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Challenges and Opportunities in Developing Project Management Decision-Making Tools

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Abstract: Including sustainability criteria for making decisions in project management poses challenges in the areas of bioenergy, biotherapeutics, and biomaterials. This is mainly due to chemical heterogeneity of bio-based materials, techno-economic feasibility, and triple constraint of time, cost, and product quality. However, bio-based technologies create opportunities as sustainable processes because they involve upvaluation of locally available renewable and biodegradable materials. This work was conducted to identify challenges and opportunities in incorporating project management tools in bioproduct development with the goal of integrating measurable sustainability criteria scores in decision-making. The scores or metrics from these tools can be used by project managers for decision-making in engineering process scale-up, evaluation of social impact, and commercialization of processing technologies.

Keywords: Triple constraint, bioenergy, biotherapeutics, biomaterials, techno-economic analysis, life cycle analysis, multi-criteria decision analysis.

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1. Introduction: Motivation and Scope

In research and development (R&D), project management (PM) decision-making tools are used to meet the customer's expectations on the triple constraint of making a product within specifications, budget, and processing time. For a bio-based chemical product, for example, PM tools and techniques are necessary to control the chemical process and chemical composition of the final product to meet customer's specifications; to comply with government regulatory standards on product quality, emissions, and disposal; and to claim it as a sustainable process from renewable resources. These tools and techniques result in desired outcomes such as patentable chemical process technology, manuscripts for submission to peer-reviewed journals, preliminary research data for proposals, reports to the funding agencies, reports for internal monitoring in their research institutions, and reports for contract research clients.

The practice of using PM tools can be linked to theories in both decision science and sustainability. Sustainability criteria can be included in the inputs during project planning while methods that measure sustainability can be part of monitoring and controlling a given process. Consideration of sustainability criteria in decision-making would add value for deliverables for project stakeholders during project initiation. In addition, the inclusion of sustainability principles in project management could prove beneficial for project commercialization as many countries offer incentives (e.g., carbon tax credit) for sustainable processes. This is particularly important for start-up companies that involve bio-based processes such as bioenergy, biotherapeutics, and biomaterials production. However, claims of sustainability (i.e., in patents or publications) of these processes should be quantitated and reported in terms of measurable sustainability attributes, which is often a daunting task.

Several commonly used PM tools and techniques are considered and discussed in this paper based on expert judgment by project managers during project initiation, planning, team building and training, communication, management of data systems, and documentation. Common experiences across bioproducts and bioprocessing industries and technologies in which PM tools are used were gathered from available literature (Ph.D. dissertations, research articles, industry reports, government agency reports, and other literature available to the public). Although not explicitly reported in the scientific literature or publicly available documents, most R&D institutions use meetings, conferences, and workshops as communication channels in and outside the project team, online and posted dashboards for communication within interdependent project groups, online instrument and equipment reservation systems, experimental data collection in computer databases and laboratory notebooks; as well as lessons learned through surveys and exit interviews for continuous improvement. Scientific and technical journals have opinions and commentary sections where these PM experiences are shared to provide insights and advice for other practitioners.

The published case studies are also presented in terms of factors for decision-making, planning, problems encountered, and lessons learned. The latest important issues on the benefits, barriers, challenges, and opportunities for tailoring PM decision-making tools are also presented for developing sustainable materials and process technologies.

This work was conducted with the overall goal of identifying challenges and opportunities in sustainability measurement in bio-based processes and how sustainability metrics can be incorporated into commonly used PM decision-making tools and techniques. This can be utilized during product ideation, proof-of-concept demonstration, process engineering scale-up, training of technical staff on specialized knowledge, and evaluation for commercialization of emerging technologies.

More specifically, this work aimed to: (1) link decision science theory and sustainability principles to the practice of using PM tools (Section 2); (2) compile case studies that include sustainability in PM (Section 3); (3) identify methodologies for measuring sustainability criteria from reports on bio-based processes and products R&D (Section 4); and (4) recommend PM decision-making tools that incorporate sustainability criteria in bioenergy, biotherapeutics, and biomaterials R&D projects (Section 5).

2. Decision Science Theory in PM Tools and Techniques

Decision-making can be guided by scientific theories which can be linked to tools and techniques in the practice of PM. One of these theories involves the 4Rs in human decision-making for consumers and marketing managers (Hamilton, 2016). The 4Rs model identified four key theories that can be applied to PM concepts: reference, reason, resources, and replacement. In the context of PM, the reference points are based on expert judgment, lessons learned and organizational process assets that influence decisions of team members or managers. References can also be the inputs to the project charter and PM plan. Reasons involve what the project manager chooses based on the most important attribute, which may be cost, time or quality. Resources in the science of human decision-making are based on a more thorough assessment of the information with the use of heuristics to focus on several aspects and ignoring the impact of other factors. For example, resources would be allocated in a work breakdown structure (WBS) based on the technical deliverables in an R&D project. These resources are time, cost, human resources, chemicals, processing equipment, computer hardware and research data management software. Replacement involves gathering information from stakeholders, making estimates for cost and time, estimating the likelihood of success, identifying risks for the triple constraint, and using a simplified strategy or approach to make a better final decision (Project Management Institute, 2000).

With regards to decision-making in R&D projects, the replacement of existing technologies with other alternatives may be chosen because of their lower environmental burden, higher benefit-to-cost ratio, and social equity, transparency or accountability. Respectively, these can be implemented using life cycle assessment (LCA) impact category metrics, financial indicators from techno-economic analysis (TEA), and human resource, communication planning, and procurement planning tools and techniques. However, these tools of sustainability assessment would take more time, cost, human resources, and communication methods to implement and would involve more complex interrelationships among project constraints; thereby making decision-making more complex and difficult. The complexities in incorporating sustainability in PM are the reason why sustainability has been an emerging field in PM research. Huemann and Silvius (2017) stated that project managers should fulfill stakeholder's needs, triple constraints, and at the same time, should also know what sustainability measurement tools would fit the specifics of the diversity of their real-life projects. Every project is a unique undertaking with a defined scope, cost, and timeline for completion. The uniqueness of real-life projects makes approaches for tailoring PM tools to be diverse. For instance, recent PM sustainability studies have shown replacing current PM models with tailored PM models that incorporate sustainability dimensions such as descriptive statistics and the triple P (people-planet-profit) approach for multi-factor analysis (Huemann and Silvius, 2017). These tailored models can be used for making decisions for project managers.

Whenever decisions are made throughout a project life cycle, PM tools with sustainability metrics could be used as a guide for bringing an R&D idea to implementation, proof-of-concept demonstration and commercialization. In the bioproduct R&D areas, PM practices have shown project completion and success in meeting deliverables that meet the sponsor's needs and expectations. Incorporating sustainability criteria in these PM practices pose challenges and opportunities. Among the challenges include chemical heterogeneity of biologically derived materials, techno-economic feasibility, social perception of emerging technologies, and the triple constraint. On the other hand, when challenges are imposed, opportunities arise. The opportunities of using bioproducts as a preferred material over others include the fact that bioproducts are derived from renewable natural sources or due to their biodegradability upon disposal. Recent studies on considering sustainability in PM also concur in identifying enterprise environmental factors, technical challenges, and opportunities in considering sustainability in making decisions in projects in various industries (Silvius and Schipper, 2010).

3. Sustainability Inclusion in PM

Recent studies by Fargnoli et al. (2014) showed the challenges and opportunities as well as barriers and benefits on incorporating sustainability in PM. Integrating sustainability in product development involves tools for design management, an integrated approach for the development of sustainable products. The design management approach aimed at the implementation of the concepts of eco-efficiency and life cycle thinking within the product development activities. Opportunities and benefits of sustainable PM include (1) holistic project control packages in infrastructure projects that complement internal PM control for stakeholders (Kivilä et al., 2017); (2) reduction of social and environmental negative impact using structural management models towards significant and positive relation between project sustainability management and project success (Martens and Carvalho, 2017); and (3) sustainable development benefits shaped by project benefits co-creation (Keeys and Huemann, 2017). The integration of the economic, social and environmental dimensions of sustainability in the scope of the project during its planning, management decision-making, and evaluation was shown by Brook and Pagnanelli (2014) to be beneficial in enhancing the ability of organizations to achieve an effective balance of investment between the economic, social, and environmental aspects of an innovation portfolio. On the other hand, challenges and barriers to be surmounted in incorporating sustainability in PM include the lack of life cycle inventory data for TEA and LCA for technology projects at their infancy and the intentional exclusion of environmental sustainability during the initial design and operation of a project because of emphasis on controlling cost and technical specifications. This was encountered in information system projects where engineering infrastructures were designed and constructed based solely on economic sustainability (Marnewick et al., 2019).

Technology management consists of planning, directing, controlling, and coordinating the development and implementation of technological capabilities in order to shape and accomplish the strategic and operational objectives of an organization. Project managers in this area are typically faced with challenges in training staff for specialized knowledge and developing a skill base, which is a concern in organizations who want to achieve sustainability (Cetindamar et al., 2016). These challenges are common in technology management of processes in innovation, operation, and strategy. Cetindamar et al. (2016) stated that technology managers monitor technology at all stages in process development and align technology-related decisions with the business strategy. They also oversee technologies that are assimilated through technology transfer from R&D into manufacturing. In innovation, technology managers make decisions on an R&D model to solve customer needs, selecting communication channels to manage the flow of information to maximize creativity while protecting trade secrets. In technology operations, technology managers make decisions on talent selection from the community for interdisciplinary (team) skills training. In strategic project management, technology managers make decisions on how to enhance community collaboration and integration instead of daily project management routines. The inclusion of sustainability into the business strategy requires project managers to use intelligent software, data analytics, and project team capabilities. Thus, sustainability inclusion involves interdisciplinary approaches and is identified as one of the waves of innovation alongside radical resource productivity, whole system design, green chemistry and renewable energy. There is a demand to incorporate sustainability in process development and eventually in the supply chain (Martens and Carvalho, 2017).

To address the lack of sustainability in organizations, PM researchers have looked at organizational factors that could influence the inclusion of sustainability frameworks. A study by Martens and Carvalho (2017) on organizational management using factor analysis and descriptive statistics identified factors at the intersection of the triple P approach (people-planet-profit) in sustainability and PM. These are stakeholders' management, environmental policies, and resource savings; economic and competitive advantage analysis; and sustainable innovation business model. The same approach in identifying critical success factors was proposed in sustainable PM practices in a study by Banihashemi et al. (2017) on construction projects in developing countries. Critical success factors were identified through a comprehensive literature review. These factors were customized for the context of developing countries by conducting semi-structured interviews and were presented in the form of a conceptual model. Validation of the conceptual model was performed using survey data with partial least squares structural equation modeling as the method of analysis. Another approach was to identify factors from the perspectives of the project organization delivering the asset as well as the host organization. These two perspectives were revealed by a systematic literature review on eight project sustainability strategies by Aarseth et al. (2017) which showed that sustainability factors vary depending on the nature of the organization and scope of the project. Overall, these studies show that to overcome these barriers in sustainability inclusion, key organizational factors that affect their execution need to be identified and considered as inputs in developing tailored PM tools and techniques.

For R&D of bioproducts, organizational factors can be defined based on sustainability metrics as identified by project managers across different industries (Silvius et al., 2017). While bioproducts R&D projects are focused on the sustainability of product and process technology, a survey of stimulus patterns of 101 project managers (i.e., intrinsically motivated, pragmatic, and task driven) showed that they chose to incorporate sustainability because they were personally motivated to utilize tools that comply with PM competency standards and industry certifications (Marnewick et al., 2019). In another experimental study, Martínez-Perales et al. (2018) concur that management system certifications in the energy sector has a significant positive impact on the success of company projects in addition to time, cost and milestones achieved during the project life cycle. Therefore, sustainability concepts and tools have been demonstrated in surveys and experimental studies to be effective in meeting targets within PM constraints.

Studies on sustainable PM indicated that sustainability concepts were included into R&D projects to evaluate project aspects that balances or harmonizes social, environmental, and economic interests; to eliminate or minimize waste; to minimize negative impacts (short-term versus long-term, local versus global); to consume income (not capital); and to consider social values, ethics, transparency, or accountability (Huemann and Silvius, 2017; Silvius et al., 2017; Silvius and Schipper, 2010). LCA methodologies can quantify the social and environmental impacts of bioprocess technologies. Combined with TEA to estimate the economic aspect of the process, conditions that provide sustainable operations can be identified. However, since technologies in the R&D stage are still at their infancy, accurate life cycle inventories and material and energy flows are often unavailable. Nevertheless, TEA and LCA of R&D projects can be estimated from experimental data and available life cycle inventory databases (e.g., Ecoinvent and federal LCA commons). A more accurate TEA and LCA are obtained as the project moves from R&D to industrial deployment where actual data inventories become available.

Tailored management tools for sustainable PM of bioproducts R&D could be as simple as a checklist for economic, environmental and social dimensions of sustainability together with the triple P approach. The checklist can be utilized as a basis in developing a maturity model, which is a practical approach to translate complex concepts into organizational capabilities and benchmarks (Silvius and Schipper, 2010). The maturity model could be created from the different categories of the sustainability dimensions, where each category has quantifiable target sustainability metrics. For instance, economic sustainability can be divided into two categories, namely; return on investment and business agility. Return on investment is measured by direct financial benefits (profit, earnings, and product value) and net present value while business agility is measured by flexibility/optionality in the project and increased business flexibility. Business flexibility situations would involve optimizing a service management process such as minimizing travel and on-line or off-line delivery of products and services. However, the approach should be more focused and specific as stated in the narrative description of the business need in the project scope statement (Silvius and Schipper, 2010). Environmental sustainability factors for bioproducts R&D can be focused on decisions whether to recycle versus dispose of (in a water category), to reuse renewable resources over non-renewable resources (in a materials and resources category), and reducing emissions/carbon dioxide using plant-based materials versus petroleum-based materials (in an energy category). The maturity assessment uses a set of descriptive questions regarding the respondent (stakeholders and/or managers), the project that is assessed (for a specific process or product), and the organizational context of the project. Then, the aspects can be derived from the sustainability checklist and are grouped in social aspects (people criteria), environmental aspects (planet criteria), and economical aspects (profit criteria) to compare the actual metrics with the target maturity metrics. An action plan can then be developed to bridge the gap between the actual and target metrics. It should be noted, however, that a maturity model is not for establishing roles and responsibilities of project sponsors, project managers, and team members in a changing R&D organization matrix. The maturity model also does not deal with risks and uncertainties in projects. Hence, the checklist serves as a PM tool for R&D organizations to set their own standards and ambitions during planning, monitoring & controlling, and document their sustainability milestones at the end of the project (Huemann and Silvius, 2017; Silvius and Schipper, 2010).

4. Bioproduct R&D Areas

Three specific areas of chemical process R&D (bioenergy, biotherapeutics, and biomaterials) are considered in this paper. In each area, case studies were examined to highlight PM tools used for sustainability criteria measurements. This was done to identify challenges and opportunities in the application of these PM tools with sustainability criteria in making decisions during the initiation, planning, monitoring and controlling phases of a research project to develop a bio-based product or process.

The bioenergy case studies involve opportunities to use PM tools in operating an anaerobic digestion process to produce value-added fuels and chemicals. Anaerobic digestion was specifically chosen as a bioenergy system because of its advantages compared to other bioenergy production routes. These advantages include high substrate-to-product and low substrate-to-cell biomass mass flux compared to the aerobic digestion process. In addition, anaerobic digestion has lower energy input compared to thermochemical biomass-to-energy conversion routes such as pyrolysis, gasification, and torrefaction (Cremiato et al., 2018; Edwards et al., 2017).

The presented biotherapeutics case studies involve outsourcing biopharmaceutical manufacturing and using disposable reactors versus stainless steel tanks for the production of protein biotherapeutics. Outsourcing contract manufacturing has advantages over locally dedicated one-product manufacturing facilities because of the reduction of the time to deliver drugs to patients and flexibility with multiple product lines for increased income. Disposable reactor technology has attracted attention due to its environmental impacts and socio-economic benefits for biotherapeutics manufacturing. Both case studies involve decision-making on whether to outsource production and use disposable bioreactor technology over existing manufacturing systems (GE Healthcare Biosciences AB, 2015; Langer, 2010; Pietrzykowski et al., 2013).

The biomaterials case studies involved reported PM tools in the manufacture of carbon fibers, specifically on the identification of manufacturing sites, evaluation of economic feasibility and measurement of environmental impacts. Furthermore, PM tools with environmental sustainability criteria for the production of carbon fibers from lignin, a polymeric biomaterial, were highlighted (Cerdas et al., 2017; Das, 2011). The use of lignin in composites to replace petroleum-based materials is a promising R&D area because lignin can be derived from renewable agro-forestry resources (Aguda, 2017).

4.1. Bioenergy

R&D projects on converting biomass to energy or waste to energy have demonstrated the utilization of biological materials from agro-forestry production systems, municipal wastewater systems, or waste treatment facilities to be technically feasible. In these studies, measurement of environmental impact and economic feasibility of the bioenergy systems have been the most commonly used PM decision-making tools. Anaerobic digestion (see Fig. 1) was chosen as a biomass-to-energy platform because of its reduction in environmental burden. A dissertation by Usack (2016) on anaerobic co-digestion of dairy farm wastes and crude glycerol for the production of biogas (mainly methane and carbon dioxide for electricity and fertilizer production), showed that the process is technically viable and environmentally beneficial when properly implemented. However, the revenues were not sufficient to recoup capital and operating costs. Based on this study, the combination of high capital cost and the lack of high-value product streams provided an insurmountable barrier for this process to be economically viable under the 2016 US market conditions. Table 1 and Table 2 present more examples of comparative assessment of anaerobic digestion commercialization projects based on their environmental and economic potential. Table 1 shows the environmental impacts of different projects from environmental LCA studies that have measured the environmental hot spots compared to a base case scenario (e.g., fossil fuel use or other waste management systems). Environmental hot spots are the areas where there is a significant environmental burden among the environmental impact categories. Among the environmental impact categories, these hot spots cause global warming, carcinogens and eutrophication potential. It should be noted that each project in Table 1 is compared to a base case scenario. Comparative assessment across projects can only be done accurately if all the projects have either the same base case scenario. The same LCA functional unit, where process inputs and outputs can be linked, would allow comparison of projects even if they have completely different scopes and boundaries (Cremiato et al., 2018; Edwards et al., 2017).

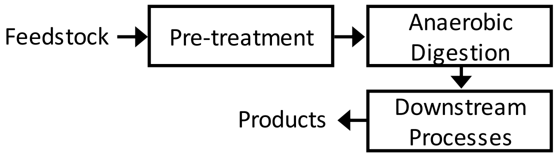

Fig. 1. Generalized anaerobic digestion process.

In a similar manner, TEA can be used as a tool to compare the commercialization potential of anaerobic digestion projects. In fact, TEA is the most commonly used PM tool to assess the viability of promising anaerobic digestion projects (e.g., a process that uses new pre-treatments technology, new feedstock or mixture of different feedstock, changes in process conditions and product, etc.) as shown in the works of Dhar et al. (2012), Tufvesson et al. (2013) and Baroi et al. (2015). Similar to LCA, TEA studies can be done by comparing the project with a base case scenario, which is typically a commercially existing process that the project is attempting to replace. For example, the TEA study conducted by Dhar et al. (2012), suggested that anaerobic digestion generates less than half of the revenue compared to incineration or gasification. However, according to this study, the use of ultrasound and thermal pretreatments for municipal waste activated sludge can lower operating costs and increasing the yield and concentration of volatile fatty acids (VFAs) can improve the cost competitiveness of anaerobic digestion systems. TEA can also be done by comparing the economic viability of projects in the anaerobic digestion process without a base case process (Baroi et al., 2015). However, the projects must be evaluated using the same economic indicators and other process assumptions (Tufvesson et al., 2013). Overall, these case studies showed that LCA and TEA models can be used for assessing the sustainability of anaerobic digestion systems to balance the environmental impact and economic benefits of the process. These tools can also be used in what-if scenarios within a project, which can provide project managers with deeper insights on operating conditions that optimize both the environmental and economic aspects of the project.

Table 1. Environmental impacts of anaerobic digestion systems from environmental life cycle assessment studies

Process Technology	Function of Product System	Base Case Scenario	Environmental Impact Hot Spots Interpretations			Reference
			Global Warming Potential (kg $CO_{2\text{-}eq}$)	Carcinogens (kg benzene$_{eq}$)	Eutrophication (moles H^{+}_{eq})	
Anaerobic Digestion of Agricultural Waste	Production of biogas	Natural gas or oil boilers, Natural gas combined heat and power plant	Reduced by 50%	Increased by 25 times	Increased by 12 times	Whiting and Azapagic (2014)
Glycerol Fermentation	Production of propionic acid	Carbonylation of ethylene	Reduced by 60%	Not Reported	Increased by 13 times	Ekman and Börjesson (2011)
Anaerobic Co-digestion of Sewage Sludge and Food Waste	Production of biogas and sludge stabilization	Local government's waste management system	Reduced by 100%	Reduced by >85%	Reduced by >85%	Edwards et al. (2017)
Anaerobic Digestion of Household Waste	Production of biogas	Local government's waste management system	Reduced by 166%	Not Reported	Reduced by 646%	Cremiato et al. (2018)

Table 3 presents the PM decision-making tools in addressing challenges and opportunities for chemical production from anaerobic digestion systems. These tools and techniques can also meet sustainability criteria, which were recommended by the Project Management Institute (2000) and by the TEA and LCA studies in Table 1 and 2.

Table 2. Techno-economic assessment studies on anaerobic digestion systems with emerging technologies

Process Technology	Process Description	Process Function	Economic Indicators	Reference
Ultrasound and Thermal Pretreatments	Pretreatment of municipal waste activated sludge prior to anaerobic digestion	Improve treatment while producing biogas	Operating costs	Dhar et al. (2012)
Glycerol Fermentation	Utilization of glycerol, a by-product from the biodiesel industry	Produce propionic acid while minimizing greenhouse gas emissions	Capital investment and operating costs	Tufvesson et al. (2013)
Wheat Straw Fermentation	Utilization of agricultural by-product	Produce butyric acid from an abundant agricultural biomass	Unit production cost, internal rate of return, and payback period	Baroi et al. (2015)

Table 3. PM decision-making tools and techniques in chemical production through anaerobic digestion

Challenges/Opportunities	Tools and Techniques	Sustainability Criteria
Challenges		
1. Financial independence (i.e., without government subsidies)	- Techno-economic analysis	Benefit-to-cost ratio (improvement)
2. Reduction of input (raw material and energy) requirements and unwanted by-products (wastes)	- Environmental life cycle assessment	Environmental impact (reduction)
3. Heterogeneity of feedstock and variability in anaerobic digestion microbes population	- Multi-criteria decision analysis	Process flexibility (to accommodate input inconsistencies)
4. Requires equipment and instrumentations that need long start-up procedures (e.g., calibrations)	- Critical path method - Critical chain method	Production capacity (improvement) and processing time (reduction)
5. Requires technicians with specialized knowledge	- Development of training plan for team members	Job creation
Opportunities		
1. Independence from non-renewable sources of chemicals and energy	- Techno-economic analysis - Environmental life cycle assessment	Benefit-to-cost ratio (improvement) Environmental impact (reduction)
2. Utilization of domestic and industrial waste streams as feedstock	- Stakeholder analysis for people-profit-planet approach	Waste elimination and social responsibility

Challenges in anaerobic digestion projects include economic viability, environmental impacts, biomass or feedstock variability, biological diversity of the population of anaerobic microbes, and lag in estimated process time. TEA and LCA can be utilized to identify areas of improvement and have better insights on how to address issues related to economic and environmental sustainability. To address the challenges in feedstock and microbial heterogeneity, PM tools such as Multi-criteria decision analysis (MCDA) can be used. The MCDA provided a systematic and objective decision-making process, which allowed for methodical comparisons of different scenarios such as different substrates (or feedstock), locations, etc. (Reeb, 2015). MCDA can be used for the management of cost (i.e., costs associated with the type of feedstock and transportation distance), time (i.e., harvestable months for a given type of feedstock), and quality (i.e., sugar yield and environmental benefits based on LCA for a given type of feedstock). MCDA is a tool for making the process capable of accommodating input inconsistencies due to the heterogeneity of feedstock and variability in microbial species for anaerobic digestion. For example, MCDA can assist in the selection of feedstock and microbial sources that can provide a target performance. Furthermore, to address challenges in long start-up procedures, the critical path and chain method can be used to identify the steps in the process where bottlenecks exist (e.g., training of technicians, equipment calibrations, etc.) and implement countermeasures to reduce overall processing time and thus, increasing production capacity. On the contrary, opportunities that could outweigh these challenges include independence from non-renewable sources of chemicals and energy by utilization of domestic and industrial waste streams as feedstock. For instance, anaerobic digestion of renewable local resources can produce a significant amount of biogas that can offset natural gas usage for heating and possibly power generation. This can have tremendous economic and environmental (carbon neutral) benefits. TEA can be utilized in assessing product streams that has the potential to provide a higher benefit-to-cost ratio, while environmental LCA can identify which among the products benefit the environment the most. During the initiation phase of an R&D project in bioenergy, stakeholder analysis for people-profit-planet can provide project managers with some insights on how to balance the benefits on the economic aspects (i.e., revenues), environmental impact (i.e., waste utilization and minimization), and social impact (i.e., social transparency).

4.2. Biotherapeutics

Biotherapeutics are products (e.g., monoclonal antibodies vaccines, and biosimilars of blood plasma-derived drugs) derived from biological sources such as bacteria, viruses, mammalian cells. For these protein biotherapeutics, the typical production process is given in Fig. 2. Studies indicated PM tools are used effectively by contract manufacturers in producing biotherapeutics or biopharmaceuticals to meet patients' medical needs. According to a report by Langer (2010), project planning tools are utilized by practitioners at biopharmaceutical contract manufacturing organizations in 35 countries for outsourcing project activities to reduce cost and time-to-patient (i.e., the time needed to deliver a drug to medical patients). Outsourcing utilizes PM decision-making tools to improve efficiency and lower the cost of new technologies. These tools include data management systems and communication channels, which are used during the monitoring and controlling phases. These are also useful for establishing working relationships, protecting intellectual property, handling cross-contamination issues, and securing supply (Langer, 2010).

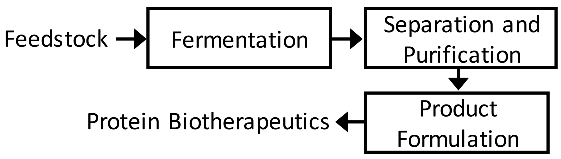

Fig. 2. Generalized biotherapeutic production process.

In protein biotherapeutics manufacturing, recent technologies on using single-use disposable bioreactors (SUDBs) versus stainless steel tanks have raised questions on fulfilling the triple constraint (i.e., cost, time, and quality), in addition to its long-term economic, environmental, and social sustainability. Stainless steel bioreactors require a significant amount of water, man-hours, and standard tests to ensure sterile conditions. Thus, products that are manufactured from stainless steel could be very expensive. On the other hand, SUDBs could provide a holistic process and facility strategy that can overcome production limitations for cost-efficient manufacturing to support the growing demand for affordable biologics (Jacquemart et al., 2016). Cost analysis studies showed that SUDB has a higher cost of production but a higher profit margin than stainless steel tanks over the same number of batches (GE Healthcare Biosciences AB, 2015). An environmental gate-to-gate LCA study showed that the impact of SUDB on the ecosystem, human health, and resources was less than the traditional stainless steel tanks due to fewer biological markers required for cleaning validations, lower water consumption, and shorter cleaning time (Pietrzykowski et al., 2013). The tools and techniques that can be used for comparisons of cost estimates and environmental impacts on biotherapeutics production, using single-use disposable bioreactors versus stainless steel tanks, are summarized in Table 4.

PM tools that can evaluate sustainability criteria scores can be adopted for the production of novel protein biotherapeutics for pilot scale testing and large-scale manufacturing (Aguda et al., 2013). The main challenges involved in the production of novel biotherapeutics include chemical recalcitrance and heterogeneity of the protein expression system (e.g., inclusion bodies from bacteria), and compliance with government regulations for water treatment, irradiation safety, and incineration. These challenges can be addressed with the aid of MCDA and other PM tools during the initiating and planning phases (e.g., stakeholder analysis and human resource allocation). MCDA would provide an assessment of the biotherapeutic production process to accommodate multiple recombinant protein expression systems and types of the expressed protein (i.e., inclusion bodies or excreted protein in the fermentation or cell culture media) with the most desirable characteristics.

Workers' perception of biosafety is another challenge that can be easily addressed by developing a training matrix for workers as well as an impact grid assessment on safety and health. The critical path and chain method can be used in the evaluation and implementation of new measures to reduce bioreactor clean-up and maintenance to minimize operating cost and waste generation. Lastly, specifications of the facility design for compliance to pharmaceutical regulatory standards can be addressed using PM initiating tools (e.g., scope definition), which could be the basis for the implementation of quality-by-design and cost-of-quality approaches to process development in biotherapeutics.

On the other hand, opportunities in this field include the conversion of renewable resources to high-value products where TEA and LCA can be used for economic and environmental impact assessment. The emerging fields in biotherapeutics could also provide opportunities to train workers with specialized knowledge and skills that could result in a significant number of new jobs. Challenges and opportunities in the biotherapeutics R&D area are presented in Table 5.

4.3. Biomaterials

Biomaterials R&D involves emerging technologies on the utilization of naturally occurring solid materials particularly those that are renewable, such as wood. There have been tremendous research efforts on the production of functionalized carbon-based materials (e.g., carbon fibers) from woody biomass (Fig. 1). These research projects are geared to support the pulp and paper industry by utilizing lignin, a by-product of the papermaking process (Aguda, 2017).

PM tools in biomaterials development have been used during project start-up, planning, site selection, and policy establishment of lignin-based carbon fiber production for applications in lightweight vehicles (Cook and Booth, 2017; Das et al., 2016; Yang et al., 2013).

Table 4. Cost estimates and environmental impacts on biotherapeutics production using single-use disposable bioreactors versus stainless-steel tanks

Case study	Tools and Techniques for comparisons	Reference
Cost analysis on single-use disposable reactors versus stainless steel tanks	- Measurement of total annual production cost over batches of product and accumulated profit with increasing percent capacity utilization - Used process economy model based on cost categories, production capacity, cost per batch, costs with varying facility utilization rate, and profit	GE Healthcare Biosciences AB (2015)
Environmental life cycle assessment on key process contributors associated with energy use and generation	- Measurement of life cycle impacts on ecosystem (climate change), human health (climate change, particulate matter formation, and toxicity), and resources (fossil fuel depletion) of disposable bioreactors and the use of heating, ventilation, air conditioning, steam, materials, and energy for stainless steel tanks	Pietrzykowski et al. (2013)

Table 5. Project management decision-making tools and techniques in biotherapeutics production

Challenges/Opportunities	Tools and Techniques	Sustainability Criteria
Challenges		
1. Chemical recalcitrance and heterogeneity of recombinant protein expression system	- Multi-criteria decision analysis	Process flexibility (to accommodate input inconsistencies)
2. Compliance with government regulations for water treatment, irradiation safety, and incineration	- Environmental life cycle assessment - Stakeholder analysis for people-profit-planet approach - Organizational chart for human resource allocation for compliance and inspections - Planning tools in developing budget and schedule with enterprise environmental factors as input	Environmental impact (reduction) Social transparency and accountability
3. Personnel perception on biosafety	- Develop training matrix for workers on specialized knowledge - Qualitative probability-impact grid on safety risks	Job creation
4. Requires long bioreactor preparation protocols (cleaning for sterility)	- Critical path method - Critical chain method - Environmental life cycle assessment	Operating cost (reduction) Waste minimization
5. Facility design specifications for compliance with regulatory standards	- Stakeholder analysis for regulations - Statement of work - Scope definition - Quality-by-design and cost-of-quality planning tool	Social transparency and accountability
Opportunities		
1. Utilization of renewable feedstock	- Techno-economic analysis	Operating cost (reduction)
2. Bioreactor development (i.e., design and operation)	- Environmental life cycle assessment	Environmental impact (reduction)
3. Workforce development	- Training matrix of workers for specialized knowledge and skills	Job creation

These PM tools include (1) communication channels, such as workshops during project start-up to identify technical challenges in technology development from stakeholders (Yang et al., 2013), (2) bottom-up estimation during development, which has been used by researchers in global carbon fiber composites supply chain (Das et al., 2016), (3) economic viability estimation including costs of labor, energy, quality, and regulatory compliance (Cook and Booth, 2017), (4) building and training tools for workforce development programs (Cook and Booth, 2017), and (5) data management tools for project monitoring. These studies suggested that communication channels are better facilitated by co-location and clustering facilities near end users. Doing so would also reduce quality control and logistics costs. Data management tools, on the other hand, have been useful in identifying manufacturing and supply chains as well as market forecasts and economic assessment in aerospace, automotive and energy applications of biomaterials (Das et al., 2016). Overall, these are the PM tools and techniques that consider factors for decisions on the selection of sites and policies for building production facilities towards the commercialization of biomaterials R&D projects.

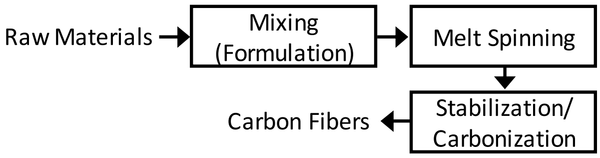

Fig. 3. Generalized carbon fiber production process.

The production of carbon-based materials from renewable and non-renewable sources is a promising area due to an anticipated increase in demand for various applications. A promising renewable raw material in the biomaterials R&D is chemically modified lignin in carbon fiber manufacturing, which can be used as catalyst supports, batteries and non-structural vehicle parts (Aguda, 2017). Studies on the technical feasibility, as well as TEA and LCA, of the production of carbon-reinforced polymer composites and carbon fiber derived from natural materials (e.g., lignin) have been performed (Cerdas et al., 2017; Das, 2011). These studies indicated a reduction of environmental impacts during production but proved to be challenging with respect to the fulfillment of the triple constraint (i.e., cost, time, and quality) for potential customer needs. Hence, challenges in the lignin-based carbon fiber R&D projects include (1) quality of the carbon fibers to meet customer specifications, (2) target usage, and (3) high energy requirements. To overcome these challenges, lean six sigma tools, PM tools, LCA, and MCDA can be used. The quality of carbon fiber products can be maintained by implementing lean six sigma tools, which can detect root causes in cases when out-of-specification products are obtained. Root causes could be changes in raw material properties or processing conditions resulting in significant product rejection. Workshops and surveys on the alternative use of carbon fibers with certain properties would be able to show the flexibility of these products with respect to potential industrial applications. Lastly, the high energy requirement of carbon fiber manufacture can be mitigated with the aid of MCDA combined with TEA and LCA, to identify the most cost-effective and environmentally benign energy source or mix energy sources. Concurrently, a stakeholder analysis could be conducted to increase social transparency and accountability in the project team.

On the contrary, opportunities in pursuing projects in this R&D area include the utilization of low-cost renewable resources and waste streams from other industries (i.e., lignin stream from pulp and paper mills). These renewable resources could be available locally or regionally and thus, could significantly reduce logistics costs. The economic and environmental benefits of carbon fiber production from these renewable resources could be assessed using TEA and LCA, respectively. Moreover, a social benefit from this opportunity is on workforce development, particularly on the training of workers with transferrable skills in the materials engineering industry. Challenges and opportunities in carbon fiber manufacturing are summarized in Table 6.

Table 6. Project management decision-making tools for challenges and opportunities in carbon fiber manufacturing

Challenges/Opportunities	Tools and Techniques	Sustainability Criteria
Challenges		
1. Quality (specifications) of carbon fiber	- Lean six sigma	Rejects (off-specs) minimization
2. Target usage	- Workshops and survey of experts in alternative uses for lignin-based carbon fibers	Application flexibility
3. High energy requirements	- Multi-criteria decision analysis	Mix energy sources
	- Techno-economic analysis	Operating cost
	- Environmental life cycle	Environmental impact (reduction)
	- Stakeholders analysis form	Social transparency and accountability
Opportunities		
1. Upvaluation of low-cost renewable resources (lignin) and waste streams from other industries (i.e., pulp and paper) as feedstock	- Techno-economic analysis	Benefit-to-cost ratio
	- Environmental life cycle assessment	Environmental impact (reduction by waste utilization)
2. Utilization of local or regional resources	- Techno-economic analysis	Logistics cost
3. Workforce development	- Training matrix of workers for specialized knowledge and skills	Job creation

5. Summary and Recommendations

In the bioproducts R&D environment, common experiences shared by project managers include considerations of PM decision criteria that involve cost (materials, energy, and labor), efficiency (processing time), and quality (technical specifications). The 4R decision theory is also linked to decision-making criteria in terms of expert judgment based on (1) PM experience (reference), (2) technical justification based on desired attributes (reason), (3) triple constraint of time, cost, and product quality (resources), and (4) alternative technologies (replacement). This review highlighted the challenges and opportunities in integrating sustainability as part of decision-making PM tools in bioproducts (bioenergy, biotherapeutics, and biomaterials) R&D projects. Generally, challenges include (1) heterogeneity of the bio-based feed or raw materials, (2) benefit-to-cost ratio that needs improvement, (3) environmental burden that needs to be reduced by minimizing energy and water use or eliminating waste. It should be noted that although these challenges are common, the three bioproduct areas may differ on how they address these challenges (e.g., process or facility modifications, raw material substitutions, etc.) Furthermore, each bioproduct R&D area has to implement unique tools and strategies to meet stakeholder expectations, personnel perception on safety, customer needs, and regulatory standard compliance. On the contrary, similarities in these R&D areas involve opportunities in developing the workforce for transferrable skills in sectors that utilize renewable resources.

The presented case studies clearly show that bioproducts R&D managers perform MCDA, TEA, and LCA in most cases. However, these assessments are often done independently. Thus, although each is a measure of sustainability, the overall sustainability rating of the case studies are incomplete.

From the case studies, this work recommends that PM tools with sustainability criteria (i.e., MCDA, TEA, and LCA) be included as part of decision-making during the implementation of bioproducts R&D. Inclusion of the tools and techniques associated with sustainability would ensure not only that the R&D challenges are assessed, but also that the project would progress sustainably (from R&D to industrial deployment). In this way, we can have some degree of certainty that the process can meet our needs without compromising the ability of future generations to meet their own needs (UCLA, 2020). These tools and techniques must be implemented together with those recommended by the Project Management Institute (2000).

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