

SOMATIC EMBRYOGENESIS



OPERATIONS PLAN

**MBA 823:
BIOTECHNOLOGY MANAGEMENT
PROFESSOR GRANT ISAAC**



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Table of Contents.....	i
1.0 Introduction	1
2.0 Internal Operations Plan.....	2
2.1 Physical Plan.....	2
2.2 Process Plan	3
3.0 External Operations Plan.....	5
3.1 Location Plan.....	5
3.2 Supply-Chain Plan.....	5
4.0 Strategic Planning Notes.....	6

List of Figures... in order following Text

Figure 1 – Layout Plan of a Hypothetical Forest Biotechnology Firm

Figure 2 – Production Process for SE seed

Figure 3 – Process Plan for Somatic Embryogenesis

Figure 3 – Process Plan for Somatic Embryogenesis

List of Tables... in order following Figures

Table 1 – Stock/Sunk Costs for a Forest Biotechnology Firm

Table 2 – Effects of a Process-Oriented Layout for a Forest Biotechnology Firm

Table 3 – Costs of a Process-Oriented Layout for a Forest Biotechnology Firm

Table 4 – Critical Success Factors for a Forest Biotechnology Firm

Table 5 – Supply-Chain Costs for a Forest Biotechnology Firm

References... in order following Tables

1.0 Introduction

Somatic embryogenesis (SE) is a process used for the vegetative propagation of premium plant germplasms. In conducting an operations plan for the successful commercialization of SE, a forest biotechnology firm must correlate their strategic planning with the This analysis seeks to explore the associated costs pertaining to both the internal and external operations plan of forest biotechnology firm commercializing SE. Firstly, the internal plan of operations is explored where a physical plan of a theoretical forest biotechnology firm is detailed followed by an exploration of the process itself to quantify the procedural steps involved in duplicating somatic embryos and the equipment required to execute the process. Secondly, the external operations plan is explored where location issues are addressed followed by an analysis of the supply chain in which the forest biotechnology firm operates.

In determining the operations plan for a forest biotechnology firm, a manager must consider ten strategic operations management decisions.¹ These ten strategic decisions, as they specifically relate to a firm operating in the SE market, are explored in relation to a forest biotechnology firm, and are as follows:

1. **Goods and Services Design** – the design of the SE process will determine the lower limits of cost, by identifying which specific inputs are needed, and the upper limits of quality, by assessing the impacts and results of these inputs;
2. **Quality** – the consumer expectations of quality must be determined. For SE, the value enhancing characteristics of the process should be clearly identified;
3. **Process and Capacity Design** – the commitment to a particular process design will assess the technology, human resources, and quality and maintenance requirements of the system. The needs for experienced scientific researchers and high technology systems required for SE will determine much of the basic cost structure for the firm;
4. **Location Selection** – determining the location decisions are critical to the impacts of cost and supply chain management. For and SE process firm, the location factors include proximity to research institutions, research infrastructure and quality of life for staff.
5. **Layout Design** – the quantification of material flows, capacity requirements, staffing levels, technology decisions and inventory requirements will influence the layout of operations. For an SE firm, these decisions should be made to help internal knowledge sharing and access to data and technology.
6. **Human Resources and Job Design** – the detailing of job descriptions and required skills, quality of work life for staff and associated costs. For an SE firm, innovative and talented staff is a key component to the generation of proprietary and commercially viable intellectual property. This component is a key contributor to the success of a forest biotechnology firm;
7. **Supply-Chain Management** – the determination of what is to be produced and what supplier inputs are required while incorporating requirements for quality, delivery, innovation and price. For an SE firm, the management of suppliers and distributors relates specifically to the owners of enhanced seed stock and the nurseries that grow the enhanced seed;
8. **Inventory** – optimizing inventory decisions as it relates to customer satisfaction, suppliers, production schedules and human resource planning. For an SE firm,

- the cost of maintaining inventory of superior germplasm is minimal and has the propensity to enhance the value of the firm's products;
9. **Scheduling** – feasible and efficient schedules of production are determined. For an SE firm, this production planning will correlate heavily with industrial contracts and the testing and field implementation of SE products;
 10. **Maintenance** – the maintenance and support of reliable and stable systems. For an SE firm, this is critical to data management protocols and access to information for researchers so systems will require regular attention to maintenance and upgrades.

Exploration into the internal operations plan will detail the layout plan or the physical plan and the process plan. The external plan will explore the detail of the location plan and the supply-chain management plan. Other components of the operations plan are not fully detailed for the purposes of this analysis.

2.0 Internal Operations Plan

The internal operations plan addresses internal planning decisions that are relevant to the operations of business. For a forest biotechnology firm, these operational decisions are critical to consider in order to successfully achieving market commercialization and revenue streams.

2.1 Physical Plan

The physical plan of operations decision making entails the consideration of layout and physical locations of resources as determinants of the long-run efficiency of operations. It establishes an organization's competitive priorities in regard to capacity, processes, flexibility, costs, quality of work life, customer contact and image.² In considering the strategy of the forest biotechnology firm, it is clear that operations should be tailored to suit the needs of research and development staff and the access to knowledge. This must be correlated to an economic layout that maximizes efficiencies and meets the firm's competitive advantages, such as knowledge sharing, information access, and quality of work life.

The important considerations and objectives to a forest biotechnology firm with respect to layout planning should include:

- 1) The higher utilization of space, equipment, and people;
- 2) Improved flow of information, materials or people
- 3) Improved employee morale and safer working conditions
- 4) Improved customer/client interaction
- 5) Flexibility for future change

Utilizing these objectives in planning, a firm must then assess which layout plan is most applicable to their operations and then apply these considerations to the development of the physical plan. The different types of layout can be established in a variety of ways to satisfy the objectives noted above. These several types include:

- Fixed-position layout where the requirements of large fixed project resources create planning decisions around the efficient flow of resources, such as bridge and home construction;

- ▶ Process-oriented layout where a wide variety of products or services is needed to be simultaneously managed and delivered and each product undergoes a different sequence of operations, such as the service of patients in a hospital or health clinic;
- ▶ Office layout where the organization of staff and resources provides for efficient movement of information and comfortable and safe environment for staff. When incorporating a laboratory, this model seems to be most applicable to forest biotechnology firms;
- ▶ Retail layout where spaces is allocated in response to customer behavior;
- ▶ Warehouse and storage layouts are designed to minimize total costs of material handling and space handling; and,
- ▶ Repetitive and Product-Oriented layout where organization is focused on the similar high-volume products that are repetitively produced.

This analysis will focus on the utilization of Office layout as the primary layout design. This layout design was chosen because of the critical success factor to a biotechnology firm of information sharing, quality of work life for employees, safe working conditions, and knowledge creation. Important considerations to the office layout plan include the ability to adapt to change and the flexibility to move work cells or groups to the most efficient place. Modular office systems can be used to help best achieve this flexibility. Heizer and Render (2004) note that, in general, office layouts allot an average of 100 square feet to each office worker, executives are allotted 400 square feet, and meeting rooms or conference rooms are allotted 25 square feet per person, up to 30 persons. The dependence on technology is a key element in layout planning and access to other research professionals and stored data are critical to the success of the strategy.

Figure 1 outlines a hypothetical floor plan utilizing the Office layout type plan and focusing on the sharing of knowledge, the interaction between employees, and the quality and safety of the work environment. This plan assumes an organization size of 40 research scientists and 11 administration and support staff and 4 management executives requiring 8,500 square feet of office space. Considerations to this plan include optics and image by placing the laboratory at the center of operations, worker quality of life by creating a central worker staff room, and develop internal harmony through seniority and innovative contribution by allocating offices to senior researchers while still allowing for flexibility and movement among offices.

One author notes that the costs for laboratory set-up are minimal in comparison to the costs of acquiring skilled staff that can successfully execute plant propagation. An autoclave or sterilizer, an accurate means of weighing chemicals, a small inventory of glassware, and chemical stocks or prepackaged media are all that is required to initiate cultures.³

Table 1 outlines an estimation of the sunk costs associated meeting the needs of the layout plan for a firm operating in the SE market.

2.2 Process Plan

The process of SE is dependent upon the mechanism chosen to implement the process. That is, there are several techniques that can be used to implement SE and

the associated costs can range from a home-based operation with a set-up cost of \$20,000 to a large scale industrial application where sunk costs could be in the hundreds of thousands or dollars. Immersion systems are the primary foundation of the SE process. Temporary immersion systems range from simple, home-made devices managing flow of liquid medium through peristaltic pumps, to rather expensive and sophisticated computer controlled bioreactor systems. However, regardless of the mechanics used in implementing the process, the major process steps will remain the same.

The identified consecutive steps during somatic embryogenesis are:

- ▶ Establishment of embryogenic cultures;
- ▶ Proliferation of embryogenic cultures;
- ▶ Maturation of somatic embryos;
- ▶ Germination of somatic embryos; and,
- ▶ Regeneration of somatic embryo plants.⁴

This analysis explores the application of SE to a large industrial application and, as such, assumes a relative amount of venture capital for successful implementation of SE at this scale.

Forestry is a cost-conscious industry. In the Southern USA, pine planting stock sells at 1-2 cents each. Somatic seedlings (aka emblings) have to compete in this market. Company economists are reluctant to spend much on planting stock that will not make a return for 20-30 years. (the laws of compound interest weigh heavily after 20 years). No one can currently produce *Pinus* somatic seedlings for less than 15 cents each⁵ Figure 2 illustrates the production process for Cellfor and the large-scale production of somatic seed. This British Columbia company employs 45 highly qualified technical personnel, including 12 Ph.D's. Their technology and product development is already well advanced and the company is poised to deliver commercial volumes to the forest seed and seedling market which totals over 13 billion seedlings per annum.⁶ The process plan at Cellfor shows that they implement a process-oriented layout in their operations planning. Labor costs may represent 65-85 % of the total costs.⁷ The goal is innovation and the product is proprietary intellectual property over novel processes of SE. Further to this, Figure 3 illustrates the internal process plan that is likely implemented by Cellfor in the production of the somatic seed.

Table 2 illustrates how this process-oriented layout can effect the operations of a forest biotechnology firm. This process plan shows the primary production steps of SE and their setting in the operations plan. Table 3 correlates this process-oriented layout to relevant costs.

3.0 External Operations Plan

3.1 Location Plan

The determination of the location of a business contributes a great deal to the firm's ability to remain competitive and achieve strategic objectives. For a forest biotechnology firm, there are several factors to specifically consider and others that more broadly apply to other sectors interrelated with forest biotechnology. The identification of critical success factors helps to focus the analysis as it applies directly to the motivations of a forest biotechnology firm. Table 4 represents the identification of 15 critical success factors (CSF's) that should form part of location planning decision making for forest biotechnology firms. This table outlines the reasoning for the CSF and applies a factor rating, which can be used to weight these factors by total contribution to success applied to the results of various identified locations.

These CSF's are correlated with some of the primary factors affecting location decisions for forest biotechnology businesses as follows:

- ▶ Labor Productivity – access to qualified research scientists, work ethic, rate of pay, quality of life for staff, tax system
- ▶ Exchange Rates and Currency Risk – stable economy, tax system
- ▶ Costs – labor, laboratory equipment, facilities management, set-up costs, regulatory requirements
- ▶ Attitudes – societal perception of biotechnology, regulatory restriction on commercialization, stakeholders and NGO's
- ▶ Proximity to Markets – access to forest industry headquarters, access to forests
- ▶ Proximity to Suppliers – access to forests, access to seed providers, access to nurseries
- ▶ Proximity to Competitors – existing competitive firms, existing intellectual property, proximity to cluster

In considering all these factors, locations should be identified that could produce a result between 0 and 100 for each CSF, then applied to the factor weighting rate. Countries to include in the analysis should include Canada, the United States, the UK, Germany, Sweden, and Japan. Each country may also have several identified cities to compare changes, advantages and disadvantages of each location.

3.2 Supply-Chain Plan

The supply chain creates the position of a firm in the market, and allows it to create relationships and positioning that create value and profit. Through the savings of expenditure on operations, on the maintenance of a firm's supply chain, a firm can increase its margins and contribute more to profitability. The management of a supply chain plan requires that managers create an evolving model of analysis, planning, implementation and control over operations, and using this model to drive strategic decision making to enhance operations. For a forest biotechnology firm, a strategy must first be adopted that pertains to the objectives of a research and development firm. With the proper investments into human resources, research facilities, and successful capture of patent breadth in the market, a forest biotechnology firm could essentially become a monopoly as the only firm legally capable of delivering a specialized product. The suppliers to the supply chain will be few due to the quantity

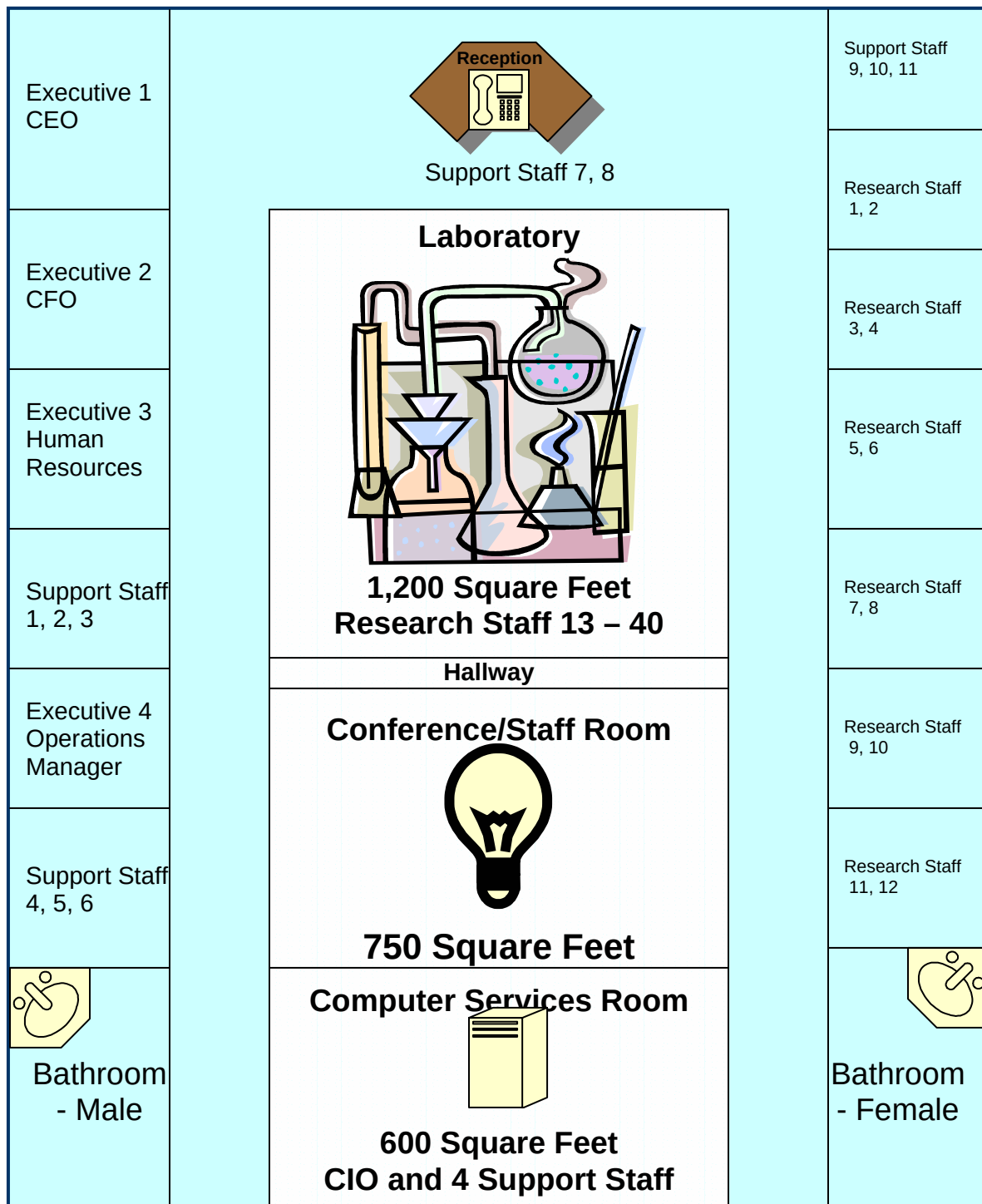
and quality of superior germplasms and seed stock. The firm may also want to consider backward vertical integration into the supplier market and develop research activities focusing on creating the most superior germplasm, or control over the seed collection process of superior forest stands. Forward vertical integration would take a great deal of capital resources to build, in acquiring and maintaining nurseries or acquiring and managing land and resource and therefore not likely. Also, considering the phase of the technology product life cycle that forest biotechnology currently exists, the strategy remains differentiation. Differentiation is defined for forest biotechnology firms as the successful development and capture of intellectual property that can be commercialized through regulatory approvals. Currently, all forest biotechnology firms are developing knowledge rights and working through regulatory approvals to find commercial, and profitable, biotechnologies. It remains to be seen whether SE can compete on cost with conventional organic propagation.

Figure 1 shows a model of the Supply-Chain plan for a forest biotechnology firm. The important considerations for a forest biotechnology firm in the supply-chain planning are in regards to the acquisition of germplasm from farmers, seed developers, woodlot owners or forest company clients. The firm will want to closely determine the costs of resource scientists and their ability to research and implement SE systems and this could be considered in outsourcing options or make-or-buy decisions. Make decisions to generate their own superior germplasm and plant stock through alliance or control with nurseries or land managers, and buy when a firm or individual owns rights to a certain optimal seed stock or preferred commercial plant. Other firms may already have claimed knowledge rights over a desired product or process so the firm could identify options as well on how to approach that. Table 5 attempts to detail some of the more specific costs for establishing and maintaining a forest biotechnology venture until the year 2010. These costs incorporate staff and planning costs, management and administrations costs, laboratory equipment and maintenance costs, and intellectual property management costs.

4.0 Strategic Planning Notes

Forest biotechnology firms are a new market force, capitalizing on research and development opportunities globally in order to create products that enhance value in the forest industry. And while regulation and commercial approval have not yet been received for the prime world markets, a forest biotechnology firm competing today is well positioned for the first-mover advantage. Important strategies to the business include the management and protection of the firm's knowledge, the implementation of regulatory approvals and the relationships with clients and nurseries. Internal to the firm, they have many considerations in determining a location primarily driven by quality of life for staff and regional cost structures. The internal layout of the office space will also need to be closely considered to ensure clients and customers can capture the true depth of skill in the research activities as well as the maintenance and fostering of capable, talented staff. The internal process of production and the implementation of a commercial manufacture of somatic embryos require a detailed scheduling of activities to ensure efficiency and quality of product. The supply chain analysis will show a firm where backward vertical integration may be an opportunity while scoping other firms for make-buy decisions that could be capitalized on by the firm. It will also be critical to develop and maintain control procedures and policies that allow for continual analysis and enhancement of the firm's supply chain.

Figure 1 – Layout Plan of a Hypothetical Forest Biotechnology Firm



Executives have 400 square feet each, support staff share 3 to an office, senior research scientists share two to an office and research support staff work primarily in the laboratory, and the computer support services houses 4 support staff and the CIO.

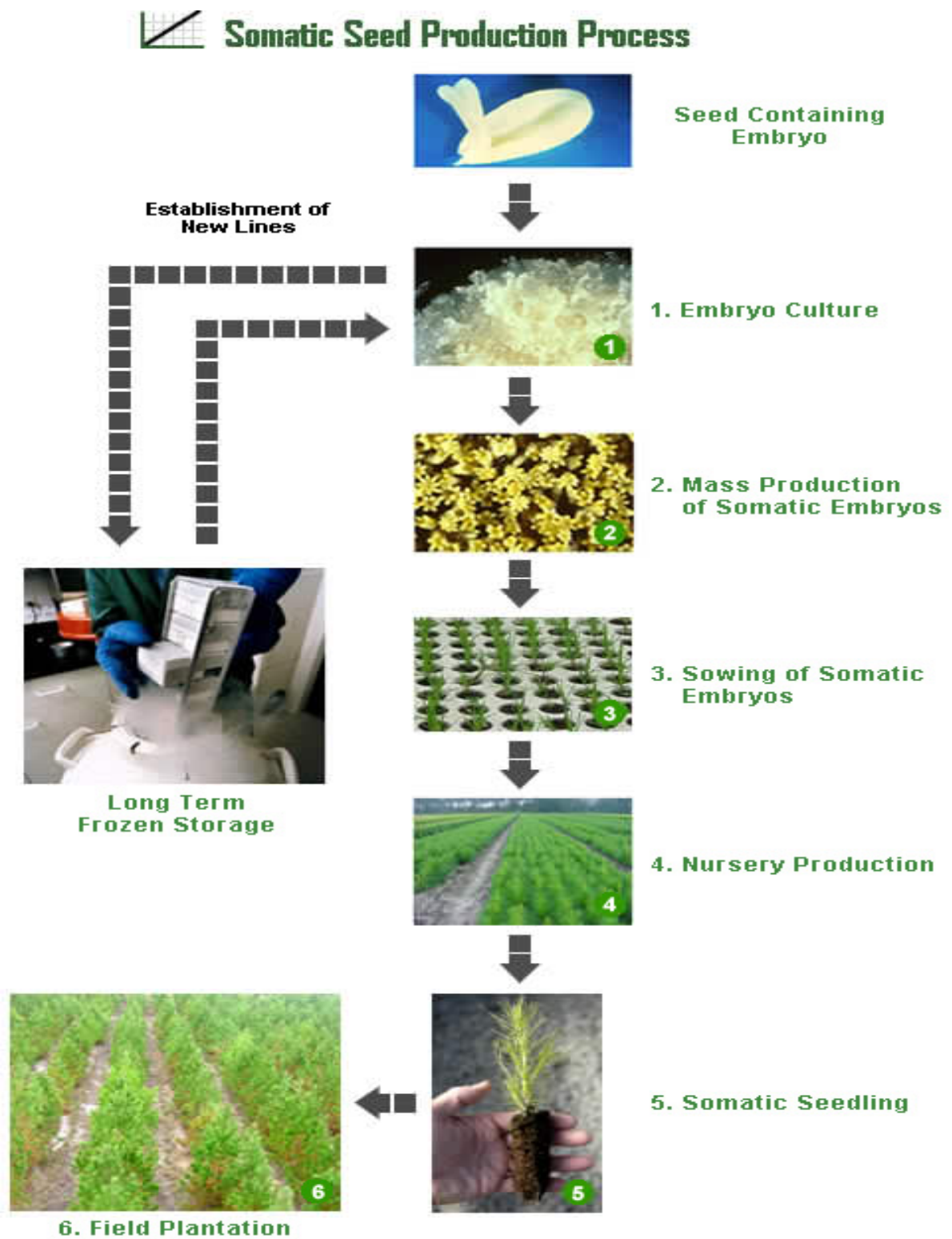
Figure 2 – Production Process for SE seed⁸

Figure 3 – Process Plan for Somatic Embryogenesis

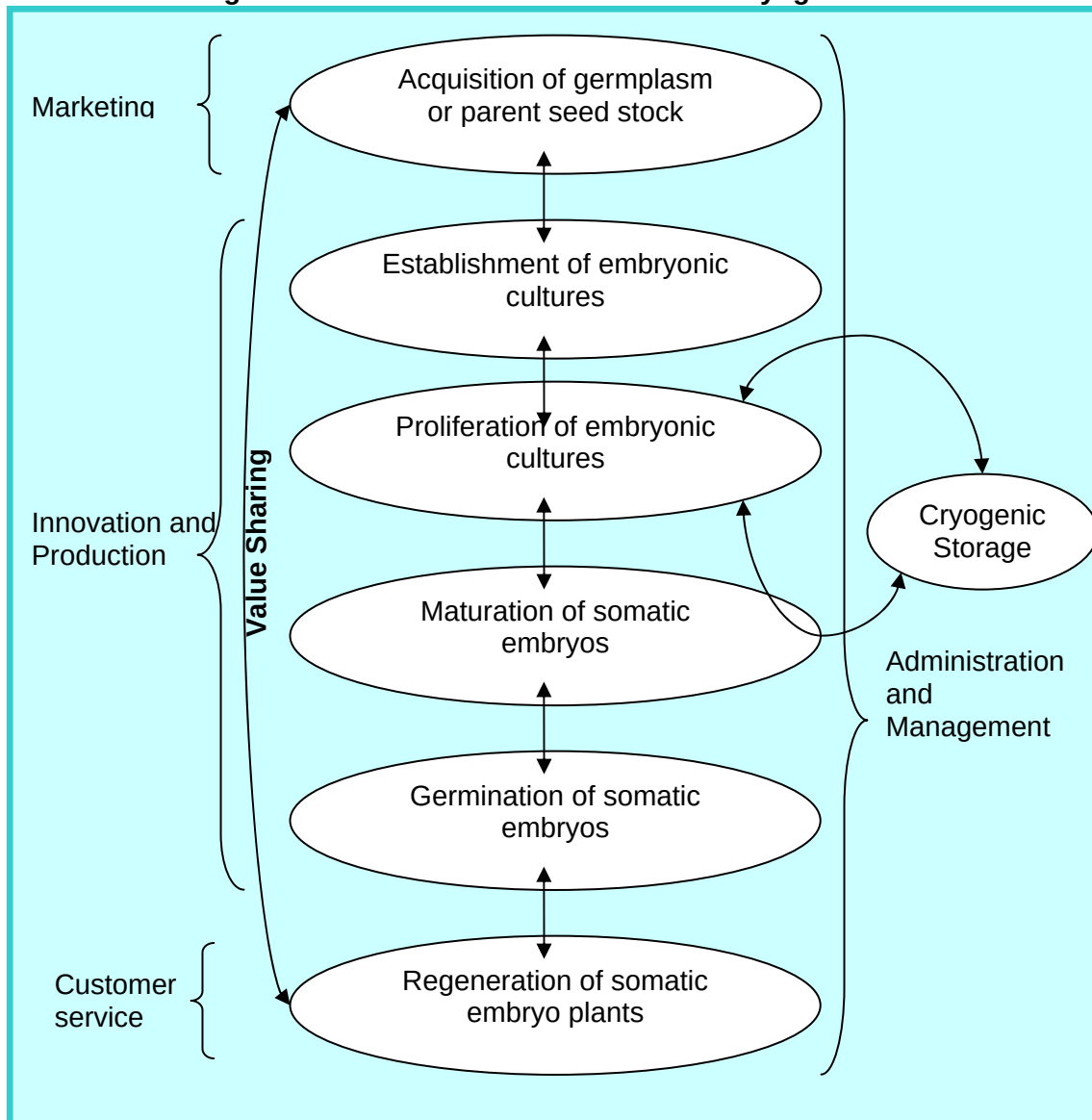


Figure 3 – Process Plan for Somatic Embryogenesis

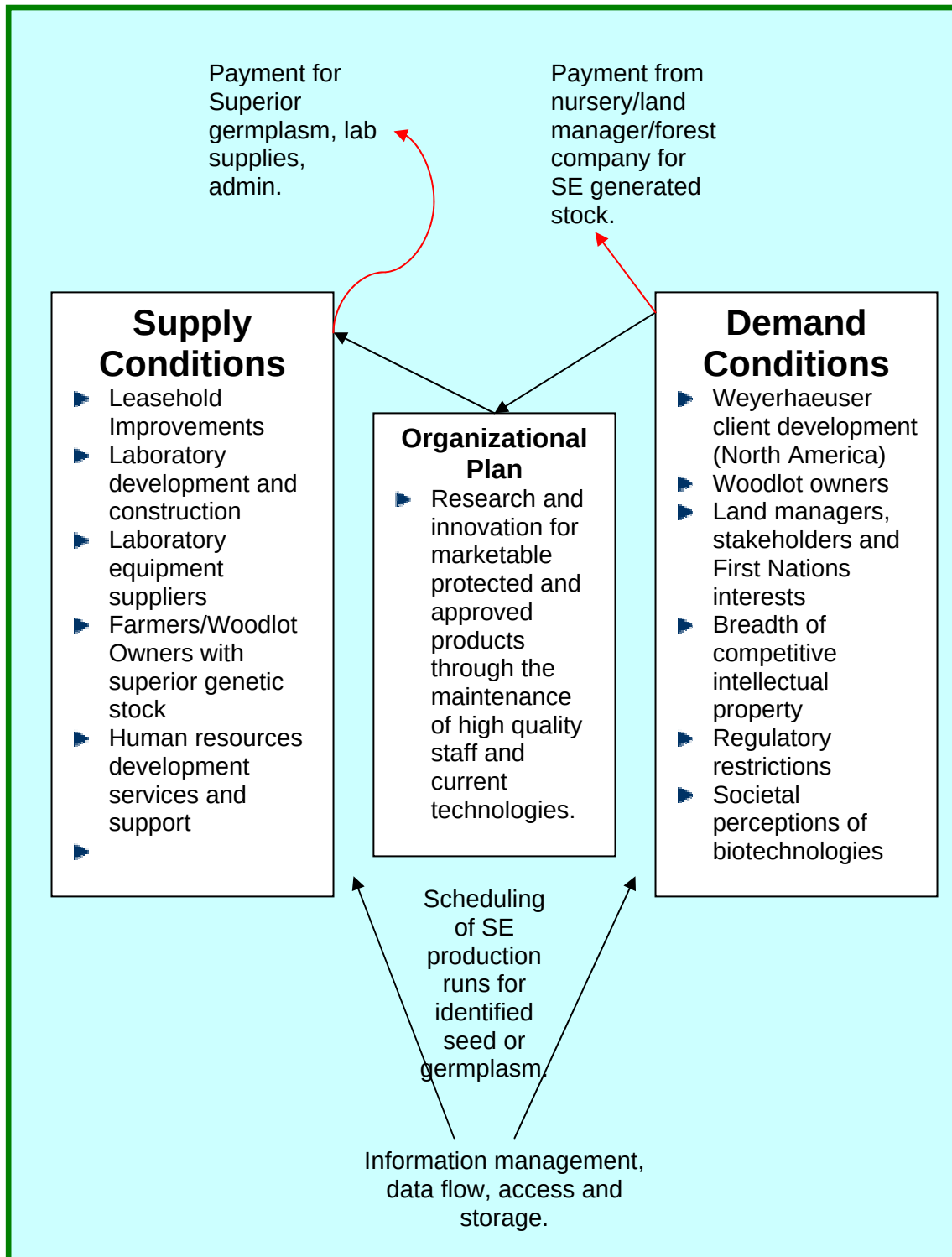


Table 1 – Stock/Sunk Costs for a Forest Biotechnology Firm

Item	Use	Cost
Technology Equipment		
▶ Database servers ▶ Personal computers ▶ Networking systems ▶ Software ▶ Set-up costs	The transfer, storage and sharing of the knowledge of the organization. Provides the tools for managing, analyzing, manipulating, storing and accessing data.	~\$40,000
Laboratory Equipment		
▶ Bioreactors ▶ Autoclaves/Sterilizers ▶ Glassware inventory ▶ Chemical stock ▶ Accurate scales ▶ Immersion systems ▶ Cryogenic systems	The creation of new knowledge, the testing of current processes, the enhancement of current knowledge, the generation of new data.	~\$80,000
Services Hook-ups		
▶ Gas ▶ Power ▶ Water ▶ Phone ▶ Internet	The access to information, the quality of life for workers, the sharing of information.	~\$2,000
Germplasm Acquisition		
▶ Plant stock ▶ Germplasm ownership rights ▶ Enhanced seed stock	The creation of high quality, innovative and value enhancing products.	~\$15,000
Leasehold Improvements		
▶ Laboratory construction ▶ Networking infrastructure ▶ Office construction	The quality of products, the creation of innovative knowledge.	~\$100,000
Totals		~\$237,000

Table 2 – Effects of a Process-Oriented Layout for a Forest Biotechnology Firm

Element	Effect	Setting
Goal: Innovation		
High labor skills	- Highly specialized research scientists - Experience and ability to implement SE - Cost of specialized research labor - Training and skill development costs - Quality congruent with skill - High production costs associated with novel products (testing, approvals, IPR)	Innovation/Production
Uneven Production Cycles	- Different processes for different seed stock - Dependent on client needs (amount of seedlings required) - Requires development of good working relationships with germplasm suppliers - Good understanding of client needs - Demand-pull creates a need for production (client dependent)	Innovation/Production Customer Service
Scheduling	- Requires dynamic scheduling and flexible hours to promote staff involvement - Requires that processes be clearly defined for all products - Expertise and cost associated with production of different seed stock	Office/ Administration

Table 3 – Costs of a Process-Oriented Layout for a Forest Biotechnology Firm

Item	Costs							
	2003	2004	2005	2006	2007	2008	2009	2010
Telephone ¹	\$26,400	\$27,700	\$29,000	\$30,300	\$31,600	\$32,900	\$34,200	\$35,500
Power ²	\$26,400	\$27,700	\$29,000	\$30,300	\$31,600	\$32,900	\$34,200	\$35,500
Water ³	\$13,200	\$13,800	\$14,400	\$15,000	\$15,600	\$16,200	\$16,800	\$17,400
Gas ⁴	\$9,600	\$10,100	\$10,600	\$11,100	\$11,600	\$12,100	\$12,600	\$13,100
Leasehold Improvements ⁵	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000
Internet ⁶	\$13,200	\$13,800	\$14,400	\$15,000	\$15,600	\$16,200	\$16,800	\$17,400
Laboratory consumables ⁷	\$50,000	\$50,000	\$50,000	\$50,000	\$50,000	\$50,000	\$50,000	\$50,000
Total (\$USD)	150,803	155,104	159,405	163,706	168,007	172,308	176,609	180,910

¹ Based on \$40 per month per employee – 55 employees, growing at 5% annually

² Based on \$40 per month per employee – 55 employees, growing at 5% annually

³ Based on \$20 per month employee – 55 employees at 5% annually

⁴ Based on heating the office at all times – fixed costs, growing at 5% annually

⁵ Based on a 10% improvement to original \$100,000 investment annually

⁶ Based on \$20 per month per employee – 55 employees, growing at 5% annually

⁷ Based on 5% of expected sales - \$1,000,000 annual revenues

Table 4 – Critical Success Factors for a Forest Biotechnology Firm

CSF	Reasoning and Scale	Factor Rating Weight*
1. Quantity/Access to Experienced Qualified Research Scientists	Access and availability to, and diverse applicants of, biotechnology researchers. 0 = Minimal, 100 = Plentiful	0.08
2. Costs of Management and Research Labor	The rate of pay for professional researchers and management staff. 0 = Very low, 100 = Very high	0.11
3. Quality of Life for Staff	Social culture and public infrastructure for staff after-hours 0 = None, 100 = Highly developed	0.04
4. Tax Structure	Amount of both Corporate Tax and Personal Income Tax that is levied by the Government. 0 = no tax, 100 = Taxation in excess of 60%	0.11
5. Education and Health	Quality and infrastructure of education and health care systems 0 = very poor, 100 = excellent	0.04
6. Research Infrastructure (societal networks)	Quality of telephony, internet, and business resources. 0 = very poor, 100 = excellent	0.05
7. Federal Regulatory Restriction	Amount and depth of legislation regulation biotechnology products. 0 = Excessive, 100 = None	0.20
8. Regional Regulatory Restriction	Amount and depth of legislation regulation biotechnology products. 0 = Excessive, 100 = None	0.04
9. Intellectual Property Legislated Protection	Amount and depth of legislation protecting intellectual property. 0 = Excessive, 100 = None	0.09
10. Size of Domestic Product of Forest Industry	Market size and output of forest sector 0 = Small, 100 = Large	0.07
11. Proximity to Forest Seedling Nurseries	Proximity with Forest Nurseries 0 = Far, 100 = Close	0.03
12. Proximity to Client	Proximity to Forest Industry Headquarters and Client Offices 0 = Far, 100 = Close	0.03
13. Societal Perception of Biotechnology	The effects that society, stakeholders and special interest groups (NGO's) have on implementation. 0 = Excessive, 100 = None	0.06
14. Existing Biotechnology Firms and Competitors	Other competitive firms in the same market and existing proprietary knowledge they may have claimed on the market 0 = Excessive, 100 = None	0.03
15. Access to Localized Network of Research Facilities (Proximity to Cluster)	Proximity to collections of research facilities and networking benefits 0 = Far, 100 = Close	0.02
Total Factor Weights =		1

*The Factor Rating Weight was assigned in accordance with the total contribution to success, with the weight factor of all 15 CSF's totaling 100%.

Table 5 – Supply-Chain Costs for a Forest Biotechnology Firm

Item	Costs							
	2003	2004	2005	2006	2007	2008	2009	2010
Layout Costs ⁸	150,803	155,104	159,405	163,706	168,007	172,308	176,609	180,910
Germplasm Acquisitions ⁹	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000
Selling and Administration ¹⁰	430,000	430,000	430,000	430,000	430,000	430,000	430,000	430,000
Research and Support ¹¹	2,700,000	2,700,000	2,700,000	2,700,000	2,700,000	2,700,000	2,700,000	2,700,000
Development Activities ¹²	210,000	210,000	210,000	210,000	210,000	210,000	210,000	210,000
Knowledge Management ¹³	40,000	40,000	40,000	40,000	40,000	40,000	40,000	40,000
Computer systems maintenance ¹⁴	25,000	25,000	25,000	25,000	25,000	25,000	25,000	25,000
Laboratory Maintenance (depreciation, replacement of equipment) ¹⁵	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000
Human Resource Spending (training, development programs, pension contributions) ¹⁶	55,000	55,000	55,000	55,000	55,000	55,000	55,000	55,000
Total (\$USD)	\$3,672,806	\$3,677,108	\$3,681,410	\$3,685,712	\$3,690,014	\$3,694,316	\$3,698,618	\$3,702,920

⁸ As detailed in Table 3 of this analysis.

⁹ Based on an average expenditure of \$80,000 in 8 years.

¹⁰ Based on 23% of \$1,000,000 sales revenues.

¹¹ Based on staff of 11 senior researchers, average annual salary \$100,000 USD/year and 40 research assistants and support staff at an average salary of \$40,000 per year.

¹² Based on 4 staff at total salaries of \$430,000 per year.

¹³ Based on an average investment per patent of \$335,000 as determined in the Intellectual Property Rights Profiles on SE, March 1, 2004. Average of \$320,000 over 8 years for the management of at least one patent.

¹⁴ Based on users of 55 employees and maintenance staff required for system upgrades and support.

¹⁵ Based on a re-investment of \$400,000 over 8 years into laboratory and equipment upgrade and maintenance.

¹⁶ Based on \$1,000 per employee per year for training, skill development and enhancement.

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