

INNOVATION IN CONNECTED INHALERS



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Mark is responsible for the Product & Health Solutions within Digital Health at TEVA Pharmaceuticals. Over ten years with TEVA and prior to that sixteen with AstraZeneca. Mark has held various positions including R&D Project Leader, VP Sales & Marketing, Strategic Planning & Business Development, and Global Brand Lead. Graduated in Aeronautical Sciences and completed his MBA at Durham University, UK. During his career he has led technology & especially inhaler development teams through engineering, CMC characterisation, clinical evidence generation, registration within US, EU and International Markets and ultimately to successful global launch. Total Brand Leadership value >\$2.5bn. Mark has numerous patents granted and pending in electronic communications, sports technologies, inhaled pharmaceutical development, and respiratory physiological function & predictive AI. Mark is the inventor of Digihaler®, the first FDA approved digital inhaler with built-in sensors.

Could you describe the current focus of your work in connected inhalers?

I defined and wrote the specification for our FDA approved digital inhaler. I remain responsible for further product definition and market development. New technology offers different, and in many ways faster innovation cycles and the goal is to make improvements for key stakeholders.

What are the key benefits of optimising digital devices? What makes technological advances in this area so exciting?

Multiple benefits for the three key stakeholders being patients, clinicians and Society – direct and more real-world engagement with patients, in-situ and in the moment of relevance. Good, i.e. high fidelity and highly usable, technology should be able to live with patients and therefore tell us totally new things and test known beliefs and hypotheses.

What have been the biggest challenges that you have faced when developing inhalation devices?

Going in a different direction from competitors and researchers meant winning internal support, or working out acceptable ways to 'skunk'. Secondly, regulatory approval while standards and approval paths were yet to be fully defined.

What are some priorities for your work on developing connected inhalers over the next year?

I believe my priority over the next year will be delivering top-quality total experience considering at least three elements of hardware, software and humanware across the US, EU and the rest of the world.

How are current regulations on inhaled therapies and devices impacting your research?

They are our daily work and represent a shifting and developing landscape that in some cases we need to co-define with stakeholders. They represent a 'limitation' and also a welcome high standard to ensure mainly seriously committed companies enter and succeed.

Why is improving patient adherence and technique such a key focus within the inhalation industry?

They are 'surrogates' or 'lead indicators' towards real improve in outcomes. As such they appear important but only for the outcomes that sit behind them. Despite >40years we've not shifted outcomes such as disease control enough and for enough people. There is still much to do and these two factors may lead to true change.

How do you see the inhalation field developing in the future?

I see greater segmentation and differentiation overall. The ability to personalise will become increasingly real. Greater technology advances will be introduced, but unless they are based on true patient/stakeholder needs and mainly passive collection, they will fail to make a meaningful impact. Prices will reduce for 'standard' inhalers through loss of exclusivity and general pricing pressures to release resource and budget towards true value-based innovation. The total inhaled market will continue to grow in accordance with population and urbanisation. Microelectronics and new analysis techniques like machine learning and artificial intelligence will sit at the heart of what we can learn about a patients every-day, and therefore what we can do to make it better.

Mark will be speaking on "Connected Inhalers" at our 5th Annual Inhalation & Respiratory Drug Delivery Congress, 22-23 April 2020, London, UK.