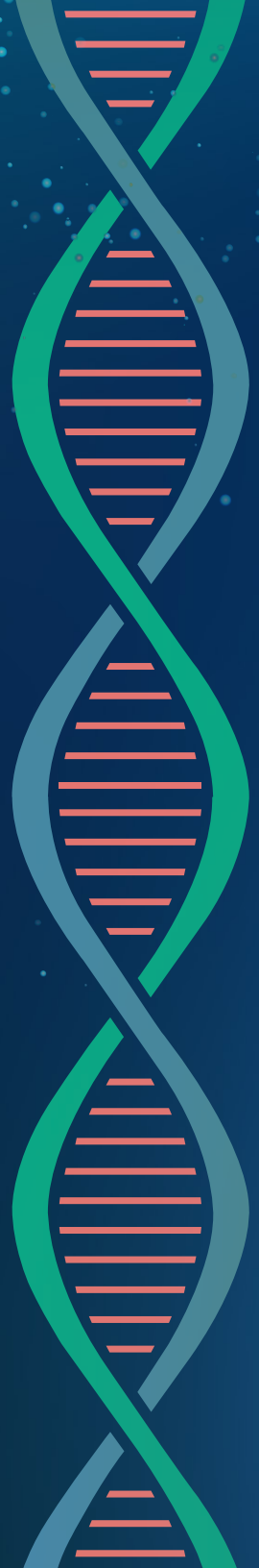
# What to Look for in an Informatics Platform for Biologics R&D



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# Introduction




*In silico* molecular biology tools, electronic lab notebooks, and systems for registration, sample management, workflow management, and request management form the foundation of informatics for biologics R&D.

When building out their informatics, most R&D organizations evaluate these solutions independently, by checking off a list of required features. This is a good starting point, but what are you missing by not evaluating the platform capabilities of these solutions?

The informatics platform you adopt and develop over time is an important consideration with serious consequences for both R&D and IT teams. It impacts the research productivity of your scientists, the decisions you make as an R&D leader, your success in bringing drugs to market — as well as the ability of IT to strategically support R&D and ensure the longer-term relevance of your infrastructure.

The five critical platform capabilities to look for when evaluating an informatics platform for biologics R&D are:

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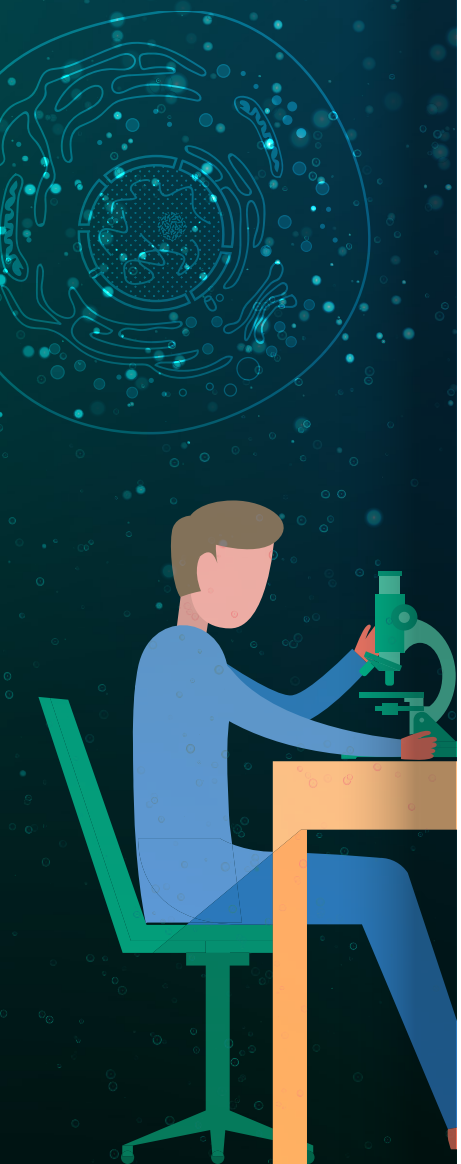
# Purpose-Built for Biologics

## MODELING COMPLEX ENTITIES AND PROCESSES



Over the last two decades, the pharmaceutical industry has seen a clear shift toward biologics, as these new classes of drugs offer the promise of higher therapeutic success. With this shift have come increased drug discovery and bioprocessing complexity and uncertainty.

The processes of small molecule R&D are, to a large extent, well-characterized and well-modeled by software. However, large molecule companies are first-and-foremost developing new and innovative technology platforms.

> *Any informatics platform for biologics needs to accommodate **rapid process changes** and capture, synthesize and report on **countless types of data** from across the organization. At the same time, it has to accomplish **seamless, often bidirectional, handoffs** between numerous teams.*

As legacy informatics providers expanded into the large molecule space, many of them simply re-purposed their small molecule software, with disappointing results. Fundamentally, platforms that are effective for biologics R&D must be built from the ground up to address the unique nature of biologics.

# Model the Complexity of Large Molecules

**Biologics R&D is built around complex molecules and entities (ex. proteins, cell lines, plasmids). Digitally expressing these molecules and entities is a challenge in and of itself, but expressing the relationships between them adds an additional layer of complexity for R&D informatics.**

## Model any type of large molecule entity

A biologics platform should enable you to model any large molecule – from antibodies, to viruses, to yeast strains – and its unique attributes.

## Structure Linkages between Entities

Flexibly structure relationships between any type of entity. For example, link plasmids to viruses, and then to cell lines.

## Surface Parent Data on Child Entities

Directly display relevant characteristics of certain entities onto related entities. For example, surface a tag from a plasmid up to a protein, so you can easily see what tag to use for purification.

## Rollup All Relevant Assay Data and Results to Lots

Centralize data and results from individual lo up to their parent lots. Create a rich history of experiments across your organization's samples.

# Model the Complexity of Biologics Processes

The processes of large molecule R&D take place across numerous teams, branches, and cycles, all of which need to be modeled using an informatics platform's workflow capabilities. Additionally, since large molecule workflows are nonstandard and not well-defined, R&D needs to quickly iterate on and analyze the results of these processes.

## Model Any Type of Workflow

Given the nonstandard nature of biologics R&D, look for a platform that's flexible enough to adapt to your organization's particular workflows for processes such as assay development or screening.

## Built for Rapid Optimization

Swiftly altering workflow structure is crucial to optimizing processes and identifying the most promising candidates.

## Combine Process Flexibility with Structured Results Capture

When processes change frequently, it's critical to have a system that provides flexible workflow design without sacrificing structured results capture that allows for easy analysis.

## Power Multi-Team, Iterative Processes

Look for a platform that can assign tasks to teams and individuals, equip them with complete experimental context, and surface their progress as tasks are carried out.

## Manage Complex Drug Pipelines and Portfolios

The platform should give managers a central dashboard on which they can track the progress, inputs, and outputs of all your organization's projects.

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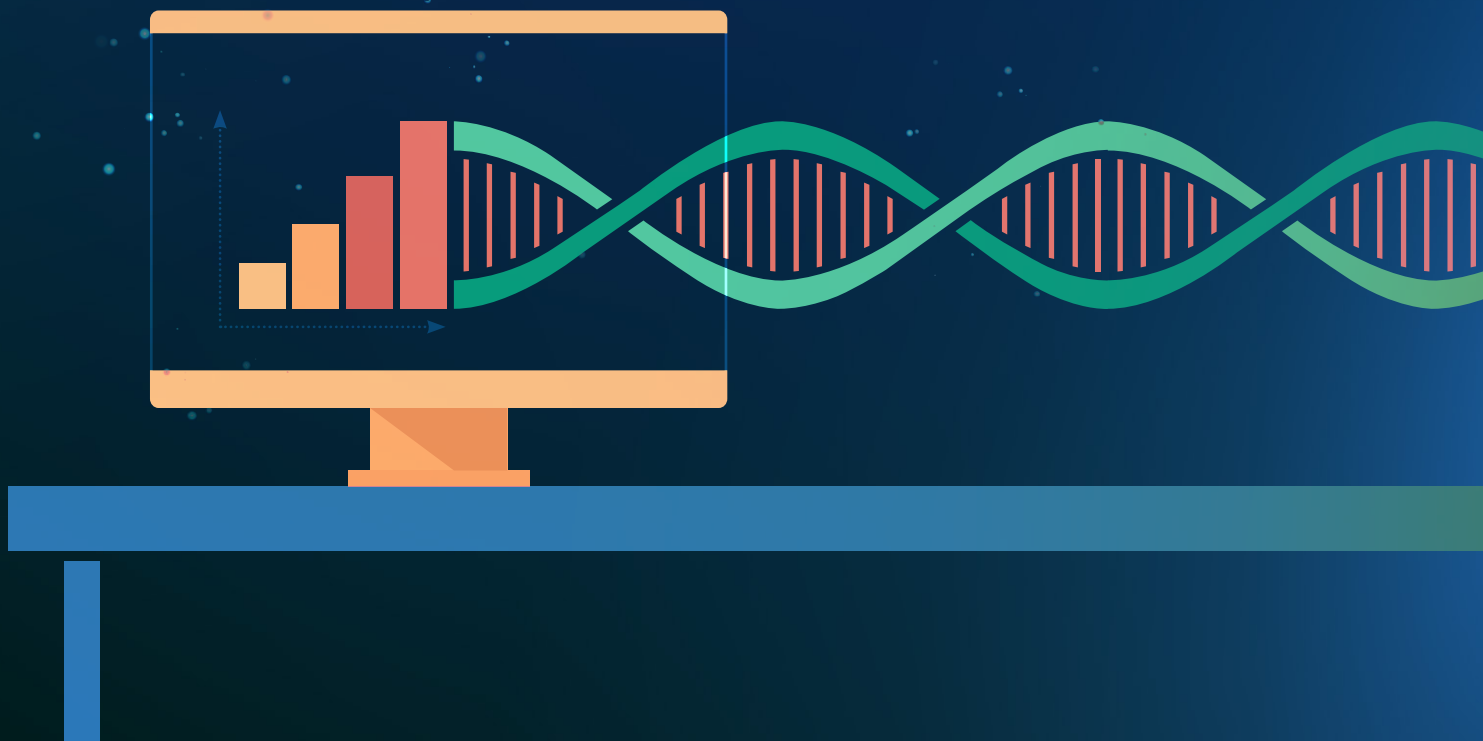
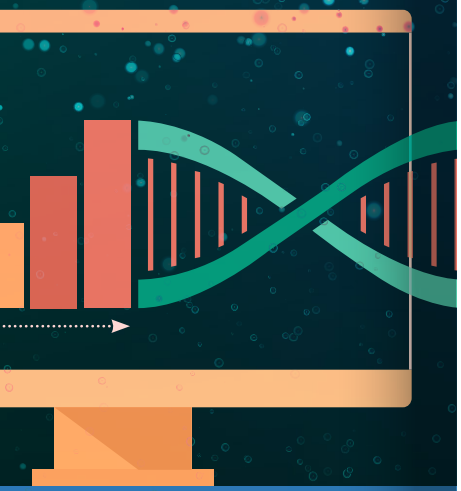
# Unified Data Infrastructure

## HARNESSING ORGANIZATION-WIDE DATA TO ACCELERATE R&D





The years of organizationally complex research that go into a single large molecule candidate scatter results and institutional knowledge across different systems. This makes it difficult for teams to synthesize data from across the organization and use it to accelerate R&D.

Connecting disparate systems, one-by-one, in an attempt to centralize data is extremely expensive and time-consuming. Inevitably, you end up with a system that doesn't really work, breaks often, and is so difficult to use that your scientists and managers will effectively ignore it.

> *The only way to make sense of all this data and harness its full potential is with an out-of-the-box platform that* ***automatically centralizes and interlinks data*** *across your organization.*

Your platform should consist of unified *in silico* design tools, lab notebook, registration, sample management, workflow management, and request management modules that work together to streamline scientists' work. By centralizing processes, inputs, outputs, conditions, and results, these modules then give scientists and R&D managers a real-time view of pipeline progress, informing critical R&D decisions with comprehensive data.

# Automatic Data Linkages Minimize Busywork

## In-Line Registration

Register entities directly from the ELN or *in silico* design suite modules.

## Auto-Linking between Physical Samples and Entities

Configure relationships that automatically link lots and containers with parent entities.

## Bidirectional Linkages

Any link between two files should be automatically bidirectional. For example, linking in a lab notebook entry to a sample will create a link on the sample record to the lab notebook entry.

## Link Functional Data with Experimental Conditions

See the particular experiment that produced a piece of data.

## Reliable Reproducibility

Completely interlinked data and conditions mean any experiment should be reproduced with minimal effort.

# Collaboration and Cross-Learning for Your Entire Organization

## Full History of Any Piece of Data

See the origin of any notebook entry, protocol, process, entity, sample, or sequence, as well as everywhere it has been used or mentioned.

## Seamless Team Hand-Offs

Give colleagues links to samples and a complete history of upstream activity.

## Institutional Knowledge Base

Deepen retained institutional knowledge over time by gradually building up your organization's records.

## Eliminate Re-Research

With easily accessible experimental records, scientists can quickly identify prior efforts relevant to their current research.

## Assign Tasks to Teammates

Structure tasks with desired protocols, inputs, and outputs, and send them to team members.

# Tracking Every R&D Sample, Process, and Result from Start to Finish

## Real-Time R&D Progress

For every project across your organization, dashboards should display step-by-step progress and up-to-date timelines.

## Lineage Tracking

After tracing from physical lots up to parent entities, compare the functional data of lots across different parent entities.

## Pinpoint Locations of Lots from Parent Entities

On any entity, see the locations of every physical lot of it that has been produced.

## Measure Output in Real-Time

Configure live dashboards with statistics around process output and efficiency.

## IND Filings

Complete IND filing in days by exporting the complete experimental history of candidates.

## View Progress Across Pipelines

Access a 360-degree executive view of all processes across different drug pipelines.

# Data-Driven Decisions That Accelerate R&D and Increase Efficiency

## Compare Results Across Different Conditions

Drive process optimization by identifying the conditions that produce desired results.

## Measure Tradeoffs

Across process iterations, measure tradeoffs between quality of results, methods used, and resources.

## Resource Utilization and Planning

With centralized experimental records, easily track resource utilization and plan for future needs.

## Identify Successful Parent Entities

Compare the functional data of different lots to identify which parent entities lead to desired results.

## Eliminate bottlenecks

Identify the processes that take the most time or resources.

## Mine Success Patterns

Across candidates, determine upstream predictors of effectiveness to maximize efficacy.

## Identify Promising Technology Platforms

Single out platforms showing the most promise to advance more effective candidates faster.

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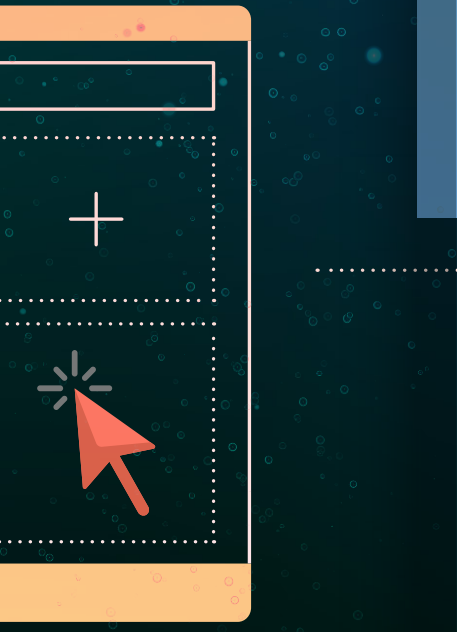
# Codeless Configuration

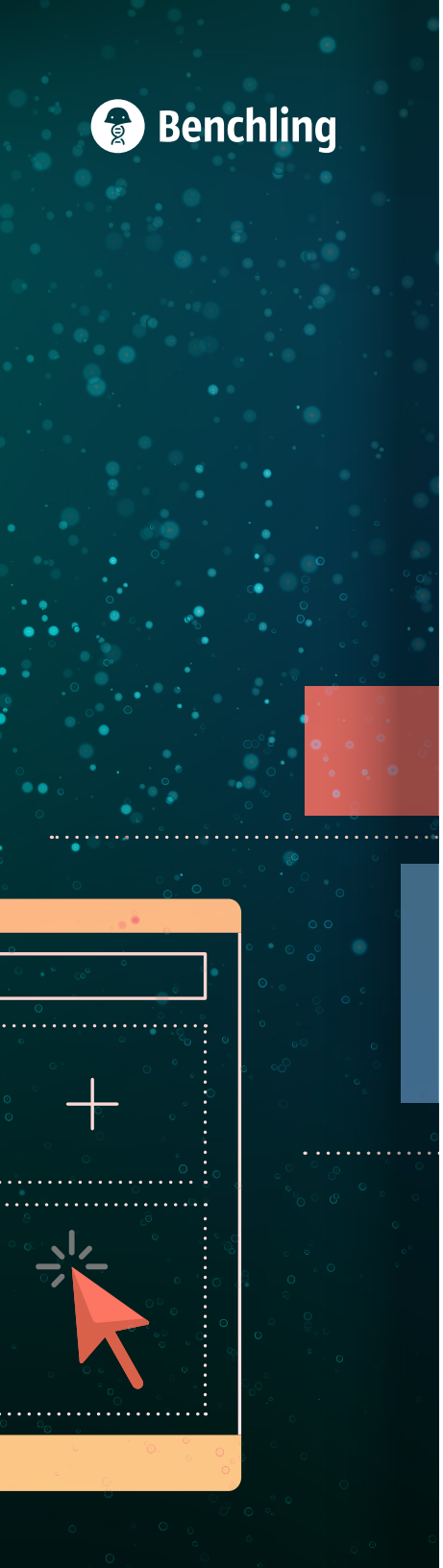
## THE BENEFITS OF CUSTOM, WITH THE EASE OF OFF-THE-SHELF

Traditional R&D informatics platforms have required vendor involvement for configuration. These processes often take months, or even years, to complete. And even following the initial deployment, simple changes that should be done with the press of a button can take months to accomplish.

> *Look for a platform that can be **configured and re-configured at the discretion of IT** or designated R&D users, without the need for extensive coding.*

The platform should offer a point-and-click interface for configuration changes, rather than require changes to code. The available changes to configuration should range from changes that IT can implement, such as modeling new entities and designing new workflows, to simpler changes that designated R&D users can make on their own, such as adding new fields to entities.





## Custom Permissions

Structure permissions based on business criteria. For example, define access to entity and data types based on a user's role, team, function, or any other user characteristic. Also configure permissions to limit the data accessible by external collaborators.

## Custom Fields

Track any data, such as the purity of a lot of antibodies, with custom fields. Define field types to align with business rules; for example, assign specific units to fields, or configure them as dropdowns, multi-select picklists, or other structures.

## Custom Formulas

Across interlinked entities, surface data from one entity onto an entity that it links to. Or, populate an entity's field by structuring calculations across the data of related entities. For example, for each lot of expression hosts, show the average yield and purity of the antibody lots it has produced.

## Custom Entity Types and Relationships

Model any biological entity, from patient samples to yeast cells. Require specific entity types to link to other entity types; for example, require that every expression plasmid have a link to the antibody that it expresses. Add and interlink new entities just as easily, such as a cell line entity that links to antibodies and expression plasmids.

## Custom Workflows

Design custom workflows with trackable stages that can be assigned to teams. Designated users should be able to model new workflows with a point-and-click interface. In a screening workflow, for example, configure stages to capture hits on individual wells. Then, link those hits to the lots of antibody libraries used.

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# Open Integration

## NOT ALL APIS ARE CREATED EQUAL




The standard for integration of R&D systems used to be hard-coded, one-to-one connections between different software products. As the number of these connections grew unmanageable, it became clear that a platform approach would be necessary. Informatics platforms promise an end to this architectural complexity, since a platform can serve as a centralized hub for many stable, API-driven integrations. But not all platforms' APIs are created equal. If the right endpoints aren't exposed in the right way, then certain integrations simply aren't possible. Other times, a platform's APIs can just be slow.

*For biologics R&D, the ideal is a unified data platform with **completely exposed REST APIs,** described with accessible documentation.*

Completely exposed APIs ensure that when you're integrating your platform with other software, you're only limited by the APIs of the other software. IT can then link every relevant application to a central platform, enabling them to exchange data in real-time. The platform standardizes the outputs of each application, making the data of each application accessible to every other application.




## Integrate Instruments

Integrate any instruments, such as smart fridges and plate readers, to automate data capture. For example, use a matrix scanner to scan a plate and open it in your informatics platform, along with the full lineage for the contents of every well in the plate.

## Integrate Databases

Alongside its APIs, your informatics platform should have a built-in data warehouse to accomplish bidirectional integrations with your other databases, warehouses, and lakes. For example, link your manufacturing and R&D databases to streamline data transfer according to business and compliance rules.

## Integrate Software Applications

Beyond instruments and data stores, an informatics platform should be able to integrate with other software when necessary. For example, directly integrate data analysis software such as Spotfire to automatically run and visualize complex queries. As another example, integrate business intelligence software such as QlikView to track R&D progress.

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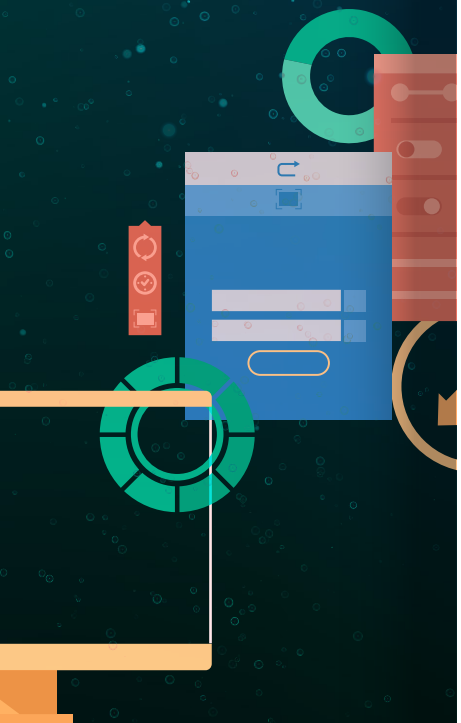
# Easy Extensibility

## DESIGNED FOR IT INNOVATION

No matter how rich the functionality of your R&D informatics platform for notebooking, registration, sample tracking, workflow management and other capabilities, R&D will always need additional functionality that no off-the-shelf software can accommodate. Building custom software for these needs typically involves spinning up a separate hosting environment, dedicating developer resources, and spending extensive time on boilerplate.

*Rather than invest in a separate development platform that would only leave scientists with yet another distinct piece of software, look for an R&D informatics solution that* ***accommodates custom development*** *within itself.*

By minimizing IT overhead and producing a smooth user experience, this approach opens up wholly new development possibilities.



## Embed Data Visualizations

Directly within the platform, embed Prism and Tableau-like functionality that enables data visualizations. For instance, a cell therapy development group might configure a widget in ELN entries to visualize the efficiencies of past transductions generated by different experimental conditions.

## Build Validation Rules

Put complex constraints on the platform's data validation, such as on the registration module's entity types. For example, require that an antibody entity links to a unique set of light and heavy chain entities. Or, define success thresholds so that only antibody lots above a certain purification value move to the next stage of a workflow.

## Custom Calculations

When an organization has its own SOPs for calculating particular properties, they often have to export their samples, run the analysis, and then re-upload the results. Look for a platform that lets you embed code for any proprietary calculation so that you can, for example, calculate the molecular weights of your proteins with whatever standards you desire.

## Build New Applications

On top of the platform, build completely new applications to support your niche workflows. For example, if you have complex SOPs around labeling, you could develop an application that prints barcode labels for a certain set of samples that you know a particular workflow will generate. By developing applications such as these within your platform, you can ensure adherence to SOPs while streamlining scientists' work.

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# Conclusion

## TRANSFORMING BIOLOGICS R&D




Across different organizations, the needs of biologics R&D are complex, variable, and fluid. To manage this complexity, you need a biologics-specific informatics platform that's built to interlink R&D data, track R&D progress, and drive R&D decisions. In addition, to accommodate the evolving R&D needs of your organization, you need an informatics platform with codeless configuration, open integration, and easy extensibility.

Put another way, biologics R&D needs a platform with unified off-the-shelf functionality that tames R&D complexity. But it also needs a platform that's flexible and easy to customize. Platforms that combine the best of both worlds eliminate vendor dependence and minimize IT overhead while increasing the software's ability to meet R&D's needs.

By evaluating platforms based on these capabilities, you will transform your R&D organization. Instead of troubleshooting unwieldy software, IT will be able to proactively focus on more strategic projects. And rather than be hindered by hard-to-use software, R&D will work more efficiently to bring drugs to market faster.


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