

HOW TO MAXIMIZE THE STRATEGIC VALUE OF FORMULATIONS DATA IN PHARMA

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Introduction

Formulating, a key part of the pharmaceutical value chain, is a 'make or break' step in developing an active pharmaceutical ingredient (API) into a viable product

Formulation scientists actively research, design, and iterate formulations that ensure the stability and efficacy of APIs, improve patient compliance with treatment regimens, and adhere to changing regulatory requirements. Without a strategic and intelligent formulating process, an API would never make it into the market.

In fact, even the prescribing success of a medication can depend on the choices formulation scientists make when designing formulations. Physicians consider different factors before prescribing pharmaceuticals to patients – e.g., effectiveness, side effects, ease of use, and cost – all of which largely depend on how a drug is formulated. Despite its substantial contribution in product development, 60% of companies experience a project delay or failure due to formulating challenges¹, with more than half of formulation project delays lasting over 12 months².

Some of the pressing challenges associated with the formulating phase include insufficient information, a

tedious search process, and time-consuming manual processing of gathered data. Moreover, formulations IP searching, another integral component of the product development pipeline that determines the company's long-term success, also suffers from information challenges, namely, the lack of reliable data resources. As a result, the collective time spent during the formulating phase is further expanded.

Here, we discuss how pharmaceutical companies **can maximize the strategic value of formulations data to shorten development timelines, stay ahead of competition, and position themselves for success.** Providing formulation scientists with accurate and well-curated information can enable them to focus on innovating new formulation designs rather than spending time on repetitive, tedious activities. Plus, by using the right tools for formulations IP searching, researchers can obtain IP insights, mitigating potential patent risks for the company.

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Optimizing formulations can offer strategic business value

In a highly competitive pharmaceutical market, companies have used formulations optimization to expand existing markets. A classic example of effectively implementing the reformulation strategy for widespread commercial success is ibuprofen, a commonly used painkiller. In its original form, ibuprofen was produced as a tablet for chronic pain. Today, it is found in diverse reformulated versions to suit different markets or disease areas. For example, the softgel presentation of ibuprofen is better suited for acute pain as the API, while reformulating into a softgel matrix sets the drug into action faster. With multiple versions of the same product, namely, topical gels, self-dissolving tablets, liquid capsules, as well as syrups and granule suspensions for children, reformulation has helped

ibuprofen expand its market, reaching and benefiting different demographics and diseases².

Reformulation can also be used to reduce drug side effects, making the drug more commercially viable. By leveraging in-depth knowledge about ingredients or possible excipient alternatives to improve drug bioavailability, prolong drug dosage effects, or reduce side effects, pharmaceutical companies can gain a competitive edge over others. Additionally, having up-to-date IP information within the pharma industry can enable companies to take prompt action on open opportunities.

Decisions made in formulating also influence patient compliance of a drug. Pharmaceuticals can only be effective when patients comply with the treatment protocols. For instance, the

formulation itself directly affects the taste, palatability, appearance, and shelf life of oral medications, all influential factors in a patient's decision to comply. If a formulation scientist is able to effectively formulate an API into an oral medication form, it can positively influence the patient experience, and in turn, impact the success of the drug compared to competitors.

Whether companies are innovatively designing formulations for a new API or leveraging a reformulation strategy to expand their market, having access to reliable information on ingredients, existing formulations, and regulations plays an integral role in leveraging business opportunities.



Current formulation scientist challenges delay product development timelines

After an API is identified, formulation scientists turn it into a safe, scalable formulation that will eventually go into clinical trials. Formulation scientists in the pharma industry need to strike a balance between increasing regulations and complexities of product development with the demands for lowering costs.

In general, a formulation scientist's diverse range of responsibilities can be summarized as:

- Finding information about ingredients to help design a formulation
- Finding an existing formulation or product as a baseline for design and iteration
- Sourcing components of a formulation
- Determining if a formulation will be patentable or if there are legal restrictions
- Identifying formulation components to meet an objective or desired effect

Formulation scientists often address research questions such as: Is it safe? Is it effective? What's been done before? How can I give it a specific "form?" As a result, formulation scientists spend significant time on research to determine how to accomplish project goals, identify baseline formulations, consider regulations, and learn about ingredients and their properties. Most information sources accessed by formulation scientists use small data libraries that are not curated. Moreover,

information scattered across disparate sources, such as Google search, free databases, or supplier websites, requires significant time to collect, sort, organize, and manually read. Despite these efforts to gather information, formulation scientists remain unsure of the quality of data, spending significant time testing ingredients that provide a desired effect or improving existing formulations. In a recent CAS survey, formulation scientists admitted to spending 60% of their lab time iterating formulations.

Moreover, to avoid any gaps in intellectual property (IP) knowledge, IP researchers spend additional time on formulations IP search strategies. To ensure an exhaustive IP search, professionals can spend weeks scouring through hundreds of patent documents to find even simple answers during the formulating phase.

The incredible time burden faced by formulation scientists and IP researchers during this phase of a company's pipeline can have significant repercussions on the overall time taken to market a product. By gaining access to reliable, well-curated information designed specifically for formulation scientists, companies can reduce the time spent on manual information processing, eliminate unnecessary iterations, and ultimately, accelerate the formulations workflow.



A formulation solution that cuts iterations and maximizes efficiency

Backed by its experience in expertly curating scientific data for over 110 years, CAS has introduced CAS Formulus®, the first solution designed for formulation scientists, combining curated formulations, ingredient property data, regulations, and vendor sourcing information. Curated from patents, journals, and product inserts by experienced CAS scientists, this interactive hub contains millions of searchable formulations and is updated several times a week, resulting in the addition of approximately 100,000 new records per month. CAS scientists maintain focus on accuracy and ensure searchability of the curated formulations by following data structuring protocols.

The world's largest literature-based collection of formulations data, CAS Formulus, has been human-curated with unique data interconnections, making searches easier, relevant, and more intuitive. Formulus will equip formulation scientists with a powerful resource for reliable data presented in an organized manner. It offers both a broad source coverage of formulations and in-depth information on each formulation, serving as a great starting point for formulation scientists.

For example, CAS Formulus allows for quick identification of

ingredients and their function in formulations, and contains all details from drug product inserts, including warnings. The formulations ingredients table in CAS Formulus displays ingredients and their function alongside patent language summary terms 'preferred,' 'mandatory,' or 'optional' summarized from the language of the source document. The 'commonly formulated with' feature provides insights into compatibility with inactive or active ingredients, empowering formulation scientists to make informed decisions faster.

Serving as a comprehensive database for reliable formulations search, CAS Formulus pairs substance information with important regulatory statuses in key countries, offering pharmaceutical companies the opportunity to factor in the global market at an early stage.

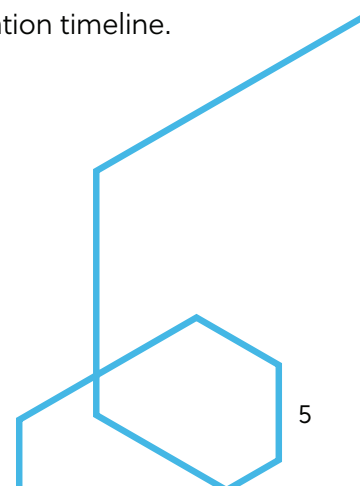
Whether a formulation team needs to explore a specific physical property, clarify a supplier claim, or simply find a substance that plays a particular role in formulations, the relevant information is one quick search away.

The three key benefits offered by CAS Formulus are efficient searching, faster iterations, and access to comprehensive data. Prior to launching CAS Formulus

to market, CAS hired a third-party consulting firm, OC&C Strategy Consultants, to conduct a market study of the product. During this survey, 73% of formulation scientists agreed that CAS Formulus was effective during initial research to get up-to-speed on a new product³. More than 70% of formulation scientists believe that CAS Formulus will allow them to narrow their research focus faster³. Based on real experiences of formulation scientists interviewed in the survey, CAS has designed CAS Formulus to resolve the top pain points encountered during the research phase. By curating formulation information and filtering results based on relevance, CAS Formulus can make research time much more productive. Even the data display format and level of indexing have been intentionally designed to ensure that the key information required for formulation scientists to make an important decision is visible at first glance. With aggregated supplier information, CAS Formulus enables easy comparisons to advance the decision-making process. The significant time saved during crucial steps of the formulation process – performing initial research, minimizing formulation test trials, and arriving at reliable answers faster – can shorten the overall formulation timeline.

89% of surveyed organizations said they began realizing ROI with CAS Formulus in less than three months.

TechValidate survey of CAS Formulus users



Moreover, to address information needs throughout the R&D workflow and alleviate current challenges with formulations IP search, CAS also recently launched CAS FORMULATIONS. Made available on STNext®, CAS FORMULATIONS offers IP professionals access to the world's largest formulation collection, and enables precise and efficient searching for formulations IP⁴. Using reliable information tools, such as CAS FORMULATIONS,

companies can have up-to-date information on the IP landscape to tap into opportunities and avoid inadvertent IP infringement.

By using relevant solutions from CAS, formulation scientists can experience more efficient workflows, increased confidence in research, stress-free decision making, and minimal testing, all of which contribute to speeding up the time to market.

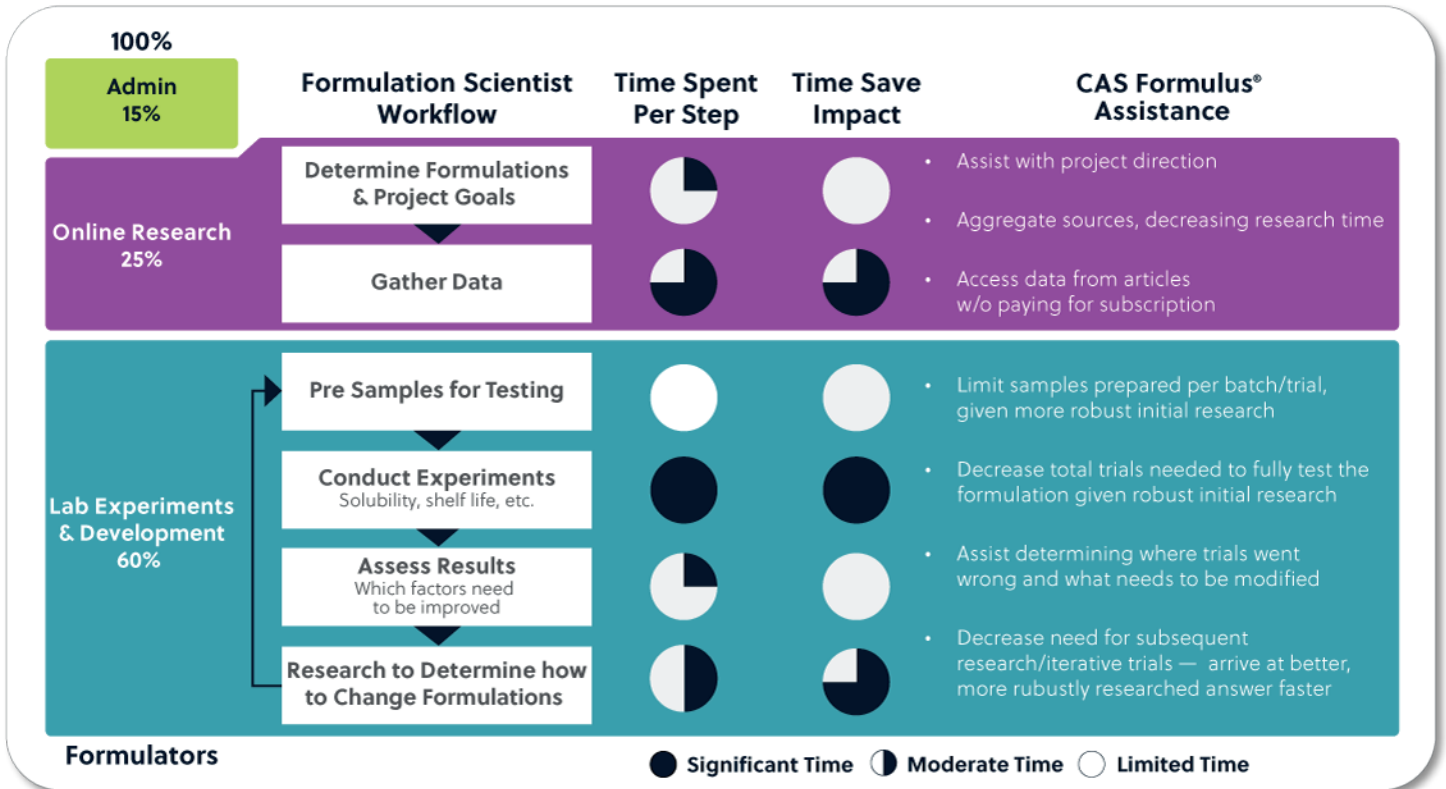


Figure 1: The time saving impact of Formulus at key stages of the formulation process

Gain competitive advantage by investing into the formulating phase

To stay ahead of the competition, pharmaceutical companies need to leverage every aspect of the value chain, especially the formulating phase. As formulations can significantly influence patient compliance and impact market success, companies benefit from providing formulation scientists with relevant research platforms that can make workflows more efficient and speed up formulations research.

company's positioning by having an information advantage over others. By incorporating content collection resources, such as CAS Formulus for formulation scientists and CAS FORMULATIONS for IP professionals, into the workflow, companies can leverage the strategic value in designing the best formulations, while staying informed on the ever-changing IP landscape.

Making an investment into different steps of a formulation scientist's workflow upgrades the

References:

1. Survey: Formulation in the drug development process. Rentschler Biopharma, Industry Insights, 2018. **2.** Stretching product value through reformulation strategies, PharmTech, 2015, <http://www.pharmtech.com/stretching-product-value-through-reformulation-strategies-0>. **3.** Survey: Formulators have unique needs, OC&C Research. **4.** Improve efficiencies and mitigate risk with comprehensive IP searches for formulations, CAS, 2020, <https://www.cas.org/blog/formulations-ip>.



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