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# Intelligent people are stupid

insight.

ISSUE No.2

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on the problems  
of being intelligent



**PUSH?**

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# Hello

BY DAN FLICOS

Users, whether they are patients, caregivers, surgeons, nurses or doctors, don't really care. They don't care about how long it has taken to design a medical device. They don't care about the process you have to go through to manage risk and make sure the device can be reliably manufactured in volume. They don't care that it takes a lot of time and effort to design the right product. What patients care about is "getting better" and that the device they are given is effective, convenient, safe and easy to use.

In this second edition of Insight, we get to grips with some of the practical ways in which we as developers can address these needs. We also provide insight into what's hot in the fields of drug delivery, orthopaedics and regenmed.

So, sit down with a mug of tea, a cup of coffee (or a glass of wine if you've had one of those days) and let us share some of our ideas and insight with you. This is a two-way thing, so we'd love to hear what you think.



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# World leading, period

Make this article come to life on your smartphone or tablet, by downloading the 'Team AR' App. 

Hover over this image to reveal a video interview with David. Alternatively, you can watch it online: [vimeo.com/teamconsulting/reddot](https://vimeo.com/teamconsulting/reddot)

BY DAVID ROBINSON

The red dot design award dates back to 1955 and is recognised globally as a stamp of outstanding product design. In the recent 2012 award, 1,800 companies submitted an impressive 4,515 products across 19 diverse categories. From these, Actegy Health's Revitive IX, which was designed by Team, received a red dot award in the life science and medicine category.

The red dot jury is made up of 30 international design experts including professors and academics from prestigious universities, commentators, architects and experienced product designers. The jury thoroughly examined, tested and evaluated each individual entry assessing the degree of innovation, functionality, ergonomics, intuitiveness, quality, ecological compatibility, durability, its ability to connect emotionally with users, and packaging. This extensive process is why the red dot award is held in such high esteem in the design world.



reddot design award  
winner 2012

## “THE CLIENT WANTED THE DEVICE TO BE ICONIC AND TO HAVE A HIGH VISUAL IMPACT”

I The Revitive IX has a simple, clean interface

II The product includes the ISOrocker, which enables the user to further improve circulation



Previous winners include a wide range of companies from Audi, Aston Martin and BMW, to Dyson, Apple and Philips. It is great to know that one of the products that we've designed is in such outstanding company. For our client, Actegy, this award supports their desire to maintain a market-leading position in this area and puts further ground between them and their competitors. The official award ceremony takes place on 02 July in Essen, Germany, after which the Revitive IX goes on display at the red dot museum as well as appearing in the online museum on red dot's website (reddot.de).

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The launch of the first pMDI in the 1950s marked a significant stage in the fight against asthma and COPD. Sufferers were provided with a robust, portable and discreet device, relatively easy to use, sufficiently effective, cheap to produce, and which became readily accessible across the world. And the pMDI is still a significant market player. According to Stephen Stein, Senior Research Specialist at 3M, speaking at 2011's DDL22 in Edinburgh, 1400 pMDI 'puffs' are activated around the world every second, representing a staggering 40bn doses delivered every year.

The widespread use of the DPI, launched in the late 1960s, has further strengthened a dominant market position which remains unchallenged to this day, demonstrated in recent findings by BCC Research, which claims that the global pulmonary drug delivery market will be worth \$44bn by 2016. Most of this growth is coming from BRIC countries where cases of asthma and COPD unfortunately continue to climb

rapidly, and where the next generation of inhaler devices for asthma and COPD will find a ready market.

But these significant new markets are emerging just as many established products are coming off-patent, and as a result pharmaceutical companies looking to actively pursue these opportunities face an important decision: to replicate or innovate in order to gain market share?

The dilemma (explored more fully in the last issue of Insight) is whether to create a fully substitutable device, eligible for shorter and significantly less costly clinical trials and therefore a faster route to market, or to invest in new, innovative solutions which could reshape the market in the longer term. The global market is now so large that many players can profitably coexist for some time - but as regulation evolves in order to push improvements and establish a baseline in inhaler performance, I believe that the optimal strategy is to innovate.

Innovation allows the creation of new and better inhalers which can specifically address problems inherent in inhaler design. For example, co-ordination (especially among users of pMDIs) and technique have long been underlying concerns for regulators. A slow, deep inhalation is often required, but defining 'slow' and 'deep' is not only difficult but is also open to personal interpretation with the result that most pMDI users rarely breathe at the ideal flowrate. Although DPIs, with necessarily higher airflow resistance, are inherently easier to use correctly, performance still remains unimpressive with many market leading products achieving operational efficiencies of only 25 per cent.

Recent advances in the scientific understanding of the complex physics involved means that many new inhalers currently in development offer significant improvements in efficiency, so we can look forward to a step change in expectations as they reach and populate the mass

market. These next-generation devices will also highlight the gulf between old technology and new approaches, putting further pressure on regulators and pharmaceutical companies to drive up standards.

So far I've talked about trends in asthma and COPD, but many companies are now actively developing inhalers capable of delivering a much wider range of therapies. These include pain relievers or vaccines, and drugs required to manage conditions such as cystic fibrosis and diabetes - applications where inhalers could offer significant benefits. For example, inhalers could deliver pain relief in seconds rather than minutes by exploiting the lungs' incredible drug absorption speed - a regular headache or migraine could be addressed virtually immediately, but so could breakthrough cancer pain, radically improving quality of life. And benefits extend beyond the therapeutic. An inhaled vaccination, for example, would eliminate the need for clean, sterile needles; a dry powder vaccine would not need to be chilled until used, greatly simplifying transport and storage; and clinicians could provide groups of users with single dose inhalers, thereby speeding up a vaccination programme. The inhaler therefore offers a realistic alternative to tablets, which take time to metabolise, and injections, which users don't like doing themselves.

The technology is coming on in leaps and bounds, as is device design, and there is real desire in the sector to modify existing drugs, extend patents, and therefore create new market segments. But if such applications are to be realised then increased efficiency becomes even more important, especially if the drug being inhaled - say an insulin dose or analgesic - could be life-saving, and even more so if the 'wrong' dose could be life-threatening. Dose composition, uniformity and delivery will come under much closer regulatory scrutiny, and as a result inhaler design will have to undergo considerable adaptation.

Typical asthma DPI formulations comprise mainly an inert carrier fraction, used simply to 'dilute' the few tens of micrograms of drug that is required for each dose, and to improve handling characteristics during production, due to the carrier's larger particle size. But drugs such as insulin or pain relief therapies do not need to be diluted with a carrier fraction, due to the higher quantities of active drug required. As well as reducing cost and simplifying the filling process, this has marked implications on the technical requirements of the inhaler, as different mechanisms are needed to create a reproducible, respirable aerosol.

The therapeutic indices of these drugs are also often significantly narrower than the usually wide therapeutic indices of drugs for asthma and COPD. As a result, even tighter controls will be needed to ensure the consistency of the delivered dose, and this is likely to be achieved by a combination of improved inhaler design, excellent human factors engineering, and clever particle engineering.

Inhaler design will also have to accommodate different dosing regimes. Current DPI products deliver 60 doses (a typical month's supply if delivered twice-daily), but new designs may have to deliver doses more frequently, in larger quantities or as single doses, or be 'ready when / if needed'. As a result, different and improved feedback mechanisms are required so that users know when a dose has been delivered correctly, when the device needs to be replaced, and - crucially - to prevent unknowing overdose. These (and many other) issues have to be thoroughly understood before pMDIs and DPIs can migrate fully into other applications, but the potential benefits and commercial opportunities are so significant that the effort will be worthwhile.

Alongside new application areas, an additional future driver is the need to adapt device design to individual user needs. Inhalers could be used across the whole population, from those with limited physical ability (as a result of their condition or their age) to those who are not even 'ill' - such as someone about to be vaccinated. As a result, devices will need to cope with user lung power that could range from just a few Watts to over 50 Watts. In response to these different, but equally valid, user needs one strategy could be to use a central inhalation engine across a range of devices, from a disposable device for vaccinations to a capsule-based inhaler for pain management. This presents a very real opportunity to make best use of R&D budgets through technology-reuse while also generating patents and other IP.

With so many drivers converging, it is not surprising that inhaler technology is now at such an exciting stage. Decades of research, development, and user experience have created a body of knowledge which is leading to innovation in new and unexpected directions, guided by evolving regulations, and supported by constant technological improvements. Device design is changing in response to the current and future drivers influencing the market, and the most successful could have just as much - if not more - impact on global health as those launched over 50 years ago.

# Beyond asthma and COPD



In this article we look at the key drivers - commercial, technological and regulatory - fuelling current innovation, and consider the challenges that need to be addressed now.

BY DAVID HARRIS



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# Running the risk

BY LAURA KAYE

Risk management – two words that make most people squirm uncontrollably. Although it is an essential part of product development - especially in the medical sector - it is often put off until documentation is being completed at the end of a development stage. To do this is to misunderstand the purpose of risk management, and is counter-productive. Risk management is nothing to be scared of, and can easily be applied throughout the development process to help create a better, safer product.

EN ISO 14971:2009 is the standard for the application of risk management to medical devices. Officially, it describes a process for managing risks associated with medical devices which provides a means of conforming to Essential Requirements of the Medical Devices Directive 93/42/EEC.

Fortunately, it also includes guidance on how to perform the risk management and clear, specific definitions of the key terms, which are subtly but crucially different from their general meanings. For example, it is important to note that the concept of risk has two components: the probability of occurrence of harm; and the consequences of that harm, that is, how severe it might be.

The risk management process is underpinned by the risk management plan. Annex F of the ISO standard has guidance on how to develop a risk

management plan, which should describe the activities undertaken at each stage of the device's lifecycle, the intended use of the device, and who is responsible for the risk management activities.

The risk acceptability criteria must be included, to define which combinations of probability of harm and severity of harm are acceptable or unacceptable (annex D contains guidance on devising risk acceptability criteria). It's also worth considering including the main categories of harm and their severities; it can take time to determine the severities of harms such as under/overdose or a dose to third party, but these are crucial for the subsequent estimation of risk.

The next stage, therefore, is to carry out risk analysis: to systematically identify and estimate the risks. This can include techniques such as Preliminary Hazard Analysis, Failure Mode and Effects Analysis, Fault Tree Analysis and State Space Analysis, and it is important to select methods appropriate to the stage of the project and the nature of the product. Annexes C and E of the standard contain questions and prompts which are also useful to help to identify risks.

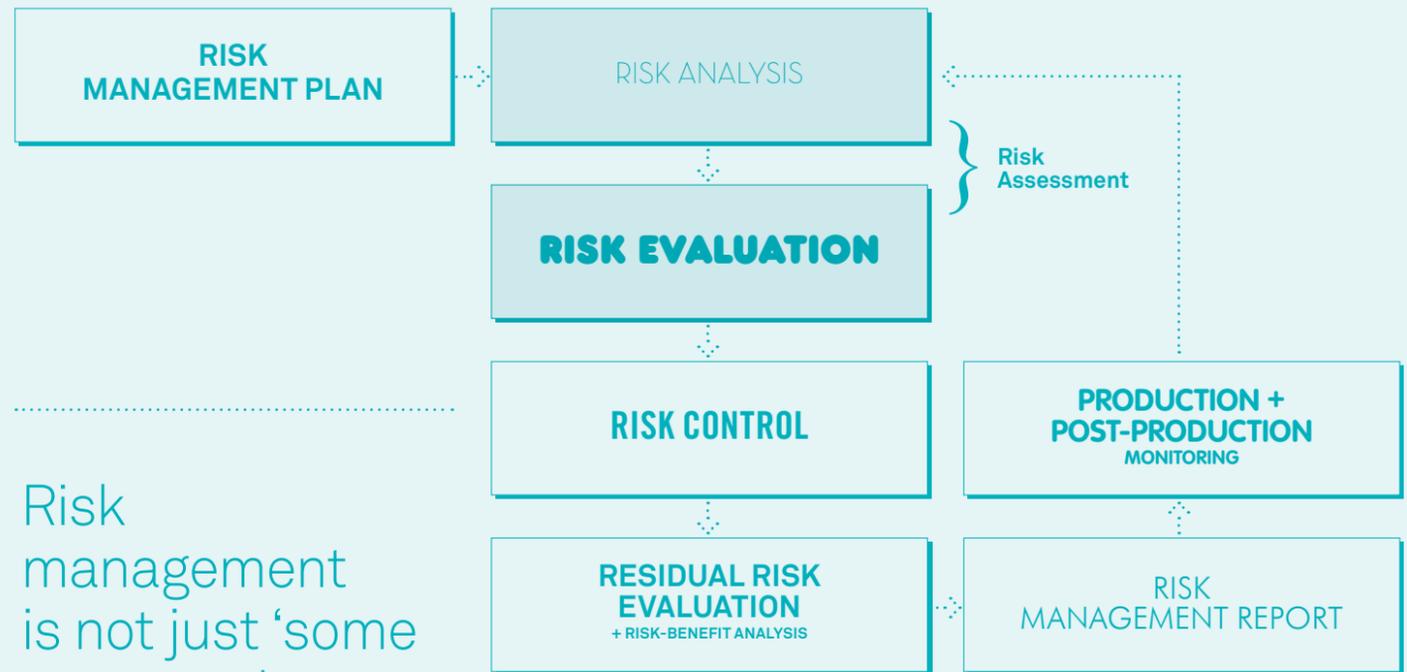
Risk evaluation is the application of the risk acceptability criteria in order to determine which risks are unacceptable and therefore require risk reduction.

The hierarchy of risk control measures should be applied to reduce risks:

- 1  
*Eliminate or reduce risks as far as possible (inherently safe design and construction).*
- 2  
*Where appropriate, take adequate protection measures, (including alarms if necessary), in relation to risks that cannot be eliminated.*
- 3  
*Inform users of the residual risks through instructions and warnings.*

The risk analysis and evaluation stages need to be re-visited throughout the development, to calculate the residual risk after control and also to determine whether the control measures themselves have introduced further risks.

## Risk Management



Risk management is not just ‘some paperwork to take care of before launching the device’

released for production and enters the market. A process of production and post-production monitoring must be employed to ensure that all relevant information is used to update the risk analysis. This process can include customer surveys, servicing records, complaints, QC reports and any other sources of data which can be used to refine the risk analysis estimates and uncover additional risks which were not foreseeable during the development process.

Residual unacceptable risks are not necessarily a barrier to marketing the device. The residual risks need to be weighed up against the benefits of using the device, and this risk-benefit analysis could require the collection of clinical or other experimental data to provide evidence of the benefits to the user.

At this stage the risk management report is produced which reviews the process so far and summarises status prior to launch, but risk management does not stop when the device is

In conclusion, risk management is not just ‘some paperwork to take care of before launching the device’; it needs to be an integral part of the development process and must continue once the device is on the market. The risk management of a medical device can be long and complicated, but when done properly it results in a better device – saving time, money and even lives.

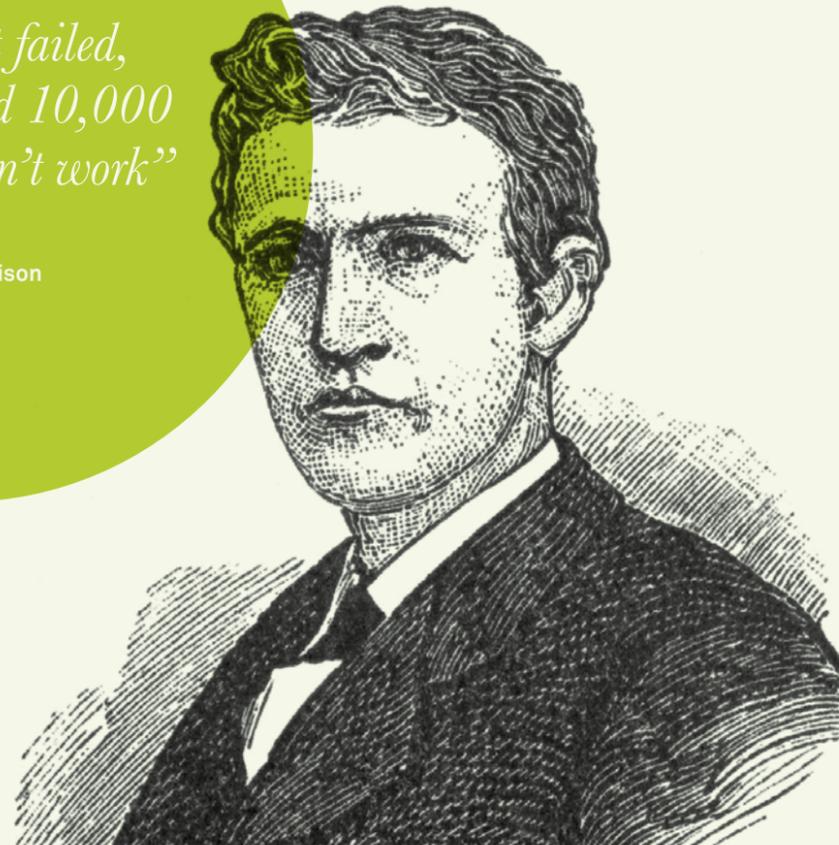


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*“I have not failed,  
I’ve just found 10,000  
ways that won’t work”*

Thomas Edison



# Iterate, iterate, iterate: the key to success

BY CHRIS HURLSTONE

In medical device design, as in engineering in general, ‘right first time’ is the cautious mantra often used to justify innovation based heavily on analysis and research. But does such a risk-averse approach deprive design teams of multiple insights that could make products so much better?

Medical device design is a complex endeavour, requiring multi-disciplinary expertise, innovative insights, a thorough knowledge of regulatory frameworks, and a real understanding of user needs. It is also a field where the failure of a device to perform as intended can have fatal consequences. Not surprisingly, ‘right first time’ is, for many, a sensible philosophy; a way to avoid not only

product failure, but also the perceived costs (in terms of time and money) of a ‘trial and error’ approach. It is also the result of a mind-set wary of multiple iterations in such a highly regulated industry, and recent developments in technology have also played their part by giving designers and engineers the opportunity to get ever closer to the ‘real thing’ - identifying and resolving errors on the way - before the first prototype is even commissioned.

For example, increased computing power has made high end engineering analysis packages more accessible, especially those capable of modelling the most complex aspects of medical device design (such as stress analysis, mouldflow, fluid dynamics and system kinetics). Corresponding developments in software have also resulted in CAD packages able to incorporate ever increasing levels of ‘reality’ into virtual models in the form of, say, manufacturing tolerances, component inter-dependencies, or material properties and finishes which allow photo-realistic visual renderings.

To support this analysis, comprehensive, sophisticated technical research can now be undertaken quickly and cheaply from virtually any computer with an internet link. The opportunity to review the work of others in the field, on a global basis, adds further depth to the research process. This helps build confidence that the development course identified is robust and well targeted, or gives a steer to change direction in the light of information obtained.

To some, these tools can feel as though they give greater certainty than ever before of being ‘right first time’ when first committing to manufacture. So why do anything else?

The answer lies partly in technological advances elsewhere in the product development field. For example, rapid prototyping has undergone a radical transformation in recent years with new advances in techniques such as SLA, SLS and 3D printing now allowing designers to generate prototypes more quickly and more accurately.

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The materials used are also evolving and – though still limited – are getting closer to representing the polymers that will be used in final production. Developments in the service offering have also helped, fuelled by growing competition within the rapid prototyping industry. Increased efficiency now makes a turnaround of 24 hours or less both commonplace and affordable, and similar improvements have been made with other rapid prototyping techniques, from CNC machining and stamping to photo- and chemical-etching. In parallel, the development of faster and more accurate rapid inspection techniques, such as 3D scanning, has enabled corresponding development activities, such as dimensional analysis, to keep pace.

But perhaps the most significant changes in rapid prototyping technologies have been in the field of rapid tooling. Injection moulded components, in fully representative materials, can now be delivered within three weeks, and at costs comparable with those for ‘old fashioned’ vacuum cast prototypes. As a result, the decision to commit to tooling is no longer one which requires either high levels of confidence in the design, or huge budgets, and this shift opens up significant opportunities for further, and more extensive development testing. Rapidly tooled parts deliver a sufficiently accurate representation of design features such as living hinges, snaps, detents and plastic springs. These are the type of details difficult to reproduce in the past but which benefit hugely from physical handling and assessment during the development process, as it is very difficult for FEA or computer based dynamic analysis to replicate – or replace – one very important but extremely subtle characteristic of a design: ‘feel’.

Manufacturers are also extremely keen to have parts in their hands as soon as possible, for example to assess potential issues with automated assembly such as bowl feeding. Rapid prototyping and tooling therefore allows quick, easy and relatively inexpensive ‘proactive iteration’, capable of yielding unexpected insights which, when planned into a development programme, can be extremely beneficial >

# NEVER UNDERESTIMATE THE VALUE OF SURPRISE

to the design process. And this is never truer than in the area of human factors engineering.

No matter how much time and effort has been expended in the design of a device, new insights will always result when it is placed in the hands of a user. When such formative studies take place at a relatively late stage of the development process, designers will not want to discover that their prototype fails to deliver the experience planned, or performance level expected. But by combining numerous small, formative studies with a programme of quick-fire iteration, undertaken earlier in the development process, 'poor' performance is no longer so significant, and the new and unexpected insights that will invariably emerge instead become a positive steer for the next stages of product development.

As our Human Factors team correctly point out, we should "never underestimate the value of surprise". User-device interaction invariably yields results that would be impossible to determine through even the most intensive desk- or lab-based research, yet these results can make all the difference when it comes to minimising potential use error and maximising eventual user acceptance. Rapid iteration is therefore a powerful

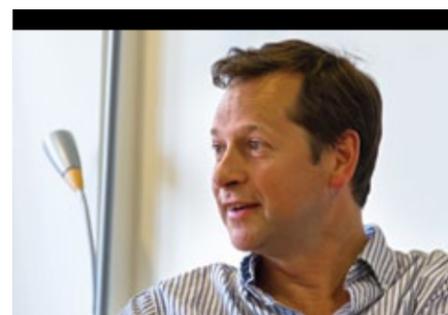
strategy for getting a product right, but it must be used with caution and skill, and as part of a structured approach. If developers become tempted to explore yet more product variations, and commission yet more prototypes, the development can become increasingly unfocused; the ability to investigate many options quickly can also be poorly exploited by a desire to prove that every potential flaw has been thoroughly explored; and there is a risk that programmes are scheduled over-optimistically, running at a pace which mirrors the speed available from these new technologies, even when this is not practicable. Rapid progress is important in product development, but must never become an over-riding priority. Risk management, for example, must be rigorous and cannot be rushed, and formal testing should be always be thorough and not compromised.

The best approach is a balance. Using the understanding generated by phases of detailed analysis, design teams should be encouraged to undergo bursts of rapid iteration with the freedom to experience surprising results and explore them in more detail. This is when 'wrong' can be good and hence it is important that design teams are aware of the new technologies available - and able to select them appropriately - in order to generate prototypes capable of

yielding the most valuable and relevant information.

Not least, developers need to be firm on when iteration should stop. Total perfection is not the goal - not only is it (probably) impossible, but with typical product lifecycles now surprisingly short in some sectors, the ideal solution will not stay that way for long. The point will always come when further iteration will not deliver any tangible user or market benefits, but skill and insight is sometimes needed to know when this point has been reached.

At Team Consulting we deploy rapid iteration to investigate a multitude of interesting ideas which we then sift - using multi-disciplinary and market experience - in order to identify the best development direction. We are not afraid of 'mistakes' early on in the process, just as we know we have to be 'right first time' at the point of design verification and validation, because faults discovered at this late stage can be extremely costly and time consuming to address. Early and rapid iteration helps us build our understanding sooner rather than later, leading to an end result that meets the brief safely, robustly and profitably.



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## Releasing IP value from regenerative medicine

BY STUART KAY

**In the previous issue of Insight, I mentioned the 2011 judgement from the European Union's Grand Court in *Brüstle v Greenpeace*, which ruled that procedures involving human embryonic stem cells (hESCs) cannot be patented in Europe, including any downstream products using these cell lines. The ban applies retrospectively, and contrasts sharply with the position in the United States, where scientists face few restrictions on patents relating to hESC applications.**

Since being handed down, there has been significant debate about the rationale and implications of the ruling amongst the scientific community, lawyers, investors, and those opposed to hESCs and embryo research - and it looks as though the debate is likely to continue for some time yet.

A key area of concern for the development community is that without patent protection, few investors will pay to develop hESC-derived therapies for conditions ranging from neurodegenerative diseases to diabetes, and that therefore the ruling effectively pulls the rug from under their feet.

However, the ruling and the resulting discussion has highlighted and reminded all interested parties that it is still possible to achieve real intellectual property value with, for example, other types of stem cells, in territories outside Europe, and from associated growth media, chemicals and enabling technologies such as processing equipment and delivery devices.

As such, I believe that the Brüstle ruling will have no substantial material impact on the regenerative medicine industry. In fact, there are innovative companies in the sector that are currently, and clearly, demonstrating that value comes in many guises. For example:

- Prof. Pete Coffey at the Institute of Ophthalmology in London and his team are working with industry partners to develop a hESC-based treatment for age-related macular degeneration, a progressive and currently untreatable disease of the retina that causes blindness. Their patents cover the placement of their retinal cells in the eye, not the cells themselves.
- Avita Medical in Cambridge has developed ReCell Spray-On Skin which is a stand-alone, rapid, autologous cell harvesting, processing and delivery technology that enables surgeons and clinicians to treat skin defects using the patient's own cells. This is a great example of a regenerative medicine technology which avoids the use of hESC.

- Organovo is continuing the development of its NovoGen 3D bioprinter, which uses human cells to print functional human tissue. "The end goal is to print human organs that can be used in transplants," said Chief Executive Officer Keith Murphy in an interview with Business Week (08/01/12).

As someone who has worked on core technology for the bio-printing of vascular grafts, and on OrganOx's normothermic organ perfusion device (which maintains organs in a fully functioning state outside the body), I find the Organovo work to be particularly exciting.

Looking to the (near) future, further developments of enabling technologies are likely to come to the fore, such as the delivery of an implant or cell therapy through a retro-injection delivery device, or scale-out autologous and allogeneic manufacture in a 'cGMP-in-a-box' system with integrated PAT (process analytical technology). Such developments will provide ample opportunity for parties to secure IP outside of hESC applications and then use this IP to commercialise their science or at least protect it.

This increased focus on enabling technologies has other benefits outside of IP generation and protection. The delivery device (or enabling technology) is the interface between the science and the patient or healthcare professional and therefore its ease of use, simplicity and safety is paramount. And not only from a user preference perspective but also from a regulatory perspective, as regulators such as the FDA look for clear evidence that the device has gone through structured user validation.



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# Overcoming the limitations of focus groups

BY JOHN REYNARD, CMR

**BIGGER**  
**CHEAPER** **SMALLER**  
**LONGER**  
**SHORTER**  
**GREENER**

Successful medical device developers understand that as well as being a regulatory necessity, market research is essential for testing the market appeal, safety and usability of their concepts and designs.

There are various market research techniques that are appropriate for each phase of device development and in this article we focus on the use of qualitative research, in the form of focus groups.

Such groups are used to gather user requirements in the early stages of product design, and user evaluation of product features at the concept stage. Typically, seven to eight people is an optimum group size; any more and it's difficult to get views from everybody. Also, it's often useful to have groups in different parts of the country, region or world to cover purchasing habits and cultural differences.

A skilled, medically conversant moderator is crucial, together with a discussion guide. The aim of the guide is to highlight areas that need to be covered, but an experienced and confident moderator will allow the discussion to go where it is needed in order to explore ill-met and un-met customer needs. Often what a client company may think is important turns out not to be and other more essential considerations emerge.

Focus groups can have limitations, however:

- Even with an experienced moderator, one or two people may dominate the group and sway the opinions of the others.
- Some people may not wish to publicly share their views on sensitive topics, but these can be important views that need to be included.
- It can be difficult to show actionable data from a small number of focus groups where there were widely differing views.
- A purely qualitative methodology doesn't satisfy the discerning eyes of stakeholders who want hard facts and figures on which to make key decisions.

The alternative is to conduct quantitative studies, conducting individual interviews with a larger number of people by telephone or face to face, but these are time consuming, costly, and lack the creative input that comes from the group dynamic. As a response to this dilemma

CMR has developed the 'integrated focus group', which combines both qualitative and quantitative methodologies. In this scenario, respondents are presented with new designs, prototypes and concepts in one-to-one interviews. They answer a quantitative questionnaire on initial impact, without interacting with anyone else.

The participants are then brought together in a group discussion. The quantitative answers are quickly analysed and the results are presented to the group. In this way the creative session begins from an unbiased starting point of knowing the views of everyone overall; discussion can then be used to dig deeper into the reasons for the responses and the session guided in such a way that the participants interact and develop the concepts further in line with true end user needs.

One consistent benefit of this type of focus group is that no one respondent dominates the group because all participants contribute equally, hence greater value is gained from each respondent, as well as their collective insight. Also, an independent and quantified assessment is made of the concepts on initial impact and, as the exercise is extended over different countries and user groups to give good coverage of the market, the total combined sample is statistically robust and helps underpin decisions.

The qualitative findings from the group give a depth of understanding to the quantitative data - why people think in the way they do - and because the group starts from an unbiased and more meaningful place the discussion can go straight to creating the 'ideal' concept. This combined quantitative and qualitative approach ensures a balanced assessment of the concepts and inspires future direction, identifying what else needs to be added or changed to ensure the ultimate success of the new product.



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# Intelligent people are stupid

BY ROB FERNALL

I've observed a lot of user behaviour in a lot of user studies over the last 20 years, and I routinely recommend to stakeholders that they observe in real-time the user's frustration or elation with their device. Seeing is believing and, to date, no client or stakeholder has been disappointed with their decision to observe – although of course they are sometimes surprised with what they see.

This also means that I've seen a lot of reactions from those observing users for the first-time. And the most striking reaction I repeatedly hear is: "Wow, people are stupid!" But the irony is that it is often the user's intelligence, not lack of it, that trips them up. So what is

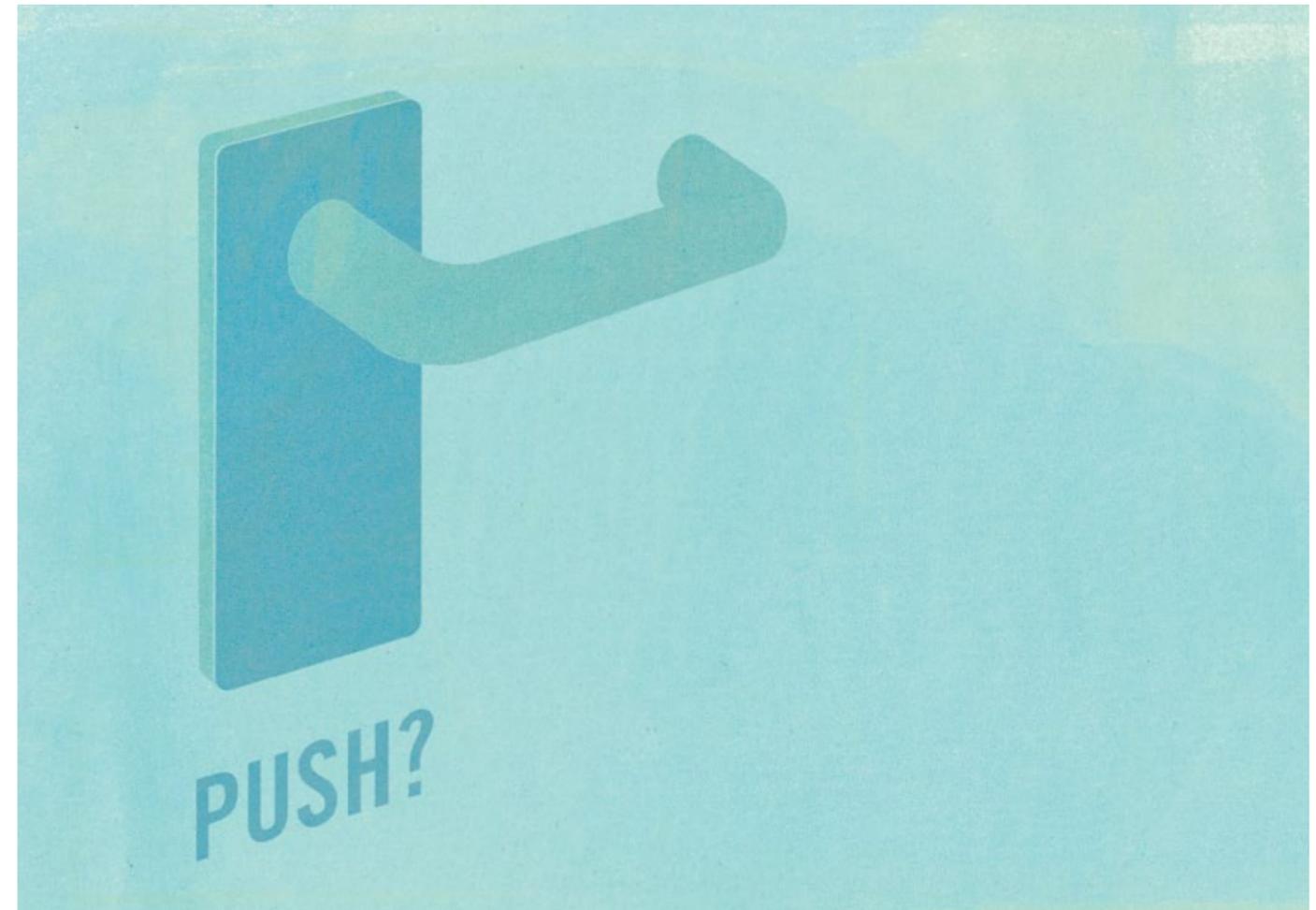
intelligence and why does it trip people up? Firstly, let's start with what intelligence is not. Intelligence is not memory, it is not (declarative) knowledge and it's not an ability to follow procedures. Computers have no intelligence. They have great memories, processing power and perfect(ish) accuracy, and they also follow procedures brilliantly, but computers have no intelligence.

Instead, intelligence is about integrating what we already know with new things we see, hear and read. Intelligence is about making quick judgements with imperfect information, and about making generalisations, spotting patterns and applying rules. But sometimes the information around us leads us to spot

unhelpful patterns and pick inappropriate rules. And that's when we trip up.

Imagine, for example, the door that we automatically pull to open when it should be pushed. When we are presented with a physical object (like a door, a chair, a pen or a medical device) we use our intelligence to quickly make sensible guesses about what it is, how it works, and how to use it based mainly on familiar visual and tactile cues. When we interact with the object we will check that it responds as we expect. If the door doesn't move when we pull the handle we may re-evaluate our assumptions and think "Ah, I assumed that I needed to pull it, but I'll try pushing it instead".

*"we use our intelligence to quickly make sensible guesses about what it is, how it works, and how to use it"*



In the absence of any corrective feedback we will assume our guess was good and carry on down the wrong path.

So with a medical device, if people do something "stupid" in a usability study, the chances are they are actually doing something "intelligent". This may be that the device (or one aspect of it) reminds them (subconsciously) of something else they are familiar with. They then operate the device based on these familiar rules and will only 'stop' if the device feedback tells them to.

So if we present a user with a device that reminds them of something else, and this misplaced familiarity causes the user to make a mistake, should we be

*"Ah, I assumed that I needed to pull it, but I'll try pushing it instead."*

surprised? And if the device doesn't give the user any obvious feedback that they have got it wrong then, who's the one being stupid?

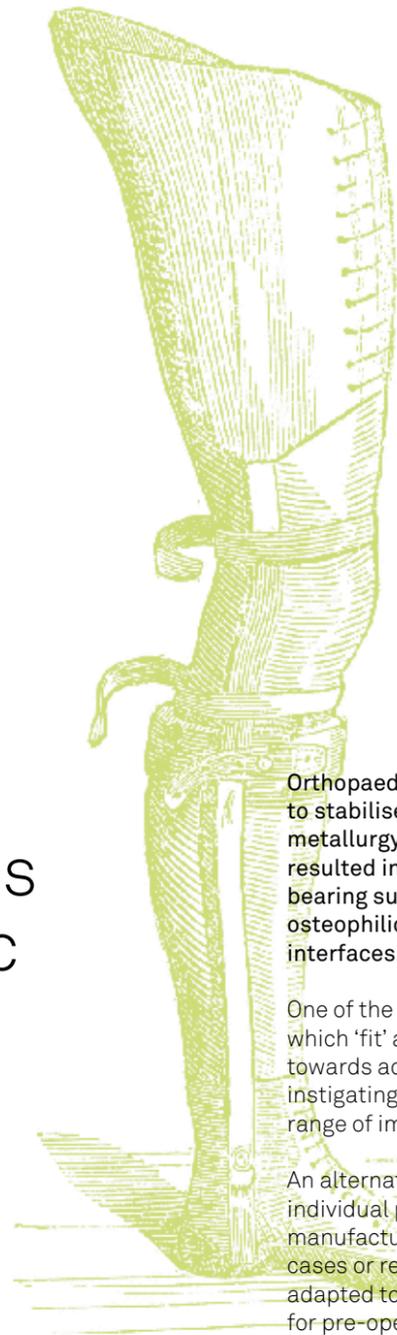


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# The role of 'smart' devices in orthopaedic surgery

BY RHONA SINCLAIR



Orthopaedic devices are, historically, lumps of metal used to stabilise or reinstate function to bones. Advances in metallurgy and tribology, as well as in surface coatings, have resulted in lightweight fracture fixation devices, improved bearing surfaces for joint replacements and also in improved osteophilic surfaces to provide strength at screw-bone interfaces.

One of the biggest remaining challenges is to develop devices which 'fit' a vastly diverse range of patients – inspiring a push towards accumulating large anatomical databases, and instigating the modularisation of components to allow a small range of implants to cover all patient needs.

An alternative strategy is to custom design implants for each individual patient, made possible by the drastic reduction of manufacturing lead times, but primarily adopted for complex cases or revision surgeries. Additionally, generic devices can be adapted to the specific patient, prior to insertion, using software for pre-operative planning.

But diversity in patients extends beyond geometry – it includes bone stiffness and strength, soft tissue characteristics and healing rates, as well as lifestyle-related variables such as activity levels which determine degree of loading and direction (for example whether the patient plays golf or hockey). As bone is also a living tissue that adapts to conditions, these parameters are unlikely to remain static.

With this in mind, can we design orthopaedic devices that themselves adapt to the individual patient to provide an optimised treatment, in other words 'smart' devices?

Some 'smart' approaches already exist. For example, biological responsive technologies have been developed, such as implant coatings which only release their pharmaceuticals when specific signals, such as low pH levels, have been identified. Other surgical devices, such as pacemakers, react to the conditions of their environment; but what about orthopaedic devices?

Considerable research has been conducted in the orthopaedic community on the use of traditional strain gauges to indicate the load levels within devices during use. This data is used to highlight device overloading, loosening, mechanical failure of implants, or to assess tissue characteristics during healing, but it has not, as yet, been transferred to the commercial market.

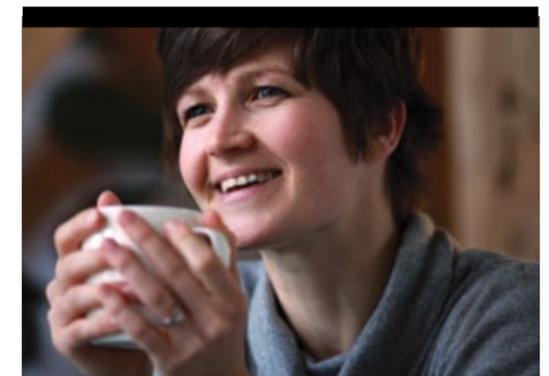
However, such devices are not 'smart' unless they change their performance in response to detected conditions. Research has been conducted into the possible use of smart devices for limb lengthening by distraction osteogenesis – for patients with a limb length discrepancy or congenital shortening of limbs. The surgery involves mechanically severing the bone (an osteotomy) and then separating the two bone ends using an extendible device. Both soft and hard tissues are gradually stretched over a number of weeks to the required final length. Traditionally, a regime of 1mm/day in four steps is adopted unless radiographic evidence suggests changes should be made.

Of course, growth rates vary considerably between patients and thus there is a risk of re-fracture (if the extension rate is too high) or premature consolidation (if the rate is too slow) amongst other complications. Using an automated lengthening device to monitor tissue stiffness and then adapt the distraction regime accordingly may allow optimisation of the procedure for each patient, resulting in improved tissue quality and reduced procedure time.

## Could this idea of smart devices be implemented in other areas of orthopaedic device design?

Could this idea of smart devices be implemented in other areas of orthopaedic device design? What about an external fixator for fracture healing which could change its stiffness relative to the stiffness of the newly grown callus? Alternatively, consider hip and shoulder replacements that could re-position the ball relative to the stem in accordance with the loading directions? Or fixation plates that could adapt relative to loading conditions?

By optimising procedures in this way, we could both improve clinical outcomes and reduce treatment costs. Although validation of decision-making algorithms will require extensive research followed by thorough verification testing, the future for smart orthopaedic devices remains an exciting prospect.



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The auto-injector market is one of the fastest growing in the sector, driven by a shift towards the self-administration of widely used therapies, and a real need for market differentiation. But with market expansion has also come a bewildering range of development options, confusing for both new and established drug companies.

According to Visiongain, the pen systems and auto-injector market is currently worth an estimated \$0.67bn, and is predicted to grow by an impressive 10-15% annually, reaching \$1.71bn in 2015. This buoyancy was clearly demonstrated at the recent PDA conference (Universe of Pre-Filled Syringes), held in Basel, in November 2011, where an impressive array of auto-injectors was on display from suppliers from around the world including SHL, BD, Ypsomed, Owen Mumford and Dali.

Two key drivers lie behind this success. Firstly, the auto-injector provides a real alternative to the vial and syringe generally administered by a healthcare professional, enabling patients to safely take control of their own medication for conditions such as diabetes, rheumatoid arthritis and ankylosing spondylitis. This improves the efficiency of healthcare provision while also increasing the independence of patients who use injected therapies.

But secondly, the drugs (or biologics) available for these conditions have to compete in an increasingly crowded space where well-known therapies jostle with competitive offerings such as high value

'biosimilars' (which replicate established drugs that have come off-patent) and 'biobetters' (new and improved versions of older, often off-patent drugs). With the difference between biosimilars being negligible, the nature of the delivery device and resulting patient experience can become the influential factor in the success of a drug launch. Companies wanting to enter, or remain, in this sector are therefore shifting development emphasis away from replicating the therapy then the device, to simultaneous therapy and delivery device design. But on choosing this path they soon face a confusing range of development options. For many years we have helped clients find their way through this particularly complex maze, a process we begin by reviewing the three possible outcomes:

**'Ground up' development** - a completely new device development process, instigated in-house but rarely chosen not only because of the costs involved, but because the expertise required is rarely core to the pharmaceutical company. However, this route can deliver a precisely tailored solution and unique selling opportunity, as well as a potential IP position that can support future drug / device combinations.

**Off the shelf, but tied to manufacture** - many companies offer a range of off the shelf auto-injector devices ready to be customised, but with subsequent volume manufacture as part of the package. Although this option is ideal for many applications, it does mean that device design may be constrained by pre-determined manufacturing capability,

which can be a disadvantage if particular patient requirements have to be met.

**Off the shelf, but licensed** - many smaller companies are developing interesting new technologies in this area, but are looking for licensing opportunities only. This can represent an interesting avenue of investigation, but skill is needed to find these companies in the first place, assess the designs available and their long term potential, and then determine the manufacturing strategy required. The development status and technical feasibility of these options can be wide ranging, and few companies want to risk being first with an unproven technology.

But before committing to a development route, it is essential to undertake a fundamental review of the whole development process, examining - in advance - all the key decisions that have to be made. The results of this proactive analysis can then be used to confirm the right development path, and make sure the resulting auto-injector fits the original brief. Our analysis focuses on eight general areas of investigation:

## Step 1

### Choosing primary packaging

As a combination device, the auto-injector wraps a sophisticated delivery mechanism round a drug-filled container, known as the primary packaging. Decisions regarding the type of primary packaging used are often made early in the process to ensure it does not affect the stability of the drug, and to allow primary packaging development to progress on a different timeline to that of the device, as clinical studies may be necessary. The choice of primary packaging is therefore fundamental to subsequent device design. Glass packaging ensures stability, but can also be fragile in use and offers limited accuracy, whereas plastic alternatives now being developed can improve accuracy, offer greater flexibility in functionality and can incorporate features designed to interact with the device. However, trials are needed to demonstrate that the plastic used is compatible with the drug.

## Step 2

### Defining user needs

User needs and expectations must be acknowledged at an early stage in the process so that subsequent device design addresses usability issues such as safe use (which can vary greatly depending on the user and their condition), and delivers a positive user experience. As noted earlier, where a difference in therapeutic efficacy is perceived as minimal, users and their clinicians may place significant emphasis on the convenience of the auto-injector design over the drug it contains, so understanding user motivation from the start of the process can increase the chances of eventual success.

## Step 3

### Development status

Some companies may opt to develop their own, brand new auto-injector despite there being many options already available. But reaching that decision can be difficult with so many criteria to assess. Firstly, the device must be usable, compatible with the primary container, and able to handle the volume and characteristics of drug required. Design availability becomes the next big issue, as development time will be required if an appropriately skilled and experienced team is needed to move the design to where the drug company needs it to be. A gap analysis that considers the competence of the development or manufacturing partner, versus the skills required to complete the programme early, can help reduce the eventual time taken to get to the ideal device to manufacture and launch.

## Step 4

### Determining robustness

Potential device designs have to prove their robustness throughout their intended life in use (from manufacturing and storage to use and disposal) especially if the device is multi- rather than single use. An understanding of

the risks and weaknesses in a design is important, and this can mean commissioning tests and evaluation during the selection process if the device supplier cannot provide the information required. Once again, thinking through these considerations in advance can help guide initial decision-making, and streamline the longer-term process.

## Step 5

### Assessing manufacturing options

In the vast majority of cases, device manufacture is handled by a third party which could be the company supplying the basic device technology. If not, then potential manufacturers have to be found and assessed in terms of their technical capability, quality control, and their potential contribution to the device development process, embodied in a realistic development plan. Manufacturing requires a long-term contractual relationship, so understanding the implications of such a relationship in advance can help guide early decisions.

## Step 6

### Cost

Auto-injector development may not be as price sensitive as other areas of medical device design, mainly because primary value remains with the drug. However, costs should still remain realistic and competitive, and so should be thought through up front.

## Step 7

### Regulatory requirements

The ideal development route is one designed to cope with the regulatory hurdles that the device will have to clear before it gets to market. An off the shelf design may have already gained certain levels of regulatory approval with other partners, but device adaptation will prompt further rounds of assessment. Seeking early advice as to the likely regulatory challenges can help forecast

the route approval will take, and hence the timing of development milestones that a programme will need to adhere to.

## Step 8

### Commercial considerations

Even though the development process may take several years, it is still important to look ahead and envision the commercial context in which the device will be available, in terms of speed to market, IP position, and exclusivity.

Increasingly, pharmaceutical companies recognise not only the potential profitability of therapies delivered via an auto-injector, but also that patients have come to expect a high standard of convenience from an injectable device. The generation of patients happy to be injected using a syringe is being replaced by patients who expect devices that are safe to handle, virtually infallible in operation, and which give them greater freedom and convenience to manage their condition wherever they may be. Exciting new developments in auto-injector technology are now resulting in innovative designs capable of meeting a wide range of user needs, but despite these developments, defining the ideal auto-injector - one which meets regulatory standards and which patients will actively accept - remains a real challenge. We find that by asking our clients the right questions as early as possible, clear and appropriate goals and objectives can be defined at the outset, and these will determine the development route with the best chance of delivering a successful end result.

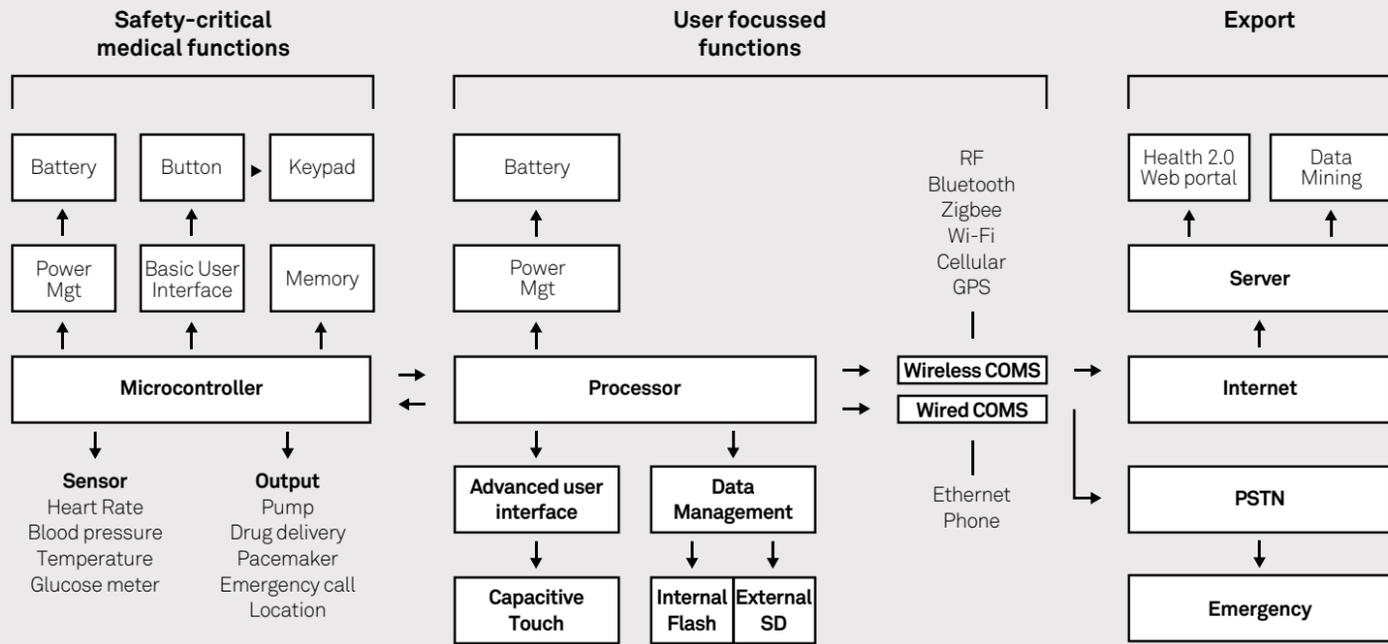


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# Auto-injectors: choosing the right path

BY ANDREW POCOCK



# Designing safety-critical devices – using the right methodology

BY SEBASTIEN CUVELIER MUSSALIAN

Offering enhanced usability and functionality may run the risk of compromising patient safety, but by using a structured development methodology developers can help ensure that safety-critical devices remain safe.

Although good design plays an important role in the market success of electronic devices, users often confuse good design with increased functionality. However, as discussed in the last issue of Insight, it's well known that increased functionality can increase user error – acceptable perhaps in a mobile phone, but not in a safety-critical device. To address this problem, Team has created a methodology specifically designed to deliver safety-critical products which

both enhance the user experience and ensure patient safety.

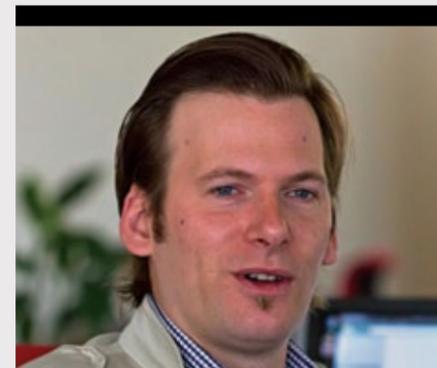
Our methodology encompasses the entire design lifecycle, from requirements definition through to eventual manufacturing support, and begins with a thorough analysis of the end user. The aim is to identify - and then to separate - the functions users desire from those they need, while also determining the user interface design that best fits the eventual application.

We then introduce our medical system architecture (above) to the design process. This architecture deliberately separates safety-critical and user-focussed functions in order to minimise

the risk of failure caused by user error or technical malfunction. For example, users may say they want a touch screen, even though such a screen makes it much easier to 'press' the wrong 'button'; touch screens also require power, and if the screen should fail then users may not be able to access essential controls. Our system architecture makes sure that such controls are not affected by the failure of less important functionality, or compromised if such functionality causes user error, perhaps due to mishandling or stress. In the example of the touch screen, this means providing additional, physical buttons with independent power supply, memory and output.

The regulatory framework for safety-critical devices is particularly demanding and so must also be acknowledged early in the development process, with a system in place for continuous documentation and reporting. SOUPs, or software of unknown provenance, can be an area of specific concern. These often feature in multifunctional devices, and although not necessarily a problem in isolation, when combined may result in unexpected outcomes which regulators want to see thoroughly researched and tested.

This provides just a brief snapshot of the extensive process we use in the development of safety-critical devices, a process we find is becoming increasingly relevant as many such devices move out of the clinically controlled environment and into the home. Greater patient freedom, however, brings greater patient risk; our methodology aims to minimise this risk from the outset in order to deliver devices designed with regulatory approval in mind, and which users will find desirable, functionally appropriate and - above all - safe.



— Sebastien is part of the electro-mechanical engineering team where he works on a range of complex medical systems and products.

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# EVENTS

## DID YOU SEE US?

**Injectable Drug Delivery**  
(March 2012, London)

Andy Fry presented 'Are electronically enabled delivery devices (EEDDs) the future?'

**Strategies for Commercial Success of Biosimilars**  
(April 2012, New York)

Andrew Pocock presented 'Device development for biosimilars'

**European Pre-filled Syringes**  
(January 2012, London)

Colin Mathews and Andy Fry ran a workshop on auto-injectors

**DDL22**  
(December 2011, Edinburgh)

David Harris presented 'Choosing the right device: the case for DPLs'

**PDA Universe of Pre-filled Syringes**  
(November 2011, Basel)

Andy Fry delivered a keynote on 'Parenteral drug delivery in the future: a view of developments, implications and opportunities'

**You can view our articles and presentations on slideshare:**  
slideshare.net/team\_medical

## DO YOU WANT TO MEET?

**RDD 2012**  
(13-17 May 2012, Phoenix)

Colin Mathews is moderating a session on human factors and Team will have a stand

**PDA Universe of Pre-filled Syringes**  
(15-17 October, Las Vegas)

Team is hoping to speak at the conference and we will have a stand

## DID YOU READ?

**Inhalation**, June 2012 – David Harris on the technical challenges of designing a DPI

**Therapeutic Delivery**, July 2012 – Andy Fry on electronically enabled delivery devices (EEDDs)

**EMDT**, July 2012 – Steve Augustyn on DFx and its benefit over DFMA

**Journal of Diabetes Science and Technology**, July 2012 – Andy Fry on future injection technologies

**EMDT**, November 2011 – Philip Canner on the unique challenges of fluid handling

**GEN**, November 2011 – Stuart Kay on reducing the cost of regenerative medicine technology

# Let's make things better

We are recognised globally as experts in the design and development of medical devices. That's all we do and we are proud of this focus. It enables us to deliver real insight and expertise to our clients.

Commercially successful products need to be safe, easy to use and ultimately make people better. Our clients like our approach, which combines design, human factors, science and engineering from inspiration right through to industrialisation.

Everybody at Team is driven by the same desire, to make things better by working in collaboration with clients and each other. Whether 'things' means people or the products we work on, we apply the same commitment to do the best and be the best that we can.

This focus and desire is a powerful combination and one that highlights why our clients trust us over and over again.

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