PRESS RELEASE

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MAPPING THE FLOW: Industrial process specialist models Ziccum dry powder vaccine methodology

Dr Anton Löfgren is an industrial process engineer specialising in unit operations in pharma manufacturing. For four months he visited Ziccum to develop mathematical models of Ziccum's LaminarPace vaccine air-drying methodology for future industrial application and design. What is his view of the viability of ambient air drying on an industrial scale, and – if the method is as simple and scalable as claimed – when can we expect to see uptake?

Dr Anton Löfgren is a graduate from the Faculty of Engineering at the University of Lund and the author of *Downstream processes for next-generation biologics.* He is now completing his project at Ziccum AB developing 2D and 3D mathematical models that set parameters of the system's air flow for future industrial design and development. As a biotech engineer Löfgren has modelled a wide range of industrial pharmaceutical manufacturing processes before including chromatography and membrane processes. This is the first time he has worked with ambient air drying connected to pharmaceutical production. As a previous collaborator with scientists from Novo Nordisk, Swedish Orphan Biovitrum and others, how has he found the novel process and what did he expect?

> ***"Ambient air drying could clearly be an efficient industrial process and I think it would be relatively easy to scale up"*** Dr Anton Löfgren, *industrial process specialist pharmaceuticals.*

"I had no preconceptions about air drying for pharmaceuticals. Obviously, I was interested because it is a new technology, but I've found it is a relatively simple concept and I think it is a smart, effective process. I think LaminarPace is definitely on its way to becoming a mature, stable system and as a potential industrial process it is energy-efficient, achievable and a good idea. We need to know the flow rate settings and optimal parameters, which is why I'm here, and in industrial pharma production validation, quality control and so on is a long process – but the basic principles are sound, and it is a strong idea."

How do you expect the model you are developing now to be used? "The model is about helping us find the optimal running conditions and to start with it will be a big help for development purposes and in the industrial design area."

What kind of timescale do we see for adoption of new production processes in pharma manufacturing? If, as has been said, the ambient air-drying process itself is comparatively simple, why is innovation and uptake of new process in production often slow?

“I covered that question in an entire section in my book” Löfgren says. “In large-scale pharma manufacturing the cost driver is not efficient production, it’s time to market. If a manufacturer has spent 10 - 15 years developing a new drug, they just want to get that drug to market as quickly as possible. So, freeze drying for example, may be expensive, it may not be fantastically efficient – *but it is well-established*. Novel relatively untested production methods are always going to face obstacles to fast adoption. However, given our models, this could clearly be an efficient industrial process and I think it would be relatively easy to scale up. The key issue will be who takes the first step. I think once it has been seen to perform successfully in one facility, uptake could be very rapid and you could see a large number of manufacturers choosing it even within a couple of years. If ambient air-drying produces vaccines that can get to wider markets faster manufacturers will quickly realize they can’t afford not to use it. At first, initial adoption could take time - but then we could very well see wider uptake more quickly.”

In parallel with the modelling work Ziccum has upgraded and improved features on a new LaminarPace rig in Gothenburg, with a larger array of sensors. “We will then have additional humidity, pressure, temperature and flow rate sensors” Löfgren says, “the extra data from these will contribute to and verify the models of the flow and temperature behaviour in the centre of the drying chamber. The modelling has already uncovered important insights into the central features of the air drying – and if anything I think it has confirmed the essential simplicity of the central concept.”

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About Ziccum

Ziccum develops new thermostable versions of the world's most urgently needed, life-saving vaccines. The Company's patented technology, LaminarPace, enables the production of new, gently air-dried formulations that can be transported easily and cost-effectively, with no need for a costly and complicated cold chain, all the way from the factory to the last child in the last mile of the supply chain.

Image Attachments

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