DOW INSTITUTE OF LIFE SCIENCES (DILS)

DOW UNIVERSITY OF HEALTH SCIENCES

STRATEGIC PLAN

(2024 – 2027)

Pioneering Excellence | Inspiring Innovation

To Heal | To Educate | To Discover


بِسْمِ اللَّهِ الرَّحْمَٰنِ الرَّحِيمِ

TABLE OF CONTENTS

DIRECTOR'S MESSAGE

As the Director of the Dow Institute of Life Sciences (DILS), I am excited to share our vision for innovation in sera, vaccines, and biological products. After launching DOWRAB vaccines, DILS has become a recognized leader in advancing healthcare solutions that cater to Pakistan's unique needs.

Our journey has taken us from producing high-quality vaccines to achieving Good Manufacturing Practice (GMP) certification. We have started working to have World Health Organization (WHO) prequalification by 2026, which is mandatory to stay at the commanding heights in the sera and vaccines in the local and international markets. It showcases our commitment to global health. We aim to serve our local community by ensuring easy access to affordable but high-quality healthcare products. At the same time, we strive to contribute significantly to the international biopharmaceutical industry.

The DILS Strategic Plan for 2024–2030 reinforces our mission to deliver top-notch biological products through contract manufacturing agreements and enhance our production capabilities. We also aim to expand our reach through strategic partnerships and by adhering to international standards. Equipped with modern facilities and a dedicated research and development team, we are eager to collaborate with others to improve global healthcare.

As funds are available, we will acquire the hardware and software based on artificial intelligence and robotic technologies to match the high global standards.

We invite you to join us on this exciting journey. Together, we can tackle urgent healthcare challenges and build a sustainable future for future generations. Let's work together to create impactful partnerships that push the limits of healthcare innovation.

Dr. Izhar Hussain

EXECUTIVE SUMMARY

The Dow Institute of Life Sciences (DILS) at the Ojha Campus of Dow University Health Sciences is a biopharmaceutical manufacturing facility for high-quality, locally relevant sera, vaccines, and biologics. Dow Institute of Life Sciences (DILS) is on a transformative path to become a leading biopharmaceutical facility in Pakistan, emphasizing excellence in biological product production, self-sufficiency, and international compliance.

Our 2024-2027 Strategic Plan outlines key initiatives designed to expand our production capabilities, diversify our product portfolio, and achieve compliance with WHO standards. This comprehensive strategy seeks to address Pakistan's healthcare needs and elevate the country's position in the global biopharmaceutical landscape.

ABOUT THE INSTITUTE

Dow Institute of Life Sciences (DILS) Biopharmaceutical manufacturing facility was conceived in 2015 in the Ojha Campus of Dow University Health Sciences. The manufacturing facility of DILS is designed and equipped to manufacture, fill, pack, and test biological products and vaccine products in compliance with clean room ISPE and WHO Guidelines and is equipped with the most advanced production machinery for Biological and Vaccine Preparations. DILS got a Drug Manufacturing License (DML) in April 2020 by way of formulation for Sera. In Jun 2021, DRAP approved the Vaccine section for manufacturing attenuated/killed vaccine.

Currently, DILS can fill and pack 10 million packs and lyophilize one million packs. A total headcount of 15 people is working. In the future, we need 45 people to operate the facility in compliance. The Future Strategy of DILS is developed as Pakistan's largest Biopharmaceutical Company and to manufacture the indigenous vaccine.

HISTORY

Dow Institute of Life Sciences was established in 2015, with a concept to develop and manufacture Anti-Snake Venom in the province of Sind. In the end, the 2019 project is revived by hiring skilled and experienced persons from the pharmaceutical industry, and a Quality Management System (QMS) is developed by a hired team. The plant is started according to regulatory requirements and standards. An inspection team from the Drug Regulatory Authority (DRAP) of Pakistan visited and audited the plant for manufacturing Licenses for Sera vaccine filling. In April 2020, a Drug Manufacturing License was issued by DRAP. Dow University of Health Sciences is the first university in Pakistan.

In Jun 2021 second section of Vaccine filling is also approved for killed vaccine filling by DRAP, this will support financial feasibility Currently three commercial batches of Rabies vaccine have been filled and will be marketed after release from NCLB (National Control Laboratory for Biologicals). The facility aims to produce other products e.g. Polio vaccine, Tetanus toxoid and is under negotiation process with third party importers.

INTRODUCTION AND OVERVIEW

The Dow Institute of Life Sciences (DILS) is a state-of-the-art biopharmaceutical facility. Established as the first and only biotech facility in Sindh province and the second fully equipped facility in Pakistan after NIH Islamabad, DILS plays a pivotal role in the nation's self-sufficiency in biopharmaceuticals.

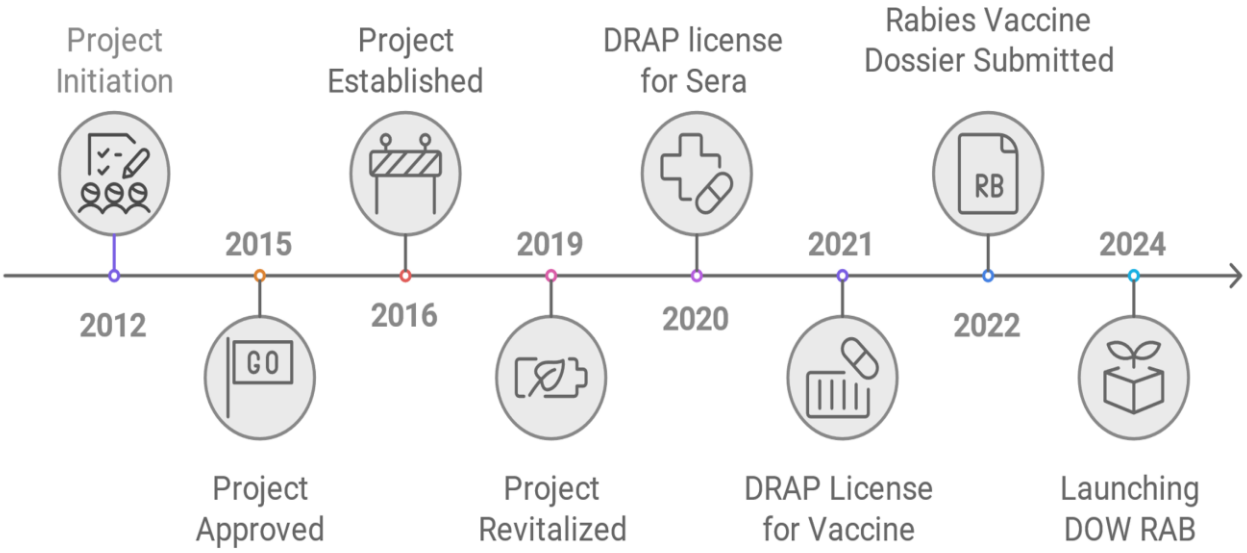
DILS complies with GMP (current Good Manufacturing Practices) and GLP (Good Laboratory Practices) compliance, ensuring adherence to the highest quality standards as outlined by the Drug Regulatory Authority of Pakistan (DRAP) Drugs Act 2012. This commitment to quality extends beyond regulations, with DILS prioritizing patient safety and trust by embedding rigorous quality checks throughout its operations.

DILS obtained the Drug Manufacturing License (DML) for sera products in April 2020 and an additional section for small volume parenteral attenuated/killed vaccine in June 2021. In 2023, DILS got the product registration of a rabies Vaccine and launched the product by the name of DOWRAB. In 2024, DILS Got the Good Manufacturing Practice (GMP) Certificate from the Drug Regulatory Authority of Pakistan.

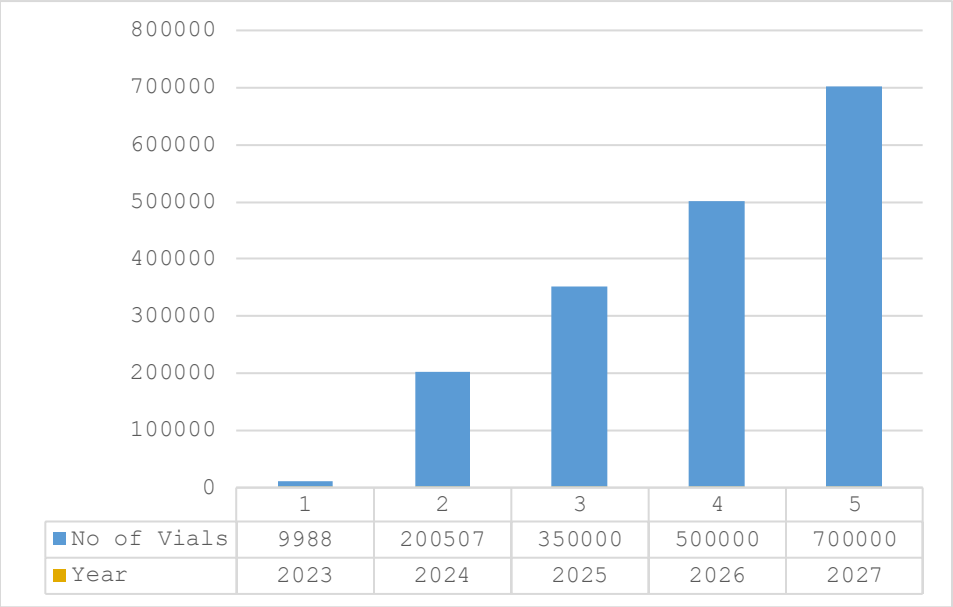
Capacities: The Production (filling) capacity in DILS is **9** million vials/ annum and the lyophilization capacity is **1.2** million vials /annum.

Leveraging the expertise of the Dow University of Health Sciences (DUHS) R&D team, DILS is positioned to develop and introduce innovative, disease-specific biological drugs and vaccines tailored to the needs of Pakistan.

Project History:



Production of Rabies Vaccine in the next 3 years:



Product Portfolio:

- **Anti-Rabies Vaccine:**
  - The Anti-Rabies Vaccine (ARV) is a life-saving biological product designed to prevent rabies following exposure to the rabies virus, commonly through bites from infected animals. Annual estimates suggest over **100,000** dog bite incidents nationwide, creating an urgent need for robust ARV production.
  - In 2024, **Dow Institute of Life Sciences** (DILS) achieved a significant milestone by producing 210 lac (**21 million**) vials of Anti-Rabies Vaccine. This achievement highlights DILS's capacity to address both local and regional demand for ARVs, ensuring accessibility and affordability for the population of Pakistan.

- **Anti-Snake Venom Serum (ASVS):**
  - The Anti-Snake Venom Serum is designed to treat envenomations caused by venomous snakes. This life-saving serum is critical for individuals in rural areas or regions where snakebite cases are more common, particularly in countries like Pakistan. **DILS** will ramp up its production of Anti-Snake Venom Serum gradually over the next few years.

- **Tetanus:**
  - The **Tetanus Vaccine** and **Tetanus Immunoglobulin (TIG) Serum** are critical components of public health strategies in Pakistan, where both childhood vaccination programs and emergency medical interventions for injuries are essential to preventing tetanus.
  - Based on epidemiological data, **50,000** to **100,000** doses of Tetanus

Immunoglobulin may be required annually in Pakistan for emergency use and treatment of severe wound-related tetanus.

- To meet the growing demand for Tetanus vaccines and TIG, **DILS** is planning its production in the next coming years.

Contract/ Toll Manufacturing

- Polio Vaccine: AJM Pharma
- Anti-Rabies Serum: 2-World
- Anti-Snake Venom Serum: 2-World/ IRIS
- Other biological products: (Insulin and other biological products)

Strengths:

1. Regulatory approval of the Drug Regulatory Authority for manufacturing killed vaccines and sera.'
2. Existing infrastructure has one line operational for producing sera or vaccines.
3. The demand for vaccines and sera is huge. All the current demand is met by imported products, mostly from China and India.
4. Potential for expansion: the DILS has space for expansion.

Challenges[1]:

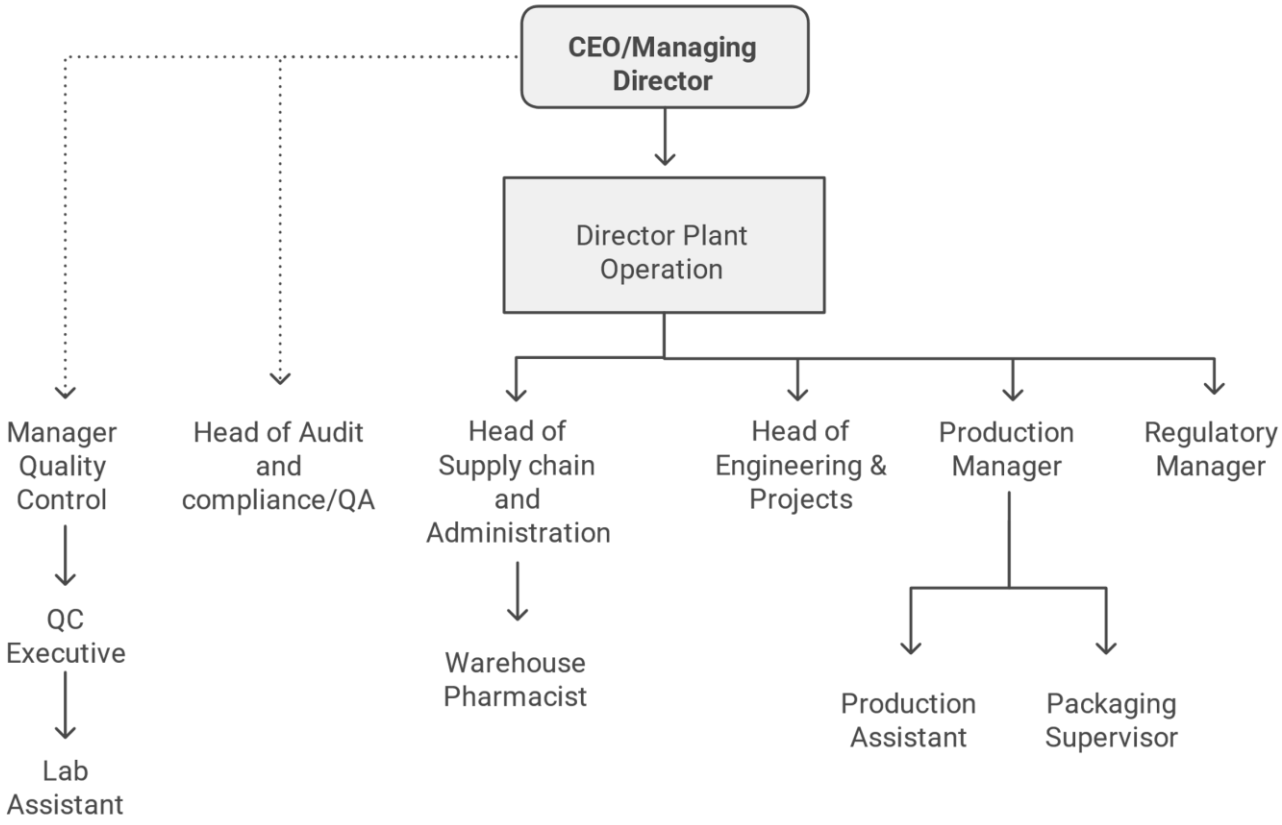
1. WHO prequalification: The DILS is not a prequalification facility.
2. Regulators' Mindset: As per the WHO, the same facility can be used for biological killed vaccine, sera, and other biological products by complying with its cleaning recommendations.
3. Plant needs Renovation: Immediate onsite work is required to plug the gaps in the metal sheets that are resting. Current machines also require rigorous revamping because of a lack of usage for several years and the mixing of the machine diagram and the spare parts. The current facility does not have an admin block, adequate cold warehouse, etc.
4. Talent Hiring and Retention: Firstly, no accomplished professional wants to come on board for a six-month contract. Secondly, the compensation and the beneficial package for less than that offered by the pharmaceutical industry. Thirdly, DILS has become a training site for young professionals who stay until they get the opportunity in the new emerging biological plants (Sami, Master, Getz, Searle, etc.). Lastly, the long-term contract requests of the DILS are still lying at the HR department of DUHS.
5. Governance Model: the governmental working model is not conducive to a commercial venture. As commercialization requires quick decisions.

[1] The private sector does not want to enter this segment of medication because it requires huge investment, has high risk, and low profit. Furthermore, there is no "BUY-BACK "policy to facilitate the industry.

6. SECP Bureaucratic Road Back: The case of registration of a non-profit company under Section 42 has been lying for the last three years.
7. Financial Constraints: Current requirement for a new lyophilizer, ampoule filling machine, HVACs, software is too expensive to be purchased.
8. Depreciation: 5 years should be 10-15 years.

INSTITUTIONAL ORGANOGRAM

Current Staff



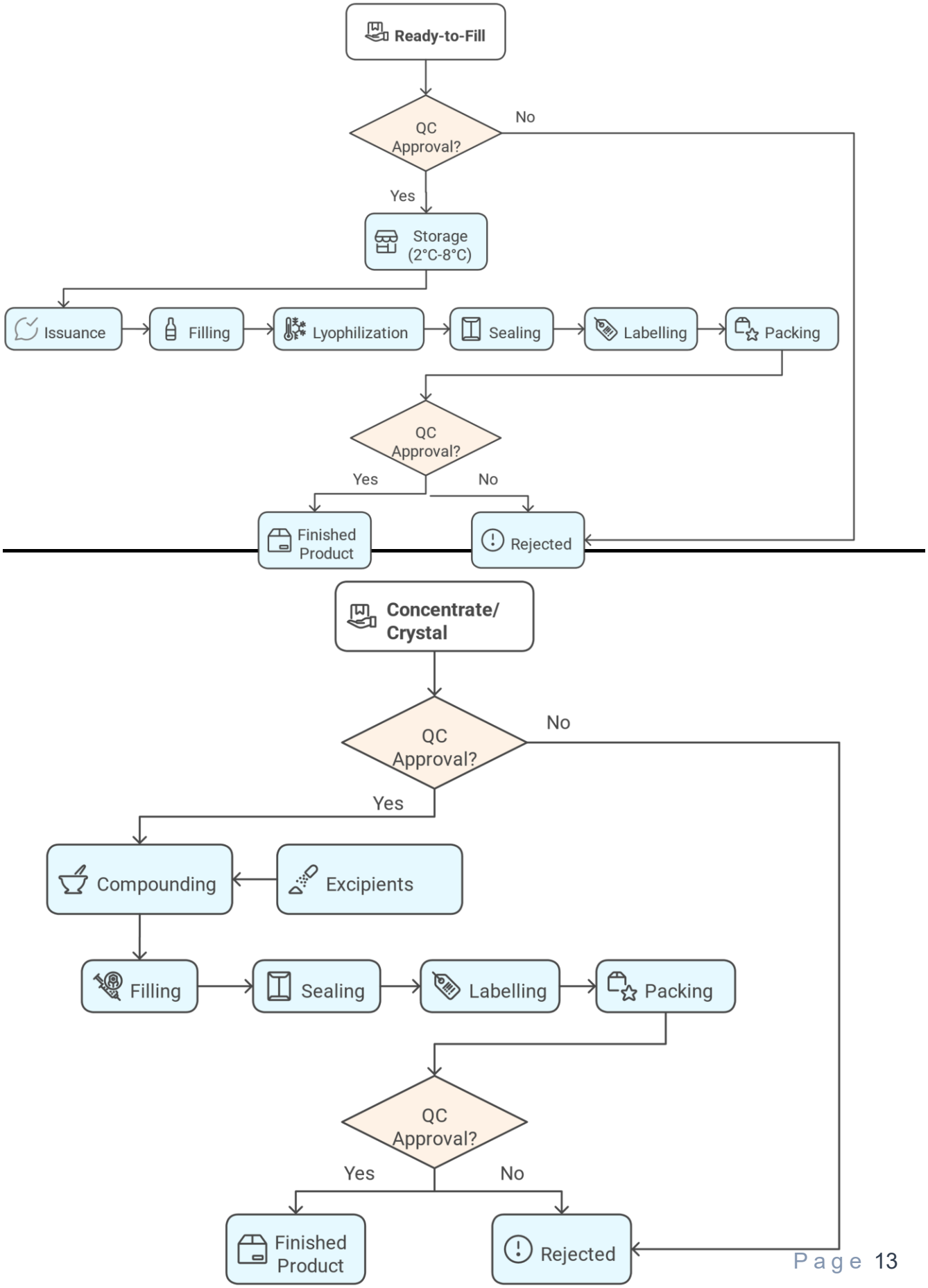
ORGANIZATIONAL STRUCTURE

Current/Proposed STAFF of DILS:

S. No.	Designation	Existing	Proposed	Salary[2]/Month (000's)
1	MD /CEO	1		3000
2	Head of Plant Operation		1	1,200
3	Head of Supply Chain & Administration	1		850
4	Head of Engineering & Projects	1		850
5	Head of Audit and Compliance/QA	1		850
6	Head of Quality Assurance		1	250
7	Production Manager	1		100
8	QC In-charge		1	100
9	Manager QC	1		100
10	Assistant Engineer		1	100
11	Regulatory Manager (Pharmacovigilance)	1		100
12	Warehouse Pharmacist	1		150
13	Officer Microbiologist	1		95
14	QC Executive	1		95
15	Utilities Engineer		1	100
16	Plant Technician	3		85
17	Production Assistant	2		90
18	Lab Assistant	1		60
19	Packaging Supervisor	1		120
20	Packaging Workers	8*		45

[2] Compensation and Benefits for all employees to be matched with the current average being offered by the industry.

FLOW CHART:


Ready-to-Fill
QC Approval?
No
Yes
Storage (2°C-8°C)
Issuance
Filling
Lyophilization
Sealing
Labelling
Packing
QC Approval?
Yes
No
Finished Product
Rejected
Concentrate/ Crystal
QC Approval?
No
Yes
Compounding
Excipients
Filling
Sealing
Labelling
Packing
QC Approval?
Yes
No
Finished Product
Rejected

FACILITIES:

This facility is a sophisticated manufacturing site compliant with ISPE and WHO guidelines for sera, vaccines, and biological preparations. DILS facility is composed of well-established state-of-the-art sections:

1. Production Facility

A cutting-edge production area for vaccine and biological manufacturing with the following capabilities:

- **Aseptic Solution Preparation Area**: Capacity: **100 liters**, ensuring aseptic handling of solutions.
- **Vial Washing & Filling Line**: Filling capacity: **2 ml–30 ml per vial**, with precision filling to maintain sterility.
- **Lyophilizer Area**: Annual capacity: **1.2 million vials**, supporting stability and shelf-life extension of products.
- **Cap Sealing Area**: Speed: **60 vials per minute**, ensuring secure vial sailing.
- **Labeling Area**: Speed: **80 vials per minute**, providing efficient labeling with accuracy.

2. Research & Development Laboratory

A dedicated space is designed for innovative biological and vaccine development, focusing on quality and efficacy.

3. Quality Control (QC)/Microbiology Laboratories:

- **Immunochemical & Wet Chemistry Lab**: Conducts comprehensive quality testing for raw materials and final products, ensuring chemical integrity and compliance.
- **Microbiological Laboratory**: Performs sterility testing and monitors microbial quality to meet regulatory standards.

4. Stability Room

A controlled environment is for stability testing under various conditions to evaluate product durability and safety.

5. Walk-in Cold Storage

- Storage Capacity: **300,000 sealed and unpacked vials** (maintaining precise temperature control to ensure product integrity).

6. Water Treatment and Distillation Plants

- **Water Treatment Plant**:
- Capacity: **500 liters/hour**, producing purified water for production processes.
- **Water Distillation Plant**:
- Capacity: **500 liters/hour**, delivering water-for-injection (WFI) grade water critical for aseptic manufacturing.

7. Engineering Workshop

- **Not Available**: Currently, the facility does not include an in-house engineering workshop. Equipment maintenance is managed externally or through dedicated on-site resources.

8. Utility Area

A centralized system supports essential utilities such as HVAC, compressed air, electrical supply, and cleanroom conditions.

SECTION I: OVERVIEW OF THE STRATEGIC PLANNING PROCESS

The Dow Institute of Life Sciences (DILS) is committed to advancing Pakistan's biopharmaceutical sector by producing high-quality sera, vaccines, and biological products. Since its inception, DILS has focused on self-sufficiency and innovation, particularly in vaccine manufacturing. With the successful launch of DOWRAB, it has positioned itself as a key player in the healthcare industry. Achieving Good Manufacturing Practice (GMP) certification marked a significant milestone, and efforts are now underway to secure World Health Organization (WHO) prequalification by 2026, ensuring international recognition and expanding market access.

The strategic plan for 2024-2030 is designed to enhance production capabilities, diversify the product portfolio, and establish DILS as a leader in the biopharmaceutical landscape. This includes contract manufacturing agreements and a strong emphasis on compliance with global standards. Investments in artificial intelligence and robotic technologies will enable the institute to meet high-quality benchmarks and improve efficiency.

DILS operates from a state-of-the-art facility at the Ojha Campus of Dow University of Health Sciences, with the capacity to produce nine million vials annually and lyophilize 1.2 million vials per year. The facility is equipped to manufacture, fill, pack, and test biological and vaccine products in compliance with international guidelines. The approval from the Drug Regulatory Authority of Pakistan (DRAP) for sera production in 2020 and vaccine filling in 2021 has paved the way for further expansion.

The future roadmap includes scaling up the production of Anti-Rabies Vaccine, Anti-Snake Venom Serum, and Tetanus Immunoglobulin while also engaging in contract manufacturing for polio vaccines and other biological products. With an increasing demand for locally produced vaccines, DILS is poised to reduce dependence on imports and contribute to national healthcare security. However, challenges remain, including the need for WHO prequalification, regulatory hurdles, infrastructure renovations, talent retention, and financial constraints. The governance structure also requires reform to facilitate commercial decision-making and improve operational efficiency.

Despite these challenges, DILS remains dedicated to its vision of becoming Pakistan's leading biopharmaceutical company. By fostering strategic partnerships, adopting advanced technologies, and strengthening its research and development capabilities, the institute is set to play a transformative role in the healthcare industry.

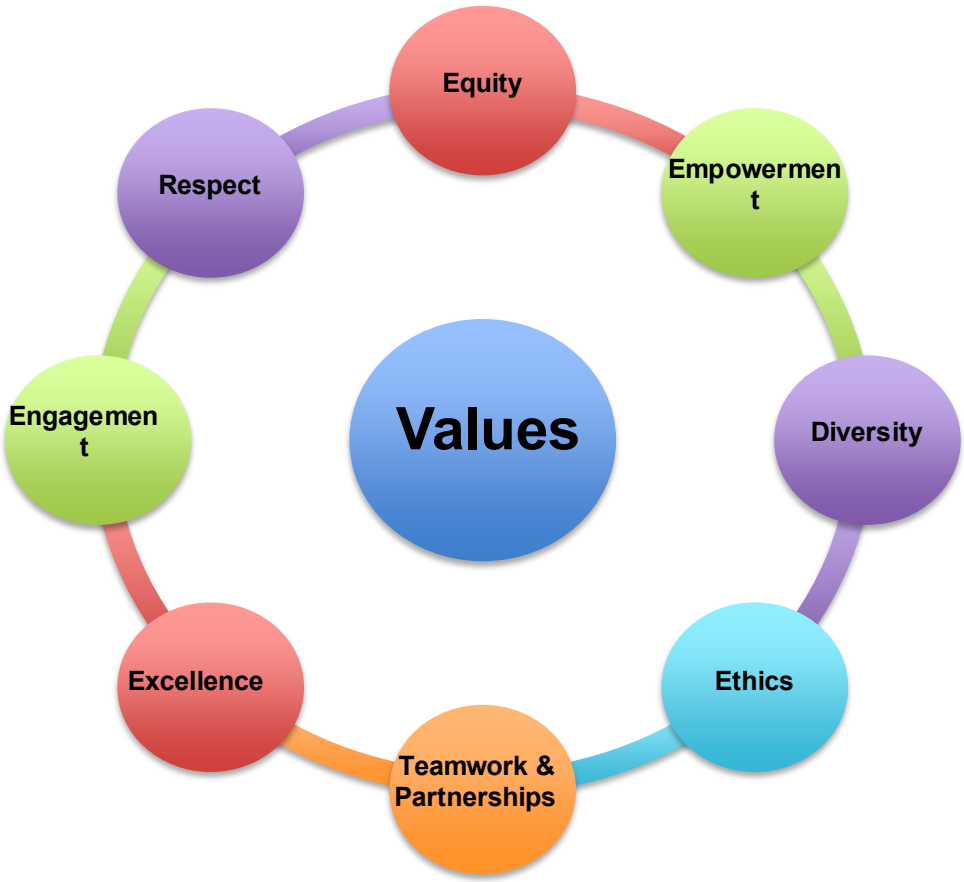
SECTION II: VISION, MISSION AND VALUES

VISION

To be a pre-eminent academic institution committed to changing and saving lives.

MISSION

Providing outstanding patient-centered education, training, and clinical care informed by cutting-edge research and innovation, generating and disseminating new knowledge.



VALUES

Customer Service

Put patients & students first.

Empathy & Compassion

Understand before you judge.

Be concerned for the sufferings & misfortunes of others.

Excellence

Be the best and commit to exceptional quality and service.

Innovation

Encourage curiosity, imagine, create, and share.

Teamwork

Engage & collaborate.

Integrity & Leadership

Be a role model and influence others to achieve their best. Have the courage to do the right thing.

Hold yourself and others accountable.

Respect & Collegiality

Be kind.

Listen to understand.

Value different opinions.

STATEMENT OF PURPOSE

We aim to acquire advanced research and development in biotechnology to produce affordable, high-quality healthcare solutions and ensure their accessibility to all socio-economic segments, thus driving positive changes in healthcare accessibility and affordability.

SECTION III: ASPIRATIONAL INSTITUTIONS

Instituto Butantan (Brazil):

https://en.butantan.gov.br/index.php

Instituto Butantan is the prime producer of immunobiological products in Brazil. It works as an autonomous organization. It is responsible for a considerable percentage of the national production of hyperimmune sera and vaccine antigens, some of which are used in the National Immunization Program (Programa Nacional de Imunizações, PNI) of the Brazilian Ministry of Health. Its technological development activities yield vaccines, antitoxins and antivenoms, and biopharmaceuticals for human use. It exports sera and vaccines to over 10 countries in Latin America and Europe.

- **Product Portfolio**: In 2023, Butantan produced:
  - **Covid-19**: 13 million doses
  - **Flu Vaccines**: 90 million doses
- **Diphtheria, Tetanus, Hepatitis A and B, chikungunya, whooping cough, dengue, HPV and rabies**: 31 million doses of vaccines against hepatitis A and B, HPV, DTaP and rabies.
  - 600 thousand units of serum against venoms, bacterial toxins, and the rabies virus
  - 380 thousand units of the monoclonal antibody: Adalimumab.

It develops basic and applied research projects, such as studies on venomous animals and pathogens. It also helps in the innovation and modernization of production processes and control of immunobiologicals.

It also offers extension courses aimed at training professionals to become multipliers of information in public health and short-term improvement courses, covering topics such as venomous animals, insects of medical importance, antitoxins, antivenoms, and vaccines intended for the public, students, teachers, military, firefighters, agriculturalists, among others.

The rationale for selecting:

- The Instituto Butantan also has the same state-owned facility as the Dow Institute of Life Sciences.
- It has the same product portfolio as DILS-DUHS wants to have for the future.
- Coordinate with them to overcome the challenges that we have been facing in snake venom sera development for years.
- Short training courses for the DILS team.
- Learn from the journey of Instituto Butantan to export DILS's products to international markets.

Serum Institute of India Pvt. Ltd (India)

https://www.seruminstitute.com/

Serum Institute of India Pvt. Ltd. is now the world's largest vaccine manufacturer by number of doses produced and sold globally (more than 1.5 billion doses) which includes Polio vaccine, Diphtheria, Tetanus, Pertussis, Hib, BCG, r-Hepatitis B, Measles, Mumps, Rubella as well as Pneumococcal and Covid-19 vaccines.

It is estimated that about 65% of children worldwide receive at least one vaccine manufactured by Serum Institute. Vaccines manufactured by the Serum Institute are accredited by the World Health Organization, Geneva, and around 170 countries are using its products in their national immunization programs, saving millions of lives globally.

Serum Institute of India was founded in 1966 by Dr. Cyrus Poonawalla to manufacture life-saving immuno-biologicals, which were in shortage in India and imported at high prices. Subsequently, several life-saving biologicals were manufactured at prices affordable to the laity and in abundance, with the result that the country became self-sufficient for Tetanus Anti-toxin and Anti-snake Venom serum, followed by DTP (Diphtheria, Tetanus, and Pertussis) group of Vaccines and then later MMR (Measles, Mumps, and Rubella) group of vaccines.

The rationale for selecting:

- The Serum Institute of India Pvt. Ltd is offering the same product portfolio that is on the wish list of the Dow Institute of Life Sciences.
- Most importantly, the aim of its inception also meets ours as we want to substitute imports by producing affordable life-saving vaccines to make the country self-sufficient.
- We also follow the path of Serum Institute of India Pvt. Ltd. for WHO Prequalification of our products, which will open various channels to export our products.

SECTION IV: STRATEGIC GOALS

Goal 1: Achieving Self-Sustainability through Operational Expansion

Objective 1: Operational Expansion and Capacity Enhancement
Objective 2: Facility infrastructure in compliance with WHO guidelines

Goal 2: Expanding Product Portfolio and Achieving Market Leadership

Objective 1: Expand Product Portfolio
Objective 2: Use of RPA/AI in plant operations
Objective 3: Hiring a Dedicated Marketing Team for DILS Promotion

Goal 3: To ensure & maintain smooth commercialization & market development of DOW-RAB (Rabies Vaccine) as a brand by Q3-2026.

Objective 1: Smooth import of Rabies vaccine bulk(RTF)
Objective 2: Product awareness session for brand creation
Objective 3: Cold chain Distributor
Objective 4: Export of Rabies vaccine to new markets

Goal 4: Launch an ISO 17025 accreditation & WHO prequalification initiative by Q1 2026, which includes staff training on WHO standards and facility for WHO Prequalification by Q2 2027.

Objective 1: ISO-17025 Accreditation
Objective 2: Staff training & Facility in compliance with the WHO prequalification
Objective 3: WHO prequalification sources identification
Objective 4: EOI & SMF for WHO prequalification

Goal 5: Develop a comprehensive workforce development program by Q2 2025, offering competitive salary packages and career development opportunities to attract and retain top talent.

Objective 1: Training/Workforce Development
Objective 2: Retain the trained & experienced resources by offering market-competitive salary packages
Objective 3: Foreign training for staff on critical procedures

Goal 6: To be registered as an entity under Section 42 company with SECP by Q1, 2025.

Objective 1: Regulatory requirement for SECP registration
Objective 2: Approval from the Sindh Cabinet of Ministers
Objective 3: Company structure

OBJECTIVES, OKRs & KPIs

<table>
<tr><td colspan="8">Strategic Goal 1:Achieving Self-Sustainability through Operational Expansion</td></tr>
<tr><td colspan="8">Goal Statement: Achieving Self-Sustainability through Operational Expansion and enhancement capacity of Manufacturing Plant to meet market demand by Q4-2025. Installation of the Second compact line by Q1 2025 that enhance production capacity by 10 million. Facility upgradation for sterile areas, micro labs, and HVAC systems by December 2024.</td></tr>
<tr><td colspan="8">OKR (Objective and Key Results)</td></tr>
<tr><td colspan="8">Objective 1: Operational Expansion and Capacity Enhancement</td></tr>
<tr><td>Objective</td><td>Key Results</td><td>KPI</td><td>Measurement Method</td><td>Target</td><td>Person Responsible</td><td>Resource Requirement</td><td>Timeline</td></tr>
<tr><td rowspan="4">To increase existing production capacity by installing an automated (compact) filling line that complies with WHO by Q2 2025 to enhance production efficiency, reduce human intervention, and ensure compliance with international standards, thus allowing DILS to scale operations up to 20 million vial filling per year.</td><td>User required specification Finalization by Q2-2024.</td><td rowspan="4">Installation & Qualification of compact manufacturing line along with its value addition realization in the Plant production capacity by Q3-2025.</td><td rowspan="4">Monitoring Project Milestones in daily Meetings</td><td rowspan="4">Installation and commission of compact line.</td><td rowspan="4">M. Irfan Malik / Hameed Khan</td><td>Budget allocation for equipment purchase, installation, and validation activities.</td><td rowspan="4">Q3, 2025</td></tr>
<tr><td>Tender Advertisement & Review by Q3-2024</td><td rowspan="3">External consultants/vendors for installation, qualification, and compliance support.</td></tr>
<tr><td>Tender Award to Qualified Vendor & LC opening</td></tr>
<tr><td>New compact line installation & Area Qualification by Q3-2025</td></tr>
<tr><td colspan="8">Objective 2: Facility infrastructure in compliance with WHO guidelines</td></tr>
<tr><td>Objective</td><td>Key Results</td><td>KPI</td><td>Measurement Method</td><td>Target</td><td>Person Responsible</td><td>Resource Requirement</td><td>Timeline</td></tr>
<tr><td rowspan="3">To upgrade facility layout by Q4 2024, to ensure requirements i.e. Policy Guidelines and SOPs for WHO prequalification by Q4-2025.</td><td>Design and approve plans for change room renovations by Q1-2025.</td><td rowspan="3">Renovation of existing areas, upgraded HVAC system, and installation as per the approved Layouts by Q3-2025</td><td rowspan="3">Monitoring Project Milestones in daily Meetings</td><td>The facility layout upgrade was finalized and implemented by Q4 2024.</td><td rowspan="3">Hameed Khan</td><td rowspan="3">• Capital budget for facility modifications.
• Engineering and quality compliance team involvement.
• External consultants for layout design and regulatory alignment.
• Staff training on revised SOPs and guidelines.
• Facility modifications to accommodate the new compact filling line.
• Utility upgrades (HVAC, compressed air, cleanroom modifications).
• Validation protocols (IQ, OQ, PQ), SOPs, and WHO regulatory documentation support.</td><td rowspan="3">Q4, 2025</td></tr>
<tr><td>Conduct third-party validation of the upgraded HVAC system to ensure compliance with Good Manufacturing Practice after the installation by Q3- 2025.</td><td>Full alignment with WHO Policy Guidelines and SOPs by Q3 2025.</td></tr>
<tr><td>WHO prequalification achieved by Q4 2025</td></tr>
</table>

Strategic Goal 2:Expanding Product Portfolio and Achieving Market Leadership							
Goal Statement: Expanding Product Portfolio and Achieving Market Leadership							
OKR (Objective and Key Results)							
Objective 1: Expand Product Portfolio							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To contract for manufacturing with the contracting party to expand the product portfolio by producing vaccines for diseases such as polio, tetanus, and other biological products. Furthermore, the product registration CTD dossier will be submitted to get registration by Q2-2026.	Identification of immensely required vaccines in the country by Q2-2024.	New product commercialization in the market to fulfill the needs of the society.	Monitoring Project Milestones in daily Meetings	Finalize and sign manufacturing contract by Q4-2024.	M. Irfan Malik	Legal and regulatory team for contract negotiation and compliance.	Q2, 2026.
	Selection of products based on market insights and technical capabilities by Q3-2024					Technical and R&D team for product development and data generation.	
	Sourcing and agreements with manufacturers & partners Q1-2026					Financial investment for contracting, dossier preparation, and submission fees.	
	CTD Dossier Preparation & Submission of ARV to DRAP by Q1-2025	Product Registration CTD Dossier submission to Drug Regulatory Authority of Pakistan		Submit CTD dossiers for product registration by Q2-2026.		External regulatory consultants for CTD dossier compilation and review.	
	CTD Dossier Preparation & Submission of IPV to DRAP with the support of Partners by Q2-2025					Project management oversight to ensure milestones are met.	
	Basic Manufacturing Area Development for Indigenous Product Development by Q2-2026						
Objective 2: use of RPA/AI in plant operations							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Feasibility assessment for the use of technology to increase the efficiency of the process by Quality Control with AI Vision Systems, Robotic Process Automation (RPA) Software for Repetitive Tasks, AI Predictive Maintenance Software, and Blockchain software by Q4-2025.	Phase 1 (0-6 Months): Start with RPA implementation to streamline production line operations.	Initiate phased implementation of costly systems, starting with RPA in Phase 1, and strategically introducing AI Predictive Maintenance in Phase 3 to balance investment with operational readiness.	Project Parked till 2027	Project Parked till 2027	M. Irfan Malik	Cross-functional assessment team (Quality, Engineering, IT, Production). Budget for consultancy, technology demos, and pilot studies. External technology solution providers for trials and demonstrations. Time allocation for cross-department workshops and review sessions.	Due to high cost, the project has been put on hold, it will be revisited after 2027.
	Phase 3 (12-14 Months): Begin AI predictive maintenance to enhance equipment reliability and reduce downtime once other systems are operational.	Establish a forward-looking approach to fully leverage these technologies by 2030, ensuring long-term efficiency gains and sustained ROI despite high initial costs.					

Objective 3: Hiring a Dedicated Marketing Team for DILS Promotion							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**		**Timeline**
To ensure effective and efficient marketing of the DILS product, it is necessary to hire a dedicated team or agency to create a clear understanding and awareness about the product among institutes and clinics.	Enhance awareness and understanding of the DILS product in institutes and clinics through effective marketing efforts.	Number of successful presentations or campaigns conducted in institutes and clinics each month.	The hiring of a dedicated marketing team or agency is completed and documented. Development and execution of marketing campaigns measured by outreach activities and engagement metrics. Awareness was tracked through feedback surveys and increased product inquiries from institutes and clinics.	Hire marketing team/agency by Q3-2024. Launch awareness campaigns by Q4-2024. Achieve measurable awareness improvement (e.g., 30% increase in inquiries) by Q2-2025.	Ahad Wasiq Sheikh	Budget allocation for hiring and marketing activities. Marketing professionals or experienced agencies. Creative content development resources (digital, print, event materials). Monitoring tools for campaign performance and analytics.	

Strategic Goal 3: To ensure & maintain smooth commercialization & market development of DOW-RAB (Rabies Vaccine) as Brand by Q3-2026.							
Goal Statement: To ensure & maintain smooth commercialization & market development of DOW-RAB (Rabies Vaccine) as a brand by Q3-2026.							
OKR (Objective and Key Results)							
Objective 1: Smooth import of Rabies vaccine bulk(RTF)							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Smooth Import of the read-to-fill Bulk of Rabies Vaccine to ensure the uninterrupted supply of immensely required Rabies vaccine every year	Appointment of Procurement lead.	Availability of RTF Bulk for manufacturing by Q4-2023	Annual procurement plan and import schedule adherence.	Ensure annual import of ready-to-fill rabies vaccine bulk without delays.	M. Irfan Malik	Procurement and supply chain management team.	LC for the required quantity of Bulk approved and Submitted Q4, 2024.
	Procurement & LC Opening		Monitoring timely arrival and clearance of rabies vaccine bulk.	Maintain continuous availability of rabies vaccine throughout the year.		Approved and reliable international suppliers.	
	Custom Clearance from DRAP		Monitoring in Demand and Supply Meeting	Strengthen supply chain reliability with contingency plans by Q4-2024.		Import licenses, regulatory approvals, and customs facilitation by finance	
	Consignment Arrival at DILS Q4-2023					Budget for procurement, logistics, and warehousing.	

Objective 2: Product awareness session for brand creation							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
At least 04 product awareness activities per quarter for brand creation in the market till 2027.	03 Product awareness campaigns across Pakistan per Quarter.	Product awareness in all Provinces of Pakistan	Track the execution of at least 4 product awareness activities per quarter.	Conduct a minimum of 4 awareness activities per quarter until 2027.	Ahad Wasiq Sheikh	Dedicated marketing team or agency.	Ongoing, Q2 2025
	Consultation with key Opinion Leaders		Monitor participation, engagement metrics, and feedback from each activity.	Achieve progressive increase in brand recognition and market reach.		Budget for events, digital campaigns, and promotional materials.	
	20 Round Table discussion in the major cities of Pakistan by Q4-2024.		Review brand recognition growth through periodic market surveys.			Tools for campaign tracking, analytics, and market feedback analysis.	
						Collaboration with institutes, clinics, and media partners.	
Objective 3: Cold chain Distributor							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To create an efficient distribution channel for cold chain distribution across Pakistan by Q1-2024.	Identification Distributor having a strong distribution Network in Pakistan by Q1-2024.	Agreement Finalization & signing with the Distributor by Q1-2024	Confirmation of agreement draft completion and legal approval. Execution of agreement signed by both parties by Q1-2024. Documentation of distributor onboarding.	Finalize and sign the distributor agreement by Q1-2024.	M. Irfan Malik/ Marketing	Marketing team, legal team	Completed in Q1, 2024
	Legal Review of Terms & Conditions						
Objective 4: Export of Rabies vaccine to new markets							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To introduce DOW-RAB in at least 03 developing countries for export by Q2-2026.	Potential International Market Identification for DOWRAB by Q2-2025.	Exporting DOWRAB in Developing countries	Monitoring in Demand and Supply meeting	Track registration submissions and approvals in target countries.	M. Irfan Malik	Regulatory and export compliance team. Logistics and export support infrastructure.	Q2, 2026 The current source is not permitting export therefore looking for a WHO prequalified source.
				Monitor export agreements and first shipment completion.			
	Product registration in the Identified country			Measure export volumes and market entry reports by Q2-2026.		Budget for dossier preparation, registration fees, and market entry activities.	
	Commercialization of product					Market research and identification of potential partners in target countries.	

Strategic Goal 4: Launch an ISO 17025 accreditations & WHO prequalification initiative by Q1 2026, which includes staff training on WHO standards and facility for WHO Prequalification by Q2-2027.							
Goal Statement: Certification of ISO 17025 and Who prequalification							
OKR (Objective and Key Results)							
Objective 1: ISO-17025 Accreditation							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
ISO-17025 Accreditation of Quality Management System by Q4-2025	Gap assessment of Quality Management System by Q1-2025.	Readiness for the ISO inspection by Q4- 2025	Monitoring Project Milestones in daily Meetings	Completion of gap analysis, corrective actions, and internal audits.	Saba Mustikhan	Quality assurance and regulatory teams. Budget for consultant support, audits, and training. Documentation systems and laboratory infrastructure upgrades (if required). External certification body engagement.	Q4 2025
	Preparation & implementation documentation as per ISO standard by Q3-2025			Successful external audit and receipt of ISO-17025 certification by Q4-2025.			
	Inspection by ISO Lead & Technical Assessors in Q1-2026			Continuous monitoring through compliance reports and audits.			
Objective 2: Staff training & Facility in compliance with WHO prequalification							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Ensure Staff training and Facility compliance according to WHO PQ requirements by Q1-2025.	Complete a comprehensive internal audit of all production & analytical facilities to identify gaps in compliance with WHO standards by Q4-2025.	Complete the internal audit of all production and analytical facilities by Q4-2025 and implement required upgrades or process improvements to achieve full compliance with WHO standards across all production facilities by Q3-2026. Ensure all staff are trained and the facility achieves full compliance with WHO Prequalification (PQ) requirements by Q1 2025.	Monitoring the training schedule adherence	Achieve staff training and facility compliance with WHO PQ standards by Q1-2025.	Saba Mustikhan	Training budget and external WHO PQ consultants Facility upgrade funds QA, HR, and Compliance teams for execution and monitoring. Audit tools and documentation systems.	Q3, 2026
	Implement necessary upgrades or process improvements to align with WHO standards across all production facilities Q3-2026.						
Objective 3: WHO prequalification sources identification							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To identify WHO Pre-Qualified source of RTF by Q2-2026.	Identify and finalize a WHO Pre-Qualified source for Ready-to-Fill (RTF) materials by Q2 2026 to ensure compliance with international standards and supply chain reliability.	Achieve alignment with WHO prequalification criteria and secure a confirmed supplier contract by Q2 2026.	Monitoring Project Milestones in daily Meetings	Identification and approval of WHO Pre-Qualified RTF source by Q2-2026.	Johar Hussain M. Irfan Malik	Procurement and regulatory teams. Budget for audits, supplier visits, and documentation reviews. External consultant support (if required). Database access for	Q2 2026

						WHO PQ listings and regulatory references.	
Objective 4: EOI & SMF for WHO prequalification							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To express interest & SMF submission WHO PQ team by Q2-2027.	Submit the Site Master File (SMF) and formally express interest to the WHO Prequalification (PQ) team by Q2 2027 to initiate the qualification process.	Achieve submission of a complete and compliant SMF to the WHO PQ team by the end of Q2 2027, meeting all regulatory and documentation requirements.	Monitoring Project Milestones in daily Meetings	Submission of expression of interest and SMF to WHO PQ team by Q2-2027.	Dr. Izhar Hussain	Regulatory affairs and quality assurance teams. External consultancy (if required) for document review. Budget for documentation preparation and submission fees. Coordination with WHO liaison officers.	Q2, 2027

Strategic Goal 5: Develop a comprehensive workforce development program by Q2 2025, offering competitive salary packages and career development opportunities to attract and retain top talent.							
Goal Statement: workforce development							
OKR (Objective and Key Results)							
Objective 1: Training/ workforce development							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Implementation of annual training plan/workforce development plan by Q1-2025	Gap assessment to identify the need for training by Q1-2025.	Implementation of personal & professional development plan	Monitoring the annual training plan.	Completion and approval of the annual training plan.	Saba Mustikhan	HR and training department team. Facilities for training delivery (onsite or virtual platforms).	Ongoing
	Preparation & implementation of training plan by Q1-2025			Training attendance records and post-training assessments by Q1-2025.		External trainers (if needed).	
	Hire and train key personnel in quality control, engineering, and HR management to build a robust operational foundation by Q3-2025.			Full implementation of the workforce development plan by Q1-2025		Budget for training materials, sessions, and certifications.	
Objective 2: Retain the trained & experienced resources by offering market-competitive salary packages							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To set a market-competitive salary package & perks to retain the trained & experienced resources by Q2-2025.	Communication with HR to explain the market scenario & strategies to retain the potential resource by Q4-2025.	Retention of Potential employees at DILS according to the need Q3-2026	Monitoring daily meetings	Conduct market salary benchmarking surveys and employee satisfaction assessments.	Dr. Izhar Hussain	HR and finance department collaboration. Market salary data and consulting services (if needed). Budget for salary adjustments and perks.	Q2 2025
	Finalization of a framework for offering perks & facilities			HR approval of revised salary and benefits structure by Q2-2025.			
Objective 3: Foreign training for staff on critical procedures							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To need identification for the foreign training of staff for critical procedures by Q2-2025.	Coordination with external & foreign trainers.	Identify the training needs for critical procedures and select suitable foreign trainers by Q2-2025 to enhance staff expertise.	Conduct skill gap analysis and department-wise training need assessment by Q1-2025.	Staff identified for foreign and scheduled training.	Dr. Izhar Hussain	HR and department head collaboration. Budget allocation for international training. Coordination with foreign training institutions or consultants.	Q2 2025
	Identify suitable trainers Q2-2025.		Prepare and approve a foreign training proposal for critical procedures.				

Strategic Goal 6: To be registered as an entity under Section 42 company with SECP by Q1, 2025.							
Goal Statement: DILS registration for Section 42 company with SECP							
OKR (Objective and Key Results)							
Objective 1: Regulatory requirement for SECP registration							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To fulfill the regulatory requirements of the SECP by Q 4 2024	Achieve compliance with SECP regulations, ensuring all required documentation, processes, and systems are in place by Q4 2024. Appointment of lawyer firm Formation of board members	Completion of SECP compliance documentation and successful approval by SECP by Q4 2024.	Monitoring in daily meetings.	100% compliance with SECP requirements by Q4-2024.	Dr. Izhar Hussain	Legal and compliance team involvement. Coordination with SECP consultants. Budget for legal advisory services and documentation processing.	Q4 2024
Objective 2: Approval by Sindh Cabinet of Ministers							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To get the approval of the Sindh Cabinet of Ministers by Q 4 2024.	Secure approval from the Sindh Cabinet of Ministers for necessary projects and initiatives by Q4 2024.	Obtain formal approval from the Sindh Cabinet of Ministers by the end of Q4 2024.	Monitoring daily meetings	Obtain formal Sindh Cabinet approval by Q4-2024.	Dr. Izhar Hussain	Policy and legal team engagement. Liaison with government representatives. Administrative support and budget for official processing and meetings.	Q4 2024
Objective 3: Company structure							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To finalize the company's structure by Q1-2025.	Appointment of Audit firm to prepare company policy and procedure. Complete the finalization of the company's organizational structure, including key roles and responsibilities, by Q1 2025.	Finalize and implement the company's structure by the end of Q1 2025.	Monitoring daily meetings	Finalize and approve the company's structure by Q1-2025	Dr. Izhar Hussain	HR consultants and legal advisors. Management team input and board review. Budget for consultations and documentation.	Q1 2025

SECTION V: RESOURCE PLANNING FOR ACHIEVING STRATEGIC GOALS

Strategic Goal	GOAL 1: Achieving Self-Sustainability through Operational Expansion and enhancement capacity of Manufacturing Plant to meet market demand by Q4-2025		Required Budget
Resources	Human Resources	• 02 Production officer • 16 operators and mechanics • 02 QC Analyst • 02 Engineer • Contractors for commissioning	19.8 M PKR/ Year
	Equipment	• Compact line Production line • Compact line for Ampoule • 03 Air Handling Units • Lyophilizer with a capacity of 10 m3 • Stand by Generator 800 KW • Optical machine • Cold Storage 100 cubic meters • 02 Vessels 200 Ltr. • Software for ERP /For tofflon lyo • Waste Management • BMS/EMS system	779 M Total 156M PKR/Year
	Space	• Space Available to maintain operations. • Facility renovation for new Compact line • Ampoule Facility construction • Area revamping will be required.	152 M total 38 M PKR/ Year
Total Budget Required for Goal -1:			**213.8M PKR/ Year**

Strategic Goal	GOAL 2: Expanding Product Portfolio and Achieving Market Leadership.		Required Budget
Resources	Human Resources	• Already covered in Goal-1	Already covered in Goal-1
	Equipment	• Predictive Maintenance Software • Quality Control with AI Vision Systems • Robotic Process Automation (RPA) for • Production • R & D	80 M PKR/ Year
	Space	• Space for Microbiology Laboratory • Microbiological Lab construction	15 M PKR/ Year
Total Budget Required for Goal -2:			**95M PKR/ Year**

Strategic Goal	GOAL 3: To ensure & maintain smooth commercialization & market development of DOW-RAB (Rabies Vaccine) as a Brand by Q3-2026		Required Budget
Resources	Human Resources	• 02 Marketing Executive	2.4M
	Equipment	• Marketing activities required • Inventory management system.	4 M PKR/ Year
	Space	N/A	N/A
Total Budget Required for Goal -3:			**6.4M PKR/ Year**

Strategic Goal	GOAL 4: Launch an ISO 17025 accreditation & WHO prequalification initiative by Q1 2026, which includes staff training on WHO standards and facility for WHO Prequalification by Q2-2027.		Required Budget
Resources	Human Resources	• 01 QA Insp. • 01 QA Officer • 01 QA Manager • 02 Document Control officer • 01 Archivist • 01 Supply Chain Officer	12M PKR/Year
	Equipment	• Already covered in Goal - 1	Already covered in Goal - 1
	Space	N/A	N/A
Total Budget Required for Goal -4:			**12M PKR/ Year**

Strategic Goal	Goal 5: Develop a comprehensive workforce development program by Q2 2025, offering competitive salary packages and career development opportunities to attract and retain top talent.		Required Budget
Resources	Human Resources	• Increase in the Salary Packages of staff. • Car Policy for Heads & Managers in • Comparison to Pharma Market • Trainers qualified in Good. • Manufacturing Practices (GMP) and machine operations.	15M PKR
	Equipment	• Office-related equipment	-
	Space	N/A	N/A
Total Budget Required for Goal -5:			**15M PKR/ Year**

Strategic Goal	Goal 6: To be registered as an entity under Section 42 company with SECP by Q1,2025.		Required Budget
Resources	Human Resources	N/A	N/A
	Equipment	N/A	N/A
	Space	N/A	N/A
Total Budget Required for Goal 6:			

SECTION VI: IMPLEMENTATION AND MONITORING OF STRATEGIC PLAN

Goal 1: To Achieve Self-Sustainability through Operational Expansion and enhancement capacity of Manufacturing Plant by Q4-2025	
Key results	Completion of feasibility study by Q1-Q2 2024. Design and approve plans for change room renovations by Q1-2025 Conduct third-party validation of the upgraded HVAC system to ensure compliance with Good Manufacturing Practice after the installation by Q3-2025. Budget approval and purchase order for the second compact line by Q3-Q4 2024. Progress reports from contractors on facility upgrade project execution (Q1-Q3 2025). Successful commissioning of the new line and achieving a planned production increase by Q4 2025. Comparison of production data pre- and post-upgrade to verify the 50% increase.
Monitoring Method	Regular project team meetings to review progress and address challenges. Review of contractor deliverables and project timelines. Production data analysis before and after the upgrade.
Responsibility	Head of Engineering, Head of Supply Chain, Director of Plant Operations.

Goal 2: To Expand Product Portfolio and Achieving Market Leadership	
Key results	Identification of immensely required vaccines in the country by Q2-2024 Selection of products based on market insights and technical capabilities by Q3-2024 Sourcing and agreements with manufacturers & partners Q1-2026 Basic Manufacturing Area Development for Indigenous Product Development by Q2-2026

	CTD Dossier Preparation & Submission to DRAP by Q1-2025 CTD Dossier Preparation & Submission of IPV to DRAP with the support of Partners by Q2-2025
Monitoring Method	The R&D team reports on development milestones achieved. Review of testing data and quality control reports. Tracking the status of dossier development and regulatory approval process. Monthly review to rule out the challenges. Quarterly review meetings will be held to assess the progress on each goal. Mid-year review to revisit timelines and necessary action for resource management. The annual review will be at the end of each year to align directions toward goals.
Responsibility	Head of Supply Chain and Administration, Director of Plant Operations.

Goal 3: To achieve self-sustainability through expanding the manufacturing capacity	
Key results	Appointment of distributors having a strong network in Pakistan for ARV distribution by Q1 2024. Launch of ARV marketing campaigns by Q1 2024. Monthly sales reports for ARV throughout 2024. Achievement of sales target (210,000 packs) and revenue target (PKR 196.6 M.) per year Inventory management reports to avoid stock-outs or overstocking. 20 Round Table discussions in the major cities of Pakistan by Q4-2024 Product awareness campaign across Pakistan per Quarter
Monitoring Method	The R&D team reports on development milestones achieved. Review of testing data and quality control reports. Confirmation of distributor partnerships.

	Review of marketing campaign materials and launch activities. Analysis of sales reports to track performance against targets. Inventory management system reports to monitor stock levels. Quarterly review meetings to assess the availability of DOW-RAB across Pakistan The annual review will be at the end of each year to align directions toward goals.
Responsibility	Head of Supply Chain & Administration, Director Plant Operations.

Goal 4: To get ISO 17025 accreditations Q1 2025, which includes staff training on WHO standards and facility for WHO Prequalification by Q4-2026.	
Key results	Gap assessment of Quality Management System by Q1-2025. Preparation & implementation documentation as per ISO standard by Q3-2025 Inspection by ISO Lead & Technical Assessors in Q1-2026 Complete a comprehensive internal audit of all production & analytical facilities to identify gaps in compliance with WHO standards by Q4-2025 Implement necessary upgrades or process improvements to align with WHO standards across all production facilities Q3-2026 Identification of WHO Pre-Qualified source of Raw materials
Monitoring Method	Monthly review to rule out the challenges. Quarterly review meetings will be held to assess the progress. Mid-year review to revisit timelines and necessary action for resource management. The annual review will be at the end of each year to align directions toward goals.
Responsibility	Head of Engineering, Production Manager, Manager QC, Head of Supply Chain & Administration, Director Plant Operations.

Goal 5: To develop a comprehensive workforce development program by Q2 2025, offering competitive salary packages and career development opportunities to attract and retain top talent.	
Key results	Competitive analysis of the DILS salary model with the market offering to the same position by Q1-2025 Presentation of Comprehensive Salary & Facilities Proposal based on competitive analysis Preparation & implementation, documentation as per ISO standard by Q2-2025 Employee Development & training schedule preparation & development by Q2-2025 Performance evaluations conducted by supervisors. External technical Training Plan by Q2-2025 Analysis of the Inputs of Employees in Professional Development by Q1-2025
Monitoring Method	Monthly review to rule out the challenges. Quarterly review meetings will be held to assess the progress. Mid-year review to revisit timelines and necessary action for resource management. The annual review will be at the end of each year to align directions toward goals.
Responsibility	Head of Supply Chain & Administration, Director Plant Operations.

Goal 6: To be registered as an entity under Section 42 company with SECP by Q1, 2025.	
Key results	• Achieve compliance with SECP regulations, ensuring all required documentation, processes, and systems are in place by Q4 2024. • Appointment of law firm • Formation of board members • Secure approval from the Sindh Cabinet of Ministers for necessary projects and initiatives by Q4 2024. • Appointment of Audit firm to prepare company policy and procedure.

	• Complete the finalization of the company's organizational structure, including key roles and responsibilities, by Q1 2025.
Monitoring Method	• A Meeting was held to review the progress of the goal.
Responsibility	CEO, Director Plant Operations.

SECTION VII: LIST OF APPENDICES

No.	DESCRIPTION
A	SWOT ANALYSIS
B	TOWS MATRIX

APPENDIX A: SWOT ANALYSIS

STRENGTHS	WEAKNESSES
1. DRAP Approval: DILS has secured approval from the Drug Regulatory Authority of Pakistan (DRAP), which enhances its credibility and enables it to produce and distribute sera and vaccines legally. 2. Well-equipped Laboratories: The presence of advanced laboratories and supporting infrastructure like a water purification plant and walk-in cold storage shows the institute's capability to handle sophisticated biological processes. 3. Stability Studies: Completing 18-month stability studies for the Rabies vaccine is a significant achievement, indicating the reliability of their product. 4. Future Expansion Potential: The availability of additional space for machinery and segregated biological lines offers potential for future growth. 5. Budgeted Compact: Planning for new equipment indicates proactive management and readiness for operational improvements.	1. Non-compliant Filling Machine: The current filling machine lacks the advancement of the latest cGMP requirements, which can impact on the quality and safety of products, posing regulatory risks. 2. Limited Capacity: The filling machine's capacity of only 9 million vials per annum could limit production scalability, affecting DILS's ability to meet higher demand. 3. Infrastructure Issues: Problems with the HVAC system and less-compliant facility layout can compromise air quality and overall production safety, leading to potential product contamination. 4. Lack of Expertise: The absence of biological sera testing and production experts is a significant gap that could affect product quality and innovation. 5. Old Equipment: The Lyophilizer with limited capacity could hinder production efficiency and scalability. 6. No Web Presence: The lack of a website for DILS limits its visibility and accessibility, which could affect partnerships, customer trust, and overall brand recognition. 7. Water Supply Incompatibility: The water supply plant's production capacity does not meet the actual requirements, potentially disrupting operations. 8. Human Resources: Low employee retention due to the implementation of six-month contracts.

OPPORTUNITIES	THREATS
1. **Market Demand**: The erratic availability of Anti-Snake Venom (ASV) and Rabies vaccines in Pakistan presents a strong market opportunity for DILS to fill the supply gap. 2. Toll Manufacturing: Interest from external parties in toll manufacturing can provide additional revenue streams and expand DILS's production capacity through collaborations. 3. Strong Distribution Partners: The availability of reliable distribution partners in the market could help DILS in effectively reaching its target customers and expanding its market share.	1. **Supplier Reluctance**: The reluctance of suppliers to work with government organizations due to SPPRA and PPRA regulations could hinder DILS's ability to secure necessary materials and resources. 2. Economic Instability: Fluctuating dollar rates and issues with Letters of Credit (LC) can impact the cost of raw materials and overall financial stability, affecting production and pricing strategies. 3. Long Payable Times: Delays in payments could strain relationships with suppliers and service providers, leading to operational challenges. 4. Reference Standards Unavailability: The lack of reference standards for biological testing can delay product testing and release, affecting time-to-market. 5. Regulatory Delays: Delays in DRAP registration for new products could slow down the introduction of new offerings, limiting DILS's competitiveness and growth potential. 6. Batch Release Requirement: The mandatory batch/Lot release by the National Control Laboratory for Biologicals (NCLB) could cause delays in product availability, affecting supply chain efficiency.

APPENDIX B: TOWS MATRIX

	OPPORTUNITIES	THREATS
	1. Growing Vaccine Demand: High demand for Rabies, ASV, Polio, and Tetanus Toxoid vaccines in Pakistan. 2. Toll Manufacturing Partnerships: Utilize DRAP approval and excess capacity for contract manufacturing 3. Technological Advancements: Automation in filling and lyophilization to enhance efficiency. 4. Export Potential: Expand into regional and international markets for biological products. 5. In-House Capability Expansion: Develop internal biological testing and production facilities. 6. Public Health Awareness: Growing vaccine adoption due to increased awareness campaigns.	1. Regulatory Delays: Lengthy DRAP approvals affecting new product launches. 2. Exchange Rate Fluctuations: Import dependency exposes DILS to foreign currency risks. 3. Supplier Dependence: External reliance may cause supply chain disruptions. 4. Supplier Dependence: External reliance may cause supply chain disruptions. 5. Economic Instability: Inflation and funding shortages impact production costs. 6. Stricter Compliance: Adapting to evolving cGMP and WHO regulations 7. Skilled Workforce Shortage: Challenges in hiring and retaining biological science professionals.
STRENGTHS	SO	ST
1. DRAP Approval: DILS has secured approval from the Drug Regulatory Authority of Pakistan (DRAP), which enhances its credibility and enables it to produce and distribute sera and vaccines legally. 2. State-of-the-Art Laboratories: Equipped with advanced facilities, including a water	1. Toll Manufacturing Partnerships: Utilize DRAP approval, well-equipped labs, and advanced infrastructure to enter toll manufacturing, creating additional revenue streams. 2. Expansion of Vaccine Production: Use available space and budgeted compact for machinery to scale up vaccine production (Rabies, ASV),	1. Diversified Product Portfolio: Use well-equipped labs and stability studies to expand into new vaccines like Polio, Tetanus Toxoid, and ASV to mitigate risks from regulatory delays and supply chain disruptions. 2. Accelerate Regulatory Compliance: Leverage DRAP approval and internal resources to

purification plant and walk-in cold storage, ensuring the institute's capability to manage complex biological processes. 3. Approved Infrastructure Expansion: DRAP approval was secured for two new sections, Ampoule and Biotechnology, enabling enhanced production capabilities and regulatory compliance. 4. Validated Stability Studies: Successfully conducted 18-month stability studies for the Rabies vaccine, demonstrating product reliability and quality. 5. Growth Potential: Ample space available for additional machinery and segregated biological production lines, allowing for future expansion.	meeting growing market demand. 3. Leverage Stability Studies: Utilize successful 18-month Rabies vaccine stability studies to build credibility and expand into other vaccine markets. 4. ISO 17025 Accreditation & WHO Prequalification: DILS's compliance with ISO 17025 standards and pursuit of WHO prequalification enhances its credibility, ensuring high-quality testing, regulatory recognition, and global acceptance of its products.	fast-track vaccine registration and commercial production, countering external regulatory and economic uncertainties. 3. Limited Skilled Workforce Availability: Difficulty in recruiting and retaining specialized professionals in biological sciences and vaccine manufacturing.

WEAKNESSES	WO	WT
1. Outdated Filling Machine: the current filling machine does not meet the latest cGMP standards, posing regulatory risks and potentially affecting product quality and safety 1. Production Limitations: With a maximum capacity of 9 million vials per year, the filling machine may restrict scalability and hinder DILS's ability to meet growing demand. 1. Infrastructure Deficiencies: Issues with the HVAC system and a non-compliant facility layout could compromise air quality and production safety, increasing the risk of contamination. 2. Expertise Gap: The lack of specialists in biological sera testing and production may impact product quality and innovation. 3. Aging Equipment: The limited capacity Lyophilizer could reduce production efficiency and scalability 4. Lack of Online Presence: The absence of a website reduces visibility, accessibility, and potential partnerships,	1. Infrastructure Modernization: Upgrade HVAC systems, water purification plants, and filling machines to meet regulatory requirements and enhance production capacity. 2. Recruitment & Training: Hire and train experts in biological sera testing and production to fill technical gaps and improve product quality. 3. Digital Presence Development: Create a website to enhance visibility, attract partners, and improve customer trust.	1. Equipment Upgradation: Replace outdated filling machines and lyophilizer with cGMP-compliant models to ensure quality production and regulatory Adherence. 2. Develop In-House Testing: Establish an in-vivo testing facility to reduce dependence on external testing and ensure compliance with regulatory bodies. 3. Improve HR Policies: Shift from short-term contracts to long-term employment strategies to improve employee retention And operational stability. 4. Financial Management: Appoint a finance manager to manage foreign exchange risks and supplier payment issues.

affecting customer trust and brand recognition. 5. Inadequate Water Supply: The current water supply plant does not meet operational needs, potentially disrupting production. 6. Workforce Challenges: Low employee retention due to short-term six-month contracts affects operational stability.		