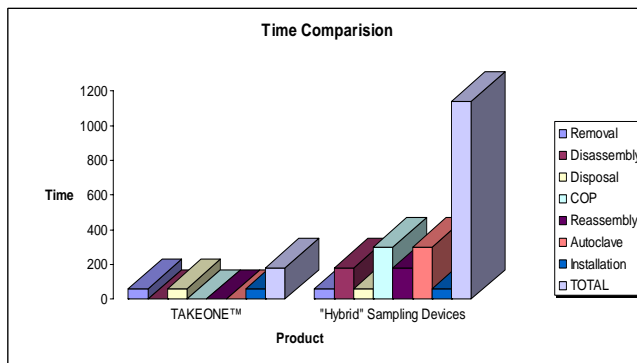


*RE: Disposing of Single-Use Products: Looking at the Total Cost of Ownership*

The broadening use of pre-assembled and pre-irradiated single-use components for biopharmaceutical manufacturing is driven by immediately recognizable benefits, including:

- Virtually no chance of cross contamination — a huge benefit to multi-product facilities and pilot plant operations.
- Lower risk of contamination — single-use components are unsoiled and require fewer operator interactions.
- Reduced logistics and maintenance management of spares parts
- Reduced labor costs — no disassembly, clean-out-of-place (COP), reassembly, autoclave or sterilization



By most accounts, labor is calculated to be one of, if not the largest cost for a biopharmaceutical manufacturing facility. Fully single-use systems, like the TAKEONE™ Aseptic Sampling system, significantly decrease labor inputs providing measurable cost savings.

These benefits aside, the environmental impact of single-use systems is being increasingly scrutinized and measured against incumbent, multi-use and hybrid systems.

In a study by Sinclair, et al. water use (purified water, WFI) measured eight times lower and cleaning chemicals more than 20 times lower with single-use systems. Reduction consumption of water consumption and cleaning chemicals translates into important environmental **benefits** for single-use systems.

Still, the question of how to deal with solid waste from single-use systems remains. Most biopharmaceutical facilities have processes in place for the collection and management of solid waste. Typical options include recycling, incineration and landfill.

Recycling requires sorting of like materials and decontamination of surfaces. The relatively low volume of waste combined with the need to decontaminate and sort materials makes this option undesirable for single-use systems.

Landfill and incineration each provide options for cogeneration. Methane from decomposition in landfills is reclaimed for power generation. From incineration, the heat value for plastics is 1.5 times higher than coal and almost 3 times higher than wood. The incineration of plastics leaves very little ash and very low emissions.

In comparing a fully single-use system with multi-use or hybrid systems, a proper evaluation of waste disposal should compare the increased cost of treating solid waste with the cost of higher water, chemical and energy demands.

The list of references below may be helpful in conducting a thorough evaluation of fully single-use systems, like the TAKEONE™ Aseptic Sampling System.



Technologies, Inc.

References

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About AllPure

AllPure Technologies, Inc. designs, manufactures and markets cutting-edge products for biopharmaceutical and pharmaceutical drug developers and manufacturers. AllPure operates in compliance with cGMP guidelines, where applicable. **You've Been Heard** is the company philosophy and is elemental to our products and services. You've Been Heard means engaging with our customers and partners to understand their challenges and helping them realize practical solutions. From enhancing operating efficiencies and perfecting process reliability to improving operator safety, AllPure launches sensible products.