



Improving Processes and Data Visibility in Life Sciences

by Automating Data Collection and Report Generation

CASE STUDY

CLIENT OVERVIEW:

A global leader in Next Generation DNA sequencing and array-based technologies, serving customers in the research, clinical and applied markets.



APPLICATIONS

- ✓ Oncology
- ✓ Agriculture
- ✓ Genetic Disease
- ✓ Infectious Disease
- ✓ Microbial Genomics
- ✓ Reproductive Health
- ✓ Molecular and Cell Biology

CUSTOMERS

- ✓ Clinics
- ✓ Hospitals
- ✓ Research Labs
- ✓ Healthcare Systems
- ✓ Academic Institutions
- ✓ Government Agencies
- ✓ Pharmaceutical Companies

CLIENT CHALLENGES AND GOALS

The lack of visibility into key equipment data was a hinderance to key decision makers and put the company at risk with the ever increasing regulatory and audit documentation requirements. As with most client environments, data acquisition imperatives include scale, speed, quality, traceability and report-ready, however our client's data collection was manual, time consuming and subject to human error.

To overcome these challenges, the client sought to implement best practice tools that would:

- ✓ Automate data collection for each process for improved speed, quality and insight
- ✓ Automate report generation for faster, more informed decision making and regulatory compliance
- ✓ Develop an off-the-shelf cloud-based software solution that would push the data from their equipment to a centralized cloud SQL server database

SOLUTION

In collaboration with the client, Verista conducted a functional and specification analysis to scope and design the software. The key elements of the design included:

- ✓ The **integration and validation of four separate and unique connections** to different automation controllers. By using one cloud server to connect to multiple controllers at once, the client was able to pull and push data at the same time. In comparison to other off-the-shelf products there was significantly less configuration and overhead.
- ✓ The **implementation of sequencing for data collection** so single reports can be generated per lot/batch instance for management insight and traceability for the FDA.
- ✓ The **development of a data structure** to push the sequencing data to a SQL server for automated system queries and reporting.
- ✓ The **development of customized and automated PDF reporting** for validation and 21 CFR part 11 compliance.

CLIENT BENEFIT

The implementation of best-in-class automation tools and software allowed the client to extract key information and parameters from their equipment (e.g., batch reports, vessel pressure, vessel temperature, etc.) so decision makers in groups such as quality and compliance could make more informed decisions faster. It also provided key reports for audits and regulatory compliance with the FDA. Other benefits included:

- ✓ Speed and quality improvements via automated vs manual data collection
- ✓ Greater insight and auditing capabilities via automated reporting of data per lot for their process equipment
- ✓ Centralized repository since all data collected would be pushed to cloud SQL server for offline analysis later

ABOUT VERISTA

Verista is a life science business and technology consultancy that helps solve critical and complex challenges across the entire product development lifecycle. Verista launched in 2020 by bringing together three trusted firms: Clarke Solutions, Covex LLC, and Acquire Automation. Verista acquired Hawkins Point in 2021. Verista's customers trust our 500+ experts to deliver consistent, safe, and high-quality results.

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