FORMULATION

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INTRODUCTION

Formulation within manufacturing industries is an important and complex process. From conception through to production, the entire development lifecycle has to be managed. Within this overall process, the formulation stage (which includes product conception and manufacturing process design) is particularity difficult to manage, and in this highly competitive information driven world, the success of a business may ultimately depend on the quality of its formulation system.

This article will attempt to demonstrate how a fully integrated formulation system can benefit an organisation. Such benefits include enhanced productivity, a smoothly running workflow, and better communications between groups. What follows will describe how formulation fits into the overall product development lifecycle, and will examine ways in which such a system could be implemented.

Manufacturing organisations from pharmaceutical and chemical companies through to paint and food producers have the sole aim of getting their products to market. Whether it is soap, pet-food, toothpaste or paint, these products have to go through a formulation process before they can be manufactured.

Everyday, interdepartmental human interactions push ideas, physical attributes, and reports through the product development lifecycle, searching for the next generation products. The original idea may be unviable, it may be a repeat of previous concepts, or alternatively, success will result in a new and marketable product. But whatever the result, the formulation stage is key: time, energy, and raw materials are continuously wasted by manufacturers simply because current systems are not up to the job. Investing in a state of the art bespoke formulation system is the first step on

the road to future profitability.

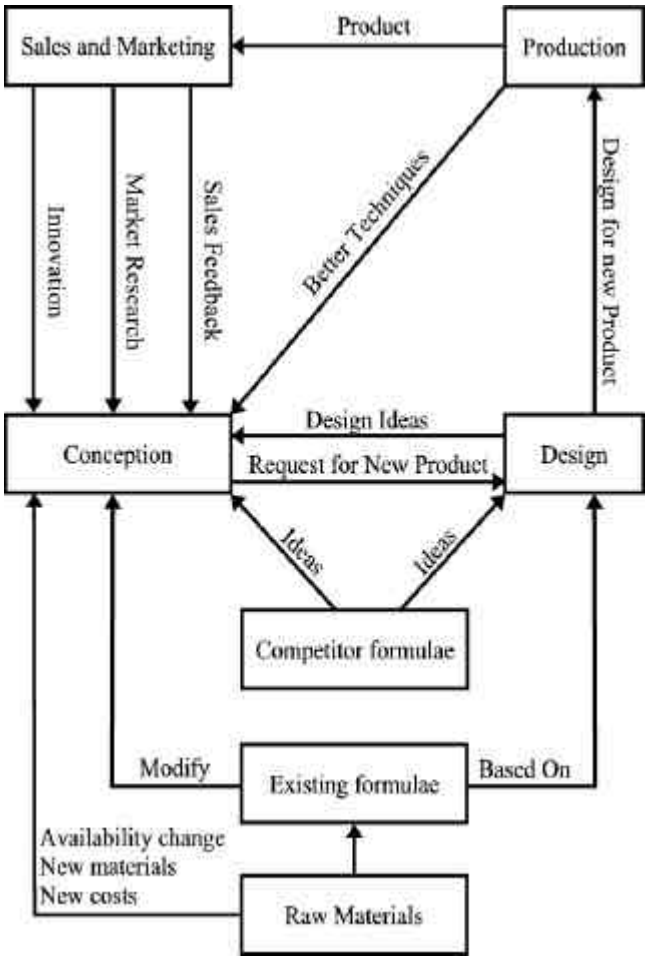
THE GENERAL PROCESS

Companies develop new products in stages: success pushes a product forward and failure provides valuable information for future ideas. Information management systems, which should include a formulation system, are used to aid organisations in this process:

- **Sales and Marketing** Sales and marketing departments provide ideas from market research and customer feedback. These ideas are new, adapted from existing products, or are driven by external factors, such as changes in regulation.
- **Product Design** Ideas are turned into concrete product specifications, including physical attributes such as pH, colour, odour, and texture. Potential products are tested via mathematical tools and models integrated into the management system, and they are then created and tested as prototypes. Costs must be considered, and compromises agreed. A new design may or may not reach the market, but either way, all experiences must be recorded and used to direct future innovation. Successful designs will be released for scaling up and manufacture.
- **Manufacturing Design** The successful design must be manufactured, potentially in large quantities, from readily available raw materials. Physical and chemical characteristics must be considered at all stages. For example, an intermediate material may be unstable or have an unsuitable form, or a chemical reaction may be necessary and allowed for. Rules, models and tools should be encapsulated in the underlying formulation system to assist the whole process. Some products may be difficult, expensive, or even impossible to produce, and information must be fed back to the product design. Design is an iterative process, managed and assisted by the formulation system for fast and efficient innovation.
- **Initial Production** The original idea now moves forward to production. Small-scale trials take place, and the results are analysed and compared to the original specification. This information, stored in the formulation management system, verifies that the specifications have been achieved, and serves as a baseline for future process monitoring. Small changes to the manufacturing process take place, and the final costs are confirmed and

documented.

- **Sales and marketing** The new product is prepared for market and launch. Customer trials will take place, and the marketing and sales plans are set and executed. Market research and customer feedback on the new product will lead to more ideas. And so the lifecycle turns full circle.



At any stage in the development process mistakes may be made, but a good information management system will not allow these experiences to be wasted - lessons learnt and ideas generated will be fed back into the lifecycle. There are many reasons why a new product may not go to market - the manufacturing design may not meet the product specifications; the product may be too expensive; the customer base may be too small for full-scale manufacturing; the market may not be ready for it. However, the information management system is there to record any problems, allowing the organisation to learn from its mistakes, and making success more likely in the future.

Valuable information can be gleaned from failures as well as successes. This is particularly true during the formulation stage. This stage, which includes product and manufacturing design, is characterised by an amount of trial and error, mixed with significant past experience. A good formulation system is crucial if this important element of the whole process is to be managed in a smooth and effec tive manner.

STAKEHOLDERS

A good formulation system will support a full range of stakeholders, which will typically be a diverse collection of people, groups and departments. Stakeholders may include:

- Sales and marketing
- Product designers
- Manufacturing designers
- Regulatory affairs department
- Quality controllers
- Managers

Product development requires satisfaction of a disparate set of aims and objectives. The trick is to ensure that the formulation lifecycle progresses in a smooth and efficient manner, giving the stakeholders satisfaction by keeping everybody informed. A well-designed, all consuming information management

system is a valuable tool for achieving this aim.

ISSUES

Before a formulation system can be selected, it is important to gain a full understanding of your current work-practices and needs:

- What is the lifecycle of your formulation process? This may be an ideal opportunity to rationalise and simplify your processes: increasing visibility, speeding up knowledge transfer, and improving productivity.
- Will the users sign up to the new system? People can be resistant to change, but a well-designed user-interface will be easy and straightforward to use, and it can assist in improving efficiency and increasing throughput. In these cases, take-up of the new system will be high, and investment payback will be fast.
- The system must be tailored with user skill-levels in mind. On-line help and user guides should accompany targeted training to maximise best use of the system.
- Are there any role specific access restrictions that must be imposed? For example, at what point does quality assurance gain access to a particular formulation? Access restrictions should be a natural and invisible part of the system, limiting visibility where needed to provide an uncluttered working environment.
- What types of reports are needed? Easy to generate, dynamic reports simplify information transfer and improve the organisation's performance. Reporting from the system must be matched to the organisation's needs, and should use the latest up-to-date information at all times.
- Are there any tools and models in common use? In many cases, these will have been created and built-up over many years by the organisation itself, and they are central to the established working methods. These will need to be integrated into the system and made available to all users in a consistent manner.
- What data validation is required? Regulation is an increasingly important concern for business that can add significantly to its costs. Regulatory checks should be part of system workflow, minimising costly mistakes and providing easy auditing.

- Are there legacy systems that must be maintained? Integration with existing data and legacy systems must be considered to allow an easy transfer to the new system.

POSSIBLE SOLUTIONS

There are many possible solutions to managing the formulation process. Listed below are some which are more common:

The traditional solution (mixing a number of paper-based systems with individually developed spreadsheets), is common throughout industry. This type of system has probably developed in an organic manner, with few thoughts to the overall aims and ambitions of the organisation. This approach lacks control, and leads to misunderstanding across departments, and even between individuals. However, it is cheap to implement, and may be appropriate for a smaller organisation.

A more robust solution might include a suite of PC-based applications, each one tailor-made for a specific part of the formulation process. Results generated from each part are stored in a central database, allowing data to be shared. This is a fairly flexible approach. Rollout can be spread over a period of time, allowing specific functionality to be added in stages. This approach, however, does have its disadvantages. Integration between the applications is relatively high-risk, and development, support, and maintenance costs are likely to be high.

A better solution is found by using a client-server architecture, where a centralised database stores the shared data, accessed and maintained via custom ‘thick’ client applications. This can provide a good experience for the users, but support and maintenance can be expensive, and access is limited to PC’s connected directly to the company network.

Web applications are obvious alternatives, and they are becoming the architecture of choice for the larger organisations. They are typically cheaper to support and update, and they can be accessed from a standard Web browser from sites across the world. Formulation information management systems of this kind quickly become standard, enterprise-wide tools that drive a company’s operating methods, and they can quickly impact its profitability.

OTHER CONSIDERATIONS

- **Form design.** As with any software system, user-experience is highly influenced by the interface design. The forms should be intuitive and responsive. Mouse clicks and movements should be minimised. Layouts should be tidy and pleasing to the eye.

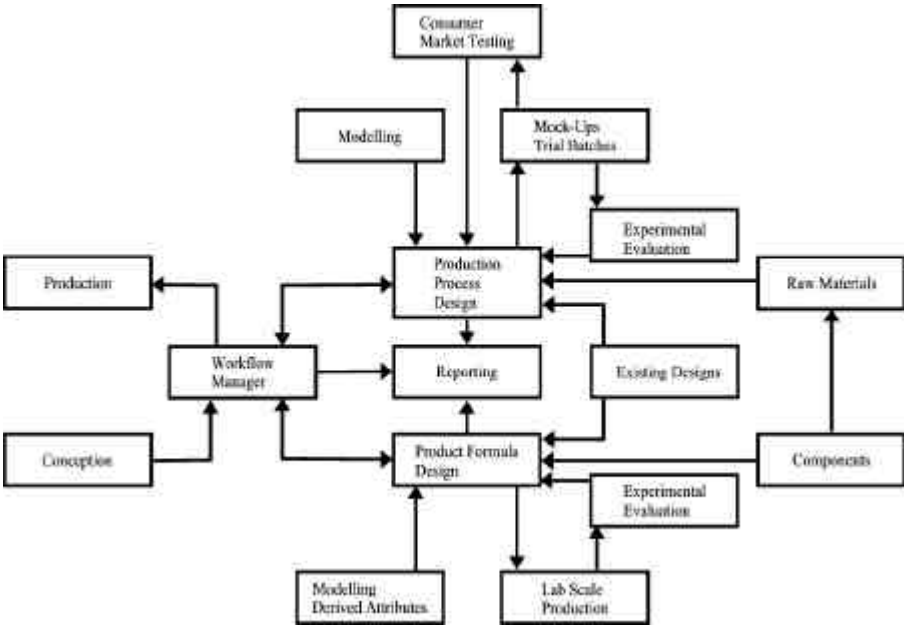
- **Error messages.** Thought should be given to any messages. Users are too frequently scared off by either incomprehensible error messages or messages that appear to blame them for incorrect behaviour. This leaves users scared of the system and reluctant to persevere. Messages should be clear and neutral. The software is there to help, not to hinder.

- **Workflow.** The system should assist the company work processes. Once data has been entered, it can be passed automatically to other interested groups. For example, a completed product design will be passed to a manufacturing designer to take it to the next stage. The system can send notification messages at key stages, enabling all stakeholders to be kept informed. This powerful scheme allows the formulation process to proceed quickly and efficiently through its lifecycle.

- **Help and System Support.** User support structures should be designed to meet an individual organisation's needs, and should cover first, second and third-line support. An email system may prove sufficient for third-line support when key users are available to cover the immediate problems, but, alternatively, would a 24x7 help desk be more appropriate?

EXAMPLE

A leading, multi-national customer needed to fully-integrate its formulation system for development of its flagship consumer products from conception through to production. The existing system relied on a range of user-owned spreadsheets, databases, and modelling tools to record and analyse data, and to produce reports. These individually customised spreadsheets were adapted to suit individual needs, leading to considerable inconsistency and to numerous errors across the organisation.

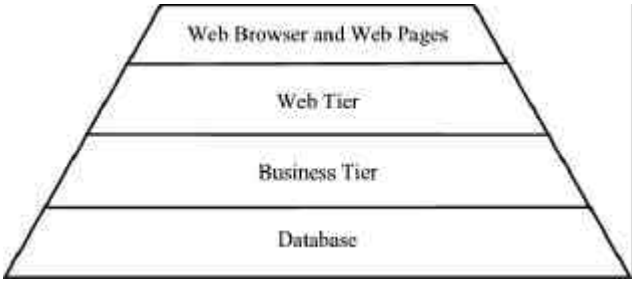


The basic formulation process was a complex trail through a number of often pre-defined steps. The result of each step had a strong influence on which step was taken next, and the work was spread between different people working on different global sites. Calculations were often handcrafted, and the results were reported back in a variety of different formats. The passing of information was slow, and the cycle times were long and inefficient. The result was that projects took too long to reach completion, and their costs were correspondingly high.

The customer wanted to preserve the core of their existing work practices, and needed to incorporate essential features of their operations. This included knowledge of their production processes, which typically included chemical reactions, losses, and physical changes to the underlying materials. They also wished to integrate other core business functions including quality standards, regulatory control and finance.

THE SOLUTION

The new, fully integrated formulation management system is a J2EE Web-based application available to all users throughout the organisation via password secured access. The application uses Oracle 9iAS on Unix with an Oracle database 9.2.0 back end. This matches the organisations I.T. infrastructure and policies. A similar system deployed using the Microsoft .NET framework would have been an equally successful alternative.



One advantage of this Web-based Intranet solution is that no application-specific software need be installed onto client PC's, and the system is accessible worldwide. The system ensures that new data is immediately available to other users, and team collaboration (even across global sites) is fast and responsive.

Essential parts of the company operations have been successfully incorporated, providing a central and verified source of information, design calculations, and models. This includes underlying features of the various production processes, allowing the move from product specification to manufacturing design to be handled quickly and accurately. Critical information concerning, for example, material composition and production plant factors, are also maintained.

The new formulation system is integrated with other key systems to synchronise essential data. This allows users to carry out cost engineering, for example, or to check regulatory compliance.

Reports:
One of the major functions of the formulation system is to produce reports. During the formulation process, reports allow easy visualisation and transfer of information. For example:

- A finance officer may need to investigate the potential cost of a product.
- The purchasing department may need to know which raw materials to buy.
- A product designer may need information on the chemical make-up of a product, or to have a break down of the end product costs.

The new formulation system allows a huge range of reports to be generated easily and accurately, and across a number of different formats. For some situations, simple static html reports are produced, whereas in other cases, dynamic excel worksheets and PDF reports have been preferred.

The formulation system is flexible enough to satisfy all of these demands, and the resulting reports are produced in a professional and consistent format, making them suitable for both internal and external consumption.

THE BIGGER PICTURE AND THE FUTURE
An all-consuming information management system is the lab of the future. It will pull together formulation, LIMS, marketing, and production data because, in the manufacturing world, all these processes are interrelated. High quality, readily available information leads to increased competitiveness. Quick and easy access to company-wide information is precisely the advantage manufacturers need to enable them to keep up with their competitors in this information-driven, fast-moving world.

Such a system should include formulation and recipe management. This major function of the system is used across the organisation to design both new products and the processes that manufacture those products.

Other functions could include:

- Tracking of production orders. Production order tracking could include the analysis of trends and the prediction of future requirements. These

- are amongst the most difficult but business-critical functions (these are amongst the most difficult functions, but also those most critical to business), and they can lead to significantly improved resource usage and to reduced costs.
- Shop floor control and resource scheduling. Efficiently managing these needs will lead to improved productivity across the whole business.
- Cash flow management. The information management system could be designed to help with job costing, payroll and human resources, quoting and estimations, and material management.

If our manufacturers are to remain competitive, they should use a good formulation management system. This will become a vital tool that will provide them with the management tools and systems to design new products quickly and efficiently, while drawing on information from across their organisations. The future will enclose such a system in a bigger and more general all-consuming information management system integrated with the entire business.

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