OVAL MEDICAL TECHNOLOGIES
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# INTEGRATING DESIGN AND INDUSTRIALISATION TO OPTIMISE COST, QUALITY AND TIME

**In this article, Pete Evans, Director of Device Development at Oval Medical Technologies, and Meredith Canty, Director Drug Delivery Systems at SMC Ltd, explore how integrating design and industrialisation teams can optimise the cost, quality and time of developing a novel drug delivery system.**

There is a well-known adage in the pharmaceutical industry: "Cost, quality or time – choose two." In other words, when considering the cost of a development programme, the quality of the end product and the time to bring a new product to market, you have to choose which two of the three to optimise as the third will inevitably suffer.

With quality necessarily taking first place, time and cost are left to fight it out, with time generally being the winner on the assumption that an earlier launch will recoup the increased costs of accelerated development. Because of this, pharmaceutical product development programmes tend to be expensive. Add to this the fact that all product development programmes face quality hurdles, which can take considerable time to resolve, and the costs tend to only move in one direction.

When considering a novel drug delivery system, potentially combined with a novel formulation – and with either element potentially requiring the development of novel manufacturing processes – there are considerable challenges involved in meeting the required quality standard, let alone optimising cost and time.

Based on the principle of developing a deep and long-standing relationship between the two major development teams responsible for bringing a novel drug delivery system to market – the design team and the industrialisation team – Oval Medical Technologies and SMC have established methodologies to manage the risks of creeping time and cost, as well as building quality into the design of a new product, which overcome these challenges.

The development of autoinjectors for challenging applications – whether that be difficult formulations (e.g. high-viscosity liquids, suspensions of insoluble API, non-Newtonian fluids, large delivered volumes, etc) or unusual usage scenarios (e.g. mentally or physically disabled users, military environments, etc) is a speciality of Oval.

By addressing the design restrictions arising from only using glass prefilled syringes as the primary drug container (Oval develops proprietary polymeric systems), placing the needs of the user at the core of the design process and building a comprehensive empirical understanding of the formulation behaviour, Oval is able to design uniquely customised solutions to meet the most challenging requirements.

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Of course, innovative design solutions bring increased development risk – this is where the relationship with the industrialisation team becomes pivotal.

## ROBUST DESIGN

As a global contract manufacturer specialising in the development of devices used in the healthcare industry, the SMC team works with the customer to ensure the design is as robust as possible with regard to optimising for the production state. The team will review components, assemblies, overall process flow and the supply chain to ensure items are as optimised as possible. The SMC team will then be responsible for building prototype moulds and assembly equipment to assist the customer in verifying and validating their design. The SMC team can also assist with handling drug product in its primary drug container, as well as complete final kitting and packaging.

In the early stages of development of a novel concept, there is a balance to be struck between further refinement of the design and commitment to mould tooling. Rapid prototyping (i.e. 3D printing) has evolved dramatically in the last 10 years but there is no substitute for real moulded parts. Although rapid prototyping has its advantages in the early stages of the programme, designers need empirical proof that their analytical assumptions are correct – so affordable, rapid mould tooling is usually the answer.

Since there are various levels of rapid prototype tooling, it is critical during the development process that the customer and contract manufacturing organisation (CMO) have detailed discussions to understand the objectives of the rapid tooling (i.e. to test a feature on a part versus to build a prototype tool to mimic the function of a production tool). It is also important to understand the likelihood that certain design features will change.

If the customer and the CMO are not aligned on the expectations of the rapid tooling with regard to tool or part performance, then the wrong type of tool could be produced, either in terms of the mould tool design via over simplification, or in terms of the moulding process with a willingness to accept an over-constrained operating window – or, worst of all, both. This leads to a false belief in the suitability of the design concept that carries through into later stages, where the cost and time required to resolve the problems are amplified significantly.

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## IN-HOUSE RAPID TOOL SERVICE

A typical rapid toolmaker is not interested in reducing the mould cycle time – the tool lifespan is too short to make a meaningful difference – and they are not worried about having to reach into the tool to manually pull out parts that have failed to eject properly. If the parts reach the designers fast, they have met their goal. Any of the learnings arising stay with the toolmaker and rarely make their way back to the design team.

To avoid this, SMC operates an in-house rapid tool service that works closely with the Oval design team from the earliest concept stages of the design process. Tool design centres on a comprehensive set of standard tool configurations that are quickly customised with interchangeable steel inserts to produce each component and provide the correct type of tool/part at the appropriate time. The preferred configuration is agreed upon with experienced production toolmakers who can advise on the best format for the longer term, when increased cavitation and optimised cycle times are the goal. Important choices such as gate position, split lines and ejector locations are also discussed with production toolmakers and these design for manufacture (DFM) considerations fed back to the Oval design team. By investing in proper DFM at this early stage, the prototype mouldings instantly become a far more meaningful representation of the final product.

## A SIGNIFICANT SAVING

Of course, design changes are inevitable and, in some cases, components may disappear altogether, with their features or functions absorbed into neighbouring or new components as the design evolves. However, such decisions ought to be made based on the learnings from parts that are representative of production. In those cases where component designs do carry over to the detailed design phase, all the knowledge and experience arising from the prototype tooling brings a significant saving in terms of time, cost and risk for production tooling.

In some cases, when it makes sense, this can even mean that the entire prototype tool can be carried over, simply by manufacturing a dedicated tool base to replace the generic parts from the prototype tooling. The same toolmakers involved in reviewing the prototype tools develop the production tool designs. Additionally, the process engineers responsible for moulding the prototype parts feed back into the design process to ensure any issues are dealt with before any steel is cut, rather than by being forced to run a constrained manufacturing process in the future. All this means the step to production mould tooling is made with greater confidence, less time and reduced cost.

When it comes to validation of production mould tools, accurate metrology of the critical dimensions is fundamental to success. Often, the availability of this data is delayed by misunderstandings between the design and metrology teams. Establishing a common understanding of part function, appropriate points of measurement, design of appropriate fixtures and development of repeatable and reproducible measurement methods all take time. By exposing the production metrology team at SMC to the prototype parts at an early stage, there is the opportunity to start this process early, before the production moulds are made. Advice can be given to the Oval design team on how to incorporate features that simplify fixturing and measurement before the production component designs have even begun. Ultimately this means the tool validation process is completed quicker and with fewer design changes or costly tool corrections.

## UNDERSTANDING POTENTIAL CHALLENGES

Of even greater potential benefit is the opportunity to involve the automation experts at SMC in the early stages of design. Building an understanding of the potential challenges and starting to plan the assembly strategy before the production design has started brings enormous benefits. The engineers understand how the device

functions so that when the assembly equipment and process flow are being developed, the team will understand how and where components can be handled and what is critical to the device function.

Introducing a seemingly small design feature further on in development may seem to be straightforward, but making such a change later could invalidate months of expensive tool and assembly validation, as well as functional design verification testing. In all likelihood, the expense of making such a change would lead to pressure to implement a sub-optimal assembly process – increasing the risk of rejects or line stoppages. By contrast, designing the parts with a coherent assembly strategy in place ensures a better yield from the production process – leading to reduced cost of goods.

By introducing this thinking at the prototype stage, it is possible to integrate the DFM and assembly with the metrology considerations and the core functionality of the components in an optimal fashion. Having an automation resource involved early helps plan for the proof-of-principle testing that will be required. It also encourages the team to start thinking about future production assembly methods to ensure the components are designed properly for automated assembly.

## INTEGRATED PROJECT TEAM

Good planning is critical and can avoid the obvious problems – but taking on the challenges associated with highly innovative products means unforeseen issues are inevitable. In a poorly integrated team, circuitous lines of communication, administrative red tape and uncertainty over roles and responsibilities can lead to even relatively small problems resulting in time consuming and expensive delays whilst bigger, unforeseen issues have the potential to become terminal.

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With a truly integrated project team, where the design team at Oval and the tooling, moulding, assembly and quality teams at SMC all know one another, and roles and responsibilities have been defined, as soon as a problem arises, the established communication lines result in a quick resolution of the issue. The familiarity from running multiple projects together means the personal relationships and established ways of working and communicating that ensure tasks are completed efficiently are in place.

In addition, the growth of the mutual understanding of core technologies and design concepts ensures that each project truly builds on the learnings from the past. From a customer perspective, the integrated nature of the combined team means fewer points of contact, more efficient dissemination of key information and quicker responses to queries or changes in requirements – essentially a more agile and adaptable team.

Ultimately, this integrated approach brings together expertise in autoinjector design, injection moulding, quality control and assembly to produce designs that result in fewer late-stage tool and assembly modifications, more efficient manufacturing and reduced risk of product failures – even in the case of complex devices designed to meet the most challenging requirements. Quality, time and cost can all be addressed in parallel.

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## ABOUT THE COMPANIES

**Oval Medical Technologies** specialises in the development of parenteral drug products, partnering with the pharmaceutical industry to provide bespoke autoinjectors that meet the most challenging requirements arising from diverse patient groups and novel drug formulations. Oval's approach is built around two key areas: establishing a deep understanding of the cognitive, physical and emotional needs of each patient group; and the comprehensive characterisation of formulation behaviours under a range of conditions. With Oval's experience in developing novel primary drug containers, which enables true design freedom, this approach allows it to customise its advanced autoinjector technologies to create truly optimised devices.

**SMC Ltd.** is a contract manufacturer that is focused solely on manufacturing products for the healthcare industry. Its teams specialise in launching medical devices, diagnostic products and drug delivery devices. The company works closely with customers to review the design of the devices in respect of moulding, tooling and assembly to ensure the design is as robust as possible in production. In addition to moulding and assembly, SMC also offers handling of drug products, final kitting and packaging.

## ABOUT THE AUTHORS

**Pete Evans** has been involved in the development of novel drug delivery devices for more than 25 years, working on inhalers and both pen and autoinjectors. With experience in both consultancy and industry, he has worked in all phases of development – from conception and realisation to validation and industrialisation – for both device and drug/device combination products. As Director of Device Development at Oval, Mr Evans leads a team of scientists and engineers developing innovative injection devices.

**Meredith Canty** is Director Drug Delivery Systems at SMC and has more than 20 years of experience in the drug device delivery field. Ms Canty has worked on launching a multitude of drug delivery devices – including different style inhalers, manual syringes, safety syringes, dial dose injectors, autoinjectors and wearable devices. Her experience also includes implementing new systems to produce combination products.