BioPhorum

PLASTICS

Estimating the volume of single-use waste produced during drug substance manufacturing of monoclonal antibodies

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Contents

List of figures

List of tables

About BioPhorum

We enable the global biopharmaceutical industry to connect, collaborate and accelerate progress for the benefit of all.

Since its inception in 2004, BioPhorum has become the open and trusted environment where senior leaders of the biopharmaceutical industry come together to openly share and discuss the emerging trends and challenges facing their industry.

Growing from an end-user group in 2008, BioPhorum's membership now comprises top leaders and subject matter experts from global biopharmaceutical manufacturers and suppliers, working in both long-established and new Phorums. They articulate the industry's technology roadmap, define the supply partner practices of the future, and develop and adopt best practices in drug substance, fill finish, process development and manufacturing IT.

In each of these Phorums, BioPhorum facilitators bring leaders together to create future visions, mobilize teams of experts on the opportunities, create partnerships that enable change and provide the quickest route to implementation, so that the industry shares, learns and builds the best solutions together.

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Executive summary

This paper focuses on the environmental impact of single-use technologies (SUTs) in biomanufacturing, specifically around the plastic waste generated by SUT during manufacturing of monoclonal antibodies (mAbs). It emphasizes the importance of data sharing and collaboration between manufacturers and waste management service providers to develop technology and processes to enable recycling of SUT and so reduce environmental impact.

The data provides a detailed quantification of plastic waste generated in the manufacture of mAbs—the largest sector in biologics manufacturing and suggests next steps, including expanding the data to include other biologics production processes, and exploring multi-organizational collaboration for recycling.

This is an important area for focus, as the proven benefits of SUTs in biopharmaceutical manufacturing is leading to growth in use and increased plastic waste.

The complex nature of this waste poses challenges for recycling. However, the high-value plastics utilized in SUTs and the resultant quality of the waste material offers opportunities for innovative solutions which may embed circularity in the design of products, enhanced recycling capabilities and reduction in reliance on virgin material extraction.

Various stakeholders, including environmental, social and governance (EGS) leads, waste management specialists, and designers of SUT products can use the data to support decision-making and improve waste management practices.

1.0

The case for data sharing and collaboration to reduce environmental impact of biomanufacturing SUTs

1.1 Context

Globally, the prevalence of chronic diseases is increasing, and with it, there is a rise in the need for successful therapeutic responses. As a result, growth in the biopharmaceuticals segment of the pharmaceutical industry is significant[1]. Considering the healthcare sector's climate footprint, which accounts for 4.4% of global net emissions[2], the rising demand for biopharmaceuticals places significant pressure on providers to minimize the environmental impact of these therapies. In this context, use of plastic is one of several factors to consider when evaluating the environmental impact of drug production. It can be considered alongside other concerns, such as carbon emissions and water usage, as was outlined in BioPhorum's *Environmental Sustainability Roadmap* (2022)[3].

1.2 SUT usage

Use of plastic in drug manufacturing has been increasing due to its ability to expedite market readiness[4].
Over the past twenty years, there has been a shift from producing biopharmaceuticals in traditional stainless-steel facilities to employing SUT, which entails high-quality plastic systems with numerous complex, interconnected components. A primary goal of this transition has been to lower capital costs[5] and accelerate time-to-market[6,7].
There may also be social and environmental sustainability benefits, including:

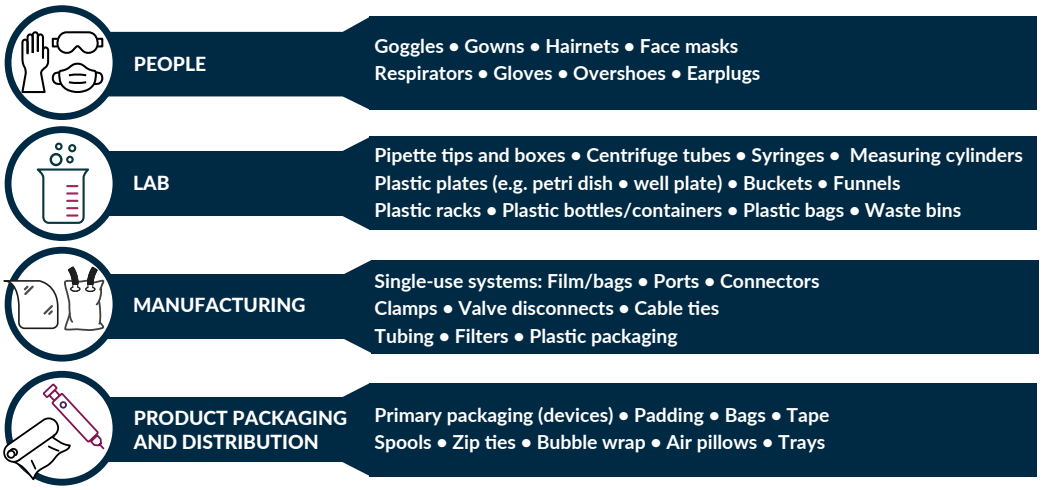
- Enhanced access to affordable medications for patients
- Reduced factory footprints that decrease energy demands
- Minimized cleaning requirements that require lower usage of water and chemicals.

The rise in chronic diseases across populations coupled with the resultant forecast growth of the biopharmaceutical sector, suggests an increasing amount of associated SUT plastic waste. In 2018, The Medicine Maker published an article which explored issues surrounding use of single-use plastics in biomanufacturing entitled *From Single Use to Re-Use*. The article stated: "Globally, we estimate that 30,000 tons of biopharma single-use products are disposed to landfill or incineration every year."[8]

Although the scope of the products included in that estimation are not outlined in the article, it provided a perspective on the possible scale of the issues to address and the need for greater understanding of the nature of waste material to explore improved waste management streams.

When the authors of this paper considered the scope of all single-use plastics used in the production of biopharmaceuticals, they identified four separate domains: people plastics, laboratory plastics, manufacturing plastics and packaging plastics (see Figure 1).

Figure 1: Four domains of single-use plastics in biopharmaceutical production



The scope of this paper and the detailed quantification that follows covers only the manufacturing domain as shown in the above diagram, however does not include tubing, filters or packaging.

This paper shares data and insights regarding the current scale of plastic SUT waste from the manufacturing domain, and its projected growth. It encourages industry leaders across the biomanufacturing value chain and the recycling community to explore innovative methods to reduce plastic waste volumes and retain some of this material's value through recycling. The paper can be used by various stakeholders, as outlined in Table 1:

Table 1: Stakeholders to the data in this paper

Stakeholders	Environmental, Social and Governance (ESG) leads	Waste management leads/Technical operations specialists	Recycling organizations/innovative waste management experts	Designers of SUT products
Use	Respond to global reporting requirements for plastics waste, such as the *Science-based Targets Initiative*[9] and the *Basel Convention*[10]	Support decision- making towards organizational targets for percentage of waste going to landfill	Pinpoint regional concentrations of waste material across multiple facilities, making the case for localized, enhanced recycling solutions and investment in infrastructure	Inform design decisions to decrease the amount of SUT waste along the value chain

1.3 A shared challenge

Globally, there is increasing focus on plastic production and end-of-life management, driven by initiatives such as the Taskforce on Nature-related Financial Disclosures (TNFD)[11] and the ongoing development of the UN Global Plastics Treaty[12]. Although there are advantages to using SUTs, the resultant increase in plastic waste presents a significant challenge for the industry.

To address these concerns, biopharmaceutical organizations are investigating alternatives to landfill disposal, including incineration with energy recovery and recycling. However, the complex, multi-layered nature of SUTs, coupled with issues relating to product contact, the classification of material as 'hazardous', and the lack of mature infrastructure, has hindered the scalability and success of recycling solutions. Even when incineration with heat recovery is utilized, there is concern that this approach fails to capture the inherent value of high-quality plastic and fosters reliance on virgin materials, perpetuating waste and emissions in the system. The emissions generated from incineration of plastics include greenhouse gases (GHGs) such as CO2, CH4, N2O, other toxic gases such as carbon monoxide and sulfur/nitrogen oxides, as well as volatile organic compounds and damaging particulates. This contributes to scope 3 emissions for suppliers' downstream emissions (Category 12—end of life treatment of sold products) and for Biomanufacturers, upstream emissions (category 5—waste generated in operations)[13].

1.4 Quantifying manufacturing waste material

Members of BioPhorum have collaborated to quantify the weight of SUT waste generated per batch run for producing monoclonal antibodies (mAbs). The data is based on actual product information from multiple suppliers, thereby supporting a high level of confidence in the modelled output.

In November 2024, The International Society for Pharmaceutical Engineering (ISPE) published their own analysis of *Plastic Process Waste in Biopharmaceutical Manufacturing*[14]. Whilst the ISPE publication had a different scope from the study outlined in this publication and did not report on batch level data, there is a general alignment in the amount of SUT being quantified when taking the respective scopes into consideration.

Both studies make the case for the need to find improved solutions for the end-of-life management of waste material from biopharmaceutical production and this goal could be supported by further discussion and analysis to compare the values and respective assumptions of different studies.

Biomanufacturers can use the data in this paper as a basis and incorporate parameters specific to their own mAbs production—such as buffer preparation philosophy, product titer, bioreactor scale, and the number of batch runs—to model their organization's overall SUT waste output and then potentially leverage it to support their corporate environmental, social, and governance (ESG) goals. For instance:

- Setting a benchmark for the quantity of plastics SUT waste generated by technical operations will help in reporting adherence to the Science Based Targets (SBTs) category 5—emissions from waste generated in operations (part of scope 3 emissions)[9]. Since single-use plastics are integral to the manufacture of biological therapies and addressing their lifecycle is essential to meet these targets
- Accessing organizational SUT plastics waste data will be beneficial when responding to the UN's Global Plastics Treaty[12]. The treaty aims to include mandatory requirements, such as extended producer responsibility (EPR) provisions which may require biopharmaceutical manufacturers to account for their single-use plastic waste, depending on jurisdiction
- In compliance with the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal[10] and specific country and local regulations, biopharmaceutical manufacturers must more accurately classify and document their waste
- Biomanufacturers can apply the data, principles, and approaches suggested in this publication to adhere to best practice guidance, such as that given in ISO 14001—Environmental Management Systems[15].
- Engineers can use the model to optimise facility and process design with regards to SUT usage and thus improve the sustainability of a drug substance manufacturing process.

1.5 Potential next steps

The absolute quantity of global SUT waste from biologics production will vary, based on annual demand, manufacturing strategies, product parameters and single-use assembly weights. While overall amounts of these high-specification polymers may be relatively small in comparison with the waste output from other parts of the value chain and from other industries, they are still important materials requiring responsible environmental stewardship. Moreover, the consistent quality of the waste material offers opportunities for material scientists to embed circularity into the designs of these products and look for other ways to reduce the need for virgin feedstock.

Once a baseline amount of SUT plastic waste across multiple manufacturers is understood, it will:

- Allow measurement of the impact of any interventions designed to reduce the overall amount of plastic in the system
- Identify enough of this high-value material to warrant necessary investment in improved waste management practices, with more circular solutions and better overall environmental impact.

Challenges not addressed in this paper offer opportunities for further research. Future work could expand the data to include:

- All biologics production processes (e.g. vaccines, ATMP)
- Processes from other stages in the value chain (e.g. clinical development, fill finish)
- Additional ancillary items such as filters, single-use tubing, and chromatography resins
- Alignment of individual waste products to their constituent polymers.
- Understanding of the volume of SUT waste generated at a regional level, that will enable licence holders and waste manufacturers to work together and develop solutions specific to geographical locations.

1.6 Is multi-organizational collaboration to recycle this material possible?

There are precedents for taking a cross-value chain approach to minimizing negative environmental impact and harnessing the value of plastics used in healthcare operations. Examples of collaborative research, pilot studies, and recycling initiatives for single-use plastics at other parts of the value chain include:

1. For personal protective equipment (PPE): **Sustainable Manufacturing: How Kimberly-Clark's RightCycle Program Helps Organizations Manage PPE Waste | Better MRO**[16]
2. For silicone tubing: Recycling of silicone scraps in some North American and European plants. Recovery and collection of scraps to recycle silicone into oil. For one of the sites, it then becomes raw material for other affiliates in the construction industry **Sustainability | Saint-Gobain Biopharma**[17]
3. Closed loop recycling for plastic trays used to transport glass vials: **MEDIA RELEASE | Circular packaging without compromising patient safety: SCHOTT Pharma, Corplex, and Takeda successfully demonstrated closed-loop recycling**[18]
4. For recovery and recycling of material in SUT bags: Recycler picks up the SUT waste and applies mechanical recycling. **Recycling BioProcess Containers (BPCs) | Thermo Fisher Scientific**[19]
5. For pipette tips and boxes: MailBack program—the end-user fills the tipcycle box (which comes with new pipette tips) with used pipette tips, racks, and boxes and the box is shipped to the recycler[20] **Product End-of-Use Recycling Solutions | Thermo Fisher Scientific**
6. For SUT bags: Technical feasibility of mechanical recycling of bioprocessing bags **Recycling of Post-Use Bioprocessing Plastic Containers—Mechanical Recycling Technical Feasibility**[21]
7. For closed-loop reuse of material in bioreactors: Sartorius and Covestro: **Concept for recycling small-scale polycarbonate-based bioreactors in a closed loop Concept for recycling a small-scale plastic-based bioreactor in a close-loop—Technical approach—ScienceDirect**[22]

Conclusion to Part 1

- Use of SUTs in the manufacture of biologics has proven benefits and its continued adoption, coupled with forecast growth in the biologics market, will result in an increased amount of associated plastic waste. A baseline, informed by real-world data and a framework for quantifying industry's SUT use, provides a starting point for optimizing the life of these materials, increasing recycling rates, and improving the overall environmental impact of the manufacture of biologics
- In 2025, BioPhorum will publish a Sustainability Maturity Model—a resource for license holders and CDMOs in the biopharmaceutical industry and their suppliers to progressively minimize the environmental impact of biomanufacturing across circularity, carbon, nature/biodiversity and data transparency. The model will aggregate and anonymize data to provide benchmarking capabilities across multiple parameters: The work of this study is one step towards that end goal.

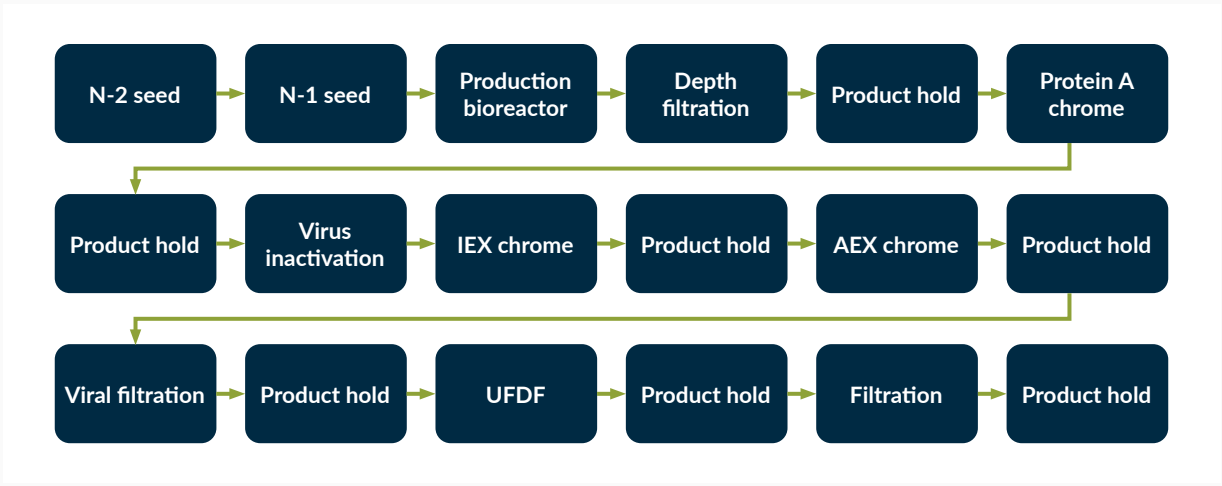
2.0

Quantification of SUT plastics waste

This data presents a comprehensive and transparent quantification of SUT waste generated in the manufacture of therapeutic proteins, with a specific focus on commercial-scale monoclonal antibody (mAb) manufacture. mAbs represent the largest sector in the biologics market[23] and data for this modality was more readily available than for other biologic modalities. It is crucial to recognize that, as only one in every ten therapies advance from clinical development to commercial production[13], the clinical development phase of production may involve substantial material consumption. While other modalities—such as vaccines—and the SUT plastics used at other stages of production—such as during the clinical phases of mAbs development—are not directly included in this study, the findings are applicable and informative regardless. By quantifying the volumes of SUT plastic waste associated with commercial mAb production, we aim to establish a data baseline that industry can use to guide future sustainability efforts and improvements.

To quantify plastic usage associated with a typical commercial-scale mAb manufacturing process, a detailed process model has been developed. An outline process flow for the considered process is presented in Figure 2. This process flow follows the template outlined in previous BioPhorum publications, making it a well-established and appropriate representative example for this study[24, 25].

Figure 2: Process flow for mAb manufacturing process



The plastics information incorporated into the process model is based on substantial quantified SUT weight data from suppliers and end-users which has been aggregated and blinded. Waste material from these SUT products is generated by license holders and CDMOs following production of the therapeutic product. Although this waste constitutes a relatively small proportion of the overall plastic waste along the value chain, the materials are valuable, high-specification polymers which, due to the complex nature of the multi-polymer films and the hazardous classification of the waste are currently lost to landfill or incineration. The scope of the products quantified in this study is highlighted by the magenta tab in Figure 3 below:

Figure 3: Manufacturing plastics—SUT products quantified in this study

The scope is specific to that produced in manufacturing of mAbs and is limited to film/bags, ports, connectors, clamps, valve disconnects and cable ties.

Two manufacturing scales have been considered, large-scale stainless steel (12,000L) and intermediate-scale single-use (2,000L) in line with the process models generated for the first edition of the BioPhorum Technology Roadmap for the Biopharmaceutical Manufacturing Industry and BioPhorum Economic Evaluation of Buffer Preparation Philosophies[24, 25].

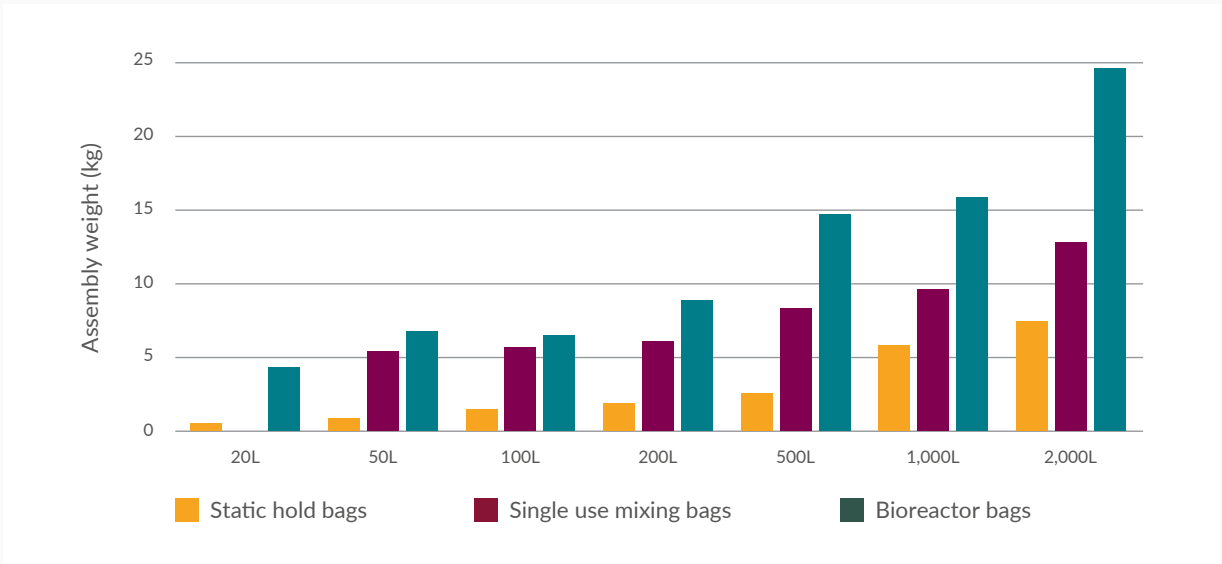
The impact of varying product titer (2g/L, 5g/L and 10g/L) and buffer preparation philosophy have been considered to support an evaluation of the sensitivity of the results.

The results provide a breakdown of plastic waste generated on a per batch basis. The per batch results have been used to estimate the associated annual SUT plastic waste quantities associated with mAb manufacturing based on published market trend data for the industry.

The key model assumptions are listed below:

- The process model and assumptions used in the first edition of the *BioPhorum Technology Roadmap for the Biopharmaceutical Manufacturing Industry and BioPhorum Economic Evaluation of Buffer Preparation Philosophies* have been used as a basis for the model[24, 25]
- Results are presented on a per batch basis with a single bioreactor and downstream train considered for each batch. A 70% product yield is assumed in all cases
- Single-use assemblies associated with single-use bioreactors, single-use product mixers and single-use buffer/media preparation and hold systems (which represent a high proportion of regular plastic waste) have been included within the scope of this study. The model does not consider ancillary plastic-containing items such as single-use filters, single-use tubing, chromatography resins, etc. Therefore the output is not a total quantification of all solid waste generated by the manufacturing process
- Assembly weights based on single-use product data from suppliers and end-users have been considered (Figure 4), provided from single-use component suppliers and manufacturing companies. Assembly weights include packaging accounting for 30–40% of the stated weight. Refer to Appendix A for a detailed breakdown of assembly weights.

Figure 4: Single-use assembly weights (including packaging) – median results



- Assembly weights in Figure 4 generally exclude cardboard. Where cardboard is included, the weight is negligible as all reported weights for the various assemblies were within a relatively narrow range
- A breakdown of polymer composition is not provided in this study. This represents an opportunity for future investigation
- Three buffer preparation approaches have been considered (given that buffers are the largest constituent by mass in biopharmaceutical manufacturing and represent a high proportion of plastic waste generation)—traditional buffer prep, buffer concentrates and in-line buffer preparation as per the definitions in Table 2. Buffer concentrates and in-line buffer preparation are implemented for chromatography buffers only
- The threshold for SUT equipment for product hold and buffer/media preparation and hold is set at 2,000L. Above this value, stainless steel equipment is used
- Buffers are prepared on a per batch basis. Stock solutions (where in-line buffer preparation is used) may be prepared for up to ten batches at a time
- For estimates of global plastic single-use waste, it is assumed that 80% of global manufacture is at large scale and 20% at intermediate scale
- Refer to Appendix B for a breakdown of the quantity of single-use assemblies required to support each scenario on a per batch basis.

Table 2: Considered buffer preparation philosophies

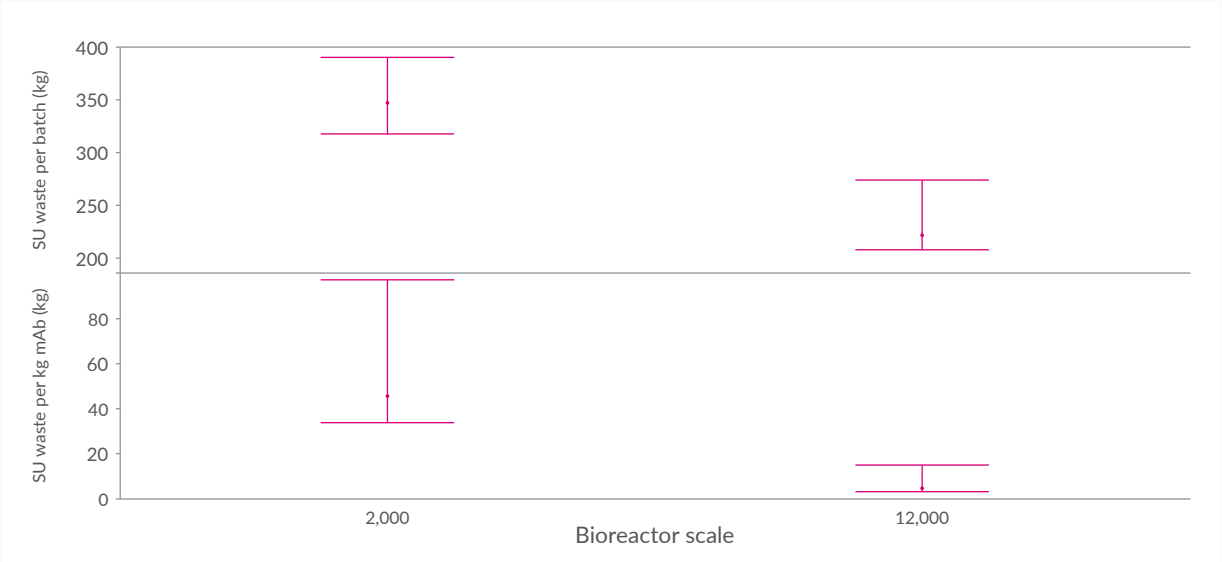
Philosophy	Description
Traditional buffer preparation	Preparation of multi-component buffer solutions in fixed vessels or single-use mixers (with preparation per unique buffer) at the final required concentration ready for delivery to the process. Each buffer requires storage prior to use.
Buffer concentrates (in-line dilution)	Preparation of multi-component buffer solutions in fixed vessels or single-use mixers (with a preparation per unique buffer) at a higher concentration than that required by the process, which must be subsequently diluted before use. Each buffer requires storage prior to use.
In-line Buffer Preparation/Buffer Stock Blending/Inline Conditioning	Preparation of buffers in-line from concentrated, single-component stock solutions at the final required concentration ready for delivery to the process. Preparation can be in a storage system or connected directly to the process. A wide range of buffers may be prepared from a relatively small number of concentrated, single-component stock solutions which require preparation and storage (as per traditional

2.1 Results

Single-use plastic waste – per batch

The quantity of single-use plastic waste generated per batch for intermediate and large-scale manufacturing is outlined in Figure 5. Refer to Appendix C for full breakdown of results for all considered scenarios.

Figure 5: Single-use plastic waste on a per batch (top)/kilogram mAb basis (bottom) for 2,000L and 12,000L manufacturing scale (weighted mean considering all variables with 95% confidence interval)



As expected, the quantity of single-use plastic waste for a 2,000L process is much higher than for a 12,000L stainless steel process. Taking a 2,000L process with a 5g/L product titer (using traditional buffer preparation), 369kg of plastic waste is generated per batch. For the same scenario, at 12,000L scale, the plastic waste per batch is significantly lower at 186kg, as a substantial proportion of the process needs exceed the considered single-use threshold.

While absolute quantities of plastic waste in large-scale manufacturing are lower, they remain substantial with SUT being utilized for seed bioreactors, smaller scale media, and buffer preparation and hold.

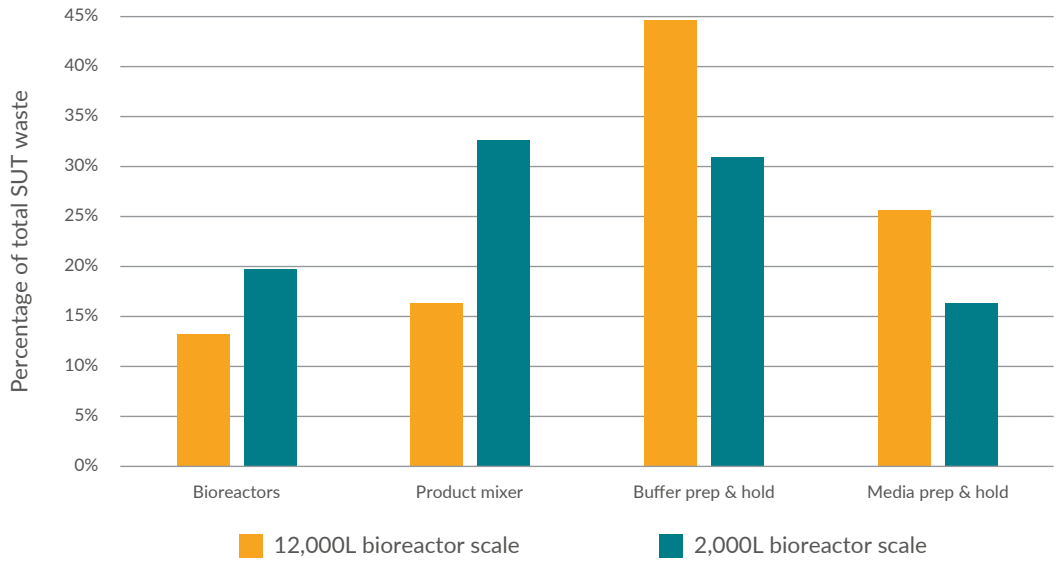
When considered on a per kilogram of product produced basis, the difference between intermediate and large-scale manufacturing grows further given the efficiencies of scale. For the same scenario above, the large-scale facility has almost 35 times lower SUT waste per kilogram of product than the intermediate-scale equivalent. The absolute difference will vary for a particular manufacturing strategy. The relative difference due to the variables considered can be observed in Appendix C.

The quantity of SUT being utilized for larger scale facilities is, however, increasing in line with greater demand for flexible, agile facilities. Advancing technologies and approaches such as buffer stock blending are resulting in greater implementation of SUT as the corresponding buffer volumes to be handled by the process are reduced.[25]

Breakdown of single-use plastic waste—by facility area

A breakdown of single-use plastic waste by area is provided in Figure 6.

Figure 6: Breakdown of single-use plastic waste by area of biopharmaceutical manufacturing process



Considering all variables (bioreactor scale, product titer and buffer preparation philosophy), the core process (bioreactors and product hold) accounts for 52% and 30% of the total waste at the intermediate and large scale respectively with media and buffer providing the remaining 48% and 70%. Refer to Appendix C for a detailed breakdown per scenario.

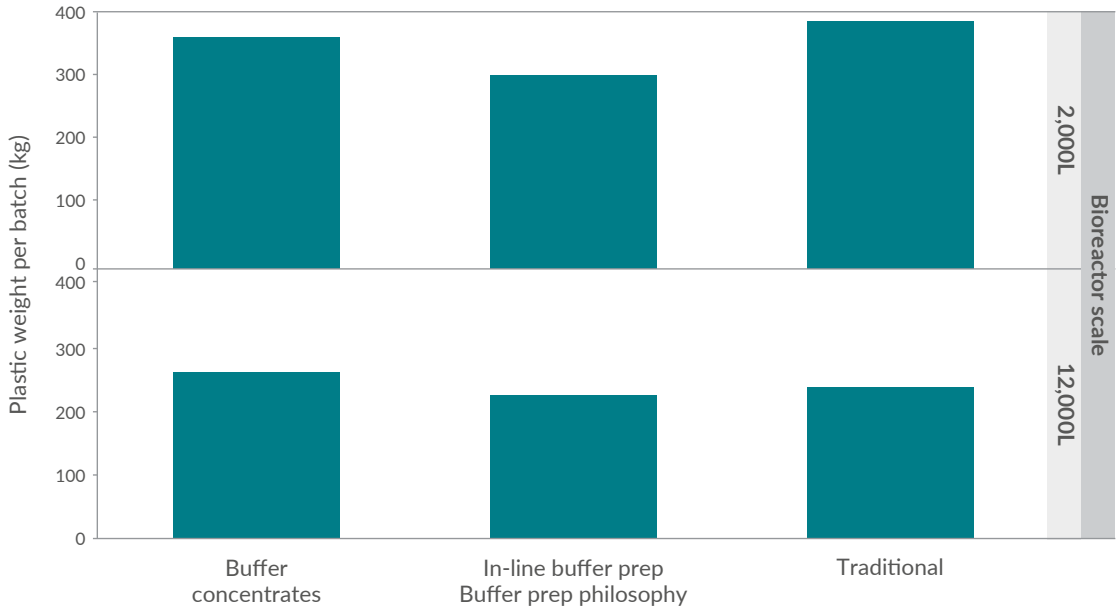
The breakdown of waste is heavily influenced by buffer preparation philosophy. Taking a 2,000L-scale process with a 5g/L product titer (using traditional buffer preparation), the proportion of waste generated by media and buffer increases to 53% when compared with the overall average of 48%. An equivalent scenario at the 12,000L bioreactor scale has media and buffer accounting for 72% of overall waste. Given the continuing prevalence of traditional buffer preparation in the industry, these figures are likely closer to the current industry state.

Buffer as the largest constituent by volume in manufacturing understandably represents a large proportion of plastic waste, representing 31% of SUT waste at intermediate scale and 45% at large scale. This is particularly relevant in the context of recycling as buffer preparation and hold systems offer significant potential for recycling given the lack of biological contamination.

2.2 Sensitivities of plastic waste volumes to process variables

The absolute quantity of plastic waste generated by a manufacturing process is highly variable and dependent on product parameters, manufacturing technology and operational strategy. The significant influence of buffer management philosophy is outlined in Figure 7.

Figure 7: Influence of buffer management philosophy on waste quantity at 2,000L (top) and 12,000L (bottom) production scale



The use of advanced buffer management strategies such as buffer concentrates and in-line buffer preparation may result in an increase in plastic waste associated with buffer at large scale and a decrease at intermediate scale. However in all scenarios the quantity of waste associated with buffer remains substantial.

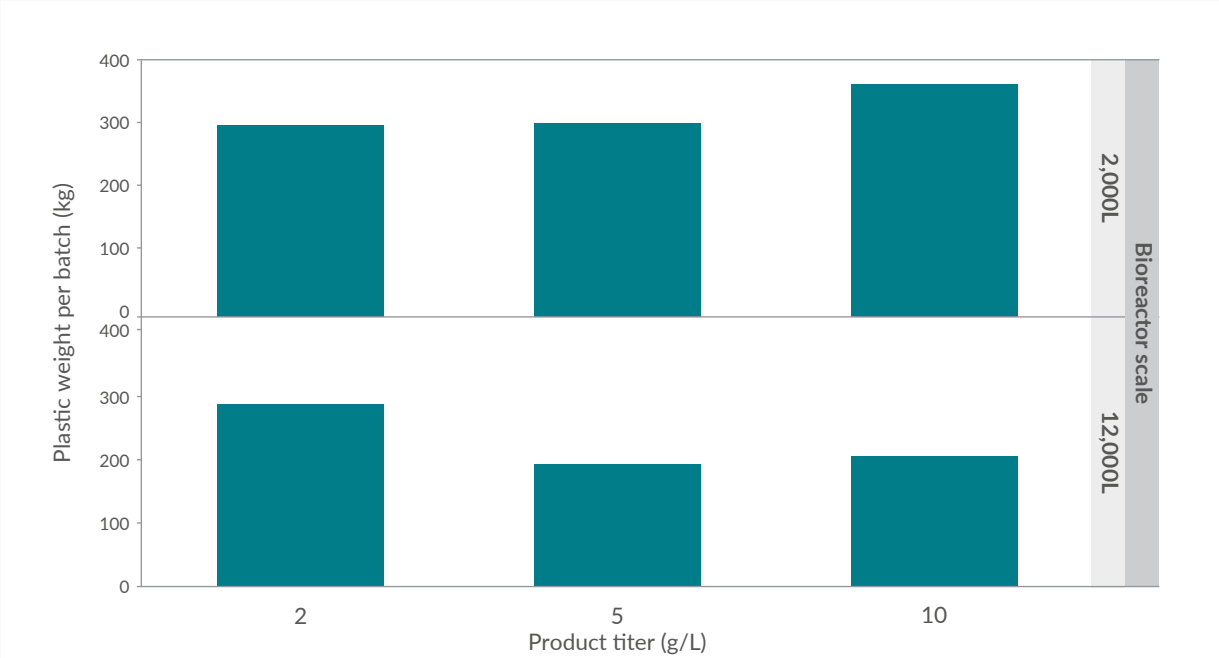
At large stainless steel scale (12,000L), the use of advanced buffer manufacturing strategies increases the potential single-use utilization as both buffer concentrates and in-line buffer preparation reduce the volumes of liquids to be handled such that a greater proportion fit within the volumes suitable for single-use technology.

The use of buffer concentrates in particular increases demand for single-use whereas buffer stock blending (or equivalent) reduces the absolute number of preparations (and storage systems) needed as well as volumes, such that the quantity of plastic waste generated is lower (compared to buffer concentrates) even though more stainless steel systems can be replaced with single-use technology.

At the 2,000L single-use scale, for a given product titer, the plastic waste quantity decreases with the adoption of buffer concentrates and in-line conditioning. As the product titer increases, the use of these strategies ensures that the facilities remain predominantly single use, as the likelihood of buffer volumes exceeding the single-use threshold decreases.

The influence of product titer is outlined in Figure 8.

Figure 8: Influence of product titer on waste quantity at 2,000L (top) and 12,000L (bottom) production scale



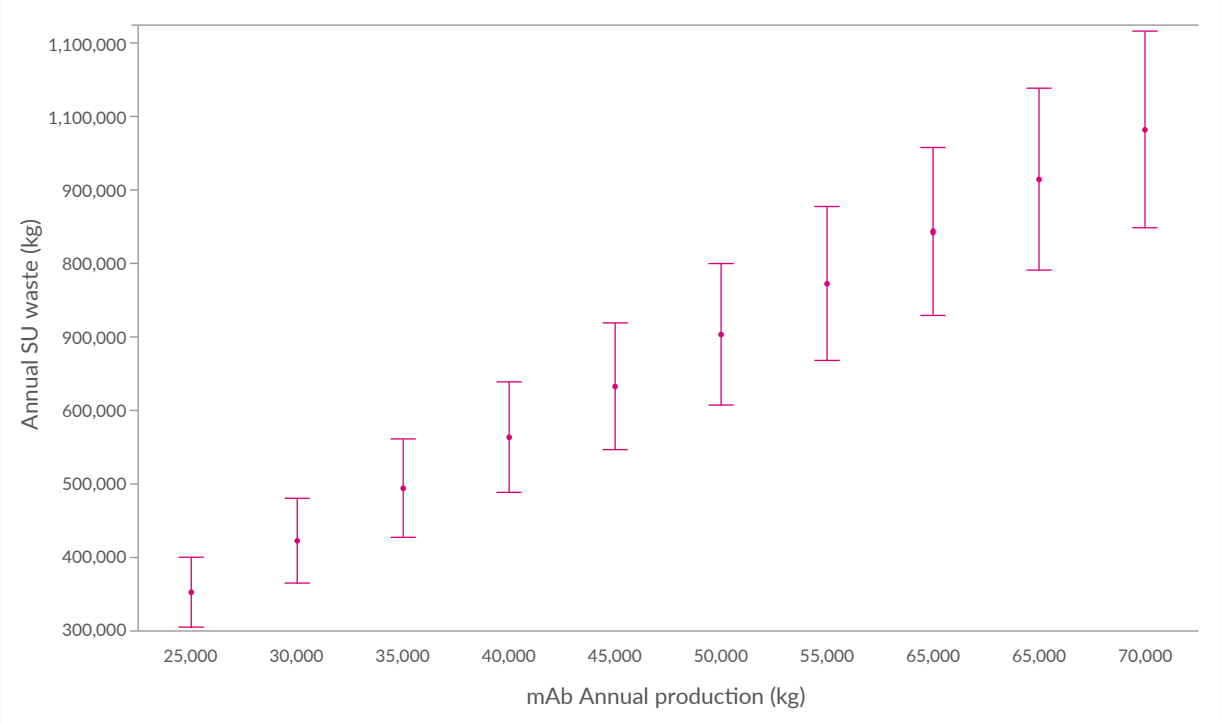
For a 2,000L scale process, the quantity of plastic waste increases as the product titer increases, particularly as the product titer rises from 5g/L to 10g/L with a 19% increase in plastic waste. The increase is associated with increased volumes of product being held and increased buffer volumes (as quantity of buffer required is product mass based). The increase is not linear in terms of plastic waste as the increased waste quantity is based on going above tipping points for equipment size (e.g. a 1,000L single use mixer may be used with a wide range of buffer volumes such as 200 to 1,000L).

As the product titer increases, the likelihood of exceeding the single-use threshold also increases, particularly for traditional buffer preparation methods. This is observed with the trend at the 12,000L scale where the quantity of plastic waste decreases as the product titer increases as the larger buffer volumes drive the use of large stainless steel systems.

2.3 Manufacturing SUT waste at global level

The data in this paper can be used to provide an order of magnitude of the quantity of waste produced by industry annually (for the components included in the scope of this study). For example, according to figures published in BioProcess Online, an estimated 25,000kg of mAbs were produced in 2019MAb Products: Market Trends and Projections—BioProcess International.[26] Based on this figure, the associated SUT plastic waste in the scope of this study would have been 352,000kg (based on median plastic weights). When other modalities are considered, as well as non-commercial manufacturing (e.g. clinical scale), the actual quantity of SUT plastic waste from the production of biologics for 2019 would likely have been considerably higher. Some estimates projected that total mAbs production would have risen to ≈56,000kg by 2024 which would represent a doubling of single-use plastic since 2019. The correlation between potential increased industry output and single-use plastic waste is outlined in Figure 9.

Figure 9: Estimated annual single-use plastic waste based on corresponding annual mAb demand



While numbers for industry output are difficult to estimate, the general trend toward growth is clear and this will result in a greater demand for SUT, a correspondingly greater amount of waste, and an increasing need for sustainable solutions.

3.0

Conclusion

Ultimately, the aim of this paper is to support those with responsibility for sustainable materials stewardship within their organizations to identify and adopt more circular practices.

The inclusion of real-world single-use assembly weights from multiple suppliers and end-users provides a robust and consistent way of benchmarking for future quantification of plastic use at site and global level, agnostic of supplier product. As the industry continues to grow, this knowledge is critical to improving sustainability and provides benchmarks from which improvement can be measured.

The detailed quantification data of plastic waste generated in the manufacture of mAbs at a batch basis provides a comprehensive evaluation of the breakdown of SUT manufacturing waste within a facility which can be used to support future recycling initiatives. The core process accounts for 52% and 30% of the considered total waste at the intermediate and large scale respectively with media and buffer providing the remaining 48% and 70%. A greater understanding of the waste source within a facility will be pivotal for future sustainability improvements and will demonstrate the importance of considering process support areas such as media and buffer, in addition to the core process.

The impact of process developments (e.g. increasing product titer) and manufacturing strategies (e.g. buffer preparation philosophy) on overall plastic waste quantities have been demonstrated. As the industry becomes more efficient with higher-titer processes, plastic usage will increase accordingly, particularly at intermediate scale. While SUT has been demonstrated to offer environmental advantages over traditional stainless steel, there remains a responsibility to minimize unnecessary waste. The complex nature of this waste poses challenges for recycling. However, the high-value plastics utilized in SUTs and the resultant quality of the waste material offers opportunities for innovative solutions which may embed circularity in the design of products, enhanced recycling capabilities and reduction in reliance on virgin material extraction. Initiatives to increase efficiency, such as implementation of advanced buffer management strategies will go some way to addressing this challenge. At the larger stainless steel manufacturing scale, these initiatives will likely increase the level of SUT utilization due to the reduction in volumes being handled. In this case, levels of plastic waste will rise, albeit providing advantages over the alternative stainless steel systems.

Licence holders can use the model to quantify their waste volumes at each site which will help build regional picture and enable solutions to be developed with waste management solutions providers for specific geographies. Indeed, in some areas there are solutions available already but this is limited to specific regions.

There is technology currently available to treat SUT waste and it is evolving. By collaborating and providing better data access, biomanufacturers, their suppliers, and waste management solution providers can develop more sustainable methods to manage valuable plastics, enhancing circularity and preserving material integrity so that global communities continue to reap their benefits.

For all stakeholders interested in finding out more about the BioPhorum Sustainability Maturity Model and in supporting this collaborative approach to sustainable biopharmaceutical manufacturing, please contact us at **hello@biophorum.com**.

Appendix

Appendix A: Single-use assembly weights

The stated ranges in the tables cover most reported data values with only a small number of outliers falling outside of the stated range. All values are rounded to one decimal place.

Appendix A: Table 1: Single use assembly weights for bioreactors (including packaging)

Bioreactor bags	Median assembly weight (kg)	Assembly weight range minimum (median minus 10%) (kg)	Assembly weight range maximum (median plus 10%) (kg)	Assembly weight range (median ±30%) (kg)
20L	6	4.2	7.8	4.2–7.8
50L	9.7	6.8	12.6	6.8–12.6
100L	9.3	6.5	12.1	6.5–12.1
200L	12.6	8.8	16.4	8.8–16.4
500L	21	14.7	27.3	14.7–27.3
1,000L	22.7	15.9	29.5	15.9–29.5
2,000L	35.3	24.7	45.9	24.7–45.9

Appendix A: Table 2: Single-use assembly weights for single-use mixing bags (including packaging)

Single-use mixing bags	Median assembly weight (kg)	Assembly weight range minimum	Assembly weight range maximum (median plus 10%) (kg)	Assembly weight range (median ±30%) (kg)
50L	5.9	5.3	6.5	5.3–6.5
50L	9.7	6.8	12.6	6.8–12.6
100L	6.3	5.7	6.9	5.7–6.9
200L	6.7	6.0	7.4	6–7.4
500L	9.2	8.3	10.1	8.3–10.1
1,000L	10.5	9.5	11.6	9.5–11.6
2,000L	14.2	12.8	15.6	12.8–15.6

Appendix A: Table 3: Single use assembly weights for static hold bags (including packaging)

Static hold Bags	Median assembly weight (kg)	Assembly weight range minimum (median minus 10%) (kg)	Assembly weight range maximum (median plus 10%) (kg)	Assembly weight range (median ±30%) (kg)
20L	0.6	0.5	0.7	0.5–0.7
50L	9.7	6.8	12.6	6.8–12.6
100L	1.7	1.5	1.9	1.5–1.9
200L	2.1	1.9	2.3	1.9–2.3
500L	2.9	2.6	3.2	2.6–3.2
1,000L	6.4	5.8	7	5.8–7
2,000L	8.2	7.4	9	7.4–9

Appendix B: Process model results: Quantity of single-use assemblies required

The stated ranges in the tables cover most reported data values with only a small number of outliers falling outside of the stated range. All values are rounded to one decimal place.

Appendix B: Table 5: Quantity of single use bags required for each considered scenario

				Production scale	2000L	2000L	2000L	2000L	2000L	2000L	2000L	2000L	2000L	12000L	12000L	12000L
				Product titre (g/L)	2	5	10	2	5	10	2	5	10	2	5	10
				Buffer preparation philosophy	Traditional	Traditional	Traditional	Buffer concentrates	Buffer concentrates	Buffer concentrates	Inline conditioning	Inline conditioning	Inline conditioning	Traditional	Traditional	Traditional
Area	Type	Sub type	Size	Unit	Qty	Qty	Qty	Qty	Qty	Qty	Qty	Qty	Qty	Qty	Qty	Qty
Upstream	Bioreactor bag	Bioreactor bag	20L	L	0	0	0	0	0	0	0	0	0	0	0	0
Upstream	Bioreactor bag	Bioreactor bag	50L	L	0	0	0	0	0	0	0	0	0	1	1	1
Upstream	Bioreactor bag	Bioreactor bag	100L	L	0	0	0	0	0	0	0	0	0	0	0	0
Upstream	Bioreactor bag	Bioreactor bag	200L	L	1	1	1	1	1	1	1	1	1	0	0	0
Upstream	Bioreactor bag	Bioreactor bag	500L	L	1	1	1	1	1	1	1	1	1	1	1	1
Upstream	Bioreactor bag	Bioreactor bag	1,000L	L	0	0	0	0	0	0	0	0	0	0	0	0
Upstream	Bioreactor bag	Bioreactor bag	2,000L	L	1	1	1	1	1	1	1	1	1	0	0	0
Upstream	Product mixer bag	Single use mixing bag	50L	L	0	0	0	0	0	0	0	0	0	0	0	0
Upstream	Product mixer bag	Single use mixing bag	100L	L	0	0	0	0	0	0	0	0	0	0	0	0
Upstream	Product mixer bag	Single use mixing bag	200L	L	0	0	0	0	0	0	0	0	0	0	0	0
Upstream	Product mixer bag	Single use mixing bag	500L	L	0	0	0	0	0	0	0	0	0	0	0	0
Upstream	Product mixer bag	Single use mixing bag	1,000L	L	0	0	0	0	0	0	0	0	0	0	0	0
Upstream	Product mixer bag	Single use mixing bag	2,000L	L	1	1	1	1	1	1	1	1	1	0	0	0
Downstream	Product mixer bag	Single use mixing bag	50L	L	0	0	0	0	0	0	0	0	0	0	0	0
Downstream	Product mixer bag	Single use mixing bag	100L	L	0	0	0	0	0	0	0	0	0	0	0	0
Downstream	Product mixer bag	Single use mixing bag	200L	L	2	2	0	2	2	0	2	2	0	0	0	0
Downstream	Product mixer bag	Single use mixing bag	500L	L	5	4	2	5	4	2	5	4	2	2	0	0
Downstream	Product mixer bag	Single use mixing bag	1,000L	L	0	1	0	0	1	0	0	1	0	0	2	0
Downstream	Product mixer bag	Single use mixing bag	2,000L	L	2	2	7	2	2	7	2	2	7	4	0	2
Buffer	Solution mixer bag system	Single use mixing bag	50L	L	2	2	2	6	4	2	2	2	2	1	1	1

Appendix B: Table 5: Quantity of single use bags required for each considered scenario (continued)

				Production scale	2000L	2000L	2000L	2000L	2000L	2000L	2000L	2000L	2000L	12000L	12000L	12000L
				Product titre (g/L)	2	5	10	2	5	10	2	5	10	2	5	10
				Buffer preparation philosophy	Traditional	Traditional	Traditional	Buffer concentrates	Buffer concentrates	Buffer concentrates	Inline conditioning	Inline conditioning	Inline conditioning	Traditional	Traditional	Traditional
Area	Type	Sub type	Size	Unit	Qty	Qty	Qty	Qty	Qty	Qty	Qty	Qty	Qty	Qty	Qty	Qty
Buffer	Solution mixer bag system	Single use mixing bag	100L	L	2	0	0	2	3	2	0	0	0	0	0	0
Buffer	Solution mixer bag system	Single use mixing bag	200L	L	1	2	0	1	2	1	0	0	0	1	0	0
Buffer	Solution mixer bag system	Single use mixing bag	500L	L	4	3	2	2	1	4	0.4	0.1	0	2	1	0
Buffer	Solution mixer bag system	Single use mixing bag	1,000L	L	2	3	1	1	2	1	1.58	1.3	0	1	2	1
Buffer	Solution mixer bag system	Single use mixing bag	2,000L	L	1	1	5	0	0	2	0	0.58	3.44	5	1	2
Buffer	Hold bag	Hold bag	20L	L	2	2	0	2	2	2	2	2	2	0	0	0
Buffer	Hold bag	Hold bag	50L	L	0	0	2	4	2	0	0	0	0	1	1	1
Buffer	Hold bag	Hold bag	100L	L	2	0	0	2	3	2	0	0	0	0	0	0
Buffer	Hold bag	Hold bag	200L	L	1	2	0	1	2	1	0	0	0	1	0	0
Buffer	Hold bag	Hold bag	500L	L	4	3	2	2	1	4	0.4	0.1	0	2	1	0
Buffer	Hold bag	Hold bag	1,000L	L	2	3	1	1	2	1	1.58	1.3	0	1	2	1
Buffer	Hold bag	Hold bag	2,000L	L	1	1	5	0	0	2	0	0.58	3.44	5	1	2
Media	Solution mixer bag system	Single use mixing bag	50L	L	2	2	2	2	2	2	2	2	2	0	0	0
Media	Solution mixer bag system	Single use mixing bag	100L	L	1	1	1	1	1	1	1	1	1	0	0	0
Media	Solution mixer bag system	Single use mixing bag	200L	L	0	0	0	0	0	0	0	0	0	0	0	0
Media	Solution mixer bag system	Single use mixing bag	500L	L	1	1	1	1	1	1	1	1	1	3	3	3
Media	Solution mixer bag system	Single use mixing bag	1,000L	L	0	0	0	0	0	0	0	0	0	0	0	0
Media	Solution mixer bag system	Single use mixing bag	2,000L	L	1	1	1	1	1	1	1	1	1	1	1	1
Media	Hold bag	Hold bag	20L	L	0	0	0	0	0	0	0	0	0	0	0	0
Media	Hold bag	Hold bag	50L	L	2	2	2	2	2	2	2	2	2	0	0	0
Media	Hold bag	Hold bag	100L	L	1	1	1	1	1	1	1	1	1	0	0	0
Media	Hold bag	Hold bag	200L	L	0	0	0	0	0	0	0	0	0	0	0	0
Media	Hold bag	Hold bag	500L	L	1	1	1	1	1	1	1	1	1	3	3	3
Media	Hold bag	Hold bag	1,000L	L	0	0	0	0	0	0	0	0	0	0	0	0
Media	Hold bag	Hold bag	2,000L	L	1	1	1	1	1	1	1	1	1	1	1	1

Appendix C: Process model results: Quantity of plastic waste generated for each considered scenario on a per batch basis

The quantity of plastic waste for all considered scenarios on a per batch basis is outlined in Table 6 and Table 5.

Appendix C: Table 6: Quantity of plastic waste generated for each considered scenario on a per batch basis

No.	Bioreactor Scale	Product titre (g/L)	Buffer prep philosophy	Plastic weight (Min/ Median/Max)	Scenario description	Batch size (assume 70% recovery)	Qty of SU assemblies	Total weight bioreactors (kg)	Total weight upstream product mixer bag (kg)	Total weight downstream product mixer bag (kg)	Total weight product hold (kg)	Total weight buffer prep (kg)	Total weight buffer hold (kg)	Total weight buffer (kg)	Total weight media prep (kg)	Total weight media hold (kg)	Total weight media (kg)	Total overall weight (kg)	Percentage bioreactors	Percentage product Mixer	Percentage buffer	Percentage media	Plastic weight per kg mAb
1	2000	2	Traditional	Min Plastic Weights	2000@2g/LTraditional Buffer Prep—Min Plastic Weights	2.8	47	48.2	12.8	79.1	91.9	93	35.3	128.3	37.4	13.3	50.7	319.1	15%	29%	40%	16%	114.0
2	2000	2	Traditional	Median Plastic Weights	2000@2g/LTraditional Buffer Prep—Median Plastic Weights	2.8	47	68.9	14.2	87.8	102	103.1	39.3	142.4	41.5	14.8	56.3	369.6	19%	28%	39%	15%	132.0
3	2000	2	Traditional	Max Plastic Weights	2000@2g/LTraditional Buffer Prep—Max Plastic Weights	2.8	47	89.6	15.6	96.5	112.1	113.4	43.3	156.7	45.6	16.3	61.9	420.3	21%	27%	37%	15%	150.1
4	2000	5	Traditional	Min Plastic Weights	2000@5g/LTraditional Buffer Prep—Min Plastic Weights	7	45	48.2	12.8	80.3	93.1	88.8	37.4	126.2	37.4	13.3	50.7	318.2	15%	29%	40%	16%	45.5
5	2000	5	Traditional	Median Plastic Weights	2000@5g/LTraditional Buffer Prep—Median Plastic Weights	7	45	68.9	14.2	89.1	103.3	98.5	41.5	140	41.5	14.8	56.3	368.5	19%	28%	38%	15%	52.6
6	2000	5	Traditional	Max Plastic Weights	2000@5g/LTraditional Buffer Prep—Max Plastic Weights	7	45	89.6	15.6	98	113.6	108.5	45.6	154.1	45.6	16.3	61.9	419.2	21%	27%	37%	15%	59.9
7	2000	10	Traditional	Min Plastic Weights	2000@10g/LTraditional Buffer Prep—Min Plastic Weights	14	43	48.2	12.8	106.2	119	100.7	49.8	150.5	37.4	13.3	50.7	368.4	13%	32%	41%	14%	26.3
8	2000	10	Traditional	Median Plastic Weights	2000@10g/LTraditional Buffer Prep—Median Plastic Weights	14	43	68.9	14.2	117.8	132	111.7	55.2	166.9	41.5	14.8	56.3	424.1	16%	31%	39%	13%	30.3
9	2000	10	Traditional	Max Plastic Weights	2000@10g/LTraditional Buffer Prep—Max Plastic Weights	14	43	89.6	15.6	129.4	145	122.8	60.6	183.4	45.6	16.3	61.9	479.9	19%	30%	38%	13%	34.3

Appendix C: Table 6: Quantity of plastic waste generated for each considered scenario on a per batch basis (continued)

No.	Bioreactor Scale	Product titre (g/L)	Buffer prep philosophy	Plastic weight (Min/ Median/Max)	Scenario description	Batch size (assume 70% recovery)	Qty of SU assemblies	Total weight bioreactors (kg)	Total weight upstream product mixer bag (kg)	Total weight downstream product mixer bag (kg)	Total weight product hold (kg)	Total weight buffer prep (kg)	Total weight buffer hold (kg)	Total weight buffer (kg)	Total weight media prep (kg)	Total weight media hold (kg)	Total weight media (kg)	Total overall weight (kg)	Percentage bioreactors	Percentage product Mixer	Percentage buffer	Percentage media	Plastic weight per kg mAb
10	2000	2	Buffer Concentrates	Min Plastic Weights	2000@2g/LBuffer Concentrates Buffer Prep—Min Plastic Weights	2.8	47	48.2	12.8	79.1	91.9	75.3	20.5	95.8	37.4	13.3	50.7	286.6	17%	32%	33%	18%	102.4
11	2000	2	Buffer Concentrates	Median Plastic Weights	2000@2g/LBuffer Concentrates Buffer Prep—Median Plastic Weights	2.8	47	68.9	14.2	87.8	102	83.6	22.9	106.5	41.5	14.8	56.3	333.7	21%	31%	32%	17%	119.2
12	2000	2	Buffer Concentrates	Max Plastic Weights	2000@2g/LBuffer Concentrates Buffer Prep—Max Plastic Weights	2.8	47	89.6	15.6	96.5	112.1	92	25.3	117.3	45.6	16.3	61.9	380.9	24%	29%	31%	16%	136.0
13	2000	5	Buffer Concentrates	Min Plastic Weights	2000@5g/LBuffer Concentrates Buffer Prep—Min Plastic Weights	7	47	48.2	12.8	80.3	93.1	77.6	25.3	102.9	37.4	13.3	50.7	294.9	16%	32%	35%	17%	42.1
14	2000	5	Buffer Concentrates	Median Plastic Weights	2000@5g/LBuffer Concentrates Buffer Prep—Median Plastic Weights	7	47	68.9	14.2	89.1	103.3	86.1	28.2	114.3	41.5	14.8	56.3	342.8	20%	30%	33%	16%	49.0
15	2000	5	Buffer Concentrates	Max Plastic Weights	2000@5g/LBuffer Concentrates Buffer Prep—Max Plastic Weights	7	47	89.6	15.6	98	113.6	94.8	31.1	125.9	45.6	16.3	61.9	391	23%	29%	32%	16%	55.9
16	2000	10	Buffer Concentrates	Min Plastic Weights	2000@10g/LBuffer Concentrates Buffer Prep—Min Plastic Weights	14	47	48.2	12.8	106.2	119	96.3	36.9	133.2	37.4	13.3	50.7	351.1	14%	34%	38%	14%	25.1
17	2000	10	Buffer Concentrates	Median Plastic Weights	2000@10g/LBuffer Concentrates Buffer Prep—Median Plastic Weights	14	47	68.9	14.2	117.8	132	106.8	41.1	147.9	41.5	14.8	56.3	405.1	17%	33%	37%	14%	28.9
18	2000	10	Buffer Concentrates	Max Plastic Weights	2000@10g/LBuffer Concentrates Buffer Prep—Max Plastic Weights	14	47	89.6	15.6	129.4	145	117.4	45.3	162.7	45.6	16.3	61.9	459.2	20%	32%	35%	13%	32.8
19	2000	2	Inline Buffer Prep	Min Plastic Weights	2000@2g/LInline Buffer Prep Buffer Prep—Min Plastic Weights	2.8	30.96	48.2	12.8	79.1	91.9	28.93	11.204	40.134	37.4	13.3	50.7	230.934	21%	40%	17%	22%	82.5

Appendix C: Table 6: Quantity of plastic waste generated for each considered scenario on a per batch basis (continued)

No.	Bioreactor Scale	Product titre (g/L)	Buffer prep philosophy	Plastic weight (Min/ Median/Max)	Scenario description	Batch size (assume 70% recovery)	Qty of SU assemblies	Total weight bioreactors (kg)	Total weight upstream product mixer bag (kg)	Total weight downstream product mixer bag (kg)	Total weight product hold (kg)	Total weight buffer prep (kg)	Total weight buffer hold (kg)	Total weight buffer (kg)	Total weight media prep (kg)	Total weight media hold (kg)	Total weight media (kg)	Total overall weight (kg)	Percentage bioreactors	Percentage product Mixer	Percentage buffer	Percentage media	Plastic weight per kg mAb
20	2000	2	Inline Buffer Prep	Median Plastic Weights	2000@2g/LInline Buffer Prep Buffer Prep—Median Plastic Weights	2.8	30.96	68.9	14.2	87.8	102	32.07	12.472	44.542	41.5	14.8	56.3	271.742	25%	38%	16%	21%	97.1
21	2000	2	Inline Buffer Prep	Max Plastic Weights	2000@2g/LInline Buffer Prep Buffer Prep—Max Plastic Weights	2.8	30.96	89.6	15.6	96.5	112.1	35.368	13.74	49.108	45.6	16.3	61.9	312.708	29%	36%	16%	20%	111.7
22	2000	5	Inline Buffer Prep	Min Plastic Weights	2000@5g/LInline Buffer Prep Buffer Prep—Min Plastic Weights	7	30.96	48.2	12.8	80.3	93.1	31.204	13.092	44.296	37.4	13.3	50.7	236.296	20%	39%	19%	21%	33.8
23	2000	5	Inline Buffer Prep	Median Plastic Weights	2000@5g/LInline Buffer Prep Buffer Prep—Median Plastic Weights	7	30.96	68.9	14.2	89.1	103.3	34.606	14.566	49.172	41.5	14.8	56.3	277.672	25%	37%	18%	20%	39.7
24	2000	5	Inline Buffer Prep	Max Plastic Weights	2000@5g/LInline Buffer Prep Buffer Prep—Max Plastic Weights	7	30.96	89.6	15.6	98	113.6	38.138	16.04	54.178	45.6	16.3	61.9	319.278	28%	36%	17%	19%	45.6
25	2000	10	Inline Buffer Prep	Min Plastic Weights	2000@10g/LInline Buffer Prep Buffer Prep—Min Plastic Weights	14	33.88	48.2	12.8	106.2	119	54.632	26.456	81.088	37.4	13.3	50.7	298.988	16%	40%	27%	17%	21.4
26	2000	10	Inline Buffer Prep	Median Plastic Weights	2000@10g/LInline Buffer Prep Buffer Prep—Median Plastic Weights	14	33.88	68.9	14.2	117.8	132	60.648	29.408	90.056	41.5	14.8	56.3	347.256	20%	38%	26%	16%	24.8
27	2000	10	Inline Buffer Prep	Max Plastic Weights	2000@10g/LInline Buffer Prep Buffer Prep—Max Plastic Weights	14	33.88	89.6	15.6	129.4	145	66.664	32.36	99.024	45.6	16.3	61.9	395.524	23%	37%	25%	16%	28.3
28	12000	2	Traditional	Min Plastic Weights	12000@2g/LTraditional Buffer Prep—Min Plastic Weights	16.8	36	21.5	0	67.8	67.8	101.4	50.8	152.2	37.7	15.2	52.9	294.4	7%	23%	52%	18%	17.5
29	12000	2	Traditional	Median Plastic Weights	12000@2g/LTraditional Buffer Prep—Median Plastic Weights	16.8	36	30.7	0	75.2	75.2	112.5	56.3	168.8	41.8	16.9	58.7	333.4	9%	23%	51%	18%	19.8
30	12000	2	Traditional	Max Plastic Weights	12000@2g/LTraditional Buffer Prep—Max Plastic Weights	16.8	36	39.9	0	82.6	82.6	123.7	61.8	185.5	45.9	18.6	64.5	372.5	11%	22%	50%	17%	22.2

Appendix C: Table 6: Quantity of plastic waste generated for each considered scenario on a per batch basis (continued)

No.	Bioreactor Scale	Product titre (g/L)	Buffer prep philosophy	Plastic weight (Min/ Median/Max)	Scenario description	Batch size (assume 70% recovery)	Qty of SU assemblies	Total weight bioreactors (kg)	Total weight upstream product mixer bag (kg)	Total weight downstream product mixer bag (kg)	Total weight product hold (kg)	Total weight buffer prep (kg)	Total weight buffer hold (kg)	Total weight buffer (kg)	Total weight media prep (kg)	Total weight media hold (kg)	Total weight media (kg)	Total overall weight (kg)	Percentage bioreactors	Percentage product Mixer	Percentage buffer	Percentage media	Plastic weight per kg mAb
31	12000	5	Traditional	Min Plastic Weights	12000@5g/LTraditional Buffer Prep—Min Plastic Weights	42	22	21.5	0	19	19	45.4	22.5	67.9	37.7	15.2	52.9	161.3	13%	12%	42%	33%	3.8
32	12000	5	Traditional	Median Plastic Weights	12000@5g/LTraditional Buffer Prep—Median Plastic Weights	42	22	30.7	0	21	21	50.3	24.9	75.2	41.8	16.9	58.7	185.6	17%	11%	41%	32%	4.4
33	12000	5	Traditional	Max Plastic Weights	12000@5g/LTraditional Buffer Prep—Max Plastic Weights	42	22	39.9	0	23.2	23.2	55.4	27.3	82.7	45.9	18.6	64.5	210.3	19%	11%	39%	31%	5.0
34	12000	10	Traditional	Min Plastic Weights	12000@10g/LTraditional Buffer Prep—Min Plastic Weights	84	20	21.5	0	25.6	25.6	40.4	21.5	61.9	37.7	15.2	52.9	161.9	13%	16%	38%	33%	1.9
35	12000	10	Traditional	Median Plastic Weights	12000@10g/LTraditional Buffer Prep—Median Plastic Weights	84	20	30.7	0	28.4	28.4	44.8	23.8	68.6	41.8	16.9	58.7	186.4	16%	15%	37%	31%	2.2
36	12000	10	Traditional	Max Plastic Weights	12000@10g/LTraditional Buffer Prep—Max Plastic Weights	84	20	39.9	0	31.2	31.2	49.3	26.1	75.4	45.9	18.6	64.5	211	19%	15%	36%	31%	2.5
37	12000	2	Buffer Concentrates	Min Plastic Weights	12000@2g/LBuffer Concentrates Buffer Prep—Min Plastic Weights	16.8	40	21.5	0	67.8	67.8	97	38.7	135.7	37.7	15.2	52.9	277.9	8%	24%	49%	19%	16.5
38	12000	2	Buffer Concentrates	Median Plastic Weights	12000@2g/LBuffer Concentrates Buffer Prep—Median Plastic Weights	16.8	40	30.7	0	75.2	75.2	107.6	43	150.6	41.8	16.9	58.7	315.2	10%	24%	48%	19%	18.8
39	12000	2	Buffer Concentrates	Max Plastic Weights	12000@2g/LBuffer Concentrates Buffer Prep—Max Plastic Weights	16.8	40	39.9	0	82.6	82.6	118.3	47.3	165.6	45.9	18.6	64.5	352.6	11%	23%	47%	18%	21.0
40	12000	5	Buffer Concentrates	Min Plastic Weights	12000@5g/LBuffer Concentrates Buffer Prep—Min Plastic Weights	42	30	21.5	0	19	19	70.7	29.9	100.6	37.7	15.2	52.9	194	11%	10%	52%	27%	4.6

Appendix C: Table 6: Quantity of plastic waste generated for each considered scenario on a per batch basis (continued)

No.	Bioreactor Scale	Product titre (g/L)	Buffer prep philosophy	Plastic weight (Min/ Median/Max)	Scenario description	Batch size (assume 70% recovery)	Qty of SU assemblies	Total weight bioreactors (kg)	Total weight upstream product mixer bag (kg)	Total weight downstream product mixer bag (kg)	Total weight product hold (kg)	Total weight buffer prep (kg)	Total weight buffer hold (kg)	Total weight buffer (kg)	Total weight media prep (kg)	Total weight media hold (kg)	Total weight media (kg)	Total overall weight (kg)	Percentage bioreactors	Percentage product Mixer	Percentage buffer	Percentage media	Plastic weight per kg mAb
41	12000	5	Buffer Concentrates	Median Plastic Weights	12000@5g/LBuffer Concentrates Buffer Prep—Median Plastic Weights	42	30	30.7	0	21	21	78.4	33.1	111.5	41.8	16.9	58.7	221.9	14%	9%	50%	26%	5.3
42	12000	5	Buffer Concentrates	Max Plastic Weights	12000@5g/LBuffer Concentrates Buffer Prep—Max Plastic Weights	42	30	39.9	0	23.2	23.2	86.4	36.3	122.7	45.9	18.6	64.5	250.3	16%	9%	49%	26%	6.0
43	12000	10	Buffer Concentrates	Min Plastic Weights	12000@10g/LBuffer Concentrates Buffer Prep—Min Plastic Weights	84	28	21.5	0	25.6	25.6	76	38.3	114.3	37.7	15.2	52.9	214.3	10%	12%	53%	25%	2.6
44	12000	10	Buffer Concentrates	Median Plastic Weights	12000@10g/LBuffer Concentrates Buffer Prep—Median Plastic Weights	84	28	30.7	0	28.4	28.4	84.2	42.4	126.6	41.8	16.9	58.7	244.4	13%	12%	52%	24%	2.9
45	12000	10	Buffer Concentrates	Max Plastic Weights	12000@10g/LBuffer Concentrates Buffer Prep—Max Plastic Weights	84	28	39.9	0	31.2	31.2	92.7	46.5	139.2	45.9	18.6	64.5	274.8	15%	11%	51%	23%	3.3
46	12000	2	Inline Buffer Prep	Min Plastic Weights	12000@2g/LInline Buffer Prep Buffer Prep—Min Plastic Weights	16.8	26.84	21.5	0	67.8	67.8	55.076	28.108	83.184	37.7	15.2	52.9	225.384	10%	30%	37%	23%	13.4
47	12000	2	Inline Buffer Prep	Median Plastic Weights	12000@2g/LInline Buffer Prep Buffer Prep—Median Plastic Weights	16.8	26.84	30.7	0	75.2	75.2	61.164	31.144	92.308	41.8	16.9	58.7	256.908	12%	29%	36%	23%	15.3
48	12000	2	Inline Buffer Prep	Max Plastic Weights	12000@2g/LInline Buffer Prep Buffer Prep—Max Plastic Weights	16.8	26.84	39.9	0	82.6	82.6	67.252	34.18	101.432	45.9	18.6	64.5	288.432	14%	29%	35%	22%	17.2
49	12000	5	Inline Buffer Prep	Min Plastic Weights	12000@5g/LInline Buffer Prep Buffer Prep—Min Plastic Weights	42	22	21.5	0	19	19	52	25.7	77.7	37.7	15.2	52.9	171.1	13%	11%	45%	31%	4.1
50	12000	5	Inline Buffer Prep	Median Plastic Weights	12000@5g/LInline Buffer Prep Buffer Prep—Median Plastic Weights	42	22	30.7	0	21	21	57.7	28.5	86.2	41.8	16.9	58.7	196.6	16%	11%	44%	30%	4.7

Appendix C: Table 6: Quantity of plastic waste generated for each considered scenario on a per batch basis (continued)

No.	Bioreactor Scale	Product titre (g/L)	Buffer prep philosophy	Plastic weight (Min/ Median/Max)	Scenario description	Batch size (assume 70% recovery)	Qty of SU assemblies	Total weight bioreactors (kg)	Total weight upstream product mixer bag (kg)	Total weight downstream product mixer bag (kg)	Total weight product hold (kg)	Total weight buffer prep (kg)	Total weight buffer hold (kg)	Total weight buffer (kg)	Total weight media prep (kg)	Total weight media hold (kg)	Total weight media (kg)	Total overall weight (kg)	Percentage bioreactors	Percentage product Mixer	Percentage buffer	Percentage media	Plastic weight per kg mAb
51	12000	5	Inline Buffer Prep	Max Plastic Weights	12000@5g/LInline Buffer Prep Buffer Prep—Max Plastic Weights	42	22	39.9	0	23.2	23.2	63.4	31.3	94.7	45.9	18.6	64.5	222.3	18%	10%	43%	29%	5.3
52	12000	10	Inline Buffer Prep	Min Plastic Weights	12000@10g/LInline Buffer Prep Buffer Prep—Min Plastic Weights	84	22	21.5	0	25.6	25.6	53.2	28.9	82.1	37.7	15.2	52.9	182.1	12%	14%	45%	29%	2.2
53	12000	10	Inline Buffer Prep	Median Plastic Weights	12000@10g/LInline Buffer Prep Buffer Prep—Median Plastic Weights	84	22	30.7	0	28.4	28.4	59	32	91	41.8	16.9	58.7	208.8	15%	14%	44%	28%	2.5
54	12000	10	Inline Buffer Prep	Max Plastic Weights	12000@10g/LInline Buffer Prep Buffer Prep—Max Plastic Weights	84	22	39.9	0	31.2	31.2	64.9	35.1	100	45.9	18.6	64.5	235.6	17%	13%	42%	27%	2.8

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