DECIMA HEALTHCARE MEGA INDUSTRIES

PROPOSAL FOR RAPID ESTABLISHMENT OF MEDICAL DEVICE & PHARMACEUTICAL MANUFACTURING FACILITES IN PLOT 1 & 2 BLOCK A, MBEZI MPONGA, MKURANGA DISTRICT TANZANIA

I. Executive Summary:

Decima Group Limited is a Tanzanian company established in 2019 and started operations in 2020 dealing with import and distribution of medical devices and specialized pharmaceuticals from foreign manufacturers located in China, India, Germany, Egypt etc. to deliver our services to health facilities throughout Tanzania.

While rural and urban health facilities demand for the services, there are only 3 manufacturing industries for medical consumables in sub–Saharan Africa which barely meet the demand. Hence a establish our own manufacturing facility that will not only provide significant cost savings but will also reduce significant delays associated with imports.

Demand for medical equipment in Tanzania & its neighboring countries is experiencing a sharp rise. The government has invested a lot in construction of new facilities in the country in all levels of care. Despite the penetration for Health Insurance is less than 10% in the country, Insured patients account for more than 80% of the hospital visits and revenue. In December 2023 the bill for Universal Health Insurance was signed into law in the country which will massively impact the healthcare network with regards to seeking medical attention.

About 95% of medical consumables used in the country originate from China and India. With the country going through a foreign exchange crisis with a constant rising US index doing up more than 20% in the past year alone. Severe shortages are being experienced by health facilities.

For reference, this is the timeline to order a simple oxygen mask in Tanzania:

1. Place an order to the manufacturer - Make payments for the production - Average Lead time - 30 days (This is assuming readily available foreign currencies in the bank, which is not the case at present)
2. Shipping from China to Tanzania - 30 - 45 days
3. Import & Custom Clearance Procedures after arrival - Minimum 15 days
4. Quality testing and Shipment to client - 3 days

Total: 75 - 90 days minimum to get simple oxygen masks from China/India to Tanzania.

In instances of crisis such as the COVID Pandemic that timeline doubled.

When compared to local manufacturing the same order would be fulfilled and delivered to the client in less than a week. This is because we have control of the production process and are less likely to be affected by supply chain issues.

II. Project Description:

The company is aiming for a comprehensive 5 phase plan which will involve 14 manufacturing units within the same location, 8 dedicated to medical devices production and 6 for pharmaceuticals manufacturing. This proposal is aimed to summarize those phases.

The company is set to build a state-of-the-art manufacturing unit The location for this project will be in a 20-acre plot owned by the company located in Msufini - Kidete village, Mbezi Gogoni ward in Mkuranga District, Pwani Region, 30 km from Dar es Salaam region, the main economic hub and most populated city in Tanzania.

During the initial phase, one steel structure pilot unit and two 6-storey buildings each with 6,750 square meters (72656 sq ft) buildings with a total combined working area of 13,500 sqm (145,312 sq ft) producing 80 unique medical consumables upon completion. This will make it the largest medical device manufacturer in the entire continent by number of products, floor space and unit volumes of production.

The units will have automated and semiautomated production lines for the following devices, We aim for at least 50% of the lines to be fully automated and the rest semi-automated.:

PHASE I

Pilot Unit: Endotracheal Tubes, Tracheostomy Tubes, Yankeur Suction Tubes, Suction Catheters, Rectal Tubes, Disposable Airway, Feeding Tubes - Nasogastric Tube, Infusion Set, Blood Transfusion Set, Ryles Tube (Gastric Tube), Neonatal Cord Clamps, Blood Lancets, Spinal Needles, Silicone Urinary Catheters, Wound Drainage Kits, Chest Tubes, External Ventricular Drains, Ureteric Stents, Breathing Circuits, Central Venous Catheters.

Unit 1: Syringes - All Standard Sizes, Auto disable, Luer Lock & Feeding Syringes, Insulin Syringes, Oxygen Masks - Adult and Pediatrics, Non-Rebreathing Masks - Adult and Pediatrics, Nebulizer Masks, IV Cannula with Wings, HME Bacterial Filters, Blood Collection Tubes, Latex Foley Catheters - 2 Way And 3 Way, Underwater Seal Drainage Bottles, Urine Collection Bags, Blood Bags

PHASE II

Unit 2: Hemodialysis Catheter Kits, Hemodialysis Blood Lines, Hemodialysis Dialyzers, AV Fistula Needles, A & B Solutions/Powder for Heamodialysis.

Unit 3: Rehabilitation Products (Arm Slings, Braces, Supports), Crutches, Wheelchairs & Ambulatory Devices, Hospital Beds, Surgical Gowns, Disposable, Patient Gowns, Isolation Gowns, Bouffant Caps, Disposable Aprons, Alcohol Swabs

PHASE III

Unit 4: Stainless Steel Surgical Instruments, Orthopaedic Implants

Unit 5: Plaster of Paris - All Sizes, Cotton Gauze, Absorbent Cotton Wool, Zinc Oxide Plaster, Crepe Bandages, Undercast Padding, Medical Cotton Wool

Unit 6: Sterile Gloves, Gynecology Gloves, Examination Gloves, Urine Test Strips, Glucose Test Strips Manufacturing, Lateral Flow Test Strip Manufacturing

Unit 7: Warehouse & Major Sterilization Unit

PHASE IV - PHARMACEUTICALS
Unit 1: Non-Beta Lactams
Unit 2: Syrups, Topicals, Nasal Sprays, Eye Drops
Unit 3: Inhalational Anesthesia

PHASE V - PHARMACEUTICALS
Unit 4: Injectables
Unit 5: Beta Lactam Medication
Unit 6: Oncology Medication

The devices and pharmaceuticals listed above for each unit were selected due to similar manufacturing techniques and equipment used could fit multiple products in their production cycle.

Representatives from company management also visited the machinery manufacturers to learn more about efficient manufacturing processes for the devices and ensure appropriate training will be given to the employees before production commences

III. Market Analysis:
Both the government and private sectors have invested heavily in healthcare especially on the point of care settings. New hospitals are being established yearly and the government has roled out a comprehensive plan to make sure quality healthcare is provided from the primary levels. In the end of year 2023 the government passed into law the universal health insurance policy. Since despite less than 10 percent of the population account for more than 80% of hospital attendance, the policy is set to lead to an overall increase in hospital attendance from the increased accessibility.

Despite the rapid growth in patient services, the increased need for medical devices especially consumables has not been sufficiently covered. Until January of 2024, out of hundreds of consumables used daily, only 11 medical devices manufactured in Tanzania were registered in the TMDA database, with 6 of them being diagnostic POC tests. The rest were all from foreign manufacturing facilities especially in China and India.

During the COVID crisis restrictions to import of the medical devices especially oxygen products was significant. The severe competition made the prices skyrocket in both the global and local markets and made developing countries clearly see the vulnerabilities of the supply chain and effects on dependence on foreign manufacturing.

19 of the 20 countries with the highest population growth in 2023 were in Africa. From its geography, a manufacturing facility in Tanzania is perfectly poised to be an efficient hub for manufacturing and supply to most countries in Sub-Saharan Africa.

Tanzania’s TMDA has one of the stringiest regulatory requirements for pharmaceuticals and medical devices in Africa. A facility with TMDA’s Current Good Manufacturing Practices (cGMP) certificates, is in most cases compliant to WHO, CE (European Union) and USFDA requirements making export certifications to these countries more in reach.

TMDA also works hand-in-hand with local manufacturers to ensure compliance and foster local industry. The company has already obtained approval for its construction plans making it avoid costly construction, production and compliance mistakes.

Consumables selected for this phase of the project are of everyday use and critical to running day to day activities of the healthcare facilities, and with the increasing waves of non-communicable diseases including chronic kidney disease, we expect demand for devices to increase significantly.

IV. Project Objectives:

The establishment of a medical consumable manufacturing facilities, aim to address critical healthcare supply gaps and contribute to the enhancement of local healthcare infrastructure. The project's comprehensive objectives are designed to ensure the production of a diverse range of medical consumables, fostering self-sufficiency, and promoting improved healthcare outcomes in the region.

1. Enhance Local Healthcare Accessibility:
    - Increase the availability of essential medical consumables locally to reduce dependency on imports and wait times and enhance accessibility for healthcare providers in East Africa.
2. Improve Healthcare Quality:
    - Manufacture high-quality medical consumables adhering to international standards, ensuring the provision of safe and effective healthcare interventions.
3. Mitigate Supply Shortages:
    - Alleviate shortages of critical medical consumables in healthcare facilities, especially in emergency and life-saving procedures.
4. Generate Employment Opportunities:
    - Create employment opportunities for the local community, fostering economic development and contributing to poverty reduction.
5. Foster Technological Transfer:
    - Facilitate the transfer of technological know-how and best practices in medical consumable manufacturing, promoting skill development and knowledge transfer to the local workforce.
6. Enhance Healthcare Infrastructure:
    - Contribute to the improvement of overall healthcare infrastructure in East Africa by establishing a state-of-the-art manufacturing facility and supporting the development of a robust supply chain.
7. Promote Sustainable Healthcare Practices:
    - Implement eco-friendly and sustainable manufacturing practices to minimize environmental impact and contribute to long-term ecological sustainability.
8. Strengthen Regional Healthcare Resilience:
    - Build resilience in the regional healthcare system by providing a consistent and diversified supply of medical consumables, ensuring preparedness for various healthcare challenges.
9. Facilitate Research and Development:
    - Invest in research and development activities to continually enhance product quality, introduce innovations, and adapt to evolving healthcare needs.
10. Enhance Health Equity:
    - Contribute to reducing health disparities by ensuring equitable access to essential medical consumables, addressing the needs of diverse demographic groups within the region.
11. Achieve Financial Sustainability:

- Establish a financially sustainable business model that ensures the long-term viability of the manufacturing facility, allowing for continued production and support of local healthcare needs.

The above objectives collectively aim to create a lasting and positive impact on the healthcare landscape in Tanzania and Africa as a whole, fostering a self-sufficient and resilient healthcare system that can effectively meet the needs of the community.

V. Project Implementation Plan:
Phased timeline for construction, equipment procurement, and production initiation.

Timeline – Phase I
We aim for the first unit to be operational by End of July 2024

- Land acquisition and Ownership transfer - Complete
- Utility Surveys - Electricity & Water - Done
- Obtain Architectural Designs - Done
- Approval of designs by TMDA - Done
- Construction Quotes Obtained - Done
- Machinery Quotes Obtained - Done
- Construction Starts – July 2024 - 30th 2024
- Borehole Drilling – August 1st 2024 – August 14th 2024
- Machinery Acquisition – July 2024 - September 30th 2024
- Training & First Product Run – September 15th 2024 - September 30th 2024
- **Official Opening - Wednesday October 1st 2024**

Implementation Plan:

1. Project Initiation:
    - Establish a project management team comprising seasoned professionals with experience in the healthcare manufacturing sector.
    - Conduct a detailed feasibility study, including site selection, regulatory compliance, and initial investment requirements.
2. Facility Design and Construction:
    - Collaborate with reputable architectural and engineering firms to design a state-of-the-art manufacturing facility adhering to international quality standards.
    - Implement a construction timeline with regular progress assessments to ensure timely completion.
3. Technology and Equipment Acquisition:
    - Source cutting-edge manufacturing equipment and technology to optimize production efficiency.
    - Develop strategic partnerships with suppliers to secure reliable and cost-effective procurement channels.
4. Regulatory Compliance:
    - Engage legal experts to navigate and comply with local and international regulations governing the production and distribution of medical consumables.
    - Obtain necessary certifications and approvals from relevant health authorities.
5. Marketing and Distribution:

- Develop a comprehensive marketing strategy to position the brand as a reliable supplier of high-quality medical consumables.
- Establish distribution networks and partnerships to ensure widespread availability of products.

6. Monitoring and Evaluation:
   - Implement a robust monitoring and evaluation system to track key performance indicators and adjust strategies as needed.
   - Conduct regular audits to ensure adherence to quality standards and regulatory requirements.

VII. Regulatory Compliance:

A. Understanding Regulatory Landscape:
- We have been working closely with local regulatory authorities governing medical device manufacturing in Tanzania, such as the Tanzanian Medicines and Medical Devices Authority (TMDA).
- Familiarize with international regulatory standards applicable to medical devices, including FDA regulations, CE Marking requirements, and ISO standards.

B. Compliance Team Establishment:
- A dedicated compliance team will be formed comprising regulatory experts, quality assurance professionals, and legal advisors.
- Clear roles and responsibilities will be assigned to team members for overseeing compliance efforts

C. Gap Analysis and Assessment:
- A comprehensive gap analysis will be conducted to identify discrepancies between current practices and regulatory requirements.
- Evaluating existing processes, documentation, and infrastructure against local and international standards.

D. Implementation of Quality Management Systems (QMS):
- Developing and implementing a robust Quality Management System (QMS) compliant with ISO 13485 standards
- Ensuring that all manufacturing processes, from design to distribution, adhere to QMS protocols

E. Training and Capacity Building:
- Regular training sessions will be provided to employees on local and international regulatory requirements.
- Investing in capacity building programs to enhance regulatory compliance knowledge and skills among staff members.

F. Documentation and Record-Keeping:
- Meticulous documentation practices will be established to maintain records of all manufacturing processes, quality control measures, and regulatory submissions.
- Documentation will be ensured in order to comply with both local regulations and international standards.

G. Product Registration and Approval:
- Working closely with the TMDA to navigate the product registration process for medical devices manufactured in Tanzania.

- Prepare and submit all required documentation for regulatory approval, including product specifications, testing results, and labeling information.

H. Supplier and Material Management:

- Stringent supplier qualification processes will be implemented to ensure all materials and components meet regulatory standards.
- Maintaining thorough records of material traceability and supplier certifications.

I. Post-Market Surveillance and Vigilance:

- Procedures for monitoring the performance of medical devices in the market will be established and collecting feedback from users.
- Developing a system for reporting adverse events or product complaints to regulatory authorities promptly.

J. Continuous Monitoring and Improvement:

- Regular audits and assessments will be conducted to ensure ongoing compliance with regulatory standards.
- Staying abreast of updates and changes to local and international regulations, and adapt processes accordingly.

K. Budget Allocation and Resource Planning:

- Sufficient budget and resources will be allocated to support compliance efforts, including training, infrastructure upgrades, and regulatory submissions.
- Prioritizing investments in areas critical to maintaining regulatory compliance and product quality.

Address any potential challenges and mitigation plans.

A. Regulatory Compliance:

- Challenge: Navigating and complying with local and international regulatory requirements.
- Mitigation Plan: Investing in a thorough understanding of Tanzanian and international regulatory frameworks. Collaborating with regulatory bodies, seeking expert advice, and will ensure that the manufacturing facility adheres to all necessary standards.

B. Infrastructure Development:

- Challenge: Inadequate infrastructure for manufacturing and distribution.
- Mitigation Plan: Existing infrastructure will be assessed, working with local authorities for improvements, and investing in developing a robust supply chain. Collaborating with logistics companies to ensure efficient transportation of raw materials and finished products.

C. Skilled Workforce:

- Challenge: Limited availability of skilled labor in medical device manufacturing.
- Mitigation Plan: training programs will be implemented, collaborating with local educational institutions to tailor courses for the industry's needs, and providing ongoing professional development opportunities. Considering partnerships with international organizations for knowledge transfer.

D. Supply Chain Risks:

- Challenge: Dependency on a fragile or unreliable supply chain.
- Mitigation Plan: Diversifying suppliers, conducting thorough risk assessments, and establishing contingency plans for potential disruptions. Maintaining buffer stocks of critical

components and exploring local sourcing options to reduce dependence on international suppliers and vertical integration by last phase of the project.

E. Quality Control and Assurance:

- Challenge: Ensuring consistent quality of manufactured medical devices.
- Mitigation Plan: Implementing stringent quality control processes, adhering to international quality standards, and investing in advanced testing equipment. Regularly training and educating staff on quality control procedures, and establishing a robust quality management system.

F. Financing and Funding:

- Challenge: Securing adequate financing for the establishment and ongoing operation of the facility.
- Mitigation Plan: Developing a comprehensive business plan to attract investors. Exploring partnerships with local and international financial institutions, government grants, and incentives. Considering phased implementation to manage initial capital expenditure.

G. Market Access and Distribution:

- Challenge: Establishing a market presence and efficient distribution channels.
- Mitigation Plan: Conducting market research to understand local demand, establishing partnerships with local healthcare providers, and working closely with distributors. Developing a marketing strategy tailored to the Tanzanian market and establishing a strong sales and distribution network.

Demonstrate a commitment to quality control and product safety.

Establishing a medical device manufacturing facility in Tanzania requires a strong commitment to quality control and product safety to ensure the production of reliable and safe medical devices. Here's a demonstration of that commitment:

A. Compliance with International Standards:

- There will be a commitment to adhering to international quality standards such as ISO 13485, which is specific to medical device quality management systems. This certification ensures that the manufacturing processes meet global standards for safety and effectiveness.

B. Regulatory Compliance:

- Working closely with the Tanzanian Medicines and Medical Devices Authority (TMDA), to ensure that the facility complies with local regulations and standards.

C. Quality Management System (QMS):

- Establishing a robust Quality Management System (QMS) that includes procedures for design control, risk management, production and process controls, and post-market surveillance. Regularly auditing and updating the QMS to ensure continuous improvement.

D. Employee Training and Competency:

- Investing in comprehensive training programs for all employees involved in the manufacturing process. This will include training on quality control processes, safety measures, and adherence to regulatory requirements.

E. Supplier Quality Management:

- Implementing stringent criteria for selecting and evaluating suppliers. Ensuring that all raw materials and components meet specified quality standards. Regularly auditing and assessing suppliers to maintain a high level of quality in the supply chain.

F. Traceability and Documentation:

- Implementing systems for traceability of raw materials and components throughout the manufacturing process. Maintaining thorough documentation of each stage of production to facilitate traceability in case of any quality issues.

G. Risk Management:

- Developing and implementing a comprehensive risk management program that identifies potential hazards, assesses risks, and establishes controls to mitigate those risks. This will cover all aspects of the manufacturing process and product lifecycle.

H. Product Testing and Validation:

- Conducting rigorous testing and validation of all medical devices before they are released to the market. This will include performance testing, safety testing, and validation of manufacturing processes to ensure consistency and reliability.

I. Post-Market Surveillance:

- Establishing a system for monitoring the performance of devices in the market, collecting feedback, and investigating any adverse events. This information will be used to make continuous improvements to the products and manufacturing processes.

J. Continuous Improvement:

- Fostering a culture of continuous improvement within the organization. Regularly reviewing and updating processes based on feedback, performance data, and changes in regulatory requirements to ensure that the highest standards of quality and safety are maintained.

VIII. Environmental and Social Impact:

Economic Impact:

The construction and operation of the medical consumables manufacturing facility will have significant economic impacts on both the local and regional levels. During the construction phase, there will be a surge in employment opportunities, ranging from skilled laborers to engineers and architects. This influx of jobs will stimulate the local economy by increasing consumer spending and tax revenues. Once operational, the facility will provide sustainable employment for a diverse workforce, offering competitive wages and benefits. Additionally, the production of medical consumables will contribute to the growth of the healthcare sector, ensuring a steady supply of essential medical supplies and potentially attracting further investment in the region's healthcare infrastructure.

Social Impact:

The project will have profound social implications, particularly through job creation and community engagement initiatives as more than 600 direct jobs to the community with up to 2000 jobs created upon completion of the final phase of the project

By providing employment opportunities, the facility will enhance the livelihoods of local residents and contribute to poverty alleviation efforts. Furthermore, the company will engage in social responsibility programs such as vocational training, healthcare initiatives, and educational scholarships to uplift the surrounding communities. Community engagement efforts may include partnerships with local schools, hospitals, and non-profit organizations to address specific social needs and foster long-term relationships built on trust and mutual benefit.

Environmental Impact and Mitigation Measures:

The construction and operation of the manufacturing facility may have environmental implications, including air and water pollution, habitat disruption, and resource depletion. We have conducted a thorough environmental impact assessment and submitted the application to the National Environmental Management Council (NEMC) and are working to mitigate any impacts by several measures.

For instance, incorporating energy-efficient technologies and renewable energy sources can reduce carbon emissions and energy consumption.

Additionally, implementing water recycling and waste management systems can minimize water usage and pollution. Furthermore, the project can adopt sustainable sourcing practices, Most waste produced will be solid waste which will be recycled, any waste which is not reusable will be sorted and transported to a recycling and waste disposal facility located less than 1km from the factory area.

Adherence to Sustainability Practices:

The project will prioritize sustainability at every stage, from construction to operation. This includes adopting green building standards for the facility's design and construction to minimize environmental impact and maximize resource efficiency.

Moreover, the company will implement sustainable manufacturing practices, such as optimizing production processes to reduce waste generation and emissions.

Continuous monitoring and assessment will ensure compliance with sustainability goals, with regular audits to identify areas for improvement. By adhering to sustainability practices, the project will not only mitigate environmental impact but also enhance long-term viability and resilience in an increasingly resource-constrained world.

X. FINANCIAL ANALYSIS & PROJECTIONS:

** All amounts shown are in US Dollars (USD)

PHASE I (PILOT BUILDING & UNIT 1 BUILDING)

	ITEM	LOCAL COST	FOREIGN COST	TOTAL	ANNUAL TOTALS
i	Raw Materials (3 months)	75,000	436,800	511,800	2,047,200
ii	Utilities (3 months)	20,500	0	20,500	82,000
iii	Wages & Salaries (3 months)	110,000	0	110,000	440,000
iv	Other Operating Expenses (3 months)	35,000	0	35,000	140,000
	Subtotal	240,500	436,800	**677,300**	**2,709,200**
	Contingencies (10%)	24,050	43,680	67,730	270,920
	Net Working Capital	264,550	480,480	**745,030**	**2,980,120**
i	Land Building anc Civil Work	2,275,000	275,000	2,550,000	
ii	Plant Machinery, Equipment and Related Costs	1,107,750	5,275,000	6,382,750	
iii	Furniture and Fixtures	75,000	220,000	295,000	
iv	Vehicles	45,000	154,500	199,500	
v	Other Miscellenous Fixed	52,000	25,000	77,000	
	Subtotal	3,554,750	5,949,500	**9,504,250**	
	Contingencies (10%)	355,475	594,950	950,425	
	Net Fixed Capital	3,910,225	6,544,450	**10,454,675**	
	Total Annual Capital Requirements at Full Capacity for Phase I				**13,434,795**

REVENUE PROJECTIONS - PHASE I

SN		YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
1	Projected Sales	8,525,000	16,458,498	18,816,996	23,385,494	27,403,992
2	Fixed Capital Expenditures	5,227,338	5,645,000	392,050	444,324	522,734
3	Working Capital Expenditures	1,490,060	2,980,120	3,427,138	3,941,209	4,532,390
4	Depreciation (Averaged at 15%)	784,101	1,630,851	1,689,658	1,756,307	1,834,717
5	EBIT	1,023,502	6,202,527	13,308,150	17,243,655	20,514,151

PHASE II (UNIT II, III & WAREHOUSE BUILDING)

		LOCAL COST	FOREIGN COST	TOTAL	ANNUAL TOTALS
i	Raw Materials (3 months)	94,500	2,640,697	2,735,197	10,940,788
ii	Utilities (3 months)	27,500	0	27,500	110,000
iii	Wages & Salaries (3 months)	240,000	0	240,000	960,000
iv	Other Operating Expenses (3 months)	65,000	0	65,000	260,000
	Subtotal	427,000	2,640,697	**3,067,697**	**12,270,788**
	Contingencies (10%)	42,700	264,070	306,770	1,227,079
	Net Working Capital	469,700	2,904,767	**3,374,467**	**13,497,867**
i	Land Building anc Civil Work	5,100,000	1,425,000	6,525,000	
ii	Plant Machinery, Equipment and Related Costs	1,706,250	8,125,000	9,831,250	
iii	Furniture and Fixtures	25,000	120,000	145,000	
iv	Vehicles	45,000	154,500	199,500	
v	Other Miscellenous Fixed	50,000	25,000	75,000	
	Subtotal	6,926,250	9,849,500	**16,775,750**	
	Contingencies (10%)	692,625	984,950	1,677,575	
	Net Fixed Capital	7,618,875	10,834,450	**18,453,325**	
	Total Annual Capital Requirements at Full Capacity for Phase II				**31,951,192**

REVENUE PROJECTIONS - PHASE II

		YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
1	Projected Sales	48,475,000	54,292,000	61,892,880	71,176,812	79,718,029
2	Fixed Capital Expenditures	18,453,325	922,666	1,383,999	1,568,533	1,845,333
3	Working Capital Expenditures	13,497,867	15,522,547	17,850,929	20,528,568	23,607,853
4	Depreciation (Averaged at 15%)	2,767,999	2,906,399	3,113,999	3,349,278	3,626,078
5	EBIT	13,755,810	34,940,388	39,543,953	45,730,433	50,638,765

PHASE III (UNIT IV, V, VI, VII BUILDINGS)

		LOCAL COST	FOREIGN COST	TOTAL	ANNUAL TOTALS
i	Raw Materials (3 months)	135,000	45,400	180,400	721,600
ii	Utilities (3 months)	32,000	0	32,000	128,000
iii	Wages & Salaries (3 months)	50,000	0	50,000	200,000
iv	Other Operating Expenses (3 months)	25,000	0	25,000	100,000
	Subtotal	242,000	45,400	**287,400**	**1,149,600**
	Contingencies (10%)	24,200	4,540	28,740	114,960
	Net Working Capital	266,200	49,940	**316,140**	**1,264,560**
i	Land Building anc Civil Work (Steel Structure Building)	1,275,000	875,000	2,150,000	
ii	Plant Machinery, Equipment and Related Costs	141,750	675,000	816,750	
iii	Furniture and Fixtures	75,000	220,000	295,000	
iv	Vehicles	85,000	32,500	117,500	
v	Other Miscellenous Fixed	40,000	35,000	75,000	
	Subtotal	1,616,750	1,837,500	**3,454,250**	
	Contingencies (10%)	161,675	183,750	345,425	
	Net Fixed Capital	1,778,425	2,021,250	**3,799,675**	
	Total Annual Capital Requirements at Full Capacity for Phase III				**5,064,235**

REVENUE PROJECTIONS - PHASE III

		YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
1	Projected Sales	8,385,000	9,391,200	10,705,968	12,311,863	13,789,287
2	Fixed Capital Expenditures	3,799,675	189,984	284,976	322,972	379,968
3	Working Capital Expenditures	1,264,560	1,454,244	1,672,381	1,923,238	2,211,723
4	Depreciation (Averaged at 15%)	569,951	598,449	641,195	689,641	746,636
5	EBIT	2,750,814	7,148,523	8,107,417	9,376,012	10,450,960

PHASE IV - PHARMACEUTICALS - Unit 1: Non-Beta Lactams; Unit 2: Syrups, Topicals, Nasal Sprays, Eye Drops; Unit 3: Inhalational Anesthesia

		LOCAL COST	FOREIGN COST	TOTAL	ANNUAL TOTALS
i	Raw Materials (3 months)	0	1,161,907	1,161,907	4,647,627
ii	Utilities (3 months)	6,500	0	6,500	26,000
iii	Wages & Salaries (3 months)	250,000	0	250,000	1,000,000
iv	Other Operating Expenses (3 months)	65,000	0	65,000	260,000
	Subtotal	321,500	1,161,907	**1,483,407**	**5,933,627**
	Contingencies (10%)	32,150	116,191	148,341	593,363
	Net Working Capital	353,650	1,278,097	**1,631,747**	**6,526,989**
i	Land Building anc Civil Work	1,100,000	1,380,000	2,480,000	
ii	Plant Machinery, Equipment and Related Costs	1,286,250	6,125,000	7,411,250	
iii	Furniture and Fixtures	55,000	105,000	160,000	
iv	Vehicles	45,000	65,000	110,000	
v	Other Miscellenous Fixed	50,000	25,000	75,000	
	Subtotal	2,536,250	7,700,000	**10,236,250**	
	Contingencies (10%)	253,625	770,000	1,023,625	
	Net Fixed Capital	2,789,875	8,470,000	**11,259,875**	
	Total Annual Capital Requirements at Full Capacity for Phase IV				**17,786,864**

REVENUE PROJECTIONS - PHASE IV

		YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
1	Projected Sales	26,540,000	29,724,800	33,886,272	38,969,213	43,645,518
2	Fixed Capital Expenditures	11,259,875	562,994	844,491	957,089	1,125,988
3	Working Capital Expenditures	6,526,989	7,506,038	8,631,943	9,926,735	11,415,745
4	Depreciation (Averaged at 15%)	1,688,981	1,773,430	1,900,104	2,043,667	2,212,565
5	EBIT	7,064,154	19,882,338	22,509,734	26,041,721	28,891,220

PHASE V - PHARMACEUTICALS - Unit 4: Injectables; Unit 5: Beta Lactam; Unit 6: Oncology Medication

		LOCAL COST	FOREIGN COST	TOTAL	ANNUAL TOTALS
i	Raw Materials (3 months)	0	968,256	968,256	3,873,022
ii	Utilities (3 months)	6,500	0	6,500	26,000
iii	Wages & Salaries (3 months)	250,000	0	250,000	1,000,000
iv	Other Operating Expenses (3 months)	65,000	0	65,000	260,000
	Subtotal	321,500	968,256	**1,289,756**	**5,159,022**
	Contingencies (10%)	32,150	96,826	128,976	515,902
	Net Working Capital	353,650	1,065,081	**1,418,731**	**5,674,924**
i	Land Building anc Civil Work	1,100,000	1,380,000	2,480,000	
ii	Plant Machinery, Equipment and Related Costs	370,000	6,740,000	7,110,000	
iii	Furniture and Fixtures	85,000	65,000	150,000	
iv	Vehicles	0	165,000	165,000	
v	Other Miscellenous Fixed	50,000	25,000	75,000	
	Subtotal	1,605,000	8,375,000	**9,980,000**	
	Contingencies (10%)	160,500	837,500	998,000	
	Net Fixed Capital	1,765,500	9,212,500	**10,978,000**	
	Total Annual Capital Requirements at Full Capacity for Phase V				**16,652,924**

REVENUE PROJECTIONS - PHASE V

		YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
1	Projected Sales	21,640,000	24,236,800	27,629,952	31,774,445	35,587,378
2	Fixed Capital Expenditures	10,978,000	548,900	823,350	933,130	1,097,800
3	Working Capital Expenditures	5,674,924	6,526,163	7,505,088	8,630,851	9,925,478
4	Depreciation (15%)	1,646,700	1,729,035	1,852,538	1,992,507	2,157,177
5	EBIT	3,340,376	15,432,702	17,448,977	20,217,957	22,406,923

Break even analysis

There will be major variations in unit pricing and unit economics due to a large range of consumables produced. To simplify that, for each phase we shall assume that the break-even point will be a total of the fixed investment costs and working capital requirements for the particular phase.

Human Resource Allocations

In the proposed manufacturing facility, strategic human resource allocation is paramount to ensure streamlined operations and optimized productivity. Leveraging a blend of skilled personnel and advanced automation technologies is essential for meeting demand while maintaining quality standards. With a focus on efficiency and cost-effectiveness, the facility heavily invests in automated production lines to enhance output and minimize overhead expenses.

Human resources are meticulously allocated to oversee, monitor, and fine-tune these automated processes, ensuring seamless integration and optimal performance. This approach not only maximizes efficiency but also allows personnel to focus on specialized tasks that require human expertise, ultimately contributing to the facility's competitiveness and success in the medical consumables market.

The following is a simplified breakdown for the cumulative number of workers in the facility in all phases

PHASE I, II, III - HUMAN RESOURCE ALLOCATION

	POSITION	PHASE I	PHASE II	PHASE III
1	General Manager (AM & PM)	2	3	3
2	Unit Supervisors	3	6	7
3	Secretary	2	3	4
4	Finance Manager & Accountants	2	4	5
5	Electrical Engineers & Technicians	2	4	5
6	Machine Technicians	2	4	6
7	Marketing Staff	20	35	42
8	Plant and Line Operators	8	16	20
9	Assembly Line Workers (AM & PM Shifts)	25	75	110
10	Quality Controllers	4	8	10
11	Quality Assurance	7	14	14
12	Others (Guards, Storekeepers, Gardeners, Labourers)	10	20	24
13	Drivers	3	6	10
	TOTAL	**90**	**198**	**260**

PHASE IV, V PHARMACEUTICALS - HUMAN RESOURCE ALLOCATION

	POSITION	PHASE IV	PHASE V
1	General Manager (AM & PM)	2	4
2	Quality Assurance	7	14
3	Production	18	25
4	Quality Control	9	13
5	Warehouse (Storage and Distribution)	4	8
6	Engineering	4	8
7	Unit Supervisors	2	4
8	Secretary	1	2
9	Finance Manager & Accountants	2	5
	TOTAL	**49**	**83**

Risk Analysis:
The following potential risks are associated with the project.

Operational changes

- These are risks associated with change of the management team or change in team roles thus may result in the distractions of the whole operation to be executed on time.

Mitigation: Operational risk can be eliminated by ensuring that the management team is well governed and well controlled.

High costs

- Cost of material in construction and on production processes may affect the timeline to complete the project as it requires significant funding to compete a certain parts of the project

Mitigation: Production automation to reduce labor requirements over the long run, obtaining multiple quote from different regions so as to analyze best price to quality ratio.

Low availability of raw materials

- During production we expect to reach a target level so deficiency on raw material could be the main problem as more time may be required since the material is not locally source. This may lead to cessation of production or low output compared to the customers demand.

Mitigation: Raw material will be ordered semi-annually in bulk volume. Since most items use similar material, bulk orders will improve our negotiating position with tight controls on material allocation for each product.

XI. Monitoring and Evaluation

The following Key performance indicators (KPIs) will track the project's success.

These KPIs should provide insights into various aspects of the business that directly impact profitability. Here are some KPIs:

1. Gross Profit Margin: This KPI measures the percentage of revenue that exceeds the cost of goods sold. A higher gross profit margin indicates better profitability. We are aiming for a GPM of 65%.

2. Net Profit Margin: This KPI measures the percentage of revenue that remains as net profit after deducting all expenses, including COGS, operating expenses, taxes, and interest. It reflects the overall efficiency of the business in generating profits. We will aim to keep this above 40%.

3. Return on Investment (ROI): ROI measures the profitability of the factory relative to the initial investment. It calculates the ratio of net profit to the total investment and is expressed as a percentage.

4. Cost of Goods Sold (COGS) as a Percentage of Revenue: Monitoring COGS as a percentage of revenue helps track the efficiency of production processes. A decreasing trend in this ratio indicates improved profitability.

5. Average Revenue per Unit: This KPI calculates the average revenue generated per unit of medical consumables sold. Increasing this metric indicates higher profitability per unit.

6. Inventory Turnover Ratio: This ratio measures how efficiently inventory is managed by comparing the cost of goods sold to the average inventory level. A higher turnover ratio indicates better inventory management and potentially higher profitability.

7. Operating Expense Ratio: This KPI measures the proportion of revenue consumed by operating expenses such as salaries, utilities, and marketing. Lowering operating expenses relative to revenue can improve profitability. We aim to keep this at less than 15%.

8. Customer Acquisition Cost (CAC): CAC measures the cost of acquiring a new customer. Monitoring this metric ensures that customer acquisition efforts are cost-effective and contribute positively to profitability. This will be optimized after assessing lifetime value of the customer.

9. Return Rate: For medical consumables, tracking the return rate of products due to defects or customer dissatisfaction is crucial. A lower return rate indicates higher product quality and customer satisfaction, which can positively impact profitability. We will aim for a return rate of less than 1 percent annually.

10. Revenue Growth Rate: While not directly related to profitability, monitoring revenue growth is essential for long-term success. Sustainable revenue growth often leads to increased profitability over time. We aim for at least 35% year-over-year for the first 5 years.

These KPIs will be tracked regularly in an online database which, the management team and investors can gain insights into the factory's performance in real time and make informed decisions to improve profitability and overall success and dedicate extreme transparency throughout the process.

XII. Key Team Members & Organizational Structure:

1. Dr. Suddeys Abdulbasat Hatibu – Managing Director/Head of Operations

Suddeys is one of the youngest executives in the Tanzanian pharmaceutical industry. Prior to joining Decima, Suddeys has worked at Taneem Foundation where he served as Project Manager and later as Assistant Branch Manager for 3 years. He also played an integral role in negotiating sales agreements with both local manufacturers and distributors and developed networks with international manufacturers in world renown companies in the US, EU and the Indo-Pacific region.

Dr. Suddeys is a graduate of the Muhimbili University of Health & Allied Sciences where he obtained his MD. He has also worked at the National Hospital and other institutes in Neurosurgical, Emergency Medicine & Surgical departments gaining the required ground experience needed to navigate the healthcare arena.

2. Dr. Mariam Mkubwa Hamad – Director & Medical Device Superintendent

Cofounder and Director of the company, Dr. Mariam has 5 years of experience as the head of Medical Device Division and Superintendent to the company.

Dr. Mariam has been foundational in the rapid growth of the company since its foundation. Graduated at Muhimbili University of Health and Allied Sciences, her key areas also involve obtaining direct patient data and analyze ways to improve product quality and delivery.

3. Richard Amos Mathias – Head of Pharmaceutical Operations

An experienced pharmacist, Mr. Richard has 6 years of experience in the pharmaceuticals arena. Prior to joining Decima, he was the Managing Director and Chief Pharmacist for Afya Bora Group which is one independent distributorship chains in Tanzania that operates stores in multiple locations.

Mr. Richard was essential in evolving Decima's distributorship network and actively supervisors all pharmaceutical sales activity and reporting nationwide.

4. Musa Beatus Koko – Head of Regulatory and Compliance

Mr. Musa is the head of regulatory and compliance in the company. Prior to this, he was an External Expert with the Tanzania Medicine and Medical Devices authority (TMDA) on which he supervised activities of Pharmaceutical and Medical Devices registration and Industrial cGMP Inspections.

Mr. Musa has audited all manufacturers that want to collaborate with the company and issues an internal certificate of compliance. He has audited more than 15 facilities in different parts of the world in the past year on behalf of the company and is well acquainted with manufacturing standards.

XIII. Conclusion:

This project touches major pain points in the country and Sub-saharan Africa. This project will ensure long term prosperity of the community, healthcare providers and overall prosperity of the company and its shareholders. The race has begun and the companies willing to enter and establish efficient manufacturing units in the country will control the market for the foreseeable future.