Embedding Sustainability in Engineering Education through Interactive Industrial Design Case Studies

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Abstract

The need for the integration of industrial concepts and applications of sustainability in engineering education is a priority for universities and especially for engineering courses. To deliver the concepts and benefits of sustainable engineering design to students requires something more than just a theoretical overview. The use of case studies in engineering education is well established and a mature concept. The scope and criticality of sustainable development is increasingly complex and diverse and continues to change and adapt as the climate crises deepens.

The biotechnology industry is perhaps the youngest of all of the process industries and is changing and adapting rapidly. Combine these two changing dynamics and the result is a compelling argument for interactive design case studies.

The design of a manufacturing process within the biopharmaceutical industry is based on various criteria such as capital investment, operating costs, process reliability and safety with an overarching focus on patient safety. While environmental impact and sustainability is a critical area from a global perspective, it has not been a key consideration within the industry with relatively little research into the environmental impact of adopting different processes and technologies.

There is a growing demand for multiproduct, flexible facilities with approaches such as modular strategies facilitating easy adaptation for different processes. This places an increasing emphasis on support services such as buffer preparation, where overheads are increasing and bottlenecks are developing. The supply of buffer solutions in particular, accounts for a large proportion of a facility's footprint, labour, equipment and operating costs. To alleviate the potential bottlenecks, reduce the impact on capital and operational expenditure and improve sustainability, alternative philosophies for buffer management must be considered.

Buffer preparation offers an ideal opportunity for collaboration with case studies as it represents a common problem within the industry in a non-competitive space, which has a clear demand for fresh thinking. While there are significant variations in core process technology, buffer preparation remains a key aspect of facility design across differing modalities.

This research aims to demonstrate the benefit of exploring the industrial sustainability design space in conjunction with third level engineering education. This synergy with utilise Interactive Design Sessions utilising approaches such as Finite Capacity Analysis to demonstrate the environmental impact of operational strategy and technology utilisation (such as Single Use Technology and inline buffer preparation) on buffer preparation within the biopharmaceutical industry, highlighting the synergy between more sustainable production and a reduction in the cost of manufacturing.

Keywords: Engineering, Education, Sustainability, Biotechnology, Finite Capacity Analysis, Buffer Preparation, Flipped learning

1. Introduction

The environmental impact of the biopharmaceutical industry is significant given the considerable usage of water, energy and raw materials. The waste to product ratio of the biopharmaceutical industry can be as high as 10,000:1 which demonstrates extremely poor efficiencies when compared to the traditional chemical industries. (Martin, 2016)

Water usage is particularly challenging given the cleaning and sterilisation requirements necessary to meet the exacting regulatory standards. For a stainless steel facility, it has been estimated that around 100,000L of water is consumed per batch at the 2,000L Bioreactor scale. (Sinclair, Leveen, Monge, Lim, & Cox, 2008) Given the scale of the industry globally with more than 16.5million litres of active production capacity, the impact should not be understated. (Rader & Langer, 2018)

The advent of single use technology has resulted in considerable reductions in water usage globally, lowering the carbon footprint of biopharmaceutical manufacturing (Rawlings & Pora, 2009) (Pizzi, Flanagan, Pietrzykowski, & Brown, 2014). Despite the improved sustainability performance, there has been a consequential increase in the quantity of plastic waste generated by the industry. It is estimated that 30,000 tonnes of plastic waste are disposed of to landfill or incineration each year. (Ignacio, 2013)

The definition for sustainable development provided by the Bruntland Commission Report states "development that meets the needs of the current generation without compromising the ability of future generations to meet their own needs" (WCED, 1987). There are three core issues associated with sustainable development, economic growth, environmental protection and social equality. (Mensah & Casadevall, 2019)

The biopharmaceutical industry presents positive metrics with respect to societal sustainability with novel healthcare products, eradicating some very challenging medical conditions and increasing life expectancy. However the industry also has a large environmental impact. With an increasingly aging global population, demand for healthcare services including biopharmaceuticals is unprecedented (Paul Kowal, 2012). A key concern is the affordability of healthcare products. (Wise, et al., April 2018) Increased sustainability may be used to lower costs through resource efficiencies but also can act as a platform to drive innovation. (Biogen, 2016)

It is imperative that the business case for new technology and innovation is used to drive sustainable development. In the design of a manufacturing facility, key considerations are, capital investment, operating costs, process reliability and safety with an overarching focus on patient safety. Although environmental impact and sustainability is a critical area of attention from a global perspective, it has not traditionally been seen as a high priority within industry.

Through the development of innovative technical solutions, the engineering profession will play a significant role in addressing the challenges associated with the climate crisis. This change in fundamental attitude needs to start within the education system. As a means of accelerating the influence of sustainability ideologies on industry and society, both parties must work closely together.

While sustainability in education is generally regarded as a priority for universities, manufacturing companies have raised concerns that sustainability has not yet effectively branched into mainstream chemical and biological science programmes. (Biogen, 2016) This highlights a gap in thinking between academia and industry, which must be bridged to accelerate change. Within the university environment, sustainability is regarded as the only priority, whereas within industry, wider economic and practical considerations must also be accounted for. For universities to foster an enhanced and genuine awareness of sustainable development requires closer collaboration with industry via the sharing of real world design issues.

This increased collaboration benefits industry with new generations of innovate engineers who have sustainability as an underlying principle guiding all design. This approach can drive innovation from the bottom up and also increases student's readiness for the workplace given the familiarity with real industry problems.

The use of case studies in engineering education is well established and a mature concept with a number of demonstrable benefits including increased critical thinking, connections across multiple content areas while fostering an increased grasp of the practical application of engineering knowledge. (Aman Yadav, 2007)

To truly improve understanding of real industry problems, a shift in the way they are approached in academia could offer significant opportunity. Rather than the traditional lecture format, flipped learning offers opportunities for more engaging active learning and detailed interaction with the problem statements.

Buffer preparation represents an ideal opportunity being the largest constituent by volume in the manufacturing process. Buffer solutions are separated from the core process and represent a common problem area in the industry in a non-competitive space. Manufacturing companies are becoming increasingly collaborative and willing to publish and share data which only serves to increase the potential for closer relationships with academia. This willingness is demonstrated by the close collaboration of manufacturing companies with organisations such as BioPhorum (BioPhorum, n.d.).

2. Flipped Learning Approach

Tracing origins back to a model of "peer instruction" implemented at Harvard University in the 1990's, the use of flipped learning is increasing in prominence in higher education (Crouch & Mazura, 2001) (Hwang, Yin, & Chu, 2019). Flipped learning involves the delivery of teaching material ahead of time, freeing up the class time for engaging collaborative activities.

The use of flipped learning provides an opportunity to combine various pedagogical philosophies incorporating traditional instructional lectures with an active learning approach (Karabulut-Ilgu, Jaramillo Cherrez, & Jahren, 2018). In line with the principal of reduced cognitive load, students are able to work through the material ahead of the class, which furthers the potential for learning within the class (Seery, 2015).

The use of flipped learning has been demonstrated to increase peer interaction and allow a deeper engagement with the material, facilitating more complex discussions and interactions in the class room setting. This furthers the development of essential professional skills such as critical thinking (Karabulut-Ilgu, Jaramillo Cherrez, & Jahren, 2018) (Seery, 2015).

Interactive design sessions based on the concept of flipped learning may be used to foster a greater level of integration between industrial concepts and applications of sustainability with university engineering courses. While collaboration between industry and academia is increasing in frequency and prominence, opportunities for further development and improvement exist.

External lectures from industry experts are frequently provided to engineering students. These typically follow the traditional lecture format whereby an overview of a topic is provided to the students. While this is engaging for students, the learning format is passive and interaction is relatively minimal. It is difficult for the students to digest the material in real time and actively engage with the subject matter. Given the availability of industry experts, follow up is minimal.

Through the utilization of a flipped learning format, students are provided the opportunity to acquire broad knowledge of the subject matter ahead of time. This allows the classroom exercise to delve into detail on specific topics of interest and practice and apply concepts to real world examples. The increased levels of interaction foster a closer relationship with industry and provide greater levels of understanding into the nuances and challenges of real world examples.

There are three essential stages to a flipped learning session

2.1 Flipped Learning – pre-class

The pre-class element of the flipped learning session is critical to the overall success of the activity. This provides the students with a framework and grounding in the subject and acts as a gateway to a rewarding interactive session. The use of video materials rather than written text for the pre-class learning has a positive impact on the readiness of students to actively participate and benefit from the flipped learning session. While written materials may be used, they should be supplemented with a general introduction at least in video format (Lee & Choi, 2019).

Critical success factors associated with pre class activities include the provision of clear and concise teaching material in a timely manner to allow paced learning with well-defined objectives and guidance. In the case of external lecturers, support should be provided by the academic staff in the preparation and outline of teaching material given the likely lack of teaching experience.

To promote engagement with the subject matter and critical thinking, a pre-class activity or assignment is desirable. Previous publications have demonstrated the importance of pre-class assignments to promote engagement with the subject matter and encourage critical thinking. The use of assignments act as a motivational factor and adds a level of accountability (Han & Klein, 2019).

2.2 Flipped Learning – in-class

It is essential the in-class learning builds upon any pre-class learning but should not be a simple replication. Regardless of the quality of pre-class material, there will be gaps in the students' knowledge. There is benefit in starting the in-class session with a brief overview with a view to tackling those knowledge gaps and addressing questions or uncertainties, which students may have.

It is essential that the primary focus of the in-class session is activity or project based. Through the use of real industry case studies, a problem statement should be provided to the students to resolve in a group manner. While the in-class element should allow space to approach the problem from multiple angles, it is important to have an overarching structure to the session in order to maximize the benefit to the students.

2.3 Flipped Learning – post-class

The engagement with pre-class material and interaction with in class elements will provide the student with a very good grounding in the subject matter and the potential industry applications. To reinforce the learning, it is essential to have a follow up to the topic which can be assignment/project based. The evaluation of assignment quality with feedback from industry experts will be used as a means of evaluating the efficacy of the teaching format.

3. The role of Buffer Solutions for the Biopharma Industry

Buffer solutions, used throughout downstream processing are critical to the biopharmaceutical industry, impacting on process robustness, product quality and yield as well as accounting for a high proportion of capital and operating expenditure (Gunter Jagschies, 2017) (Haigney, 2016). It has been reported that solution preparation for a biopharmaceutical industry represents over 20% of the facility footprint and overheads for larger manufacturing facilities (Langer & Rader, 2014).

In the drive to reduce the cost and thus improve availability of medicinal products enhancing the social sustainability, there have been considerable improvements to the efficiency of manufacturing processes. A great number of these improvements such as higher titre cell lines have taken place in upstream processing (cell culture) (Jacquemart, et al., 2016). As downstream operations are mass based, improvements to upstream productivity result in a proportional increase in the demand for buffers. This is illustrated in Figure 1, which illustrates the impact of scale, and titre on a typical Monoclonal Antibody manufacturing process (generated using The BioSolve Process software application from Biopharm Services Ltd).

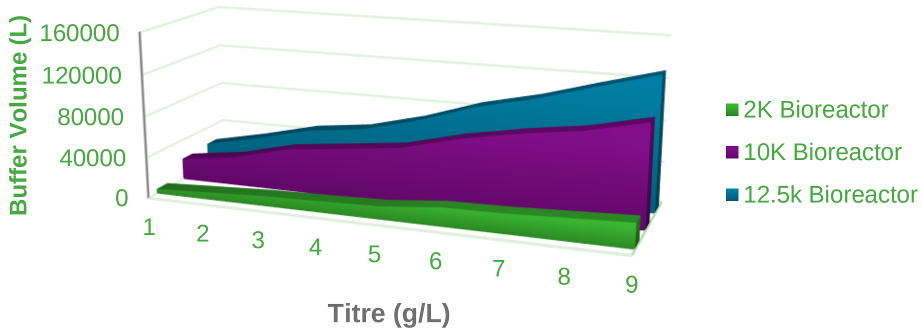

Figure 1: Impact of scale and production capacity on buffer demand per batch

To support the manufacturing process, buffer solutions must be prepared, transferred, stored and delivered to the process. There are typically three buffer preparation philosophies available to manufacturing companies.

- **Traditional Buffer Preparation:** Preparation of multi-component buffer solutions in fixed vessels or single use mixers at the required process concentration, which must be held in an intermediate storage system prior to delivery to the process.
- **Buffer Concentrates:** Preparation of multi-component buffer solutions in fixed vessels or single use mixers at a higher concentration than that required by the process, which must be held in an intermediate storage system and diluted prior to delivery to the process.
- **Inline Conditioning/Buffer Stock Blending:** Preparation of buffers inline from concentrated single component stock solutions at the final required concentration ready for delivery to the process equipment without the need for intermediate storage.

The overall efficiency and consequently sustainability of buffer preparation is significantly impacted by the overall solution management philosophy due to factors including technology selection, operational strategy and logistics and cleaning requirements for equipment.

- **Facility Construction:** Necessary buffer volumes associated with a buffer philosophy impact on overall facility footprint and energy loading to support the building.
- **Equipment:** The decision to use of fixed stainless steel (or higher grade alloy) vessels, single use equipment or inline condition systems has a direct impact on the raw materials required for fabrication, the ongoing utility demand associated with preparation and cleaning and the levels of solid waste generated by a facility.
- **Logistics:** Given the complexity and criticality of the logistics, the design of a buffer preparation area is typically based on design tools such as discrete event simulators or finite capacity scheduling tools. The buffer preparation philosophy and operational strategy have a direct impact on equipment requirements, headcount and hours of operation.

4. Application of Flipped Learning to Buffer Preparation

Buffer preparation offers an ideal opportunity for increased collaboration between industry and academia. The use of a flipped learning session based on real industry problems would increase student’s engagement and learning potential while at the same time encouraging an innovative mind-set, which can support process design innovation from the bottom up in the industry.

Industry involvement will be key to success. As preparation for the class exercise, it will be essential to develop concise training material, ideally in video format, which provides a broad overview of biopharmaceutical manufacturing, the criticality of buffer solutions and the various buffer preparation philosophies used by the industry, giving insight into the key sustainability issues. The use of industry experts as participants, the support of academic staff in the preparation and outline of teaching material will be important.

To encourage activate student participation and integrated group engagement; a pre-class assignment is provided. Various student groups will be assigned different areas such as facility design, equipment/technology, material and logistics, requiring them to collaborate and pool their information during the main design session.

The in class exercise will therefore be based on active integrated participation reflecting the way in which commercial design companies operate. While allowing time for an overview of the topic and provision of clarifications, it is critical that the exercise does not become a traditional lecture. The class exercise is to be based on a clear real world problem statement focused on improving the sustainability of buffer preparation through innovation while considering traditional drivers such as capital and operating costs.

5. Conclusion

To improve sustainability in the biopharmaceutical industry, there is a clear need for innovation and change in design thinking. A key factor in driving this change will be an enhanced relationship between academia and industry to drive industry change from the bottom up. Collaboration with industry will allow universities to experience genuine awareness of sustainable development as it applies to real world design issues, accounting for economic and practical design considerations also.

The flipped learning approach is an ideal methodology to develop this closer symbiotic relationship. Through participation based classes, active learning will facilitate critical thinking on real world design problems, resulting in more engaging complex discussions.

There are many opportunities to improve sustainability in the biopharmaceutical industry with buffer preparation being an ideal starting point. As a support function, buffer solutions are the largest constituents by volume in the manufacturing process and are a common feature across the industry regardless of modalities or processing technology. In conclusion, this research brings together a number of critical factors in a hitherto untried format: Industry, Education, Flipped Learning, Applied Design, Optimisation, Real World Metrics with enhanced sustainability as the overarching principle

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