

SUT DIGITIZATION AND INFORMATION MANAGEMENT: ENABLING AGILE AND SUSTAINABLE SYSTEMS

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Single Use (SU) technology has revolutionized operations, bringing significant benefits such as reduced capital expenditure, faster time to market, and minimized cross-contamination risks. However, this advancement has concurrently introduced complex information management challenges for biomanufacturing end-users. This is where the principles of sustainability and agility can play a transformative role. In this abstract, we look at strategies and considerations for enhancing information management through digitization to see how implementing these can help drive agility and sustainability.

By coupling the simplicity and power of a naming convention with an SUT 'library of designs' end-users can achieve comprehensive oversight, streamlining the process of implementing changes in the supply chain and inventory ERP systems. For instance, consider the situation where a supplier issues a notification of change. If an end-user has developed a robust information management system, they can use the digital tools of library and ERP system to identify areas of impact and implement the change appropriately.

A centralized qualification program can simplify change control work required to maintain the qualified state of materials. In the event of a subcomponent alteration, for example, an update would only need to be executed in one centralized document, rather than in multiple documents for each product or application the assembly is utilized in. This approach minimizes redundancy and maximizes efficiency, contributing to both the agility and sustainability of the operation.

Single Use Diagrams (SUDs) are instrumental in increasing process understanding, clarity, and traceability. They are the SU equivalent to P&IDs. SUDs can provide manufacturing teams with a deeper insight into their operations, aid supply chain departments in establishing a Bill Of Materials (BOMs), and assist process engineering with material and process reviews and aseptic boundary establishment, among other benefits. Standardization in assembly designs can contribute to significantly streamline the qualification process and further enhance the 'reuse' potential of existing SUT designs. Standardization also facilitates the inclusion of these designs in a global SUT library, enabling their widespread application across different process areas, which greatly reduces the proliferation of bespoke SUT designs, increases purchasing power and reducing inventory costs.

The future of SU information management may be significantly transformed by advances in artificial intelligence and digitization. Currently, the extraction of key information from vendor documents, such as subcomponent data, quality claims, extractables data, and supply chain information, is often performed manually. This process is not only time-consuming, but also prone to human errors. The use of information scraping software, coupled with AI to learn and categorize the data for retrieval could give end-users far greater control of their SU materials. A proof of concept demonstrated a 97% accuracy in data collection and categorization across a range of vendor documents and information types in a small sample size.

By reducing the human effort and potential for error, increasing clarity and traceability with the intersection of digitization of SU technology opens new avenues for boosting agility and sustainability.

