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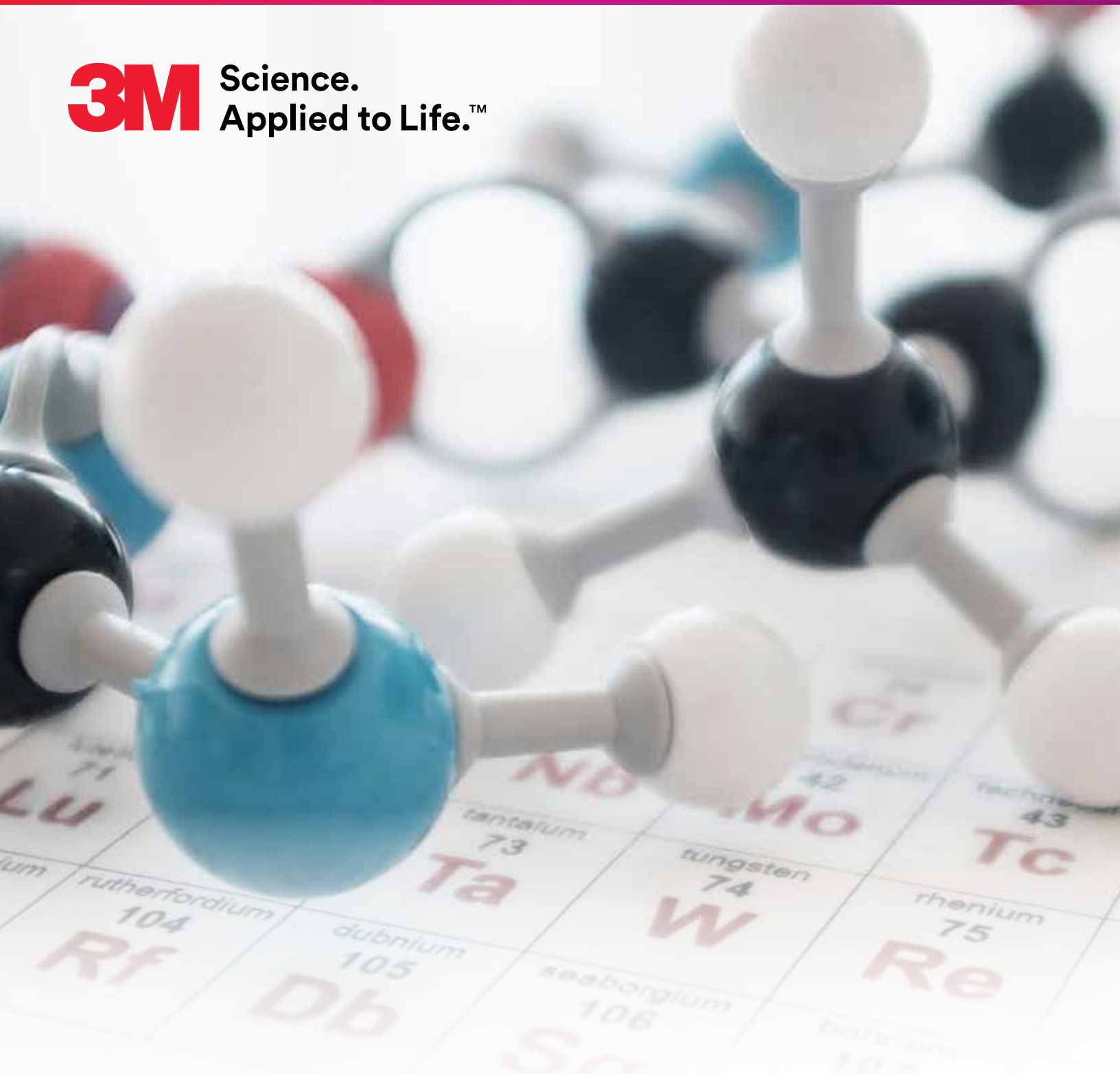

A Peek Inside the Lab: Top Tips Learned from Innovating on a Deadline

Medical Materials & Technologies

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Innovating on a deadline

Mercury is the planet with the shortest year. It swiftly orbits the sun every 88 Earth days, and because of its proximity to the sun, eccentric orbit and lack of atmosphere, it creates an extreme environment that'd take a lot of adaptability to survive.[1]

It sounds a lot like developing a new product.

It almost never seems like there is enough time, and the nature of the job requires the entire development team – from engineers to project managers – to adapt every day, sometimes every minute, to what's being learned and what's evolving.

It feels especially true in the medical device world. The demand for accurate, real-time data and less interaction with medical devices is becoming the standard expectation from users. It puts pressure on developers and manufacturers to design devices that continue pushing the boundaries of wear time and that truly integrate into people's lives.

It's a challenge, but it's also an immense opportunity.

We hold the power to help change the trajectory of a person's life. From reactively dealing with a condition's effects to proactively managing symptoms – to living an active, independent lifestyle. They keep components adhered together and the device attached to the user's skin.

As adhesive experts at 3M, we take our role in the device stack to heart. So in the spring of 2021, we embarked on a journey to develop an entirely new adhesive and do it in one year – a Mercury-like orbit, indeed – to improve wear-time capability.

What follows is a peek inside the lab – a recounting of our most notable successes, trials and tribulations, as well as learnings. We share them with the hopes that they will help you in your next product development process.

The blueprint for development

Setting out to create a new adhesive – and do it in a year – felt like an exciting challenge. It was exhilarating to know we were attempting a feat that hadn't been done by us before, and it felt daunting for the same reason.

We were aiming to develop a brand-new adhesive that'd be capable of adhering to skin for up to 21 days. It needed to be comfortable, biocompatible, reliable, aggressive so it withstands the daily tribulations of an active life and yet gentle.

User experience had to be superb.

The vision was intentional. With a longer wear time comes the potential for better health economics and more data. More data can mean users have more informed discussions with care providers. More informed discussions can make for smarter, proactive decisions to manage health.

What added a level of complexity was the COVID-19 pandemic. Hurdles like limited availability of clinical trials due to pandemic safety protocols were variables in our ambitious timeline that we'd

COVID as the backdrop to innovation

with Del Lawson

The realities of living in a pandemic had a deep influence on this project. That will likely be the case for many products developed during this time, but it was felt acutely across the team in this instance because of our timeline. It wasn't all negative, though. The pandemic also gave us what was most critical to making the entire project happen – the tools for global collaboration.

have to navigate. It also surprised us with unexpected positives, like increased collaboration capabilities and limited access to on-skin clinicals forced the team to improve laboratory test methods.

To help us reach success, we kept our list of priorities narrowed to what was going to be most important.

Quality over speed

The timeline was our map to the finish line. While we were going for a Mercury-like orbit, speed could not be prioritized over quality (the timeline would be moot if what we produced didn't actually work, after all). We started with when we wanted to launch and worked backward from there, prioritizing what would fit and eliminating what would not.

Through the innovation process, we had to consider how the adhesive performed, and if there were areas to gain development momentum without sacrificing quality to achieve our accelerated timeline.

This made for an intentional teamwork approach that also provided a level of in-the-moment flexibility we knew would come in handy.

Successful performance indicator one: Skin health

There's a big difference between medical adhesives and industrial adhesives. For industrial applications, an adhesive is considered successful if it takes chunks of the substrate with it during removal. Medical adhesives are a stark contrast. This is because they're often adhered to skin, a unique substrate with its own set of characteristics.

Skin is a living, breathing organ that grows hair, expels moisture, produces oil and regenerates itself every 14-21 days on average.[2] It protects the body from environmental harms and regulates temperature. As the largest organ, skin has many duties to fulfill to keep bodies healthy.

If too strong of an adhesive is adhered or removed too soon or incorrectly, the skin's integrity could be compromised. If the adhesive

isn't sufficiently breathable, skin can macerate, breaking down from being too waterlogged. Each of these could lead to additional issues, especially if the user has a condition that can affect skin, such as diabetes.

When we set out, applying this knowledge to how we wanted the adhesive to perform was a given. At the end of the day, the adhesive had to be gentle towards skin. If it wasn't, we didn't care how long it stuck – end-user safety and compliance is what's best for everyone.

Successful performance indicator two: Wear time

A seemingly easy way to achieve a long wear time is by using the strongest adhesive to stick your device to the body. Then once it's adhered, it's there until the device needs to be swapped out or removed.

But does the adhesive have a breathable backing? Does the lifetime of the device and the lifetime of the adhesive match? How old is the end-user? Would you describe the skin where the device is adhered as thin and delicate? Sturdy and elastic?

Depending on how these questions are answered, the device could be over-designed. And if someone experiences pain from a device's adhesive, they're less likely to wear it again or recommend it to others.

Finding a way to balance the importance of skin health and skin's uniqueness as a substrate with meaningfully extending possible wear time became our mission.

Going all in

This project stood out. As engineers, scientists and the lab team, we're typically working on multiple endeavors at once. But to be successful on the timeline, we knew we needed a dedicated, cross-functional team committed to the work.

One part of the team was based in Japan, and the other in the U.S., making it so the project was being worked on virtually every hour of the day. Management helped keep the team protected from other distractions.

Staying motivated on a timeline

with Yasuhiro Kinoshita

The tighter the timeline on a project, the clearer it is on what needs to be done, and I was in a situation where I could just push forward without thinking about anything extra. I was also really happy to work with excellent team members beyond Japan. Every day there are new findings and progress, and every day there are some troubles and failures. I couldn't find any reason for losing motivation. This project was just exciting for me.

While we believed in what we were doing, it was stressful and scary to go all in. We wondered whether we'd be able to fit everything in and if we were asking too much.

We had strong motivation, though. The wholehearted belief that people deserve better experiences with their devices, and our role within making that happen, was a driving force. Every day was a new adventure with new learnings and new opportunities.

Top four lessons learned

Not a project goes by where something is not learned. The unique circumstances of this one – the timeline, the pandemic, the team, our motivation for making it happen – created lightning in a bottle. Learning had to happen and changes had to be made, and both needed to be done quickly and thoughtfully. Throughout the entire year, four lessons stood out the most and were themes throughout development.

Lesson one: A longer wear time means more variables at each stage of life

The longer an adhesive spends on skin, the longer each stage of its life becomes. In development, a longer lifespan means problem-solving for more what-ifs, including new ones that may not have been encountered or required as much dedication before. In the end-use setting, it means the adhesive must make it through each stage successfully so data can be collected and the device can fulfill its intended purpose.

Beginning: Application

If an adhesive is applied incorrectly, we can't expect it to perform. The challenge is that perfect application doesn't always happen in the real world. People are busy – caring for loved ones, picking their kids up from school, balancing work priorities with life priorities – or they may not know how an adhesive should be applied for optimal performance.

Development needs to take real life into account. Testing different ways of application and correlating performance, and then finding ways to incorporate what's learned is one way to account for real life.

Middle: Maintenance

The middle of an adhesive's life is particularly interesting. Performance during this time dictates whether what the adhesive is adhering will make it to its intended length of wear.

It's where life really starts to seep in, with all of its what-ifs. What if the device needs to be removed partway through the adhesive's lifetime? What happens to skin then? What if it gets bumped on a doorframe, caught on a shirt, or soaked in a pool?

People want to know what's going to happen, and engineers need to try to find the answers. Simulate the most influential what-ifs in the lab so you can maintain apples-to-apples comparisons while still trying to solve for unknowns.

End: Removal

Just as meticulous applications don't always happen in real life, the best approach to removal isn't always followed either. In development, finding the end point and an intuitive, safe way to remove an adhesive and what it's adhering is a challenge too.

It's at this point we're able to understand how the skin underneath was doing and whether it remained healthy and unharmed. When testing, look to see if any irritations occurred as well as vet different removal approaches. Both will help influence overall performance.

Lesson two: Never design in a vacuum

Another way to bring real life into the development process is by asking for feedback. Customers, end-users, clinical trial participants, mentors – whoever it may be who will give you honest, realistic feedback.

Doing it early and throughout development will be your best bet to be able to pivot. In early conversations, ask substantive questions

The grip and the guts
with Audrey Sherman

A phrase we lived by during development was that we need the grip and the guts. Both are needed, and they helped us determine the ultimate performance. If the adhesive doesn't have grip at application, it doesn't matter if it has guts, or the potential to stay adhered for a long time. It speaks to the importance of finding how best to apply an adhesive to set it up for success throughout its lifetime.

about what functionalities are needed the most and to understand the end-user's skin. Questions throughout development can then focus on whether the device is meeting those criteria.

Try to proactively identify points throughout the timeline where it would be most critical to get feedback, and then integrate those questions into existing meetings if possible. That makes for a more efficient approach for the people whose perspective you're asking. If a new meeting needs to be scheduled, identifying those early and in advance will demonstrate a thoughtful approach and that you value their time.

While it's yet another item to think about in the beginning, it helps inform what needs to be left on the cutting room floor quickly.

Lesson three: Lack of availability of clinical trials is an opportunity

Clinical trials are immensely important to be able to gauge how a product performs. Finding trial participants that fit the needed criteria is always a challenge, and the realities of COVID-19 has made it even more so. It forces you to get even more selective on which product candidates you put forward.

While we were developing the adhesive, we had no access to clinical trials until halfway through the timeline due to the COVID-19 pandemic. We pivoted to bench testing beforehand, finding ways to simulate skin and gather what data we could. But they are not perfect. It can be difficult to estimate actual performance, but it still put us in a smarter position when clinicals became available. Three candidates were put forward because we knew we could pivot to any one of them.

That said, always use a control when testing. Even though it takes up a spot on the body, which are a premium, you won't have anything to compare against. It'll be hard to know the impact of the results.

Lesson four: Collaborate, collaborate, collaborate

It's true the pandemic has changed a lot. One positive affect it has had is pushing companies to integrate digital tools that enable collaboration. Video meetings, digital workspaces and more make it incredibly easy for teams across the world to be in the "same room" and work on the same project at the same time. Or even different times – it's still functional because teams can see what others have updated, learning from colleagues and building on what each person knows in real time.

Being able to do that as a development team that spanned continents made all the difference. It is what made our timeline – and the new adhesive – possible.

Even if you aren't collaborating across the world, find ways to collaborate with others, especially those with different experiences and knowledge. What's being built gets the power and benefit of more real-world experience put into it. Ask a mentor, a clinical expert, a business leader, another engineer. Each will bring unique perspectives to round out what's getting created and gives ample learning opportunities to be smarter for the future.

Collaboration accelerates development

with Yasuhiro Kinoshita

In this development process, we shared and built our plan together. We also respected each idea and work style and leveraged each strength. We learned from each other and improved our technology and teamwork. I don't think there is "their team" and "our team." We are one team.

Mercury's next orbit

We were able to make our Mercury-like orbit around the sun. A true challenge, it was an incredible journey that spurred innovation, collaboration and analytical rigor.

Future projects may not accumulate the same set of circumstances, but product development won't go back to what it was exactly pre-pandemic. It will keep moving forward. It will build on what happened last, spur deeper levels of partnership and chart a new path – all to advance the medical device world and improve the lives of those who need it most.

How will you make your next orbit a success?

If you're looking for more support on designing medical devices, download "The engineer's guide to wearables: Lessons learned from design mishaps."

References

[1] https://solarsystem.nasa.gov/planets/mercury/in-depth/

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