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# Process Intensification: Sustainability and its Impact on Process Efficiency and the Environment

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## ABOUT

Andrew Sinclair is the president and founder of BioPharm Services. In this presentation, Andrew and John Bonham-Carter, Vice President of Erbi Biosystems, discuss how process intensification and sustainability are connected.

**Andrew Sinclair,**
**President and Founder**
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**John Bonham-Carter, VP Business Development and Product Management,**
**Erbi Biosystems (now part of MilliporeSigma)**

*John Bonham-Carter: I'm very happy to introduce Andrew Sinclair to have him explore a new area—sustainability and how it impacts our industry. Andrew, the word sustainability is quite broad. Let's start by defining what you mean by sustainability within bio manufacturing and why is this now becoming important?*

Andrew Sinclair: Well, it is all driven from the interest by the global community on how we manage global warming. If you look at COP26 (the most recent UN climate change conference), it talks about sustainability. There are two key points that have an impact on what we do as an industry. The first relates to global net-zero by mid-century. The reason that is set as a target, is to keep global warming within the 1.5 degrees Celsius range. The second is to protect communities and natural habitats.

If you look at the US and Europe, we've seen the incorporation of the sustainability objectives in legislation and government policy and have seen it feed down the supply chain. The National Health Service in the UK has net-zero requirements which they're going to ask all suppliers to commit to. That means if you're supplying pharmaceuticals or components to the NHS, they will want to see that your organization is meeting the requirements of net-zero, or are on the road to that.

All the major pharmaceutical companies have in place environmental sustainability programs: GSK is committed to hitting net-zero by 2030; Abvie has a net-zero waste to landfill by 2035; and Novartis is set to reduce water consumption in all its operations by half by 2025. This is really the background to which we

are developing our products. This means that as we develop and optimize our manufacturing processes, we have to know how these innovations are helping us meet sustainability goals.

*JBC: Just to be clear, when you mentioned GSK and we talk about net-zero, we're not just talking about them, it is them through their supply chain. They are going to enforce net-zero through their supply chain. Is that correct?*

AS: Yes. There are what are called scope 1, scope 2, and scope 3 emissions. Scope 1 are those emissions that a company is adding—energy and resources. Scope 2 is the translation of those into carbon that is associated with electrical energy supply. And scope 3 looks at the whole supply of materials coming in, and the emissions associated with them. The goal of a lot of organizations is to look at scope 1 and scope 2 with regard to their own operations, and then to require their suppliers to start meeting the requirements of net-zero to address scope 3. That's how it is trickling down through the supply chain.

*JBC: When we think about a bio manufacturing plant, there's a huge amount of water involved, there is clean-room space, and various electrical appliances. What does this mean in a manufacturing process in terms of sustainability? Can we link these two things together?*

AS: Sustainability, in some sense, has gone back a long time. I was heavily involved in studying, in the early 2000s, on the adoption of single-use technologies. A lot of people running facilities were focused on the amount of plastics we were handling in the move to a single-use paradigm. What they'd forgotten was that stainless steel facilities use a lot of water for cleaning equipment. No one had considered we were making very significant savings in water consumption. But you were also generating this plastic waste stream. That was a very good example of technology adoption, where people were raising environmental concerns, but when you actually looked at them, it was much more complex. Just to give you a feel, my product, made in a stainless steel plant at that scale, used about nine liters of water per gram of product, and over half of that water was CIP-related. Replace that with single-use, and you're stripping out about six liters of water compared to the original nine. So you're reducing the water load and the CIP chemical load, but at the same time you're adding about 80 grams of plastic. That's the offset. In tangible terms, when you look at the inputs in terms of materials, you can start to analyze the impact of that technology on the process. That was the starting point in 2002, and that's something that is playing out now when we think about process intensification. Because what process intensification is doing is trying to look at the way we use materials and facilities more efficiently.

*JBC: You talked about water, which to a large degree is something we take for granted. But as climate change starts to impact water availability in places like California or Texas or certain parts of southern Europe, or Asia, that's going to become a real issue. In the next decade or so, might this become a key decision point about where you manufacture and how you manufacture?*

AS: We require maybe 5,000 or 9,000 grams of material per gram of product. If we contrast that with an API, a small molecule, pharmaceutical API that requires 100 grams of material per gram of product, we're orders of magnitude different and a lot of that is driven by water. So if you take a six-pack stainless steel plant, 15,000 liters, that's going to require 27,000 meters cubed of water per year just for the process and cleaning. It's a lot of water for a small amount of product and what we're doing in reality is extracting this water from the environment, purifying it to a very high level, pushing it through our process, and then throwing it away, basically, into the water systems. It is a very wasteful way of thinking about how we use water. In places like

California, or India and parts of Europe, a lot of their natural water sources are going to decline due to global warming. So it is a big issue. Something we should start thinking about now is how much more do we know? How do we intensify our processes? How do we produce our water? Then how do we use our water more efficiently and is there a way to recycle some of this water, or reusing through the process ?

*JBC: In process intensification, we are trying to get more out of less for whatever unit operation we're looking at. But is water the key? We've spoken about it quite a bit. Or are there other ways that sustainability and process intensification are linked that we need to start thinking about?*

AS: We can look at sustainability from many angles. Material use is one aspect. There is a simple metric that's been developed by the industry called the process mass intensity index, which is just that ratio of how much stuff goes in, to what comes out. But also there are net-zero requirements being imposed. That means we have to look at net-zero as it applies to new manufacturing processes: how much energy we are using, and how we made that energy cleaner.

People who design buildings are always looking at more efficient ways of using energy. But we haven't really looked at it from a process perspective. The key metric for processes is making them more intensive. If you take a meter-cubed cleanroom, the building designer will ask how energy efficient can they make it. We're looking at a different question, which is, 'how do we make more material or more product out of that one-meter cubed cleanroom?' That's where process intensification comes in. Our user base has been very interested in driving us to generate outputs that measure total energy use. The challenge is it's very easy to measure the process energy use, but it's a lot more difficult to estimate a cleanroom's energy use over a year. Sixty to 70 percent of the energy use of a facility in our industry is associated with the cleanrooms. So you can measure your processes, but that's not giving you a real picture.

What we can clearly see in the analysis we've been doing, is that process intensification has a significant impact on facility productivity in terms of grams of product or doses of product made per unit volume of cleanroom, and this translates into less energy use. Now, the absolute value of that energy use will depend on location. A key challenge with net-zero is what is your electrical supply? If you're in a location where the electrical supply comes from coal power stations—places like India and parts of Germany have high potential for coal—then you're not going to get to net-zero easily using those supplies of electricity. Which means you then you have to think about a renewable component. Some of the work that Genentech has been doing, for instance, is to invest in solar arrays to decarbonize their operations.

*JBC: Essentially, you're making the link that any process intensification, if it achieves some goal, is going to have benefit. But what are the steps a company can take to either learn more, or start acting on it?*

AS: One of the first key metrics that was developed at the ACS was this process mass intensity (PMI) index. That's a core indicator of sustainability in the sense that the goal is to get your PMI as low as possible. The second goal is then how compact can you make your process. What we see as important when you're starting this journey, is to set a baseline, identify your key KPI of interest and then set targets for your process development. Then, using models, get that understanding, evaluate your tech options, and feed that back into development as an iterative process.

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This case study was presented at Evaluating Biopharma's Process Intensification: Improving the Process Status Quo virtual networking and educational event which included two additional presentations and two interactive networking sessions.

Details of future events can be found here.

You can watch Andrew's presentation in full and on-demand here.


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