



**INSIGHT-DRIVEN**  
FORMULATIONS  
DEVELOPMENT

HOW AN INTEGRATED DEVELOPMENT PLATFORM  
CAN **PROVIDE END-TO-END VISIBILITY** ACROSS  
PRE-FORMULATIONS AND FORMULATIONS DEVELOPMENT

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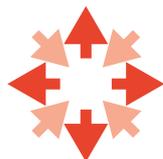
CHEMISTRY



INTEGRATIONS



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REQUEST



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INVENTORY

A considerable amount and variety of data is generated during the process of optimizing the formulation of a novel therapeutic. Without a consistent approach to managing this information, making sense of it all can be a challenge.

In the whitepaper ‘The Integrated Pharmaceutical Development Platform - A Modern Approach to Transform the Commercialization of Innovative Therapeutics’<sup>1</sup> we describe how deploying a common data management environment across the development organization can expedite the development and transfer of robust processes, reduce costs, improve quality and enhance corporate image.

This whitepaper describes how deploying such a platform can provide end-to-end visibility across Pre-formulations and Formulations Development and expedite the identification and progression of safe, efficacious formulations.



**Also in this Whitepaper series:**

- The Integrated Pharmaceutical Development Platform
  - Delivering Quality Results, Faster
  - Agile Process Development
- 

## Generating a Formulations Knowledge Base

Without access to knowledge of what has been tried before, formulators run the risk of reinventing the wheel and repeating work already done by their colleagues. Unfortunately, this is a common occurrence, mainly due the fact that the myriad data generated during a formulations project is typically spread across paper notebooks, spreadsheets and in people's heads. So formulators have a difficult task to find what has been done on their current project, never mind across all formulations projects, past and present. With the adoption of high throughput formulations technologies, this problem increases exponentially.

If the composition of formulations is recorded electronically in a consistent way and stored in a central, searchable repository then it becomes easy to check if a recipe has been created previously and unnecessary rework can be eliminated.

This need not be limited to recording a final composition – recording the planning and preparation of the formulation electronically will not only add additional context to the repository, it will also improve quality.

For example, by centrally maintaining a library of approved or preferred excipients, a formulator can select these as they create their recipe. Eliminating manual entry of the names of ingredients will improve consistency and facilitate comparisons.

When recording the recipe, an electronic system will be able to generate relative percentages automatically, avoiding any errors associated with manual calculations.

Furthermore, by connecting the planning and preparation of a formulation to inventory information, it is possible to alert the formulator of any issues, such as selecting ingredients that are approaching, or have exceeded, their expiry date or where too much or too little of an ingredient has been added.

To aid processing workflows, electronic procedures can guide formulators through standard processes to ensure compliance, consistency and proactively flag deviations. By taking a modular approach, such procedures can be maintained as interoperable unit operations, such as blending and lyophilisation.

As the formulation knowledge base grows, it becomes possible to not only identify the most effective combinations of excipients, but also to discover the optimal combination of processing steps for a given molecule type.

The platform approach inherently increases the traceability of both information and materials. By maintaining linkages between preparation, processing and use, a data management platform can automatically create a searchable genealogy.

For example, when the details of all processing steps are recorded in the same system, it is possible to track the progress of material from one unit operation to another. This also aids troubleshooting.

If an issue is identified with an excipient, formulators can rapidly determine where it has been used and identify all formulation batches that are affected.



## Integrating preparation and testing

The characterization of a novel formulation requires tens of discrete and diverse analytical tests, both during processing and on the final material. The results of in-process tests are used to inform critical decisions made by formulators. Receiving timely results is key to efficient formulations development, yet the communication between formulations and testing teams frequently relies on email and informal exchanges, particularly when testing is outsourced.

Deploying an Integrated Pharmaceutical Development Platform will improve communication between formulators and analytical scientists. The requesting process is streamlined, making it easy for formulators to create, update and track testing requests and the associated results.

For example, formulators can see more than just a result – they can see context-rich information about how their formulation was tested.

Test results are automatically associated to a specific batch, process step and/or ingredient, improving traceability of information.

When planning, preparing and testing data is combined in a single location, it results in a context-rich electronic record of all relevant information about the development of a given formulation.

This information can be used to rapidly generate a formulation summary report but also to answer exploratory questions across multiple formulations projects. For example, it becomes possible to generate a list of all formulations within a specific pH range and to collate and compare the test results of all formulation batches that used a defined amount of a specified excipient. Both such lines of enquiry are almost impossible when data is stored in silos. Routine reports and ad hoc questions require the underlying data to be structured and contextualized.

## Real-time stability analysis

Testing the influence of storage conditions (such as temperature, light, pH, relative humidity and type of storage container) on the critical quality attributes (CQA) of a formulation generates a large volume of data. For each storage condition tested, samples are taken and subjected to a wide variety of tests to confirm the activity and integrity of the drug molecule.

Testing just a few different formulations results in thousands of data points that need to be brought together to identify any trends over time. When details of the formulation are stored separately from the associated testing results, this can be a laborious manual process, requiring several days of effort from multiple scientists.

Because of this, the data collation and process analysis is frequently only performed at the end of a study. When stability studies take 6 months or more, only identifying issues at the end can result in costly re-work and lead to significant delays to the development process.

It can be collated rapidly, visualized and analyzed at any point in the study, facilitating interim analysis and enabling formulation scientists to make adaptations and adjustments as the study progresses. It also becomes possible to perform meta-analyses and trending across a range of different stability studies.



### Fewer costly repeats

When relying on paper or file shares, experiments are often repeated needlessly, either because of issues with experiment execution (including both protocol deviations and not recording all the required information) or the use of out of date reagents, resulting in wasted time and materials.

Consider a six-month stability study on a tablet dosage form, under accelerated storage conditions. While labour and the use of the stability chamber incur costs, the largest contributor to study costs is sample testing.

Multiple samples will be pulled for testing at a minimum of three time points during the study and each will be subjected to a series of analyses. For a complete evaluation of all test parameters, 80-100 tablets will be pulled per time point, including tests for activity, hardness, dissolution, disintegration, friability and moisture determination.

Some tests are simple, requiring relatively rudimentary equipment, whereas others are more sophisticated and costly to execute.



## Predicting in vivo performance

The value of combining formulations and testing data in a single location is not limited to stability testing.

Where the same platform is also used by pre-clinical departments, such as pharmacokinetic and toxicology groups, the resulting comprehensive pool of data can be used to identify relationships between in vitro and in vivo data. The ability to characterize correlations between in vitro and in vivo data (IVIVC) can guide the optimization of a formulation and reduce development times and such analysis is now recommended by regulatory authorities.

With an Integrated Pharmaceutical Development Platform, as data from different testing groups is recorded, it becomes available immediately and potential correlations can be identified in near real time, enabling recipes to be refined and enabling a dynamic approach to formulations development.

Similarly, when information on the preparation of a formulation is also recorded in the same system as the associated testing data, relationships can be revealed between processing variables and biophysical characteristics, such as the effect of a particular homogenization technology on bioavailability and toxicity.



## Efficient, quality formulations

Subtle changes to a formulation can impact its efficacy and safety. A thorough characterization of products and the processes by which they are developed is at the heart of Quality by Design (QbD). The Biopharmaceutical industry is being driven by regulators to adopt the QbD development model, which offers the potential to reduce costs and development timelines by simplifying the regulatory filing process. It requires traceability of the design of a formulation recipe and process and the primary data that supports the decisions made during its development.

QbD requires a comprehensive understanding of how small alterations to a recipe (e.g. the amounts or source of ingredients), modifications of process parameters (e.g. the duration of a processing step) and changes to packaging impact

the attributes and performance of the final product – all things that are challenging without an Integrated Pharmaceutical Development Platform supporting the process.

The level of knowledge and understanding required to support QbD can also help formulations teams be more efficient. When developing a new formulated product it is impractical to test every conceivable combination of variables, so statistical techniques such as Design of Experiment (DoE) can be employed to increase confidence that the range of possibilities has been adequately explored.

Formulations teams can leverage the wealth of organizational knowledge to explore a more comprehensive design space with the same resources. By making it accessible, context-rich historical formulation data can be used to inform statistical analyses and deliver the insight required to guide the development strategy for formulations projects.

## Summary

When an Integrated Pharmaceutical Development Platform is used to record the processes of planning, preparing and testing formulations, the resulting context-rich knowledge base becomes a valuable resource for the organization. **It provides end-to-end traceability and enables formulators to create better, safer formulations faster and reduce development times.**

IDBS understands the challenges faced by biopharmaceutical organizations. Our Integrated Pharmaceutical Development Platform is the culmination of almost 30 years of experience and knowledge of capturing and managing biopharmaceutical data.

Global pharmaceutical companies, emerging biotechs and leading CDMOs have partnered with IDBS and have leveraged our unparalleled know-how to transform their development operations.

If you'd like to make better, safer formulations, talk to one of our experts today or email us at: [info@idbs.com](mailto:info@idbs.com)  
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<sup>1</sup> <https://goo.gl/8HMIOR>



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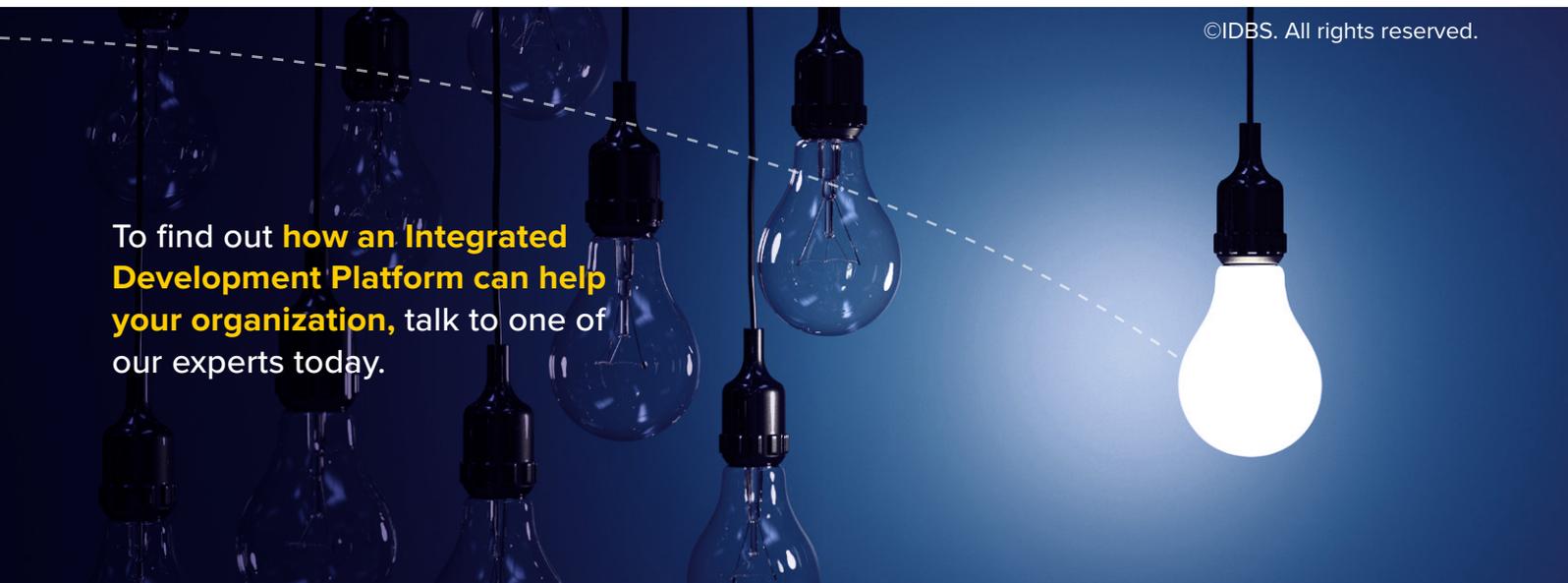
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