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174

DrugDelivery

JUNE 18TH 2025

CONNECTIVITY IN DRUG DELIVERY

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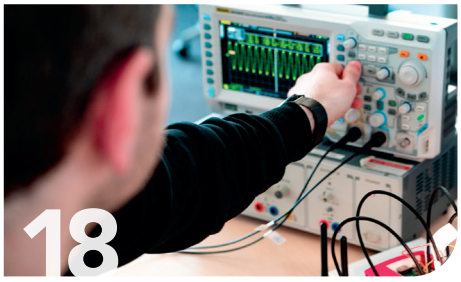

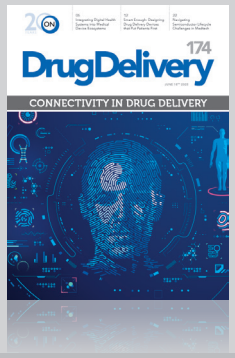

CONNECTIVITY IN DRUG DELIVERY

ONdrugDelivery Issue N° 174, June 18th, 2025

This edition is one in the ONdrugDelivery series of publications. Each issue focuses on a specific topic within the field of drug delivery, and is supported by industry leaders in that field.

EDITORIAL:
James Arnold, Production Editor
james.arnold@ondrugdelivery.com
Subeditors: **Sarah Tomblin, Zoe Billyard**

CREATIVE DESIGN:
Simon Smith, Head of Creative
simon.smith@ondrugdelivery.com

SUBSCRIPTIONS:
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Guy Furness, Founder and Publisher
+44 1273 47 28 28
guy.furness@ondrugdelivery.com

www.ondrugdelivery.com

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Connected reusable pen injector

Reviewing Connectivity:

Key Principles for Developing Connected Devices

In this issue of ONdrugDelivery, we cover connected technologies and their inclusion in drug delivery devices. This topic has been a mainstay in conversations around the future of drug delivery for many years now and remains a key consideration for advanced drug delivery device developers. Rather than specific technologies, the articles in this issue focus on some key guiding principles for developing successful connected devices and why this is a goal worth aiming for.

Our Key Sponsor, **EdgeOne Medical** (Page 6), opens the issue with an overview of the primary stakeholders when designing a connected drug delivery device, going over the various – sometimes conflicting – motives and needs that each stakeholder brings to the table. The article goes on to discuss how to bring these various factors together holistically to ensure the best possible chance of success when incorporating connectivity into a device development programme.

Next, Andy Pidgeon of **42 Technology** (Page 12) offers hard-earned insights in an article that pushes back against some pervasive assumptions about connectivity in the drug delivery device sector. By interrogating the value of connectivity, the article argues that usability and simplicity should always be seen as the priority in device design, rather than including advanced and cutting-edge technology for its own sake, and asking what real-world needs any given technology addresses through its inclusion.

The issue continues with an article from **ITK Engineering** (Page 18) on the critical topic of cyber security. The inclusion of connectivity in drug delivery devices brings with it a whole raft of new challenges and complexities, not least of which is how to ensure security against cyber-attacks – a novel challenge for the drug delivery industry, and one for which expert guidance is often required to be tackled effectively.

Lastly, **Cirtec Medical** (Page 22) concludes this issue with a discussion of the semiconductor industry, and the unique challenge that the timescales of combination product development introduces when semiconductor technology and drug delivery devices meet. The article offers expert opinion on how to approach the challenge of the rapid iteration of semiconductors leading to chip obsolescence only partway through a standard drug delivery device lifecycle, and how to avoid very costly redesigns and re-validations by using bespoke, application-specific integrated circuits.

James Arnold
Production Editor

EdgeOne medical

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INTEGRATING DIGITAL HEALTH SYSTEMS INTO MEDICAL DEVICE ECOSYSTEMS: CONSIDERATIONS AND STRATEGIES

Jerzy Wojcik and **Liat Shochat** from **EdgeOne Medical** take a look at how digital health technologies are transforming the pharmaceutical and combination product sectors. They consider the challenges in bringing these technologies to market and how the full potential of connected health technologies can be achieved.

As advancements in healthcare continue to evolve, so too must the products and systems that support them. For companies developing drug-device combination products, such as autoinjectors, inhalers, infusion systems and prefilled syringes (PFSs), the question is no longer whether connectivity will be required but when and how to integrate it effectively. Successful integration requires a holistic approach that spans stakeholder alignment, design innovation, development rigour and strategic business transformation.

Connected combination products are the next frontier in value-added medicine. These digitally enabled devices do more than just deliver therapies – they provide real-time insights into patient behaviour

"FOR COMPANIES DEVELOPING DRUG-DEVICE COMBINATION PRODUCTS, SUCH AS AUTOINJECTORS, INHALERS, INFUSION SYSTEMS AND PFSs, THE QUESTION IS NO LONGER WHETHER CONNECTIVITY WILL BE REQUIRED BUT WHEN AND HOW TO INTEGRATE IT EFFECTIVELY."

"SUCCESS DEMANDS A STRATEGIC, CROSS-FUNCTIONAL APPROACH THAT NOT ONLY INTEGRATES THESE ELEMENTS BUT ALSO ALIGNS PRODUCT DEVELOPMENT WITH REGULATORY EXPECTATIONS IN A DYNAMIC LANDSCAPE."

and wellbeing, enable proactive clinical intervention and create new opportunities for differentiation in a competitive marketplace. Integrated sensors and communication modules can track dosing events, monitor device usage and adherence patterns and feed data to cloud-based platforms that can support clinical decision making, pharmacovigilance and population health analytics. This convergence is enabling a shift from episodic treatment to continuous, personalised care.

However, bringing these technologies to market is inherently complex, requiring careful considerations across four key domains – stakeholder needs, device design, development programmes and business strategy (Figure 1). Success demands a strategic, cross-functional approach that not only integrates these elements but also aligns product development with regulatory expectations in a dynamic landscape – including the US FDA's evolving approach to software as a medical device and the EU Medical Devices Regulation (MDR)/*In Vitro* Diagnostic Medical Devices Regulation (IVDR) requirements for software and general safety and performance, as well as the classification implications for connected systems.

STAKEHOLDER CONSIDERATIONS

Connected combination products sit within a complex ecosystem of stakeholders whose perspectives and needs are central to success. These include:

- **Patients**, who seek intuitive, reliable and discreet devices that deliver meaningful insights while ensuring privacy and security
- **Healthcare providers**, who require actionable, accurate and timely data that integrates seamlessly into clinical workflows
- **Caregivers**, who benefit from tools that provide support, guidance and monitoring capabilities for those they assist
- **Regulatory authorities**, who demand robust evidence of safety, effectiveness, performance and cyber security compliance
- **Payers and healthcare systems**, who evaluate the economic impact and clinical value of connected solutions
- **Internal stakeholders**, such as R&D, quality, regulatory affairs, marketing and executive leadership, who drive development priorities, ensure compliance and guide strategic direction.

Each of these groups define "value" and "risk" differently. Patients value usability, privacy and support in managing their condition. Providers prioritise clinical utility and workflow integration. Regulators focus on compliance and public safety. Payers evaluate cost-effectiveness and outcomes. Internal teams may focus on time-to-market, resource allocation and long-term competitiveness.

Stakeholder needs must be considered from the earliest stages of product planning. Their input informs design, risk management and commercial strategy. Failure to involve all stakeholders early can lead to significant consequences: delayed approvals, product redesigns, low adoption rates, negative user experiences and reputational harm.

A holistic stakeholder engagement strategy ensures that development efforts are aligned with real-world needs, thereby reducing rework, improving usability and increasing the likelihood of successful adoption and sustained market presence.

DESIGN CONSIDERATIONS

Designing connected devices fundamentally differs from designing traditional standalone systems in several ways. Traditional systems typically focus on mechanical performance and drug delivery functionality. Connected systems, by contrast, require integration of software, wireless communication, data management and cyber security into a cohesive platform. This expands the scope of design to include usability under dynamic conditions, additional data integrity, cloud-based data exchange and interoperability with digital health infrastructure.

Connectivity must be a core design element, not an afterthought. Adding connectivity to an already designed device often results in misaligned components, user dissatisfaction and regulatory delays. A holistic, end-to-end design approach is essential to ensure that each element – from hardware architecture to user interface – is optimised for interoperability, usability, safety and performance (Figure 2).

However, intentional retrofitting of legacy systems – particularly when the base product is well-established and clinically proven – can be a strategic path forward. In these cases, design considerations must focus on carefully preserving the core functionality and regulatory approvals of the legacy device while thoughtfully

Figure 1: Key considerations and inputs into developing a connected combination product.

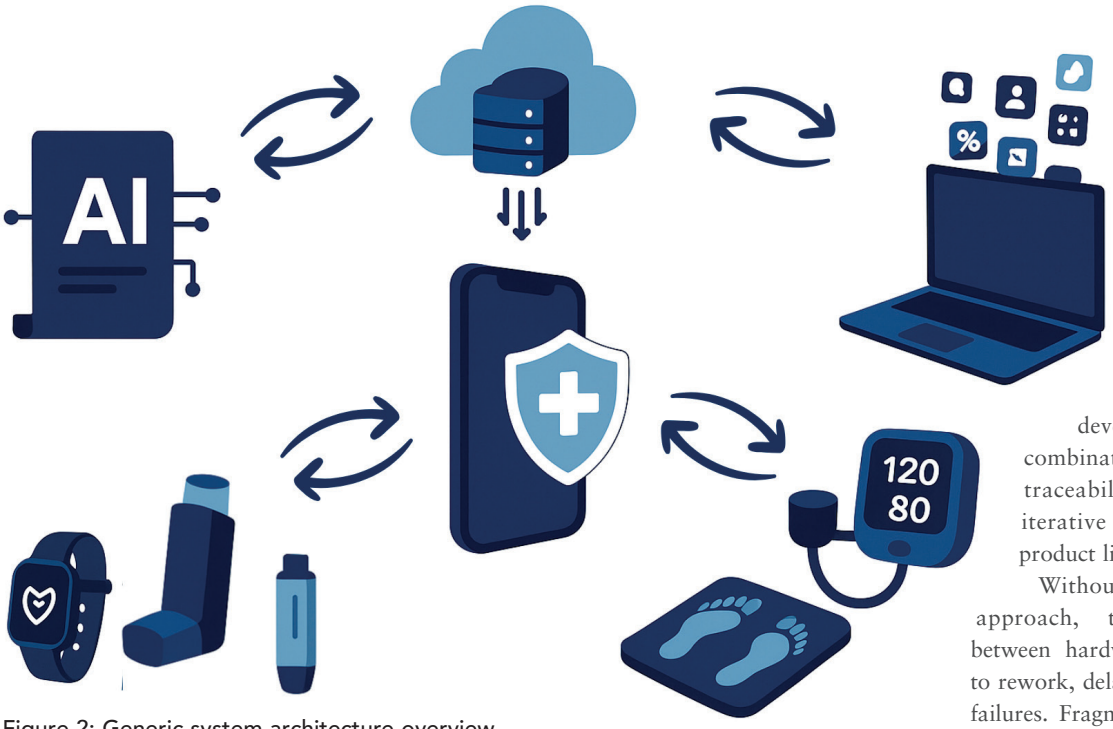

Figure 2: Generic system architecture overview showing the interactions between subsystems.

integrating digital components. Success with this approach requires a disciplined risk assessment to evaluate the impact of new components on device and drug stability, usability and user interface design. Custom enclosures, modular add-ons or external smart accessories may be employed to introduce connectivity with minimal disruption. Human factors testing and re-validation of drug-device interactions are essential to mitigate the risks associated with retrofit solutions and to ensure compliance with current standards.

Key Design Aspects

- **Human Factors:** Connected devices alter user interaction. Interfaces must support a range of abilities, environments and experiences with minimal cognitive load. IEC 62366-1 usability validation ensures devices are both safe and user-friendly.
- **Cyber Security:** Connected devices are susceptible to evolving digital threats. Security must be embedded from the outset using standards such as ISO/IEC 27001 and FDA guidance. Inadequate planning can result in data breaches or device manipulation.
- **Power Management:** Wireless communication and onboard computing increase energy demands. Trade-offs must balance battery life, device size and user expectations.
- **Interoperability:** Systems must be able to seamlessly exchange data with health IT platforms. HL7 fast healthcare interoperability resources (FHIR) compliance, harmonised data formats and reliable data synchronisation are foundational considerations.
- **Compatibility with Drug Product:** Thermal or mechanical impact of sensors, wireless modules and other electronics may affect the drug's stability. These impacts require re-evaluation of stability studies and extractables/leachables profiles.

Design missteps can lead to severe downstream consequences. Failure to address human factors may result in user errors that can compromise therapy adherence. Inadequate cyber security exposes patient data and brand reputation. Poor interoperability hinders clinical workflow integration and delays adoption. Each of these factors underscores the need for rigorous, multidisciplinary design planning from project inception.

DEVELOPMENT PROGRAMME CONSIDERATIONS

Adopting the right development approach is critical for connected systems. These products demand a level of integration and complexity that surpasses traditional device development. A systems engineering framework can provide the structure to harmonise functional requirements, technical specifications, risk controls and regulatory demands while still integrating into the drug development programme as a combination product. It facilitates traceability, accountability and iterative validation across the product lifecycle.

Without a systems engineering approach, teams risk misalignment between hardware and software, leading to rework, delays and potential compliance failures. Fragmentation often results when teams are assembled ad hoc or operate in silos, causing communication gaps, inconsistent documentation and missed dependencies across subsystems.

Cross-functional collaboration is essential from the start. Effective development programmes integrate engineering, clinical, quality, regulatory, cyber security and commercial stakeholders in a co-ordinated and continuous manner. This multidisciplinary engagement allows organisations to foresee and address critical challenges early.

Defining the development scope early is equally vital. It sets the foundation for resource planning, partner selection, budgeting and timeline management. Programmes that delay scope definition often face cascading issues – unclear requirements, missed regulatory expectations, unanticipated testing needs and friction between technical and commercial teams.

Best Practices

- **Cross-Functional Teams:** Embed a collaborative culture by involving key disciplines from planning through execution.
- **Systems Engineering:** Use structured methodologies to ensure alignment of system functions and quality requirements.
- **Risk Management:** Use ISO 14971 and ISO 60812 principles to proactively

identify, assess and mitigate risks to safety and quality – including those related to cyber security and interoperability.
- **Early Scope Planning**: Clarify goals, constraints and success criteria early to guide the entire development process.

BUSINESS CONSIDERATIONS

Connectivity affects business models, operations and commercialisation strategies.

Key Business Shifts

- **Organisational Capabilities**: Companies must develop new competencies in data governance, cyber security operations, cloud platform management, software validation and post-market surveillance. Supporting digital operations requires establishing a robust infrastructure for firmware updates, managing back-end systems and addressing ongoing customer support for digital products.
- **Demonstrating Value**: Demonstrating value to stakeholders requires targeted messaging. For patients, this means clearly showing how the device enhances quality of life, improves adherence or offers actionable health insights. For providers, value may lie in workflow integration and better clinical outcomes. Payers look for cost-effectiveness, reduced hospital visits and data that support reimbursement models. Health economic evaluations, user feedback and real-world evidence are essential in building a strong value proposition.

"CONNECTIVITY AFFECTS BUSINESS MODELS, OPERATIONS AND COMMERCIALISATION STRATEGIES."

- **Strategic Partnerships**: Partnerships with cloud infrastructure providers, cyber security experts, software developers and digital health startups can accelerate development, reduce technical complexity and ensure compliance. Collaboration with healthcare institutions and patient advocacy groups can also strengthen clinical relevance and user engagement.
- **Lifecycle Management**: Even more than traditional devices, connected products require continuous lifecycle oversight. Software updates must be planned, validated and deployed securely. Cyber security threats must be monitored and mitigated through real-time surveillance. Changes to companion apps or back-end systems must maintain regulatory compliance, interoperability and data integrity. Lifecycle management becomes an active, iterative process that demands co-ordination across technical, regulatory and customer-facing teams.

Executives and technical leaders must recognise that connected product development is more than a one-time investment – it is a commitment to long-term digital operations. Organisations must evaluate their readiness, not only to build these products but to support them post-launch. This shift impacts budgeting, staffing and strategic planning. Traditional go-to-market frameworks need to evolve to reflect the continuous nature of digital health engagement and regulation.

CONCLUSION

Connected devices are reshaping the future of care delivery. However, success demands more than technical innovation – it requires aligning stakeholder needs, designing holistically, executing robust development programmes and evolving business strategies.

As leaders reflect on their connected product initiatives, they must ask:

- "Do I fully understand the complexity of connected product development, and where the major risks and blind spots exist?"
- "What qualities and expertise should I look for in a development partner who can support both the technical and regulatory demands of a connected device?"
- "How do I evaluate whether a partner can align with my business strategy and manage cross-functional integration effectively?"
- "Who within my organisation should be leading these conversations, and who should we engage with externally to ensure a comprehensive strategy?"

The ideal development partner should have a proven track record in regulated digital health product development, a deep understanding of global regulatory frameworks and the ability to operate across the software, hardware-mechanical interface, human factors and cyber security domains. They must be capable of supporting collaborative workflows and offer a strategic vision that complements the company's internal goals and infrastructure.

Internally, leadership should involve key members from R&D, regulatory affairs, clinical, quality, IT, marketing and business development. These teams must work together to form a unified vision and execution plan. Externally, companies should engage not only with technology vendors and regulatory consultants but also with clinical partners, patient groups and healthcare systems to ensure the product delivers tangible value across the healthcare ecosystem.

To conclude, connected products are not simply innovations, they are platforms that can transform how therapies are delivered and experienced. Choosing the right partner – one who can bridge technical, regulatory and strategic demands – is critical to unlocking the full potential of connected health technologies and delivering lasting impact.

Jerzy Wojcik

Jerzy Wojcik is Vice President of Regulatory and Quality Services at EdgeOne Medical, and has over 25 years of industry experience in quality and regulatory leadership within the medical device and pharmaceutical industries. His expertise includes identification and execution of regulatory activities across all stages of product development and lifecycle management, with a focus on medical devices and combination products with device constituents, including wearable sensors and mobile medical applications. He has particular strength in creating integrated development strategies that align regulatory requirements, quality management, product development and strategic partnerships to support innovative product development approaches. Mr Wojcik also has expertise in US distribution and dispensing compliance, as well as regulatory surveillance for drugs, biologics and devices. In addition to regulatory responsibilities, Mr Wojcik also helps to develop and implement quality systems and various process quality compliance initiatives.

E: jerzy.wojcik@edgeonemedical.com

Liat Shochat

Liat Shochat is Vice-President of Combination Product Development and has over 20 years of experience in design and development management of combination products and medical devices. Her expertise includes strategic and technical development, lifecycle management and global launch of various single-use, disposable electro-mechanical drug delivery platforms, drug-device combination products and medical devices. Throughout her career, Ms Shochat has held management roles in R&D, engineering, project management, regulatory, human factors and clinical trials.

E: liat.shochat@edgeonemedical.com

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Expert View

SMART ENOUGH: DESIGNING DRUG DELIVERY DEVICES THAT PUT PATIENTS FIRST

Andy Pidgeon of 42 Technology challenges the assumption that more advanced technology is always better, re-examining the design approach to connected autoinjectors from the patient perspective and highlighting the value of simplicity and usability – digging into the idea that, by investigating the real-world needs of patients, drug delivery device designers can ensure that their devices are serving those needs, rather than creating unnecessary new challenges for users.

INNOVATING FOR PATIENTS, NOT TECHNOLOGY

As a designer of drug delivery devices, and a passionate advocate for patient usability, I have learned that innovation only matters if it truly helps real patients. In the rush to create "smart" connected autoinjectors, the drug delivery industry risks forgetting that many patients just want something simple, reliable and easy to use. The real question is not how advanced we can make our devices, but whether or not those features are solving critical user needs.

This article explores how development teams can choose technologies that genuinely support patients, rather than adding features merely for the sake of progress. From artificial intelligence (AI) and Bluetooth to wearable injectors and platform designs, it will look at where technology adds value and where it adds unnecessary complexity. It will also examine the challenges of delivering high-viscosity, high-volume drugs and question whether features such as skin sensors benefit patients or simply reassure manufacturers. The aim is to shift focus back to simplicity, reliability and usability, supported by real-world evidence.

"THE AIM IS TO SHIFT FOCUS BACK TO SIMPLICITY, RELIABILITY AND USABILITY, SUPPORTED BY REAL-WORLD EVIDENCE."

THE ALLURE OF "SMART" INJECTORS VERSUS PATIENT REALITIES

It is tempting to imagine a fully connected autoinjector ecosystem – syncing to an app, logging each dose, providing feedback and perhaps even offering AI-powered coaching. In theory, this promises better adherence, useful data for clinicians and more empowered patients. But it must be asked: are these features genuinely helping patients, or just ticking the innovation box?

"IT MUST BE ASKED: ARE THESE FEATURES GENUINELY HELPING PATIENTS, OR JUST TICKING THE INNOVATION BOX?"

Too often, high-tech devices are launched without clear evidence they meet a real patient need. Non-adherence is a genuine issue, and connected devices are often seen as the answer, with some studies showing encouraging adherence[1] – one showed over 90% adherence in multiple sclerosis patients using a connected injector and app over a year.[2] However, the number of patients using the device dropped to 76% after one year, so many of these positive studies are short-term and may not reflect long-term behaviour.

On the ground, complexity can make things worse. I have seen patients with arthritis struggle with tiny Bluetooth buttons, and others sigh in frustration at pairing requirements. Simplicity should not be seen as a compromise – it is often the best design choice.

As designers, we also need to ask who we are designing for. A tech-savvy early adopter may welcome new features, but many patients are older, time-poor or anxious, and just want treatment that works without fuss. If technology makes their lives harder, it has failed, no matter how advanced it looks (Figure 1).

Adherence is not always about forgetfulness. Most self-injecting patients do not forget their dose – it is often uncomfortable and emotionally charged. Many patients build routines around it.

Figure 1: It is crucial to keep the intended user, along with their specific desires and problems, in mind throughout the design process.

Others choose to skip a dose to feel in control – a small act of agency in a life shaped by treatment. No flashing LED or push notification will change that.

WHEN COMPLEXITY CREEPS IN – THE PITFALLS OF HIGH-TECH FEATURES

Looking under the bonnet of today's smart injectors, a few recurring "features" stand out – both their potential and their pitfalls.

Bluetooth Connectivity (and the Pairing Problem)

Most connected devices use Bluetooth to sync data to an app. In theory, this works in the background. In practice, pairing can be difficult, especially when users are already anxious. Entering codes or changing phone settings adds pressure. Some devices now avoid this with automatic Bluetooth or near-field communication (NFC), which does not require pairing.[3] This seamless approach matters, as even scanning a QR code each time a patient needs to inject can become an unwanted chore. Unless a feature works instantly and effortlessly during use, patients will avoid it – and frustration can outweigh any potential benefit.

AI-Driven Guidance and Reminders

AI is becoming a common feature in healthcare, including drug delivery. It is often imagined as a helpful digital nurse – reminding patients when to inject, offering tips and, perhaps one day, adjusting doses. This vision is appealing, especially if AI can learn habits and provide support in the background.

However, designers must be cautious. If AI starts giving instructions without explanation – such as telling a patient to delay a dose – it may lead to confusion or conflict with clinical advice. Patients and clinicians need to understand and trust what AI is doing, and it must be clear who is accountable if it gets things wrong. The danger of black box decisions is very real.

To be genuinely useful, AI features must be transparent, easy to understand and optional. For now, its best use may be supporting adherence behind the scenes. Because no matter how advanced the technology, the key to successful treatment is still a person who feels confident using it.

WEARABLES AND HIGH-VOLUME DELIVERY

A key challenge in injector design is the rise of biologic drugs needing larger volumes or higher viscosities. Standard spring-loaded pens can manage around 1 mL without trouble, but pushing more than 2 mL of a thick antibody solution through a fine needle is another story – the forces required skyrocket as viscosity increases.[4]

This is where wearable injectors come in. Worn like a patch, these devices deliver medication slowly over time, making large doses more comfortable. These devices are ideal when volumes exceed 2–3 mL, a limit for most autoinjectors. Though bulkier, their real value lies in solving a real need – reliable home delivery of difficult drugs.

While some wearable injectors include connectivity to track doses, their main strength is mechanical – not digital. They reduce patient burden and improve access without unnecessary complexity. Rather than adding smart features for their own sake, we should take cues from these devices: identify real barriers to treatment and use technology to remove them.

OFF-THE-SHELF PLATFORMS VERSUS BESPOKE SOLUTIONS

Autoinjectors were once bespoke for each drug. Now, platform devices offer pre-designed solutions that pharma teams can adapt. These platforms have already been tested with different volumes and syringe types, saving time and cost while improving reliability. Owen Mumford's (Woodstock, UK) Aidaptus, for example, claims to fit both 1 mL and 2.25 mL syringes, automatically adjusting to varying fill volumes.[5] This flexibility is especially useful during clinical trials or if doses change. Platforms such as Aidaptus also

"A MODULAR APPROACH KEEPS THE FOCUS ON USABILITY WHILE AVOIDING OVER-ENGINEERING. INSTEAD OF BUILDING COMPLEX SYSTEMS FROM THE GROUND UP, PLATFORMS ALLOW DEVELOPERS TO CHOOSE THE FEATURES THAT BENEFIT PATIENTS."

offer smart features, but only where needed. The core device is simple, robust and designed for ease of use. Optional extras like NFC and sensors can be added later.

A modular approach keeps the focus on usability while avoiding over-engineering. Instead of building complex systems from the ground up, platforms allow developers to choose the features that benefit patients. It is a more efficient, patient-centric way to innovate – one where technology earns its place rather than being included by default.

SKIN SENSORS AND SAFETY INTERLOCKS

A subtler example of potential over-engineering is the use of skin contact sensors in some electromechanical injectors. These aim to prevent misfires unless the device is correctly positioned, and to stop the injection if it is pulled away mid-dose. While this sounds helpful, the real-world need is debatable.

Traditional spring-loaded injectors managed safety with mechanical features alone – the patient had to press firmly to trigger the spring, and the dose was delivered in seconds, limiting the chance of early removal. Electronic injectors often take longer, with start and pause buttons and variable speeds, so designers introduced sensors to pause and retract if contact is lost.

For instance, UCB's (Brussels, Belgium) ava Connect can halt injection and resume after repositioning, preventing wasted doses.[6] This is clever, but is the added complexity really essential? A clear "do not remove" indicator and proper training may be enough in most cases. Skin sensors can be useful, but they add cost, use power and may fail. Of course, this approach is helpful for gaining adherence data, but is it useful for the patient? Unless a therapy frequently faces interrupted injections, such features may be better used selectively, not by default.

CHOOSING TECH THAT EARNS ITS PLACE

How, then, do designers decide which innovations to include and which to leave on the cutting-room floor? The following are a few guiding principles can help keep us honest.

Always Start with the User Problem

Before adding any feature, be clear about which patient problem it addresses. Is forgetfulness the issue? A simple SMS reminder might be enough. Is needle anxiety causing hesitation? A hidden needle or slower injection could help. Every added feature should answer the question: "What specific user pain point does this solve, and have we verified that the problem really exists?". If the benefit is unclear, or a simpler solution exists, reconsider. Before adding another app, chip or update, always ask: "What real problem are we solving?"

Complexity Must Earn Its Place

This oft-repeated design principle means any added complexity – mechanical, electrical or digital – must bring clear, proportionate benefit. It is tempting to include features because they might be useful in some cases but, if only a few gain from them while all users have to deal with the added burden, they do not justify inclusion. For example, streaming detailed injection force data to the cloud might appeal to the engineering team, but it rarely improves patient care. Beyond confirming a dose was taken, extra data "provides no additional added value"[3] and can even clutter the system. Designers should be ruthless in pruning features that are cool in theory but superfluous in reality.

Design for the Worst-Case User, Not the Ideal User

To truly make devices inclusive, imagine the person least likely to succeed with a device, and make it work for them. That might be someone who has never used a smartphone, has limited dexterity or is too busy to read the manual. Real-world studies reveal issues like patients forgetting to sync Bluetooth or skipping injection aids that slow them down, even if it only adds a minute to their routine.

These insights can help to simplify the design. Perhaps the device always stays on in a low power mode, removing the need for a power switch. Maybe it comes pre-paired to avoid setup. Or maybe it includes a mechanical backup, like the Owen Mumford UniSafe, to ensure that the injection works even if the electronics fail.[7] Empathy in design should lead to real, practical decisions that make the device easier for everyone to use.

Embrace Simplicity as an Outcome

It is easy to think that "simple" means "unsophisticated," but designing something that feels simple takes real skill. The best autoinjectors are often one-step devices – remove the cap, press to the skin and the injection is done. They appear straightforward, yet involve precise engineering for needle control, drug delivery and safety. We should celebrate designs that achieve more with less – using clever mechanical ideas rather than relying on electronics.

Focusing on the essentials often creates more reliable, user-friendly devices. Even companies building advanced injectors prioritise clear, patient-focused design. Technology should support care, not get in the way. Sometimes the smartest approach is to reduce features and focus on what matters most – ease, clarity and confidence.

Provide Value to All Stakeholders – But Prioritise the Patient

This is a delicate balance – healthcare providers and pharma companies value the data from connected devices, but, if collecting it worsens the patient experience, it becomes counterproductive. The user experience must come first, even if that means gathering less data.

There is a tendency to want to satisfy everyone – doctors ask for adherence logs (though most do not use them), marketing wants a flashy app and regulators want layers of safety. The result is often an overbuilt device that suits no one, especially not the patient. A better solution is offering a range of device options. Simplicity for

"REAL-WORLD STUDIES REVEAL ISSUES LIKE PATIENTS FORGETTING TO SYNC BLUETOOTH OR SKIPPING INJECTION AIDS THAT SLOW THEM DOWN, EVEN IF IT ONLY ADDS A MINUTE TO THEIR ROUTINE."

those who want it, technology for those who need it. This kind of choice respects individual needs and helps developers stay grounded – if most people avoid the tech-heavy option, it may be time to reassess what really adds value.

REDEFINING "INNOVATION" IN DRUG DELIVERY

True innovation in pharmaceutical devices is not about cramming the most technology possible into a product; it is about intelligently applying technology to solve meaningful problems. A connected injector is only useful if it improves outcomes without adding effort. A wearable injector that enables at-home treatment is valuable because it improves quality of life. Features that confuse or overwhelm users are not progress.

Designers should shift from asking "What can we add?" to "What should we add to make things better for patients?" Sometimes that means advanced technology, and sometimes it means a simpler shape or clearer instructions. Perhaps the most patient-centric innovation is simply a better ergonomic shape that an elderly patient can hold securely in their hand, or a Bluetooth implementation that does not require pairing or user thought – it just works out of the box. Every new feature should be judged on whether it improves simplicity, usability, reliability or empathy. If it does not, it may not belong.

FINAL THOUGHTS

The future of drug delivery will bring more digital and connected tools, and that can be a good thing – if used wisely. Success should be measured by whether patients can and will use the device with confidence. Impressive features mean little if they complicate the experience or stop treatment from happening.

We must design for people, not platforms, and recognise when a simpler approach is actually more effective. Real-world feedback should guide us, not just what works in the lab. True innovation lies in knowing what to add – and what to leave out. Simplicity, used well, is powerful.

ABOUT THE COMPANY

42 Technology (42T) is a Cambridge (UK) based technology and product development consultancy, helping businesses tackle design, engineering, usability and regulatory challenges. 42T delivers practical, strategic solutions to drive innovation and create user-centric medical technologies.

REFERENCES

1. *Antalfy A et al, "The Adherence and Outcomes Benefits of Using a Connected, Reusable Auto-Injector for Self-Injecting Biologics: A Narrative Review". Adv Ther, 2023, Vol 40(11), pp 4758–4776.*
2. *Bryson S, "Most Patients Adhere to Betaseron Therapy Over 1 Year, App Data Show". Multiple Sclerosis News Today, Mar 2022.*
3. *Song J, "Key Design Considerations For Digitally Connected Injectors". Med Device Online, May 2022.*
4. *Roe MJ, "Challenges in High-Viscosity, High-Volume Drug Delivery". ONdrugDelivery, Issue 125 (Oct 2021), pp 40–43.*
5. *"Aidaptus - The next generation platform disposable auto-injector". Manufacturing Chemist, Mar 2022.*
6. *"UCB Gains CE Mark for ava Connect[®], a first-in-class electromechanical device for use with biologic treatment in rheumatology and dermatology". Press Release, UCB, Mar 2021.*
7. *"UniSafe® 1mL Auto-injector". Company Web Page, Owen Mumford, Accessed May 2025.*

Andy Pidgeon

Andy Pidgeon is Head of Usability at 42 Technology where he helps global pharmaceutical and medical device clients develop safe, effective and user-centric drug delivery systems. With over 20 years of experience in human factors engineering and a background in industrial design Mr Pidgeon brings a pragmatic, design-led approach to complex healthcare challenges. He has led usability programmes across a wide range of combination products from autoinjectors to inhalers and is a regular speaker at international conferences. Mr Pidgeon is passionate about balancing innovation with usability, ensuring that technology serves the user rather than the other way round.

T: +44 1480 309486
E: andy.pidgeon@42T.com

42 Technology
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20 YEARS ON drugDELIVERY

CONNECTED BUT PROTECTED – SECURELY CONNECTING DRUG DELIVERY DEVICES

Dr Joachim Wilke of ITK Engineering discusses wireless connectivity in novel drug delivery devices, highlighting the possibilities for improved patient outcomes and care. The associated security risks, as well as examining the wide range of cyber security solutions and standards to mitigate these issues.

Healthcare is no longer confined to hospitals and doctors' surgeries; it is increasingly expanding into everyday environments such as homes, workplaces and public spaces. To keep pace with this evolution, drug delivery devices must be intelligently connected. This enables seamless integration of medical care into daily life, improving both treatment outcomes and patient comfort – all while meeting stringent safety and compliance standards (Figure 1).

SECURING DATA TRANSMISSION RELIABLY

One key technical feature of modern drug delivery devices is their wireless connectivity. Interfaces such as Bluetooth Low Energy (BLE), Wi-Fi, and Near Field Communication (NFC) are essential for enabling interaction between the device and external systems such as mobile apps, health platforms and cloud-based analytics services. However, this connectivity also introduces new security risks – unencrypted or poorly secured transmission channels can compromise sensitive patient data or, in extreme cases, even affect the device's functionality. Therefore, implementing advanced encryption standards for data security in transit and at rest.

Additionally, robust authentication methods, such as multi-factor authentication and biometric procedures, are becoming the new standard to control access to devices and their data. This is particularly critical

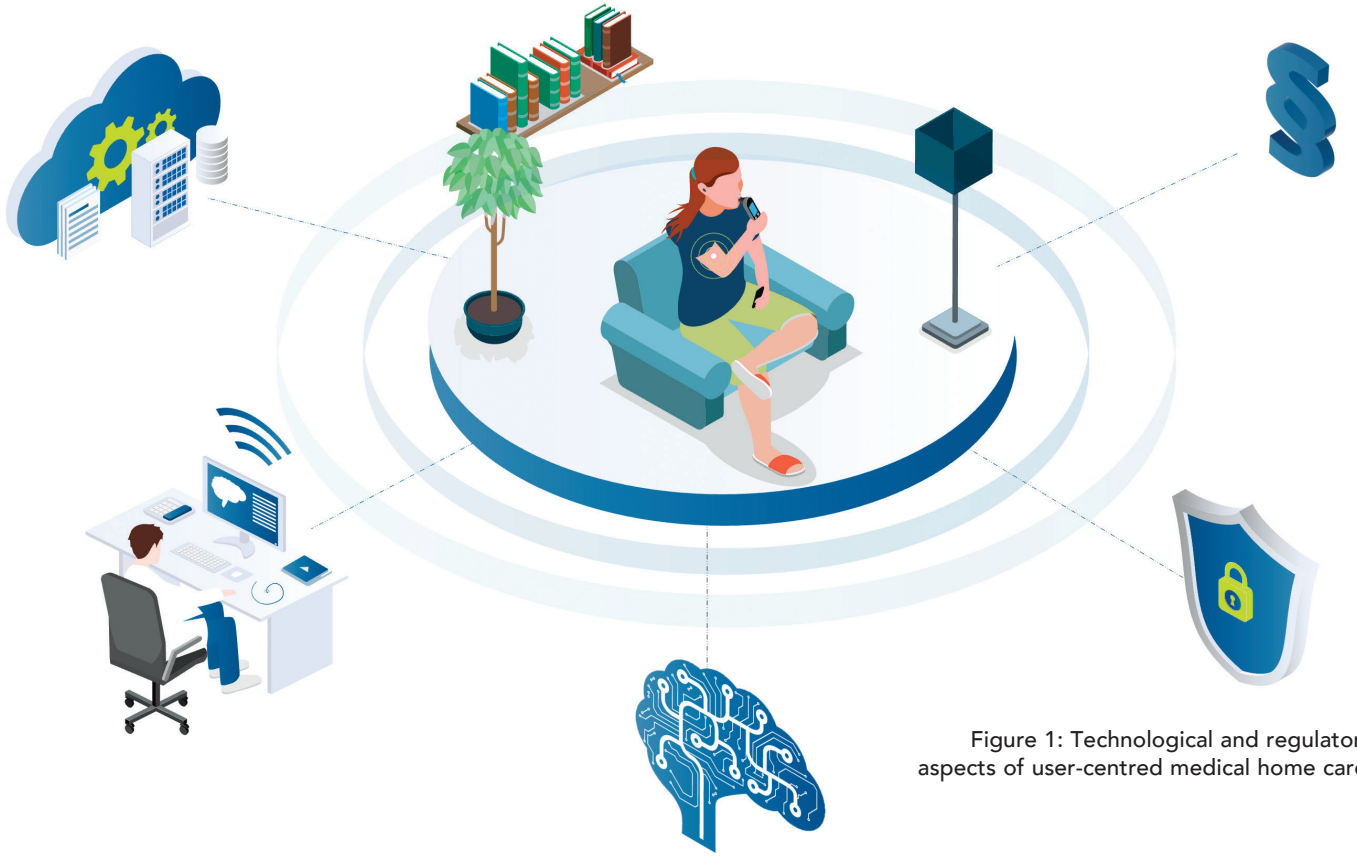


Figure 1: Technological and regulatory aspects of user-centred medical home care.

"TO ENSURE THE RELIABILITY OF DRUG DELIVERY DEVICES EVEN UNDER THREAT SCENARIOS, IT IS CRUCIAL TO INTEGRATE CYBER SECURITY PROACTIVELY THROUGHOUT THE ENTIRE LIFECYCLE."

for drug delivery devices involving patient-specific dosing, where only authorised individuals should be able to operate the device. Increasingly, device-bound digital certificates, challenge-response methods and hash- and time-based one-time passwords are being employed.

Another trend is the local validation of sensitive actions directly within the device itself, for example, by using hardware security modules or secure elements. These components protect private keys and perform cryptographic operations in a hardware-supported manner.

IDENTIFYING RISKS BEFORE THEY ARISE

To ensure the reliability of drug delivery devices even under threat scenarios, it is crucial to integrate cyber security proactively throughout the entire lifecycle – from development and design to commissioning and ongoing maintenance. Standards such as IEC 81001-5-1, which focuses on secure design principles,[1] and ISO 14971,[2] which governs risk management for medical devices, provide important guidelines for manufacturers. Cyber security measures may also become relevant in the context of the new post-market surveillance requirements introduced by the UK Medicines and Healthcare products Regulatory Agency (MHRA), which will come into effect on 16 June 2025.[3]

STRIDE

Proactive cyber security means already conducting threat and risk analyses during the development phase, for example, by using the STRIDE methodology (spoofing, tampering, repudiation, information disclosure, denial of service, elevation of privilege). STRIDE systematically identifies potential threats through the creation of data flow diagrams, enabling comprehensive yet efficient risk assessments.

CVE scanning

Since no single method can guarantee full coverage of all potential risks, it is advisable to combine several identification techniques. Alongside STRIDE, a common vulnerabilities and exposures (CVE) scan of the software components used can be performed. CVE refers to publicly known vulnerabilities in software and hardware documented in the international CVE database. These vulnerabilities can cause serious risks, such as data leaks or system manipulations. Regulatory bodies, including the EU and the US FDA, have set clear requirements: manufacturers must integrate CVE scanning processes into their workflows and produce reports listing affected components, their criticality and the mitigation measures taken. These analyses are essential to detect security risks early. Furthermore, all decisions must be traceably documented, helping to minimise liability risks and meet auditor requirements.

Conducting a CVE scan requires a software bill of materials (S-BOM) – a comprehensive list of all the software components comprising the system under review. Often, S-BOMs must be maintained manually. However, automation tools can assist in both creating S-BOMs and performing scans – only the subsequent assessment of discovered vulnerabilities still demands meticulous manual work (Figure 2).

Penetration testing

Another essential building block for ensuring cyber security is penetration testing (pentesting). This is a structured security test explicitly required by IEC 81001-5-1,

"THE PRIMARY GOAL OF PENTESTING IS TO IDENTIFY WEAKNESSES THAT MIGHT HAVE BEEN OVERLOOKED DESPITE THOROUGH RISK MANAGEMENT AND SECURE IMPLEMENTATION – OR THAT WERE INHERENTLY UNDETECTABLE BEFOREHAND."

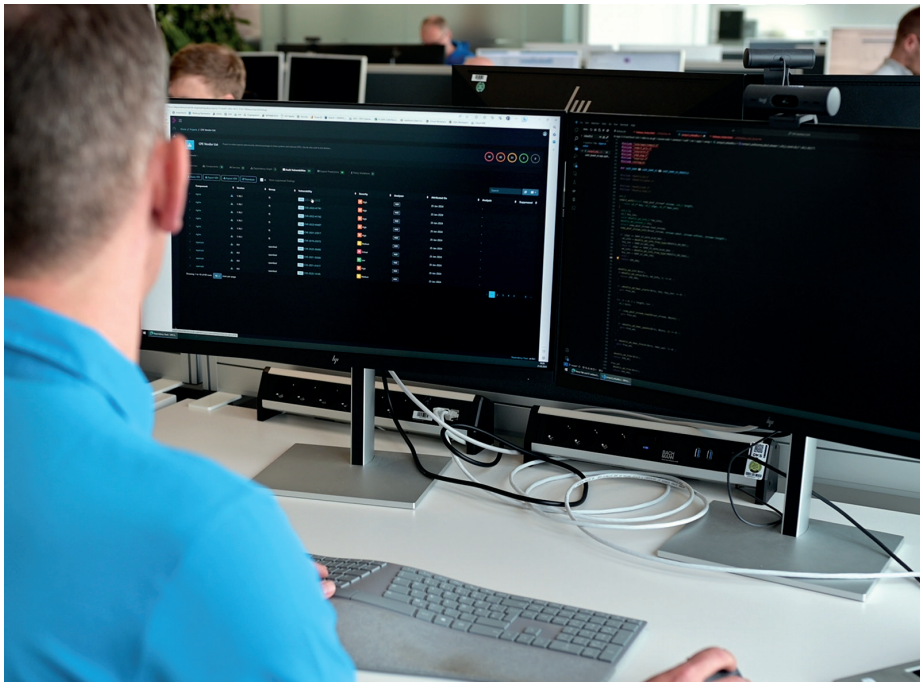
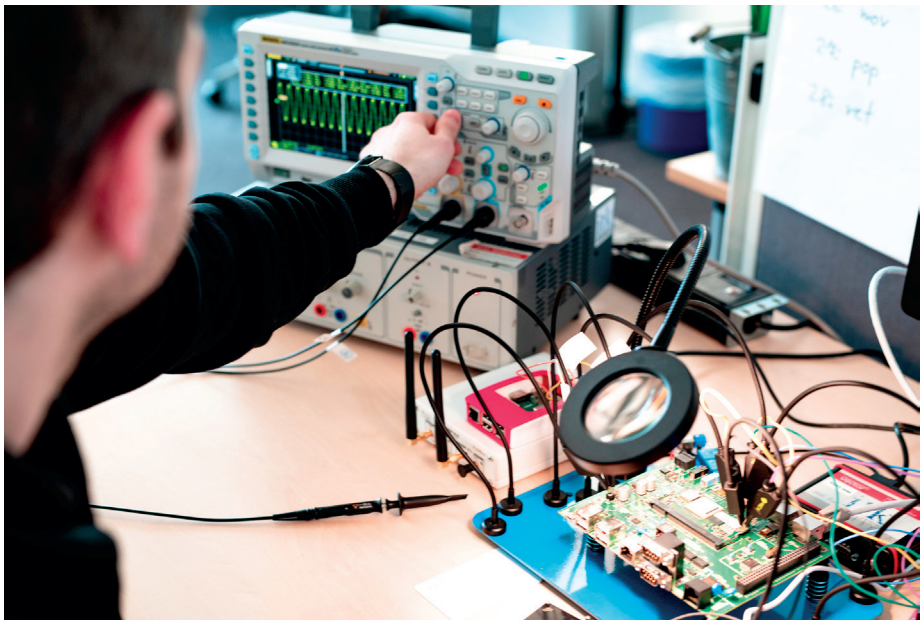


Figure 2: Setting up a CVE scan requires considerable manual work, such as converting software components into a machine-readable S-BOM.



"ZERO TRUST ARCHITECTURES ENABLE FINE-TUNED CONTROL OVER THE DATA FLOW BETWEEN DEVICES, APPLICATIONS, AND USERS, THEREBY SUPPORTING THE SECURITY OF SENSITIVE DATA AND COMPLIANCE WITH REGULATORY REQUIREMENTS."

Figure 3: In-depth penetration testing of a connected medical device.

designed to uncover vulnerabilities within a product. The primary goal of pentesting is to identify weaknesses that might have been overlooked despite thorough risk management and secure implementation – or that were inherently undetectable beforehand, which is more often the case in practice. Additionally, pentesting offers a valuable opportunity to validate a product's security from an independent perspective, particularly towards the end of the development phase. In practice, a combination of black-box and white-box testing has proven to be effective (Figure 3).

MANAGING DATA SECURELY WITH THE RIGHT INFRASTRUCTURE

The choice of data infrastructure significantly impacts the security of connected drug delivery devices. Whether opting for public cloud, private cloud or hybrid solutions, decisions should be based on several factors, such as data sensitivity, regulatory requirements and cost considerations. Infrastructure decisions must also take into account the energy demands of data processing, ensuring that data management remains robust without placing an undue burden on device energy resources. Encrypting data both during transmission and at rest is essential to prevent unauthorised access.

Dr Joachim Wilke

Joachim Wilke, PhD, Cyber Security Specialist, Healthcare, at ITK Engineering, has played a key role as a group leader and project manager in the connectivity of medical devices for various renowned clients in the healthcare sector since 2013. He is an expert in identifying security vulnerabilities and implementing comprehensive security concepts in medical systems. Prior to this, he conducted academic research in the field of telematics and earned his doctorate studying wireless sensor-actuator networks at the Karlsruhe Institute of Technology (Germany).

T: +49 162 1057339
E: joachim.wilke@itk-engineering.de

ITK Engineering
Im Speyerer Tal 6, 76761 Ruelzheim, Germany
E: healthcare@itk-engineering.de
www.itk-engineering.de/en/

Role-based access control and zero trust architectures are effective strategies to enforce strict role-based access permissions and ensure continuous validation and adjustment of authorisation rights. Especially in healthcare, zero trust architectures enable fine-tuned control over the data flow between devices, applications and users, thereby supporting the security of sensitive data and compliance with regulatory requirements.

CONCLUSION: CONNECTIVITY REQUIRES SECURITY FROM THE START

The increasing connectivity of drug delivery devices offers tremendous potential – for personalised therapies, improved care outside traditional medical institutions and enhanced quality of life for patients. However, this progress can only succeed if security is embedded from the very beginning. A comprehensive "security by design" approach ensures that drug delivery devices are equipped with robust security mechanisms right from the start. Regular vulnerability analyses, structured threat modelling and targeted penetration testing can help identify risks early – before they can escalate into real dangers.

As the use of cloud technologies and artificial intelligence-based analytics increases, so too does the complexity of potential attack scenarios. It is therefore all the more important to regularly review and adapt cyber security strategies to new risk landscapes, keeping them flexible and resilient. This way, connected drug delivery devices can be developed that not only impress technically but also sustainably build trust among users, healthcare professionals and regulatory authorities – ensuring long-term market success.

ABOUT THE COMPANY

ITK Engineering, a global tech company and wholly owned subsidiary of Robert Bosch, draws on methods-driven expertise to provide standards-compliant and platform-independent software and system development services to customers across several industries. In its healthcare branch, which is certified according to EN ISO 13485:2016, ITK Engineering implements standards-compliant system and software solutions for medical products – from medical devices and robotic systems to diagnostic solutions.

REFERENCES

1. *"IEC 81001-5-1: Health software and health IT systems safety – Part 5-1: Security – Activities in the product life cycle". IEC, 2021.*
2. *"ISO 14971: Medical devices – Application of risk management to medical devices". IEC, 2019.*
3. *"The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024". UK Government, 2024.*

Expert View

NAVIGATING SEMICONDUCTOR LIFECYCLE CHALLENGES IN MEDTECH: A STRATEGIC SHIFT TOWARDS ASICs

Andy Kelly of Cirtec Medical considers the evolution of semiconductor technology and the impact of the release of new and upgraded components. This article discusses how strategic decisions during the early stages of product design can determine the future viability of a medical device and considers the cost savings offered by application-specific integrated circuits through a reduction in the number of components required.

"IN CONSUMER-DRIVEN MARKETS, SEMICONDUCTOR TECHNOLOGY CHANGES RAPIDLY TO MEET PERFORMANCE, EFFICIENCY AND COST TARGETS. NEW FABRICATION TECHNOLOGIES AND ENHANCED CIRCUIT DESIGNS ARE INTRODUCED REGULARLY."

Semiconductor technology is evolving at a rapid pace,[1] providing ever-increasing levels of complexity, performance and efficiency for consumer and industrial products. While these advances benefit all product categories, they also present a unique dilemma for medical device developers. The frequent release of new and upgraded semiconductor components increases the risk of their predecessors becoming obsolete. This is an especially critical issue for implantable medical devices, which typically involve long cycles of development and regulatory approvals, as well as long product lifetimes.

SEMICONDUCTOR LIFECYCLE CHALLENGES IN MEDTECH

In consumer-driven markets, semiconductor technology changes rapidly to meet performance, efficiency and cost targets. New fabrication technologies and enhanced circuit designs are introduced regularly. Due to these technological advancements, shifting market demands and manufacturers prioritising high-volume, short-lifecycle applications, standard semiconductor components, such as power management integrated circuits (ICs), sensor ICs, driver ICs and microcontrollers often become obsolete within a few years of their introduction.

As implantable medical devices require extensive, multi-year regulatory approval processes and are expected to remain in the market for a decade or more, the potential for component obsolescence is particularly challenging. When a key component becomes unavailable, medical device manufacturers are forced to choose between an expensive lifetime buy (purchase of enough components to support the entire product lifecycle) or a redesign of the device electronics – both of which present high costs and risks.

DESIGNING FOR LONGEVITY AND COMPLIANCE

To navigate these high-stakes challenges, medical device manufacturers should take a proactive, forward-looking approach to design and development – one that prioritises component longevity and aligns with performance requirements and long-term regulatory cycles. Strategic decisions made during the initial design phases often determine the future viability of a medical device. Selecting components with short lifecycle expectations introduces unnecessary risks in the form of obsolescence and potential supply disruptions. Conversely, overinvesting in unproven technologies may not necessarily pay off if future support vanishes due to low adoption, shifts in market demand or discontinuation of the product line by the manufacturer.

This is where expert semiconductor product development partners play a critical role. Design teams with a deep understanding of semiconductor roadmaps, medical regulatory requirements and circuit design partitioning can help companies make smart choices early, avoiding costly disruptions later (Figure 1).

THE VALUE OF ASICs IN MEDICAL DEVICE DESIGN

Application-specific integrated circuits (ASICs) offer a compelling solution for many medical device developers. By integrating multiple analogue and digital functions into a single, application-

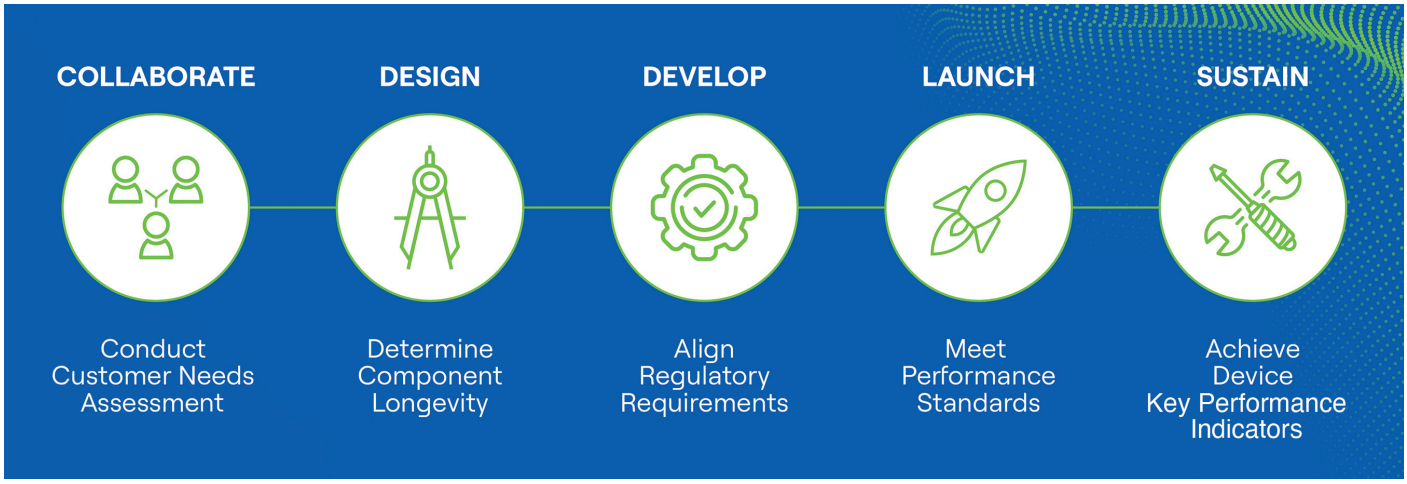


Figure 1: Design teams can help companies to make smart choices early, avoiding costly disruptions later.

specific chip, multiple standard components can be eliminated from the device. As a result, there are fewer suppliers in the supply chain, and components at risk of obsolescence are reduced – thereby making the continuity of supply more secure. Unlike off-the-shelf components designed for high-volume, short-lifecycle markets, ASICs are engineered for specific applications and exclusively sold to specific device developers. This specificity gives manufacturers greater control over design and lifecycle planning, reducing their exposure to industry-wide fabrication changes, shifting consumer trends or other common obsolescence factors.

To reduce ASIC obsolescence risk, the underlying silicon technologies used to build ASICs are typically selected for long-term availability. Medical device makers can typically secure 10–15 years of reliable component support – enough to span an entire product lifecycle without needing to revisit the design (Figure 2).

THE ASIC DESIGN PROCESS VERSUS STANDARD COMPONENTS

Designing an ASIC involves a different approach than traditional printed circuit board-level integration. Instead of selecting discrete ICs to perform specific functions, engineers define the desired behaviour and build those functions into a single integrated circuit. This enables:

- **Miniaturisation:** Consolidating multiple components into one ASIC dramatically reduces board size, which is critical for implantable devices.
- **Power Optimisation:** ASICs are tuned specifically for their use case, allowing for lower operating currents – enabling smaller batteries and longer battery life.
- **Improved Reliability:** Fewer interconnects and components can lead to fewer potential points of failure.

> "TO REDUCE ASIC OBSOLESCENCE RISK, THE UNDERLYING SILICON TECHNOLOGIES USED TO BUILD ASICS ARE TYPICALLY SELECTED FOR LONG-TERM AVAILABILITY."

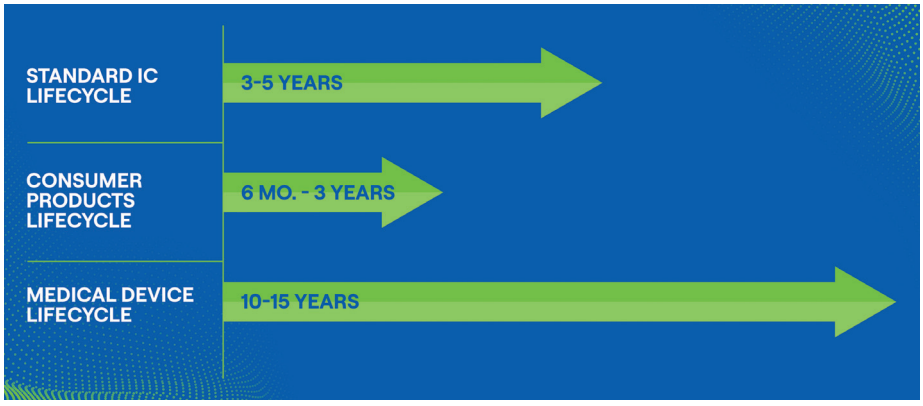


Figure 2: Component obsolescence lifecycle.

For some medical devices, ASICs are not just advantageous, they are essential. Applications requiring ultra-low power consumption, extreme miniaturisation or highly unique requirements cannot typically be achieved with standard components alone.

THE SUPPLY CHAIN BENEFITS OF ASICs

While ASIC development may require higher upfront investment, the long-term benefits are substantial. By avoiding mid-lifecycle redesigns, companies can save millions on redesign and re-validation costs, and prevent costly interruptions to product availability. In high-volume applications, ASICs can also offer unit cost savings by reducing the number of components, simplifying manufacturing processes and improving test yield.

"WITH THE CONTINUOUS DEMAND FOR SMALLER, MORE CAPABLE AND LONGER-LASTING DEVICES, ASICS WILL PLAY A PIVOTAL ROLE IN REDUCING POWER CONSUMPTION WHILE INCREASING FUNCTIONALITY AND PERFORMANCE – WITHOUT COMPROMISING SAFETY OR RELIABILITY."

REAL-WORLD EXAMPLES

These benefits are not just conceptual – they are already being realised in a range of advanced medical applications where ASICs are driving measurable improvements in performance, reliability and manufacturability – in addition to their obsolescence risk reduction. Examples include implantable neuro-stimulators, implantable cardiac pacemakers and defibrillators, implantable bio-sensors and implantable drug delivery devices. These typically include a wide range of analogue, digital and mixed-signal circuits that are optimised to work in harmony to meet a very specific set of requirements. In most cases, these implantable devices would be impractical at best, and likely impossible to realise, without the use of ASIC-based circuit designs.

THE ROLE OF ASICs IN THE NEXT DECADE

Semiconductor technology innovation will continue and likely accelerate throughout the next decade. This means that the obsolescence risk of standard semiconductor components will continue and become even more prevalent.

Going forward, the medical ASIC industry will gradually evolve towards denser, smaller-geometry semiconductor technologies. This evolution is likely to enable increased integration of microcontroller units, self-checking circuits, redundancy mechanisms and built-in test functions into ASIC designs that, historically, have been analogue-centric. This hybridisation will bring more programmability, diagnostics and data-handling capabilities to ultra-low-power applications, enabling more intelligent devices that can adapt and self-correct in real time.

EMERGING TECHNOLOGIES TO SUPPORT MINIATURISATION

As the semiconductor industry progresses to smaller-geometry technologies, the standard operating voltages used in ASICs will be reduced and result in further reduction in power consumption, which will support the design of even less invasive devices that can improve patient comfort and reduce implant risk.

Along with semiconductor technologies, ASIC packaging technologies are also evolving rapidly. Wafer-level chip-scale packaging and 3D stacking can allow designers to push the boundaries of miniaturisation even further.

These advancements are positioning ASICs as key enablers of the next generation of implantable medical devices. With the continuous demand for smaller, more capable and longer-lasting devices, ASICs will play a pivotal role in reducing power consumption while increasing functionality and performance – without compromising safety or reliability.

PREPARING FOR THE FUTURE: PROACTIVE STRATEGIES FOR MEDTECH COMPANIES

To effectively realise the potential of ASICs and ensure long-term success, medtech companies should adopt proactive strategies throughout the product development lifecycle. These strategies include:

- **Designing with Foresight:** To fully realise the benefits of ASICs, medical device developers should consider their feasibility from the earliest stages of concept development. ASICs are less effective in designs that were not built with custom integration in mind. Early planning enables smoother integration of all device functions and better alignment with regulatory documentation and validation protocols.
- **Anticipating Industry Shifts:** Proactively exploring ASICs also positions companies to stay ahead of major industry trends, including wireless power and communications standards, and battery innovations that enable smaller, more efficient devices.
- **Building Strategic Partnerships:** Engaging with ASIC design and manufacturing partners during initial feasibility assessments can help teams to evaluate trade-offs in size, performance and cost while ensuring that long-term supply and manufacturability are built into the product roadmap. This foresight also supports more efficient clinical and regulatory timelines by reducing the risk of design changes late in the process.

ABOUT THE COMPANY

Cirtec helps customers bring therapies to market quickly and cost effectively, from startups to Class II or III medical device manufacturers. The company offers services

at every stage of the product development cycle, including design, development, pilot and clinical build, manufacturing and finished device assembly. Cirtec has a 30-year track record of developing medical devices fabricated under 21 CFR 820 and ISO 13485 quality standards. Cirtec helps customers bring products from concept to commercialisation on time, on budget and as seamlessly as possible.

REFERENCE

1. *"State of the U.S. Semiconductor Industry 2024". Research report, Semiconductor Industry Association, 2024.*

Andy Kelly

Andrew Kelly is a seasoned engineering leader with over three decades of experience in medical device innovation. As Director of Applications Engineering at Cirtec Medical, he leads Cirtec's efforts to define ASICs that use the latest technologies and Cirtec's IC design expertise to provide optimised solutions for novel implantable medical devices. Mr Kelly plays a key role in bridging the gap between customer needs and engineering execution, overseeing application development from concept through commercialisation. His leadership ensures the successful deployment of neurostimulation, drug delivery and other advanced therapeutic systems that meet rigorous performance and regulatory standards. Prior to Cirtec, Mr Kelly held various senior engineering roles within the medtech industry, with a primary focus on ASICs for medical devices. Throughout his 35+ year career, he has defined and designed more than 40 full-custom mixed-signal ICs for a wide range of portable, wearable and implantable medical devices.

T: +1 480 200 0650
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