), a powerful approach to evaluating environmental impacts, benefits, trade-offs, and burden shifts of a product "from cradle to grave"



might say, as in the case of grocery bags, "why not simply choose a reusable instead? That solves both problems." Or does it?

Sustainability is not just about saving resources at one particular time or preventing pollution within a narrow context; true sustainability consists of a long-term holistic approach that takes all ecologically relevant impacts into account (4). Sustainability studies should include all environmental concerns, from mineral-resource depletion to solid-waste disposal. The emphasis in various contexts can range from long-term (e.g., such living-environment connotations as maintaining the physical beauty of the countryside and native ecosystems) to the immediate (e.g., acute concerns about unpleasant noise or odor generation).

As many as 18 distinct environmental-impact categories are evaluated throughout a product's life cycle in modern life-cycle assessment (LCA) studies. For ease of discussion, those impacts and different life-cycle phases often are grouped into more general themes or topical designations (5) (Figure 1). A science-based approach allows companies to evaluate environmental impacts, benefits, trade-offs, and burden shifts objectively across every product's life cycle, "from cradle to grave." When discussing such concerns as atmospheric carbon, water eutrophication, and water depletion, individuals, towns, and societies can have different ecological priorities. That is especially true for the considerations of immediate, short-term, and long-term environmental pressures as well as the relative costs of eliminating the release of pollution. LCAs provide a means of evaluating all areas of environmental impact so that specific areas of concern can be compared with each other to determine the context of overall impact.

True ustainability consists of a long-term HOLISTIC approach that takes all ecologically relevant impacts into account.

Biopharmaceutical Industry Action

Some biomanufacturers have taken the initiative to implement sustainability programs during the design and operation of their

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facilities and processes. Trade organizations have established committees and programs to research and educate their members and other stakeholders on the best approaches to building more sustainable biomanufacturing plants and operations. Suppliers of single-use materials support those working groups, and many have initiated programs of their own to study both the comparative impacts of SUS manufacturing and ways to reduce the overall environmental footprint of single-use technologies (SUTs).

About 10 years ago, the **American Chemical Society's** (ACS's) Green Chemistry Institute Pharmaceutical Roundtable (GCIPR) expanded its reach by establishing a biopharmaceutical processing team to work on applying the principles of green chemistry into biologics development and manufacturing. With about 20 member companies participating, GCIPR is now designing efficient ways to improve the industry's environmental footprint in process development, cleaning science, and facilities operations (**6**). Another ACS group, the Committee on Environmental Improvement (CEI), describes its vision of "a sustainable world enabled through the sustainable practice and use of chemistry." Members work to accomplish that through advancing "sustainability thinking and practice across ACS and society for the benefit of Earth and its people."

The **Bio-Process Systems Alliance's** (BPSA's) Sustainability Committee was formed to provide information about the environmental impact of SUTs and focus member company enthusiasm on this topic. The committee's rapid growth demonstrates that sustainability is a priority to BPSA. Team accomplishments so far include summaries of available studies, a list of existing recycling/reuse programs, visits to existing recycling facilities, and an investigation of related efforts by similar groups.

General Electric supports many sustainability initiatives on its own. For example, the IEA (International Energy Agency) predicts that by 2040 the total global power-generation capacity will increase by >60%, and renewable energy will make up >45% of that total (**7**). In support of that goal, GE offers products for such technologies as onshore/offshore wind and water-based power generation. GE Healthcare has been active in studying the sustainability of biomanufacturing for several years, having produced two comprehensive studies comparing single-use and traditional (reusable) bioprocess manufacturing technologies. The first assessment compared the environmental impacts of using either single-use or traditional manufacturing process technologies (**5**). That study focused on production of monoclonal antibodies (MAbs) at three scales chosen to reflect clinical, scale-up, and commercial phases of a drug. The results were surprising even to many people who are experienced in this type of work, indicating that (compared with a traditional fixed-in-place process train), SUTs exhibited lower environmental impacts in each of 18 categories studied (Figure 2). The second study evaluated a broader range of scenarios (**12**). For example, it introduced the concept of a hybrid installation with some portion of available SUTs used with conventional and durable technologies, it expanded the range of volumes modeled, and it added adenovirus vaccine manufacturing with a functional unit of 200 L.

Organizational Links

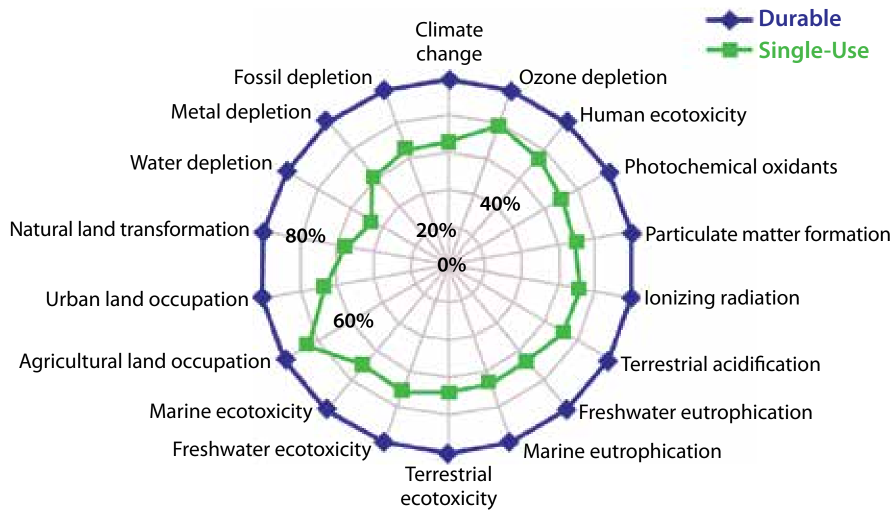
American Chemical Society
Green Chemistry Institute's Pharmaceutical Roundtable: https://www.acs.org/content/acs/en/greenchemistry/industry-business/pharmaceutical.html

Committee on Environmental Improvement: https://www.acs.org/content/acs/en/about/governance/committees/cei.html

Bio-Process Systems Alliance
Sustainability Committee: http://bpsalliance.org/committees

Life-Cycle Assessment

Figure 2: On average, SU facilities are more eco-frendly than conventional (durable) facilities in 18 distinct categories of environmental pressure (**5**).



As with most other issues of great social concern, the only way to seriously approach the sustainability problem is to use a science-based approach. Only if we supply clear, unequivocal measurements and analysis to all elements of the problem do we have a chance of selecting the best approaches from available options. And a rational, objective tool does exist for analysis of environmental issues. LCA (also known as life-cycle analysis, ecobalance, and cradle-to-grave analysis) is an internationally accepted method for assessing the environmental impacts of a product comprehensively, from extraction and processing of its raw materials through product manufacture, use, repair, and end-of-life or retirement. LCA outputs include emissions to air, water, and land; inputs include consumption of energy and material resources. ISO documents from 2006 describe a four-stage methodology — plan, do, check, act — for executing such an assessment (**8, 9**).

LCAs prevent industrial engineers from taking an inaccurately narrow or personal outlook on the environmental stress of a particular activity by identifying all relevant energy and material inputs and environmental outputs, then evaluating their real effects on all environmental parameters. This approach considers all environmental impacts across the entire life cycle of each process component, from materials extraction and refining through component manufacturing, packaging, distribution, use, and ultimate disposal.

The paper-or-plastic example is a good way to demonstrate the value of LCA. Most people are concerned with the source of paper in grocery bags and the ultimate destination of plastic bags. LCA is valuable in illuminating the relative environmental pressures exhibited by each option at all points in its life cycle, not just at those that attract the most attention. And it suggests that there is no "best" for paper or plastic; each option affects the environment in different ways. If your concern is plastic in the ocean, then paper is best; if it's land transformation, then plastic is your choice.

LCA now is used in the medical and pharmaceutical sectors both for measuring sustainability and providing a metric for use in comparisons and discussions (**10**). One of LCA's powers is to illuminate a comprehensive scope of environmental stresses produced and the time periods involved. This ensures that when environmental impacts are advertised as reduced in one area at one time, they are not simply being shifted to another time or another environmental impact area.

LCA studies not only identify opportunities to improve the environmental performance of products, but they also can aid in

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establishing objective and informed decision-making regarding those products. In fact, a life-cycle view has become the principal approach to evaluating products' environmental performance and making environmentally minded decisions on product purchase and use. Studies have been performed on the overall environmental impact of single-use and traditional bioprocess technologies and reveal many important truths about SUS in biomanufacturing (**11**). One principal finding has been that the upstream manufacturing processes (SUS supplier activities) and operational inputs (SUS user activities) have far greater effects on cumulative environmental impact than does the process waste stream (post-use SUS management).

Newer LCA studies commissioned by GE Healthcare not only identify and compare the potential environmental impacts of using single-use (plastic) or durable (stainless steel) systems in bioprocessing of biologic pharmaceuticals, but also provide an understanding of the change in individual potential environmental impacts at different production locations and assess the impact of regional differences on the overall burdens (**12**). Conclusions from these studies are surprising. William Flanagan (cofounder and director of Aspire Sustainability in Albany, NY) has pointed out that "Compared with traditional technologies, and in aggregate, SUT for monoclonal antibody production provides up to 55% reduction in total impact across the five environmental impact categories" (**5, 13, 14**) (Figure 2).

From published studies, it appears that the largest factors in comparative stress analysis are

- how power is generated in the region of a given manufacturing facility (thus the stress resulting from cleaning and steaming of durable facilities)
- the distance that facility is from SUS manufacturing and disposal (thus the stress resulting from shipping SUS materials).

A number of "end-of-life" scenarios are commonly prominent topics in most discussions about SUT and the environment. That may be because plastic materials are very visible at that point in their life cycle, and it requires handling by operators that is not required with traditional durable systems. A startling fact revealed by LCA is that end-of-life scenarios actually play a very small part of SUT's total environmental impact. In fact, the different means commonly proposed for handling of disposable materials after their primary use show very small net differences in the overall equation (Figure 3). Management of post-process SUS materials is important operationally, but it has relatively little influence on sustainability.

Some questions readily receive direct answers through the rigor and format of an LCA approach. Others can be more complex or subjective. For example, when considering the many impacts of converting production operations to SUT, it does add to the warehouse space and the amount of material handling required at a biomanufacturing facility. In application, cardboard and other secondary packaging materials need to be removed and disposed of. SUS themselves need to be removed from production areas and managed in some way either as

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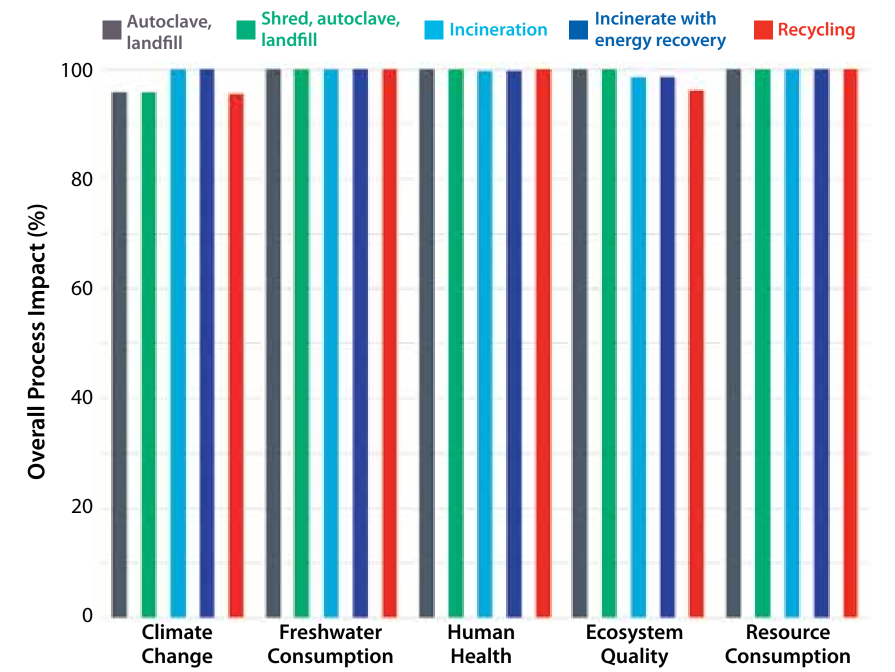
waste or recyclable material. Those and other new tasks and materials contribute not only to the LCA of environmental stress, but also to the financial cost of operations. Sophisticated LCA analysis might show that the environmental stress impacts of such activities are offset (e.g., by a reduction in cleaning and sterilization) but what is obvious to operations managers is that they must address both new processes and the related costs.

Figure 3: Comparative LCA-based environmental impact assessment of alternative end-of-life disposal options for a single-use monoclonal antibody (MAb) process in Boston, MA, at the 2,000-L scale; note the very small difference (e.g., 5%) that any given option makes relative to the overall (100%) environmental impact (5). At 200-L scale, the difference is so small that it barely shows up on a similar graph.



Reduce–Reuse–Recycle

LCA is a valuable tool for examining the comparative state of different types of operations in light of current technologies and materials. However, creative lean-manufacturing thinking is needed to contemplate, redesign, and improve the systems involved in biomanufacturing (e.g., to reduce the number of disposables or amount of consumables used). That could include designing for increased packaging efficiencies, streamlining the structure of SUS themselves, and/or specification of their more efficient use in operations.

Relatively sustainable packaging solutions can be effected through simple reduction of packaging mass, through engineering of efficient packaging designs, or by using different packaging materials. The return, reuse, recycling, or second application of packaging materials, shipping containers, or pallets can be evaluated. End-of-life solutions for operational materials (including product-contact materials) may include some kind of second-use (e.g., as fuel-to-power) or recycling. But it also could include process engineering to support multiple or continuous use of ultimately disposable materials in bioprocessing. End-of-life solutions considerations must take into account collection of used materials in biotechnology facilities, decontamination or sterilization, break-down and segregation of component parts (e.g., integral metal parts), transportation and aggregation of used materials, and examination of the many viable end-of-life options.

As discussed above, acquisition and transportation geographies are important factors in the environmental pressure of SUS consumables. However, geography also is a factor in determining the "right" way to manage those products after their use in biomanufacturing. All things considered, it appears that more than one reuse, reprocessing, repurposing, or disposal solution will be needed. That is especially true considering the many distinct types of environmental stresses; their

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sometimes conflicting or material-contraindicated possible solutions; the scope of different products, therapies, and manufacturing scales under consideration; and geographical, infrastructure, regulatory, and national factors.

A Science-Based Approach

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Single-use materials have become powerful tools in biomanufacturing for many good reasons. However, concerns about environmental impact could impede their further implementation. Among all of us who care about the environment, few have carefully studied the distinct categories of potential environmental stress. The harm imposed by some activities is more obvious and apparent than it is for others. People care about sustainability, and it's good to know where to focus that caring. Having no focus at all can lead to counterproductive choices, which is why science-based decision making is important. A science-based analysis is the best way to determine precisely what harm is caused by any given activity.

The LCA approach has been applied rigorously to compare single-use manufacturing equipment with traditional (durable) bioprocess systems. The results are that, on average, the sustainability or "eco-friendliness" of SUTs is better than that of traditional approaches. LCA also has revealed ways to discover when SUTs do not provide an advantage. It's a pleasant surprise that end-of life handling of disposable materials plays a small role in the overall equation. The largest factors affecting LCA results are the means of power generation, the distance of a biotech facility from single-use materials manufacturing, and local emphasis of one category of stress over another.

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