

Challenge

REGENXBIO is a leading clinical-stage biotechnology company seeking to improve lives through the curative potential of gene therapy. With several therapies in development, the company engaged a contract manufacturing organization (CMO) to manufacture clinical trial materials and contract research organizations (CROs) for analytical testing. Also, the company has recently built and staffed facilities for analytical testing and process development.

Due to the complexity of development operations, the company recognized the need for an IT system:

- To integrate and manage the in-house testing activities associated with internal process development and outsourced manufacturing.
- To coordinate and manage outsourced testing of manufactured materials.
- To manage the in-house inventory of samples of manufactured materials.

With the goal of having an IT system operational when new facilities and staff were in place, the company engaged BioIT Solutions to deploy the 1PLATFORM4® Software Suite, a flexible IT foundation for REGENXBIO's complex operations.

Approach

BioIT's approach to this challenge exemplifies our unique methodology. We start with a rapid deployment of our configurable 1PLATFORM4 Software Suite then tune functionality to streamline information management processes.

The project began with the BioIT team learning REGENXBIO's specific needs; the company clearly articulated its desire to build a collaborative tool suitable for use by the entire company. Data needs, workflow rules and access control requirements were then determined and captured as objects or rules managed by the 1PLATFORM4 Software Suite.

Members of the REGENXBIO team worked with early versions of the system, gaining experience and influencing the next iteration. This step ensured that the system evolved organically in a manner that fits the way they work.

Results

Within six months, the BioIT Solutions 1Platform4 Software Suite was operational and in use when the new facilities were opened. Examples of operational efficiencies:

- An integrated visual display facilitates searching for and retrieving CMO material samples for stability testing, retains, and reference standards.
- The system provides visibility for outsourced sample testing including certificates of testing and test results.
- Online submission of process development samples for in-house analytical testing replaced paper sample-submission forms.

Customer Experience

"The 1Platform4 Software Suite is now a vital part of REGENXBIO's operations. It has transformed the way the company works by eliminating clerical work and freeing up more time for science. We now have an IT system that acts as the backbone for development operations and is used by process development, QC, and analytical development." *Zhenhong Li, Senior Director of Analytics – REGENXBIO Inc.*

1PLATFORM4® Software Suite

The 1PLATFORM4 Software Suite integrates multiple scientific and business processes. The suite consists of a web-based software foundation on which various configurable modules are assembled and tailored to each client's specifications and needs.

The 1PLATFORM4 Suite includes integration tools for connecting to external systems and laboratory instruments.

- User-defined workflow modules transform complicated tasks into routine activities.
- Complex processes are managed without custom software, adapting to each client's scientific and business practices.
- Easily and rapidly deployed based on widely supported technologies (SQL Server, Microsoft ASP.NET, web browser access).
- System hosting by BioIT Solutions ensures data integrity and security without customer-supplied IT infrastructure. Systems security is verified with routine vulnerability assessments; SOPs ensure operational consistency.

About BioIT Solutions

BioIT Solutions offers a range of services from enterprise systems built on our 1PLATFORM4 Software Suite for advanced computational, workflow, and data management systems for biological research, drug development and diagnostics to ... IT strategy, architecture and management consulting.

Company founders have worked in biotechnology for over 20 years in a variety of information-technology capacities, including senior positions as CIO, and directors of Bioinformatics, Quality Systems and Clinical Systems. The breadth of our experience makes us an ideal partner for early-stage companies, as well as those with legacy systems in need of modernization.

Manage In-House Sample and Material Inventory

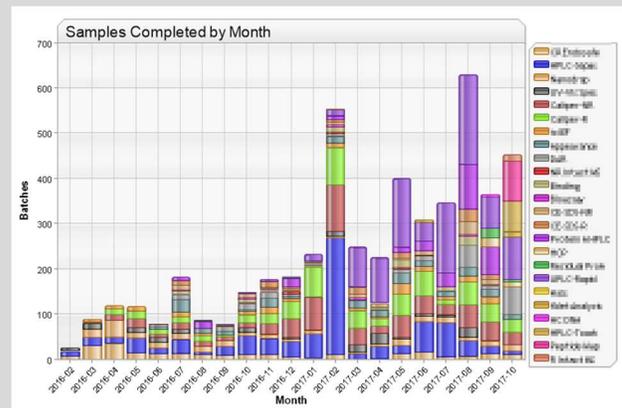
- Accession and bar code samples
- Manage inventory with an integrated repository visual display
- Track location of inventoried items throughout their entire life cycle
- Search for samples to be used in analytical testing, e.g., reference samples and stability samples.
- Associate documents and data with inventoried items
- Determine status of samples for stability testing and reagents used in testing, e.g., quantity on hand
- Trace the history of samples and other materials:
 - Where they are used or have been used
 - Where/when they were created or purchased along with vendor information and expiration date
 - Sample relationships, e.g., pooling, mixing, aliquoting
- Set event-specific triggers for alert notifications, e.g., low quantities of materials, approaching stability testing date

Inventory Box Entry Form

Container Name: Box 003
 Logical Name: Box 003
 Rows: 9
 Columns: 9

Container:	1	2	3	4	5	6	7	8	9
A	1-008A	1-008C	1-008D	1-008E	1-008F	1-008G	1-008H	1-008I	1-008J
B	1-009A	1-009B	1-009C	1-009D	1-009E	1-009F	1-009G	1-009H	1-009I
C	1-007A	1-007B	1-007C	1-007D	1-007E	1-007F	1-007G	1-007H	1-007I
D	1-007A	1-007B	1-007C	1-007D	1-007E	1-007F	1-007G	1-007H	1-007I
E	1-007A	1-007B	1-007C	1-007D	1-007E	1-007F	1-007G	1-007H	1-007I
F	1-007A	1-007B	1-007C	1-007D	1-007E	1-007F	1-007G	1-007H	1-007I
G	1-008E	1-008F	1-008G	1-008H	1-008I	1-008J	1-008K	1-008L	1-008M
H	1-008E	1-008F	1-008G	1-008H	1-008I	1-008J	1-008K	1-008L	1-008M
I	1-002A	1-002B	1-002C	1-002D	1-002E	1-002F	1-002G	1-002H	1-002I

Scan Entry Mode: Update Inventory Box:



Manage and Integrate In-house Analytical Testing

- Accession and bar code samples for testing from process development or manufacturing
- Control and monitor testing of samples with digital dashboards and a flexible calendar
- Set up instruments for sample processing online and automatically capture results via instrument integration, e.g., plate readers, HPLC, Mass Spec.
- Review results and drill down to raw data such as gel images, chromatograms, or slide stains.
- Generate and approve test reports

Coordinate and Manage Outsourced Analytical Testing

- Monitor the status of outsourced testing of process development and production samples
- Upload and review results of outsourced testing

