Operations | Healthcare / Pharmaceuticals | Improved process performance | N/A

Biomanufacturing Automation Plug & Play

BUSINESS PROBLEM

Next generation biomanufacturing requires modular equipment to enable flexible processes. While the adoption of single use technologies has introduced modular and portable unit operations, the automation that controls equipment operation often requires custom software. To fully realize the potential benefits of flexible, modular processes, the component hardware and automation systems must support a plug-and-play level of interchangeability. This requires consensus standards for automated equipment interfaces across equipment manufacturers, control system suppliers, and end users in the biopharmaceutical industry.

APPROACH

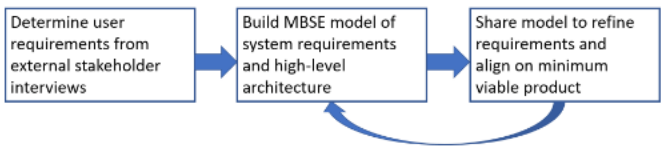
To align the various stakeholders on the high-level architecture of a plug and play automation system, a Model-Based Systems Engineering tool will be used to capture relationships between user requirements, capabilities, and design elements. In parallel, a business case analysis will be constructed to discern the cost / benefit trade-off of different capabilities and the overall economic impact.

DATA SOURCES

Both user needs and impact assessment data will be gathered via interviews with Amgen and NIIMBL members. Current values of relevant metrics will come from Amgen business leaders and automation SMEs.

Data Types and Format

The key data for this project will be the performance metrics impacted by plug and play automation, their current values, by how much they could change, and the economic impact.



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IMPACT

Achieving plug and play automation would benefit manufacturers across the biopharmaceutical industry. The primary benefit is speed to market: enabling instruments and equipment to work together seamlessly would eliminate the time required to write and validate custom automation software when commissioning a new process. Certain functionalities could be considered extensible, meaning additional copies could easily be added to meet a specific process requirement without requiring new software and validation efforts. Additionally, for existing processes, the ability to easily swap out alternative components may reduce batch setup times, increase reliability, and reduce inventory of unique change parts. Finally, plug and play automation would promote the use of commercial-off-the-shelf equipment and support mix and match use of best-in-class equipment rather than equipment that is custom or produced by only a single supplier.

DRIVERS

While end users and equipment vendors may use custom automation and proprietary software, there are relatively few different types of equipment being used, (e.g., bioreactors, chromatography columns) and the control system architecture is largely similar. This commonality provides an opportunity for the development of plug-and-play solutions that require minimal changes to equipment or the overall control system architecture.

BARRIERS

My research project was a small part of an ongoing, multi-year collaboration within an industry consortium external to Amgen and was therefore subject to constraints in the participants' time and the availability of subject matter experts to drive the technical design work. Additionally, there was little data available about existing problems that interchangeable sensors were meant to address, preventing a robust business analysis.

ENABLERS

Because plug-and-play is fundamentally achieved through standardization, it was critical that this project was hosted by an industry-wide collaboration. A major part of my research involved interviews with industry experts through this team, which allowed me to create a framework for plug-and-play capabilities and associated technologies.

ACTIONS

The technical aspect of this research contributed to an ongoing design project that has not yet been completed and therefore was not implemented. In the course of my research I explored some potential challenges with implementation of plug-and-play within an organization and the adoption of plug-and-play across the industry.

INNOVATION

This project used a model-based systems engineering tool to collaboratively work on the new design. This tool presents system designs in simple graphical models that are easily readable, enabling collaboration across a wide spectrum of functional disciplines and levels of expertise.

IMPROVEMENT

The technical aspect of this research contributed to an ongoing design project that has not yet been completed and therefore was not implemented during my internship. However, interchangeable sensors could potentially provide millions of dollars in saved downtime cost through improved reliability, the availability of a ready spare, and the prevention of human error in certain scenarios.

BEST PRACTICES

The most important best practice is to work collaboratively, both across functional groups and across the industry, including suppliers and end-users. The design should capture the critical user needs for as many stakeholders as possible while simultaneously having the least possible impact on the existing design to promote compatibility.

OTHER APPLICATIONS

While this project focused specifically on design changes to control system architecture to support interchangeable sensors, a similar design would likely also support interchangeable actuators, such as pumps and valves.