



ESTABLISHMENT OF PMO AT
HORIZON HEALTHCARE

PVT LTD

FALL 2025

APPROVAL FOR EXAMINATION

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It is to certify that the above student's project has been completed to my satisfaction and, to my belief, its standard is appropriate for submission for examination. I have also conducted a plagiarism test of this thesis using HEC prescribed software and found similarity index _____% that is within the permissible limit set by the HEC for the MS degree thesis. I have also found the project in a format recognized by the BU.

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Date: _____

Name: _____

DECLARATION

We hereby declare that this project report is based on our original work except for citations and quotations which have been duly acknowledged. We also declare that it has not been previously and concurrently submitted for any other degree or award at Bahria University or other institutions.

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Date: Dec 27, 2025

DEDICATION

Specially dedicated to my
Parents, My Wife and
Teachers

(Allah Bakhsh)

My Parents and Teachers

(Muhammad Shabraiz Butt)

ACKNOWLEDGEMENT

We would like to thank everyone who had contributed to the successful completion of this project. We would like to express our gratitude to our course instructor Respected sir, Ahsan Maqbool for his invaluable advice, guidance, and his enormous patience throughout the development of the report.

In addition, we would also like to express gratitude to our loving parents and friends who had helped and given us encouragement.

Allah Bakhsh

Muhammad Shabraiz Butt

ABSTRACT

Horizon Healthcare (Pvt.) Ltd. is one of Pakistan's leading pharmaceutical companies, operating in a highly regulated environment governed by Drug Regulatory Authority of Pakistan (DRAP) and WHO–GMP standards. With rapid organizational growth, multiple manufacturing units, and increasing project complexity, Horizon Healthcare faces challenges related to inconsistent project documentation, reactive risk management, lack of standardized governance, and vulnerability to regulatory compliance risks.

This report focuses on the establishment of a Supportive Project Management Office (PMO) at Horizon Healthcare with a primary emphasis on risk management, regulatory compliance, and organizational standardization. An “As-Is” analysis and structured stakeholder interviews revealed critical gaps in documentation consistency, absence of formal stage-gate reviews, limited portfolio-level visibility, and inefficient use of project management resources. These gaps expose the organization to audit failures, unpredictable operational losses, and loss of institutional knowledge.

To address these challenges, the study proposes and designs a Supportive PMO framework that provides standardized project management templates, a unified project life cycle, mandatory GMP -aligned stage gates, and a centralized knowledge repository. The PMO operates as an enabling and advisory function rather than a directive authority, ensuring minimal bureaucracy while enhancing compliance, efficiency, and proactive risk mitigation.

The implementation plan includes stakeholder engagement strategies, governance structures, training policies, risk management SOP's, and performance measurement mechanisms. Successful implementation of the proposed PMO is expected to improve audit readiness, enhance visibility of enterprise risks, reduce administrative overhead for project managers, and support Horizon Healthcare strategic objective of sustainable growth within a regulated pharmaceutical environment.

CERTIFICATE OF ORIGINALITY

This Witness statement/Originality of work certificate is issued to two students for the partial fulfillment of their MS (Project Management) program requirements being carried out at Bahria University Lahore Campus (BULC).

It is witnessed that Mr. Allah Bakhsh Class MSPM 2 Weekend, bearing Registration number 03-398251-001 and Mr. Muhammad Shabraiz Butt Class MSPM 2 Weekend, Registration Number 03-398251-007 have frequently visited Horizon healthcare Offices and utilized our premises and participated in our real-time projects for implementing Project Management Office (PMO) at Horizon healthcare of Pakistan.

Both students, during their visits to Horizon healthcare, have been found skillful in establishing PMO at Horizon Healthcare. They implemented Risk Management policies in light of GMP code define, Training Policies for the available staff for loading and unloading of dangerous good.

Additionally, It is noteworthy to mention that Mr. Allah Bakhsh and Mr. Muhammad Shabraiz Butt demonstrated good ethical practices, enthusiastic approach to work, task convergence capabilities, professionalism while their connection with Horizon Healthcare of Pakistan.

COMMANDER IDREES BHATTI (R)

MD HORIZON HEALTHCARE OF PAKISTAN

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CHAPTER 01

PROJECT INITIATING



Your health's companion

1.1. Company Selection

Horizon Pharmaceuticals (Pvt) Ltd. is one of Pakistan leading pharmaceutical manufacturers, dedicated to delivering world-class healthcare solutions.

Headquarters: Karachi, Pakistan

Established: Over a decade of excellence in pharma manufacturing

Employees: Approximately 500–1,000 professionals

Facilities: State-of-the-art GMP -compliant production and modern QC laboratories

Focus: Manufacturing, Research & Development, and nationwide distribution



Your health's companion

Head Office

Horizon Pharmaceuticals Private Limited.

House No 197-A, Sindhi Muslim Society. Block-A, Karachi Pakistan.

92 (0) 0213-8674966

info@horizonpharma.com.pk

www.horizonpharma.com.pk

Manufacturing Unit- 1

Horizon Healthcare (Private) Limited.

33. Sundar Industrial Estate, Lahore, Pakistan.

Manufacturing Unit- 2

Horizon Healthcare (Private) Limited.

35-A, Small Industrial Estate. Texila Punjab, Pakistan.

Warehousing facility

Horizon Healthcare (Private) Limited.

Plot 192-193. Triangular Industrial Area, Near Yamaha Chowk.

Kahuta Road. Model Town Islamabad.



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OUR VALUS



Vision & Mission


To be the leader in the global pharmaceutical industry by providing innovative healthcare solutions. We are passionate to be among the most admired healthcare companies of Pakistan in a decade.




Your health's companion




VISION




To be the leader in the global pharmaceutical industry by providing innovative healthcare solutions. We are passionate to be among the most admired healthcare companies of the world in a decade.



MISSION



To combine the skills and attributes of our people with latest manufacturing technologies and R&D to provide high-quality products that meet international standards and fulfil patient needs.



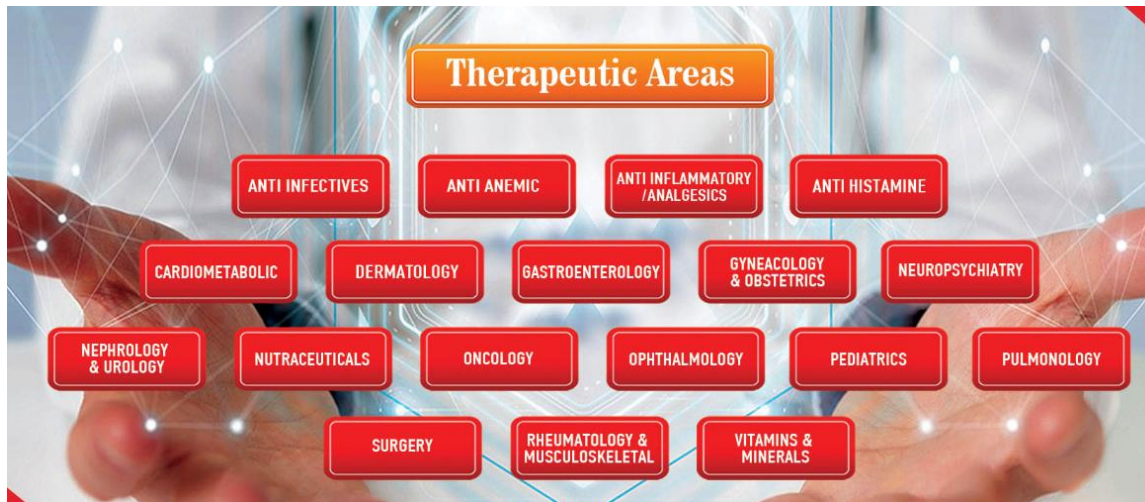
1.2. Company Strengths:

Horizon Pharmaceuticals has demonstrated consistent growth with strong domestic sales and expanding export potential.

- Broad therapeutic
- Cutting-edge manufacturing facilities
- Skilled workforce and R&D culture
- Nationwide distribution network
- Regulatory compliance with DRAP and WHO -GMP standards
- Strong reputation in Pakistan’s pharmaceutical market

1.3. Organization

Therapeutic Includes:



R&D, regulatory, and marketing divisions ensuring top-tier quality and accessibility support these.

1.4. Projects / Programs

- GMP Compliance Modernization Program
- Research Collaboration for Innovative Formulations
- Quality Assurance Enhancement Program
- Academic & CSR Initiatives
- Health, Safety & Environment (HSE)

Program Focus Areas:

- Manufacturing efficiency
- Product innovation
- Workforce training
- Patient safety and awareness campaigns

1.5. Industries Served / Markets

Industry:

Pharmaceutical Manufacturing & Healthcare

Markets:

Domestic: Pakistan (nationwide distribution)

Emerging: Export markets in Middle East and Africa (expansion under progress)

Clients: Hospitals, Clinics, Pharmacies, and Healthcare Institutions

1.6. Projects Overview

Completed Projects: 20+

Ongoing Projects:



Key Focus: Manufacturing automation, R&D infrastructure, quality certifications, and environmental compliance.

1.7. Services & Solutions

Core Services:

Formulation Manufacturing (Tablets, Capsules, Syrups, Injections)

Quality Control & Regulatory Testing

R&D and Product Development

Contract Manufacturing Partnerships

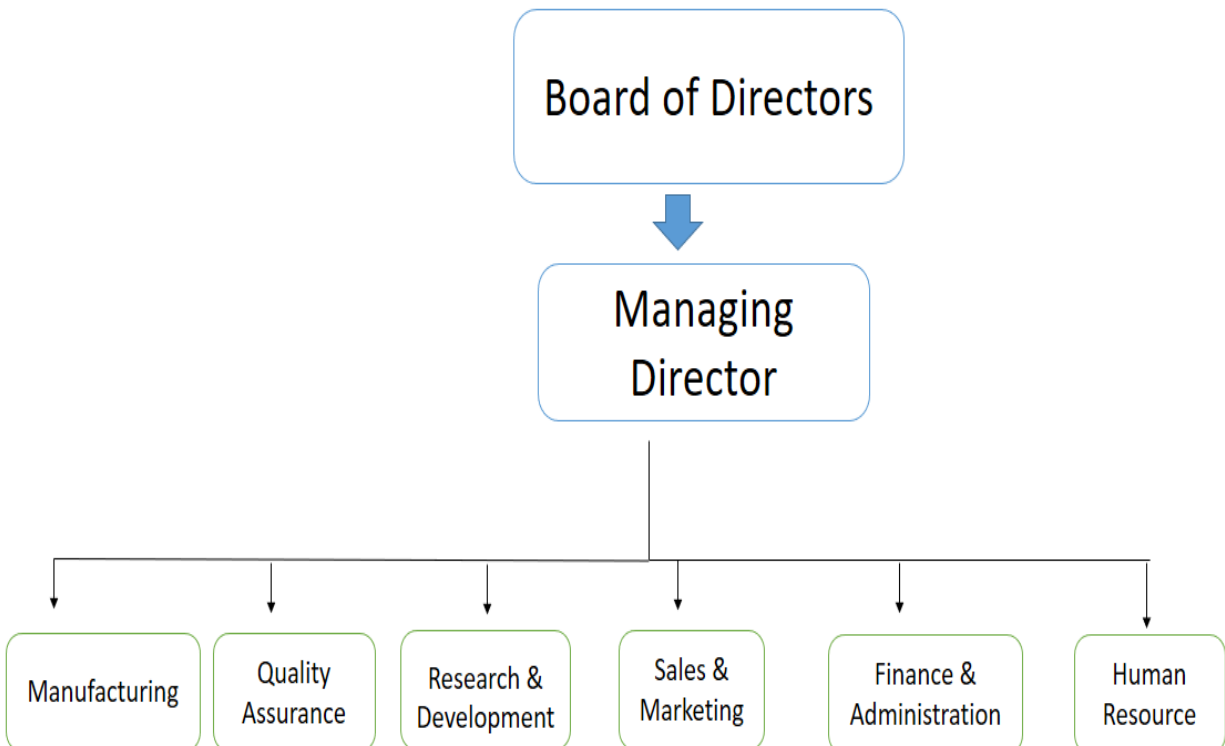
Distribution & Logistics

Academic & Professional Training

Services Solutions:

Comprehensive end-to-end pharmaceutical production ensuring safety, efficacy, and compliance.

1.8. Organization Structures



1.9. Department / Unit Structure

Quality Control Department

QC Manager

- Analytical Testing Unit
- Microbiology Unit
- Stability & Validation

Unit Responsibilities:

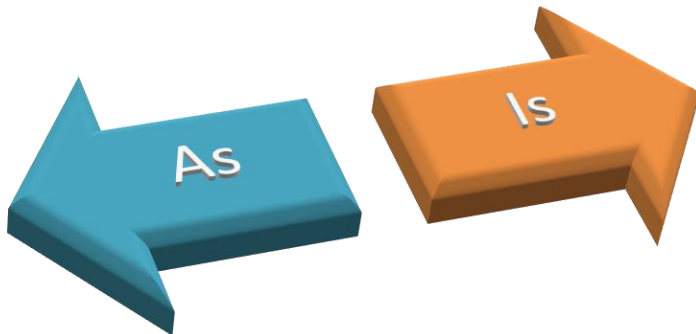
Routine Quality Testing

Validation & Calibration

Regulatory Documentation

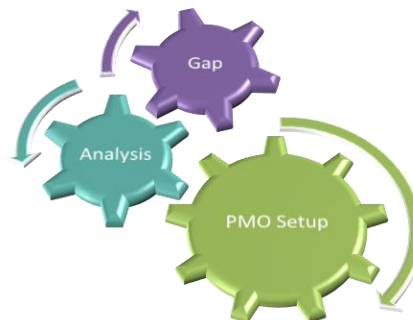
Continuous Improvement in Quality Processes

1.10. As-Is Analysis: Current State of Project Management in Horizon Health care



Company focused more on its stakeholders, the customers, vendors; suppliers are fully satisfied from the Horizon healthcare. According to the information provided the roles and responsibilities of all personal are well clear, the team is more cautious about the satisfaction of customers.

1.11. Gap Analysis for PMO Setup:



A gap analysis helps to identify the differences between the current state ("as-is") of project management practices at Horizon healthcare and the desired state with a fully functional PMO.



1.12. Interview

The structured interview was conducted with the officials of the company incorporates on questions composed on seven project management areas which are Risk, HRM, Stakeholders, Integration Management, Quality, Procurement and Communication. The triple constraints cost, scope and time are major concern.

QUESTION No. 1: Are different project managers or departments using consistent documentation i.e. standard templates used for project charters, risk registers, status reports, and project closure?

As per information provided by managers Horizon Healthcare (Pvt) are not using consistent documentation. Moreover, all departments follow different documentation whereas; there is strict regulatory requirements inherent in the pharmaceutical industry. As a pharmaceutical manufacturer Pakistan, the company is subject to rigorous oversight by bodies such as the Drug Regulatory Authority of Pakistan (DRAP) and adheres to international guidelines like Good Manufacturing Practices (GMP) instructions.

QUESTION No. 2: Are there mandatory stage gates (reviews and approvals) before moving from one phase (e.g., Design) to the next are implemented at Horizon healthcare?

According to the information provided by the company managers there is no stage gates procedure follow as per project management life cycle however, our PM follow as and when required basis as per need of project.

QUESTION No. 3: How much time is spent by PM and team simply collecting data for reporting verses actually managing project, did you predict uncertainties before to launch project?

According to information provided by senior management at **Horizon Healthcare (Pvt Ltd)**, a significant amount of time by the Project Manager and project team is currently spent on collecting, consolidating, and formatting data for reporting purposes. This indicates limited standardization and automation of project information systems. Regarding uncertainty and risk prediction prior to project launch, At Horizon Healthcare, uncertainties are not identified and documented subsequently, risk response strategies were not consistently conducted before project execution. As a result, several uncertainties materialized as issues during execution, leading to reactive management rather than proactive control.

1.13. Identified Gap

By using interview we identified gaps incorporate on three specific domains.

1.13.1 Standardization and Visibility Gap

The current "As-Is" state confirms inconsistent documentation and a lack of a proper reporting and monitoring methodology. This directly translates into a risk management gap because project risks are not captured, analyzed, or reported uniformly across the organization. Since project managers use different formats for risk tracking, senior leadership lacks the visibility needed to assess threats (e.g., a single vendor delay impacting multiple projects). The Supportive PMO must introduce a standardized Risk Register template and a consistent reporting mechanism to ensure risks are surfaced, compared, and prioritized, moving risk management from time beings departmental task to an organizational discipline.

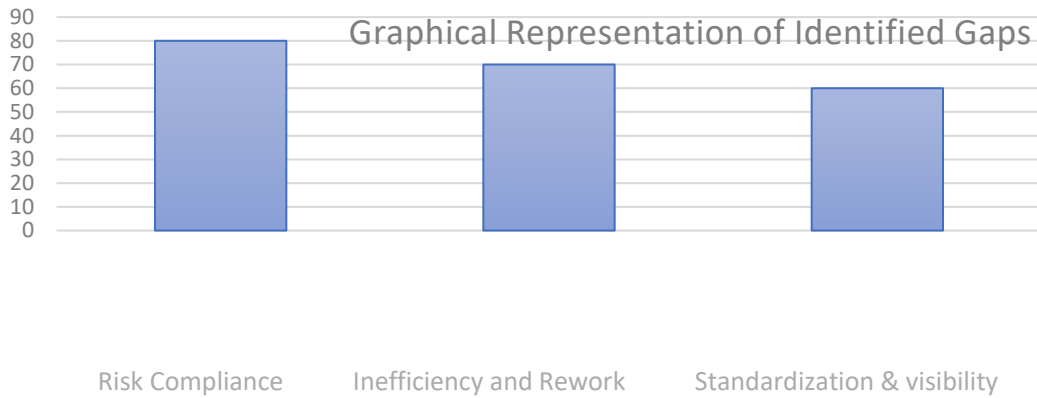
1.13.2. Regulatory and Compliance Risk Gap

Our analysis identifies that uncertainty prediction was not properly considered, leading to unpredictable loss and confirming that risk management is currently reactive rather than proactive. This is the biggest gap in a pharmaceutical environment. GMP - compliance projects, like the Inject-able Manufacturing Line, inherently require mandatory, sign-off-based stage gates (like Design Qualification or Installation Qualification). The failure to formally manage risks at these critical junctures (e.g., procurement delays, validation errors) creates a direct Compliance Risk that could result in audit failures or delays to achieving the target WHO -GMP certification. The Supportive PMO is essential to formalizing these risk-based stage gates and providing the tools to proactively mitigate threats that could affect product quality and patient safety.

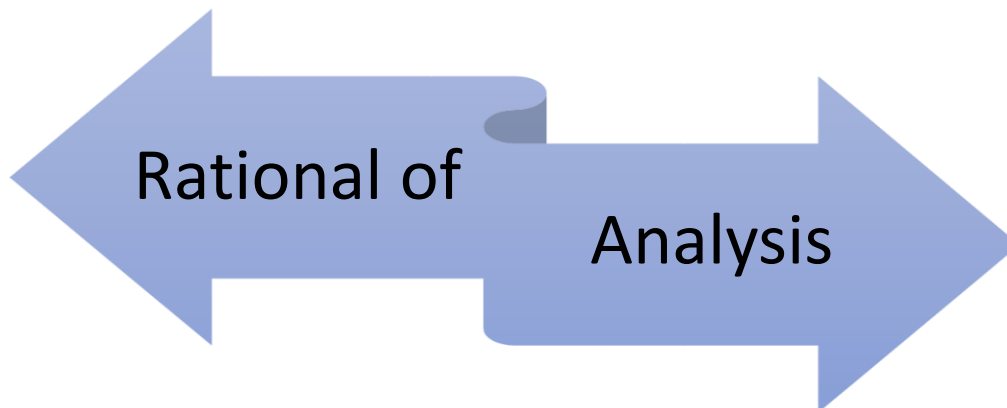
1.13.3. Inefficiency and Proactive Management Gap

My current analysis state shows that project assignment follows the departmental hierarchy and that PMs spend an excessive, undefined amount of time collecting data for reporting rather than managing the project. This confirms that valuable PM time is

consumed by administrative overhead instead of focusing on proactive risk mitigation. The PMO is required to shift this balance by introducing a risk management framework that saves time. By providing standard templates and methodology, the PMO frees up the PM's time to perform high-value activities, such as identifying and mitigating the specific uncertainties that currently cause "unpredictable loss," thereby enhancing the project's ability to achieve targets like the 20% reduced rejection rate.



1.14. Rational of Analysis



The rationale for this analysis is to systematically justify the need for establishing a Supportive PMO for Risk Management by evaluating the organization's current ("As-Is") project management practices against recognized best practices, regulatory requirements, and objectives. The analysis is evidence-based, drawing primarily on interviews and operational observations, which revealed structural and process-level deficiencies across risk governance, compliance assurance, and project efficiency.

The focus on regulatory compliance is important due to high risks and regulatory requirement involved.

1.15. Finding and justification:

Finding: Lack of consistent documentation.

Justification: The analysis focuses on standardization and visibility because inconsistent documentation and reporting practices directly undermine project-level risk oversight. Without standardized risk registers and uniform reporting mechanisms, risks remain siloed at the project or departmental level, preventing senior management from identifying systemic threats or inter-project dependencies. This lack of visibility increases the likelihood of unanticipated escalations and delays, justifying the need for a supported, PMO -led risk framework.

Finding: Lack of regulatory compliance.

Justification: The analysis prioritizes regulatory and compliance risk due to the organization's pharmaceutical operating environment, where compliance with GMP and WHO -GMP standards is mandatory rather than optional. The findings indicate that risk management is currently reactive, with insufficient attention to uncertainty prediction at critical stage gates such as Design Qualification (DQ) and Installation Qualification (IQ). This exposes the organization to audit failures, certification delays, and potential product quality risks, providing a strong regulatory rationale for formal PMO intervention.

Finding: Lack of efficiency and proactive approach.

Justification: The analysis addresses inefficiency and proactive management gaps, recognizing that project managers spend excessive time on manual data collection and reporting instead of risk mitigation and decision-making. This mismanagement of effort leads to rework, schedule slippage, and "unpredictable loss." A Supportive PMO is therefore justified as a value-enabling function that introduces standardized tools and processes, reduces administrative burden, and enables project managers to focus on proactive risk control and performance improvement.

1.16. Project Charter

1.16.1. PMO Vision Statement:

"To be a strategic enabler of organizational success by delivering high-value projects through standardized practices empowered leadership and a culture of continuous improvement by reducing cost via risk management."

This vision reflects the PMO's role in driving efficiency, and value creation across the organization. The vision statement is also used to provide leadership, standardization, and support for project management within Horizon healthcare, fostering a culture of

excellence and continuous improvement to consistently deliver successful projects by reducing uncertainties.

1.16.2. PMO Mission Statement:

"To establish and uphold project management excellence by providing governance, standardized methodologies, and support for risk management, that enable the successful delivery of projects by fulfilling triple constraints aligned with organizational goals.

1.17. Project charter:

Project Title: Establishment of a Supportive PMO for Risk Management.

- **Project Manager:** Mustaqeem.
- **Project Sponsor:** Chief Operating Officer (COO).
- Start date: 3 Nov 2025
- End date: 4 January 2026
- **Overall Budget:** Four million PKR.

Project Purpose:

To respond the Task of Project Management Office Course assigned by Assistant Professor Mr Ahsan Maqbool in the MS (PM) Bahria University Lahore Campus. To establish a Project Management Office (PMO) within Horizon healthcare to standardize project management practices, improve project delivery, reduce risks (especially related to regulatory requirements), enhance compliance, and increase overall organizational efficiency.

Business Need and Justification

The "As-Is" analysis of Horizon Healthcare reveals critical gaps:

- **Inconsistency:** Lack of standardized documentation and reporting methodologies across departments.
- **Compliance Risk:** High vulnerability to GMP audit failures due to missing regulatory sign-offs and fragmented records.

Reactive Risk Management: Risk management is currently reactive, leading to unpredictable losses.

Project Objectives

The PMO will be considered successful if the following are achieved:

- **Standardization:** Create and pilot a mandatory, standardized templates like Risk Register, project charter etc.
- **Compliance:** Integrate mandatory risk-based stage gates into the project life-cycle (e.g., for the Inject-able Manufacturing Line).
- **Visibility:** Implement a reporting framework that includes risk status and escalation for senior leadership.

Efficiency: Reduce administrative overhead by providing a set of standard templates to Project Managers.

Project Scope

- **Standardization:** Developing mandatory templates (Project Charter, Risk Register, Status Report, and Closure Report).
- **Risk management:** Provide risk management framework for projects.
- **Governance:** Formalizing a project life cycle with QA-approved stage gates.
- **Knowledge Management:** Establishing a centralized electronic repository for project documents and lessons learned.
- **Support:** Providing training and workshops to PMs on the new standardized methodology.

Out-of-Scope Activities:

- **Direct Execution:** The PMO is supportive, not directive; it will not manage individual operational projects.
- **IT Development:** Development of new enterprise IT systems (only configuration of existing tools).
- **Authority:** Restructuring departmental reporting lines or budget reallocation.

High-Level Requirements & Constraints

- **GMP Alignment:** All artefacts and stage gates must explicitly support Good Manufacturing Practice (GMP) compliance.
- **Minimal Bureaucracy:** The PMO must not increase the administrative burden on PMs; its role is to save time through standardization.

- **Resource Reliance:** Implementation relies heavily on existing IT systems and the cooperation of the Quality Assurance department.

Assumptions

- Top management is committed to providing the necessary support and resources for the PMO.
- Stakeholders are willing to collaborate and adopt the new project management practices.
- The current organizational structure can accommodate the PMO.

Timeline 10 weeks

1.18. Key Stakeholders

- **Project Sponsor (COO):** Ultimate authority for funding and overall approval.
- **Steering Committee:** Key decision-makers for project-level resource allocation.
- **Quality Assurance (QA) / Regulatory Affairs:** Critical for validating the compliance of stage gates.
- **Project Managers (PMs):** Primary users and adopters of the new templates and processes.

1.19. Risks

- **Resistance to Change:** PMs or departments may continue using inconsistent documentation.
- **Compliance Miss:** Defined stage gates may fail to meet full internal or external regulatory requirements without rigorous QA validation.
- **Scope Creep:** The PMO's role may inadvertently shift from "Supportive" to "Directive," causing delays.

1.20. Approval and Sign-Off

Role	Name	Signature	Date
Project Sponsor	COO Horizon Healthcare	_____	
Project Manager	Mustaqeem	_____	

1.21. Stage Gate Review

There are six mandatory stage gates designed to ensure GMP compliance at horizon healthcare the ultimate destination of supportive PMO is to attain strategic alignment.

The following table outlines the specific review points for your project:

Gate	Name	Timing	Primary Focus for Review
Gate 1	Initiation Approval	Week 01	Project Charter: Formal approval of the PMO's scope and objectives by the COO.
Gate 2	Design Approval	Week 02	PMO Operating Model: Approval of the governance structure and roles by the Steering Committee.
Gate 3	Framework Approval	Week 03	Compliance Validation: QA and Executive sign-off on standardized templates and mandatory stage gate criteria.
Gate 4	Systems Readiness	Week 04	Repository Access: Confirmation that the IT-hosted centralized document library is live and secure.
Gate 5	Training Readiness	Week 05	Capability Check: Verification that 100% of Project Managers have completed mandatory methodology training.
Gate 6	Go-Live/Operational	Week 5 to 10	Full Deployment: Final executive sign-off and closure of the establishment project.

The stakeholders are categorized into internal and external groups, with specific management strategies defined to ensure project success and regulatory compliance

CHAPTER 2

PMO PLANING

2.1 PMO Scope

The scope of the proposed Supportive Project Management Office (PMO) at Horizon Healthcare is to provide structured guidance, standardized methodologies, professional tools, and expert advisory support to project teams across clinical, administrative, information technology, and infrastructure development projects. The PMO will initially operate in a supportive capacity, focusing on improving project consistency, enhancing risk management, strengthening regulatory compliance, and increasing overall project success rates without exerting direct control over project execution.

The PMO will function as a centralized knowledge and support unit, ensuring that project teams are equipped with standardized processes while maintaining operational flexibility within departments.

The key areas within the PMO scope include:

- The PMO will develop documents, and maintain a standardized project management. This includes the provision of standardized templates, tools, checklists, and best practices for all phases of the project life cycle. The PMO will guide departments in consistently applying these methodologies across clinical, pharmaceutical, IT, human resource, and facilities projects.
- A comprehensive project risk management framework will be developed and implemented by the PMO. This framework will include standardized processes for risk identification, qualitative and quantitative risk assessment, response planning, monitoring, and escalation. Particular emphasis will be placed on healthcare-specific risks, including patient safety risks, clinical process failures, regulatory non-compliance, medical equipment implementation risks, and data privacy breaches. Healthcare-specific risk registers, mitigation plans, and monitoring checklists will be developed to proactively reduce adverse events and operational disruptions.
- The PMO will assess organizational project management maturity and identify competency gaps among staff. Based on these assessments, structured training programs will be developed and delivered covering project management fundamentals, healthcare risk management, quality assurance, regulatory compliance, and change management. The PMO will also provide ongoing mentoring and coaching support to project managers and project teams.
- The PMO will provide expert advisory and consultation services to project managers and department heads. This includes support in project planning, scheduling, budgeting, execution, monitoring, and closure. The PMO will assist in resolving project issues, facilitating escalation, and supporting informed decision-making by senior management.

- Standardized project performance metrics and dashboards will be developed by the PMO. These will enable consistent monitoring of project progress, cost, schedule, scope, quality, and risk. The PMO will consolidate project status reports and present structured performance insights to executive leadership, thereby improving transparency and accountability while maintaining a supportive monitoring role.
- A centralized project knowledge repository will be established to store project documentation, lessons learned, best practices, and historical data. The PMO will promote organizational learning by capturing knowledge from completed projects and facilitating continuous improvement across Horizon Healthcare.

In summary, the Supportive PMO at Horizon Healthcare will act as a center point, empowering project teams with standardized tools and expertise while safeguarding patient safety, regulatory compliance, and operational efficiency.

2.2 Current PMO Structure (As-Is State)

Horizon Healthcare is currently operating without a formal Project Management Office. Individual departments, resulting in inconsistent project management approaches, limited documentation standards, and the absence of a unified risk management framework, conduct project management activities independently. Risk identification and mitigation are largely reactive, increasing the organization's exposure to patient safety incidents, regulatory non-compliance.

The lack of centralized governance also limits visibility into project performance, making decision-making and prioritization challenging for senior management.

2.2.1 Recommended PMO for Horizon Healthcare

Given the complexity of healthcare operations and the critical importance of patient safety, quality assurance, and regulatory compliance, the establishment of a Supportive PMO is strongly recommended. Healthcare projects operate in high-risk environments where failures can have severe clinical, financial, and reputation consequences. A structured PMO will enable Horizon Healthcare to shift from reactive project management practices to proactive, risk-focused governance.

2.3 Proposed PMO

It is proposed that Horizon Healthcare establish a Supportive PMO that reports to senior executive leadership. The PMO will function as a central support entity responsible for standardizing methodologies, strengthening risk management practices, and enhancing project governance across all departments.

The PMO will operate with advisory authority and may include roles such as PMO Director, Project Management Analyst, Risk and Quality Specialist, Training and Development Coordinator and Project Support Officers.

2.3.1 Recommended PMO Structure

A Supportive PMO is recommended for Horizon Healthcare. Initially, a decentralized supportive approach should be adopted to gain stakeholder buy-in. Over time, the PMO should evolve into a hybrid structure with stronger governance, compliance oversight, and strategic influence.

2.3.2 PMO Core Values

Core Value	Description
Accountability	Ownership of outcomes and patient safety
Transparency	Clear visibility into project performance
Excellence	High standards in clinical and operational delivery
Collaboration	Cross-departmental coordination
Innovation	Continuous improvement and adaptability
Integrity	Ethical conduct and regulatory compliance

2.4 PMO Governance

2.4.1 Roles and Responsibilities of the Supportive PMO

The Supportive PMO at Horizon Healthcare will:

- Develop and maintain standardized project management methodologies
- Provide training, mentoring, and coaching
- Support performance reporting and dashboards
- Facilitate project reviews and health checks
- Promote governance and compliance awareness
- Support stakeholder communication
- Recommend and support project management tools

2.5. RACI Chart

To establish the Supportive PMO at Horizon Healthcare, a RACI Chart (Responsible, Accountable, Consulted, and Informed) is essential to clarify roles, especially given the integration of QA/Regulatory Affairs for GMP compliance. The following chart outlines the responsibilities for key activities during the 20-week implementation period.



Activity / Task	PMO Lead (Mustaqeem)	Project Sponsor (COO)	Steering Committee	QA / Regulatory Affairs	Project Managers (PMs)	IT Dept
Develop PMO Project Charter	R	A	C	I	I	I
Design Governance & PM Framework	R	A	C	C	I	I
Create Standard Templates (Risk Register, charter etc.)	R	I	I	C	C	I
Define Mandatory Stage Gates	R	I	A	C	C	I
Configure Centralized Document Repository	C	I	I	I	I	R/A

Conduct Methodology Training	R/A	I	I	I	C	I
Validate Compliance of Stage Gates	C	I	A	R	I	I
Formal Project Sign-Off	R	A	C	C	I	I

2.6 PMO-Defined Project Lifecycle Process

Initiation Phase

- Project charter development
 - Business case validation
 - Stakeholder identification
- PMO Role: Templates, guidance, and alignment validation

Planning Phase

- Scope definition and WBS
 - Schedule and budget development
 - Risk, quality, and communication planning
- PMO Role: Review, standardization, and advisory support

Development Phase

- Deliverable execution
 - Stakeholder coordination
- PMO Role: Progress monitoring and issue resolution support

Monitoring and Controlling Phase

- KPI tracking and reporting
 - Change control management
 - Risk register updates
- PMO Role: Performance analysis and corrective guidance

Closing Phase

- Deliverable acceptance
 - Lessons learned documentation
 - Knowledge archiving
- PMO Role: Knowledge capture and dissemination

2.7 Value Proposition

The PMO will significantly enhance Horizon Health-care's project management capabilities by improving predictability, efficiency, compliance, and stakeholder satisfaction. Through standardized methodologies and proactive risk management, the PMO will reduce clinical and operational risks while supporting organizational objectives. Key value contributions include improved project success rates, reduced adverse events, enhanced regulatory compliance, increased efficiency and productivity, improved stakeholder satisfaction, greater consistency in project outcomes, enhanced organizational learning, and strengthened competitive advantage.

2.8 PMO Category

The PMO at Horizon Healthcare will act as supportive PMO.

2.9 PMO Future Road-map

Phase 1: PMO Establishment

- Focus on foundational structures, methodology development, basic tools, risk management framework implementation, and training.
- Success Metrics Adoption rate of standardized methodology
- Number of staff trained
- Initial reduction in project risks and issues

Phase 2: PMO Expansion and Control

- Focus on enhanced governance, project management, compliance audits, and advanced reporting.
- Success Metrics
- Reduced project delays and cost overruns
- Improved forecast accuracy
- Increased compliance scores

Phase 3: Strategic PMO Alignment

- Focus on strategic project selection, data-driven decision-making and continuous improvement.
- Success Metrics Alignment of projects with strategic goals
- Measurable organizational and clinical impact Improved PMO maturity level

CHAPTER 3

PMO DEVELOPMENT

3.1. Stakeholders List:

The stakeholder is an individual or organization who effect or perceived effects by the objectives of the project



3.2. Internal Stakeholders

Project Sponsor (COO): The ultimate authority who authorizes the project, provides funding, and mandates adherence to new standards.

CEO: Part of the executive leadership overseeing the alignment of the PMO.

Steering Committee: Key decision-makers responsible for resource allocation and major scope changes across the project.

Project Manager (Mustaqeem): Responsible for the establishment and execution of the PMO.

Existing Project Managers (PMs): The primary users of the new tools and methodology; their buy-in is critical for adoption.

Quality Assurance (QA) / Regulatory Affairs: Validates that the new stage gates and documentation meet GMP and regulatory requirements.

Finance Department: Involved in the financial oversight and budget alignment for project resources.

IT Department: Provides the infrastructure and repository platform for PMO documentation and templates.

Functional / Department Managers: Managers who oversee departments where PMs reside; they may be sensitive to changes in departmental hierarchy.

Project Team Members: The individuals executing tasks under the newly standardized methodology.

3.3. External Stakeholders

- Regulatory Bodies
- Vendor
- Supplier

3.4. Stakeholder Management Matrix

This stakeholder register classifies key stakeholders by their level of influence and interest to determine the best engagement strategy.

Stakeholder	Influence	Interest	Management Strategy
Project Sponsor (COO)	High	High	Manage Closely: Regular reports focused on progress and mitigation of Compliance Risk.
Steering Committee	High	Medium	Keep Satisfied: Standardized status reports demonstrating clear Risk Visibility.
Project Managers (PMs)	Low	High	Manage Closely: Involve early in template design to ensure the PMO reduces their workload.
QA / Regulatory Affairs	High	High	Manage Closely: Consult and gain formal sign-off on mandatory stage gates to ensure GMP compliance.
IT Department	Medium	Low	Keep Informed: Provide clear requirements for the documentation repository and security.
Department Managers	Medium	Medium	Keep Informed: Communicate the value of standardization in reducing "unpredictable loss".

3.5. Critical Engagement Factors

Supportive Perception: The PMO must be seen by Project Managers as a support system that reduces administrative burden rather than increasing it.

Compliance Sign-off: The QA/Regulatory Affairs department's buy-in is non-negotiable because of the high risk associated with audit failures and patient safety.

3.6. Stakeholders Requirement Register

To establish the Supportive PMO at Horizon Healthcare with a focus on risk management, the Stakeholder Requirements Register translates high-level needs into specific, actionable project requirements. This ensures the PMO addresses the identified gaps in standardization, compliance, and efficiency.

Stakeholder	Requirement Description	Category	Acceptance Criteria
Project Sponsor (COO)	Centralized visibility of project risks across the entire organization.	Business	Monthly project dashboard showing the "Top 5 Risks" for all active projects.
Quality Assurance (QA)	Mandatory sign-offs at critical project phases to ensure GMP compliance.	Regulatory	Formal "Go/No-Go" checklists for Design (DQ) and Installation (IQ) qualifications.
Project Managers (PMs)	Reduction in time spent on manual data collection and report formatting.	Functional	Standardized, pre-filled templates (Charter, Risk Register) that reduce reporting time.
IT Department	A secure, centralized platform for document storage and version control.	Technical	Functional electronic repository with role-based access for all PMs and QA staff.
Steering Committee	Formal escalation path for project-level threats (e.g., vendor delays).	Business	A defined "Risk Escalation Matrix" that triggers leadership alerts based on risk score.
Regulatory Affairs	Preservation of all project records and validation documents for audit readiness.	Compliance	100% of project closure reports must include a validated audit trail of regulatory approvals.

3.7. Stakeholder Register

Stakeholder	Role in Project	Influence	Interest	Management Strategy
Project Sponsor (COO)	Authorizes project, provides funding, and mandates standards.	High	High	Manage Closely: Regular, concise reports on schedule, budget, and Compliance Risk.
Steering Committee	Decision-maker for resource allocation and major scope changes.	High	Medium	Keep Satisfied: Standardized status reports focused on risk visibility.
Project Manager (Mustaqeem)	Responsible for direct execution and establishment of the PMO.	Low	High	Manage Closely: Early involvement in template design to ensure reduced overhead.
Quality Assurance (QA)	Validates that stage gates and documents meet GMP requirements.	High	High	Manage Closely: Gain formal sign-off on mandatory gates and closure templates.
IT Department	Provides the repository platform for PMO documents.	Medium	Low	Keep Informed: Provide clear requirements for repository access and security.
Functional Managers	Departmental heads who may resist changes to existing hierarchies.	Medium	Medium	Keep Informed: Communicate value in reducing "unpredictable loss."
Finance Department	Oversight of project budget and resource expenditure.	Medium	Low	Keep Informed: Periodic budget and resource utilization updates.

Stakeholder	Role in Project	Influence	Interest	Management Strategy
Project Team Members	Execute tasks under the new methodology.	Low	Low	Monitor: Ensure PMs adequately train and communicate changes.

3.8. PMO SCOPE STATEMENT

Scope Statement

3.8.1. Project Title

Establishment of a Supportive PMO at Horizon

3.8.2. Scope Statement:

Horizon Pharmaceuticals requires a standardized and compliance-aligned project management environment to address existing gaps in documentation, inconsistent practices, reactive risk management, and vulnerability to GMP audit failures.

This project aims to establish a Supportive PMO that provides methodologies, templates, risk governance, and training without imposing additional bureaucracy on Project Managers.

The PMO will enhance regulatory compliance, organizational visibility, and proactive risk mitigation, enabling leadership to make informed decisions and reducing unpredictable operational loss.

3.8.3. Project Objectives

Develop and implement standardized project management templates, tools, and documentation processes.

Establish a regulatory-aligned, risk-focused governance framework using mandatory stage gates.

Improve organizational visibility through formal risk reporting and project-level escalation mechanisms.

Create a centralized repository for project documents and institutional knowledge (e.g., lessons learned, risk history).

Provide training and mentoring to Project Managers to ensure consistent adoption of methodologies.

Support compliance with GMP and internal audit requirements by embedding mandatory approvals and documentation standards.

3.8.4. Project Scope Description

A. PMO Standardization & Knowledge Management

Development of mandatory project templates (Project Charter, Risk Register, Stage Gate Checklist, Status Report, Closure Report).

Definition of a unified project life-cycle, methodology, and reporting structure.

Establishment of a central electronic repository for all PMO document.

B. Risk & Compliance Governance

Creation and enforcement of mandatory stage gates with QA/Regulatory Affairs sign-off.

Development of a standardized risk identification, monitoring, and escalation framework.

Introduction of risk analytic, trend reporting, and visibility dashboards for leadership.

Integration of compliance checkpoints within the project life-cycle.

C. Training, Mentoring & Support

Training modules on project methodology, templates, and proactive risk management.

PMO help-desk function to support PMs in using tools and passing stage gates.

Change management communication plan to encourage adoption across departments.

D. Stakeholder Collaboration

Engagement with Project Managers, QA/Regulatory Affairs, Finance, and IT for process design.

Alignment workshops with the Steering Committee and Executive Leadership.

Development of communication updates to stakeholders during implementation.

3.8.5. Out-of-Scope Items

Execution or management of individual operational projects (PMO is supportive, not directive).

Development of new IT systems (only configuration of existing tools/platforms).

Budget reallocation or restructuring of departmental reporting lines.

Hiring of new full-time staff; temporary support may be utilized if necessary.

Performing quality audits (QA will retain ownership, PMO only supports documentation standards).

3.8.6. Deliverables

PMO Charter and Governance Framework

Standardized Template Suite and PM Methodology Guide

Mandatory Stage Gate Review Checklists & Approval Forms

Centralized Project Repository (IT-provided platform)

Risk Register Structure and Reporting Mechanism

Training Manuals, SOP s, and PMO On-boarding Material

Lessons Learned Repository and Knowledge Library

Stakeholder Engagement and Communication Plan

Final PMO Operationalization Report

3.8.7. Project Constraints

Must comply with GMP, regulatory requirements, and internal audit expectations.

Must not increase administrative burden on PMs

Limited IT development capacity; project relies heavily on existing systems.

Implementation must fit within approved budget and timelines set by the Project Sponsor (COO).

3.8.8. Assumptions

Executive Leadership will provide timely decisions and approvals during stage gate design.

QA/Regulatory Affairs will actively participate in compliance-related document validation.

Project Managers will adopt the new tools once training is completed.

IT department will provide repository access and configurations as required.

Departments will cooperate in sharing historical project data for knowledge capture.

3.8.9. Risks

Resistance from Project Managers or Functional Managers due to perceived administrative overhead.

Delayed sign-off from QA/Regulatory Affairs affecting stage gate finalization.

Insufficient training uptake leading to inconsistent adoption.

IT repository limitations affecting usability.

3.8.10. Acceptance Criteria

The PMO establishment will be considered complete when:

All standard templates and methodologies are approved by QA/RA and Executive Leadership.

PMO repository is operational and accessible to all stakeholders.

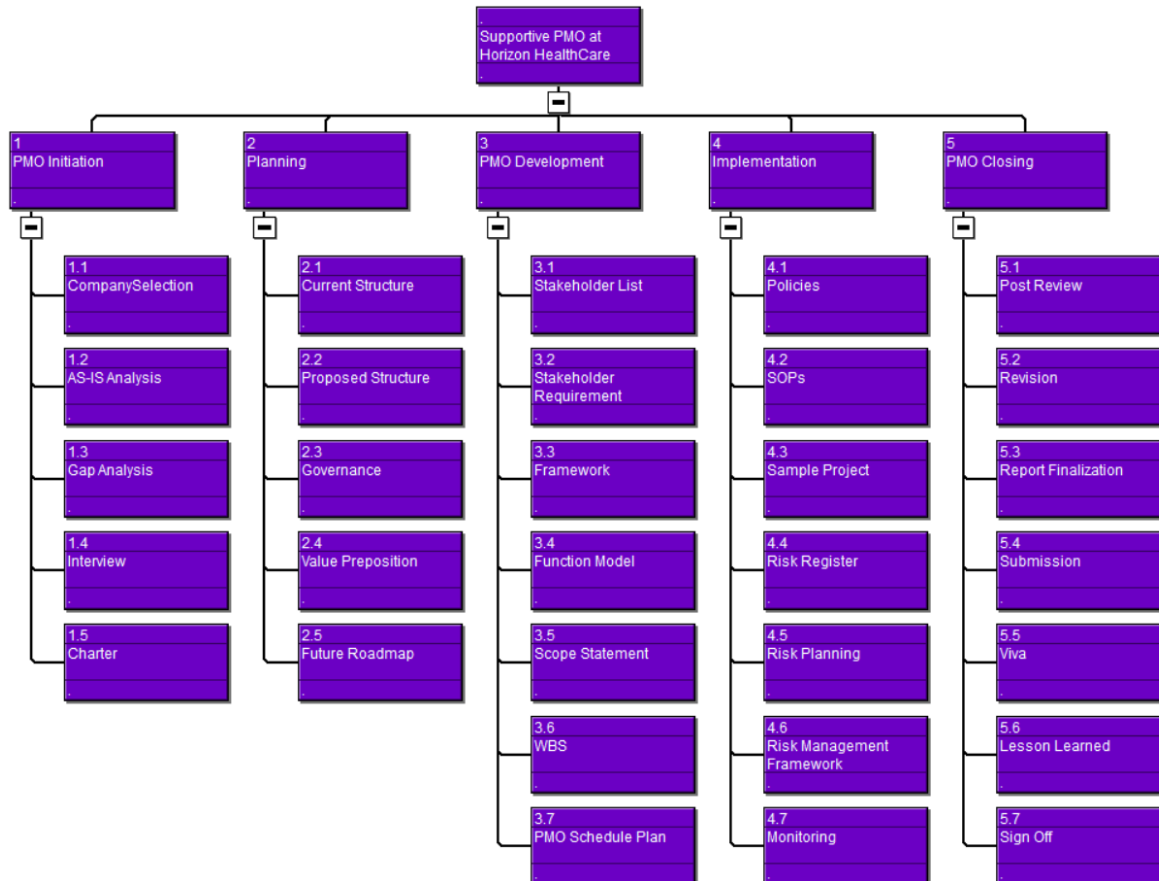
Training sessions have been conducted for 100% of Project Managers.

Mandatory stage gates are incorporated into the organizational project life-cycle.

First cycle of risk reporting and lessons learned practices are functioning.

PMO is capable of providing ongoing support without external project resources.

3.9. WORK BREAKDOWN STRUCTURE



3.10. PMO Schedule

To establish the Supportive PMO at Horizon Healthcare, the project is divided into a 10 week implementation timeline. This schedule is structured to move the organization from its current "As-Is" state to a fully operational, GMP -aligned PMO.

PMO Implementation Schedule

Project: Supportive PMO at Horizon Healthcare

Duration: 10 Weeks

Calendar: 5 Working Days per Week

1.0 PMO Initiation (Weeks 1–2)

Activity ID	WBS	Activity Name	Duration	Predecessor
PMO-101	1.1	Company Selection	2 days	-
PMO-102	1.2	As-Is Analysis	2 days	PMO-101
PMO-103	1.3	Gap Analysis	2 days	PMO-102

PMO-104	1.4	Stakeholder Interviews	2 days	PMO-103
PMO-105	1.5	PMO Charter Development	2 days	PMO-104

2.0 Planning (Weeks 3–4)

Activity ID	WBS	Activity Name	Duration	Predecessor
PMO-201	2.1	Current Structure Analysis	2 days	PMO-105
PMO-202	2.2	Proposed PMO Structure	1 day	PMO-201
PMO-203	2.3	Governance Framework	2 days	PMO-202
PMO-204	2.4	PMO Value Proposition	2 days	PMO-203
PMO-205	2.5	Future PMO Roadmap	3 days	PMO-204

3.0 PMO Development (Weeks 5–6)

Activity ID	WBS	Activity Name	Duration	Predecessor
PMO-301	3.1	Stakeholder List	1 day	PMO-205
PMO-302	3.2	Stakeholder Requirements	2 days	PMO-301
PMO-303	3.3	PMO Framework Development	2 days	PMO-302
PMO-304	3.4	PMO Functional Model	1 days	PMO-303
PMO-305	3.5	PMO Scope Statement	2 days	PMO-304
PMO-306	3.6	Work Breakdown Structure (WBS)	1 day	PMO-305
PMO-307	3.7	PMO Schedule Plan	1 day	PMO-306

4.0 Implementation (Weeks 07– 08)

Activity ID	WBS	Activity Name	Duration	Predecessor
PMO-401	4.1	PMO Policies Development	1 day	PMO-307

PMO-402	4.2	SOPs Development	1 day	PMO-401
PMO-403	4.3	Sample Project Implementation	2 days	PMO-402
PMO-404	4.4	Risk Register Development	2 days	PMO-403
PMO-405	4.5	Risk Planning	1 day	PMO-404
PMO-406	4.6	Risk Management Framework	2 days	PMO-405
PMO-407	4.7	Monitoring & Control	1 day	PMO-406

5.0 PMO Closing (Weeks 09–10)

Activity ID	WBS	Activity Name	Duration	Predecessor
PMO-501	5.1	Post-Implementation Review	2 days	PMO-407
PMO-502	5.2	Revisions & Improvements	2 days	PMO-501
PMO-503	5.3	Final Report Preparation	3 days	PMO-502
PMO-504	5.4	Final Submission	1 day	PMO-503
PMO-505	5.5	Viva / Presentation	1 day	PMO-504
PMO-506	5.6	Lessons Learned	1 day	PMO-505
PMO-507	5.7	Final Sign-Off		PMO-506

3.11. PMO Function Model

For Horizon Healthcare, the Function Model for Risk Management represents how the Supportive PMO operational risk oversight to protect the company from "unpredictable losses" and audit failures. This model functions as a continuous feedback loop between the Project Managers, the PMO, and the Quality Assurance (QA) department.

3.11.1. Proactive Risk Identification & Methodology Support

The PMO acts as the primary provider of tools and methods to move the company from a reactive to a proactive state.

The Risk Register: Every project must maintain a standardized Risk Register (provided by the PMO) that tracks potential threats to product quality, safety, and project timelines.

Expert Mentoring: The PMO provides coaching to help Project Managers (PMs) identify "weak signals" of risk—such as subtle vendor delays or early equipment calibration issues—before they escalate into GMP non-compliance.



3.12. The Stage-Gate Governance Function

This is the "Control Room" of the risk model. The PMO manages formal review points where the project's risk status is scrutinized by a cross-functional panel.

Mandatory Checkpoints: Projects cannot advance from Planning to Execution or from Installation to Validation without a formal "Go" decision at a Stage Gate.

QA Alignment: At each gate, the PMO ensures that the Risk Register is updated and that all mitigation strategies align with DRAP and WHO -GMP requirements.

3.13. Escalation & Project Visibility Function

This function ensures that critical risks are not buried within individual departments but are visible to senior leadership.

Risk Escalation Matrix: The model uses a scoring system to determine when a risk must be raised to the Steering Committee or the COO.

Project Dashboard: The PMO consolidates individual risk registers into a single "Project Dashboard," allowing the COO to see common threats across the organization (e.g., a nationwide shortage of a specific raw material).

3.14. Knowledge Capture & Continuous Improvement

The model treats every risk as a learning opportunity to prevent future occurrences.

Lessons Learned Library: Once a risk is resolved or a project is closed, the PMO captures the outcome in a centralized electronic repository.

Predictive Analysis: By reviewing historical data in the repository, the PMO can predict common risks for future projects (e.g., frequent delays in the "Inject-able Manufacturing Line" setup) and suggest pre-emptive mitigation strategies.

3.15. Summary of the Functional Interaction

In this model, the Project Manager is the "First Res-ponder" who identifies and manages daily risks, while the Supportive PMO is the "Strategist" providing the framework and visibility. The Quality Assurance (QA) department serves as the "Auditor" who ensures the entire process meets pharmaceutical regulatory standards.

CHAPTER 4

PMO IMPLEMENTATION

4.1. Sample Project

A sample project for Horizon Healthcare (Pvt) Ltd. is the Implementation of a Centralized PMO Document Repository, which serves as a pilot to address the organization's critical gaps in visibility and audit readiness. Sponsored by the Chief Operating Officer, this project focuses on establishing a secure, electronic platform to house mandatory standardized templates such as Project Charters and Risk Registers ensuring they are easily accessible to all Project Managers and Quality Assurance staff. The scope includes designing the repository structure, setting up role-based access controls, and uploading verified templates, while explicitly excluding the development of new enterprise IT systems. Key risks, such as potential user resistance and IT configuration delays, are managed through early stakeholder engagement and training, with successful implementation being measured by improved compliance confirmation and the capture of institutional knowledge in a centralized "Lessons Learned" library.

Training Policy

4.2. Policy Statement

To address the identified gaps in proactive uncertainty prediction and audit readiness, Horizon Pharmaceuticals will implement a comprehensive Risk Management Training Policy. This policy is designed to equip Project Managers (PMs) and key stakeholders with the skills to move risk management from reactive to proactive.

4.3. Training scope & Objectives

The primary objective is to shift the company from a reactive approach to a proactive risk handle.

Target Audience: All current Project Managers, QA/Regulatory personnel, and relevant functional leads.

4.4. Core Goals

Achieve 100% training completion for all Project Managers and all other project relevant staff.

Equip PMs to identify, analyse, and mitigate specific uncertainties before they cause "unpredictable loss". Ensure consistent use of the mandatory Risk Register and Stage-Gate Review checklists.

4.5. Mandatory Curriculum Modules

The training is divided into three critical areas focused on standardization and compliance:

Module	Focus Area	Key Deliverables & Skills
Foundation	PMO Methodology	Navigating the unified project life cycle and using standard templates (Charter, Status Reports).
Risk Execution	Proactive Mitigation	Quantitative and qualitative risk analysis; mastering the mandatory Risk Register.
Compliance	Stage-Gate Governance	Conducting risk-based sign-offs for GMP - Compliance projects (e.g., Design/Installation Qualification).

4.6. Training Delivery and Methodology

On-boarding: All new PMs must complete an initial orientation session on the PMO standards before managing their first project.

Interactive Workshops: Training will incorporate active workshops where PMs apply proactive uncertainty prediction techniques to real project scenarios (e.g., the Inject-able Manufacturing Line).

Continuous Mentoring: The PMO will provide ongoing coaching and a "help-desk" function to assist PMs in navigating complex stage gates and risk escalations.

4.7. Assessment and Certification

To ensure the policy's effectiveness and maintain audit readiness.

Competency Review: PMs will be evaluated on their ability to accurately complete a Risk Register and participate in a mock Stage-Gate Review.

Documentation: 100% of training attendance and evaluation records will be stored in the centralized PMO repository for review during regulatory audits.

Feedback Loop: The PMO will gather initial feedback from participants to refine training materials and improve future PMO maturity.

4.8. Standard Operating Procedure (SOP) of training

This Standard Operating Procedure (SOP) defines the mandatory training requirements for risk management within Horizon Healthcare. It ensures all Project Managers (PMs) are equipped to shift from reactive to proactive risk handling, directly addressing the identified "Inefficiency and Proactive Management Gap

4.8.1. Purpose

To standardize the training of Project Managers on risk identification, mitigation, and the use of the mandatory PMO Risk Register to ensure GMP compliance and prevent "unpredictable loss".

4.8.2. Scope

This SOP applies to all Project Managers, QA personnel, and Functional Managers involved in project execution at Horizon Healthcare.

4.8.3. Responsibility

PMO Lead: Responsible for developing training materials, conducting workshops, and providing ongoing mentoring.

Project Managers: Responsible for attending sessions and applying the methodology to active projects.

Quality Assurance (QA): Responsible for validating that training content meets regulatory and audit standards.

4.9. Training Procedure

4.9.1. Curriculum Development

The PMO Lead will develop training modules covering the unified project life cycle and proactive risk identification techniques.

Materials must include instructions on completing the Mandatory Risk Register Template and preparing for Stage Gate Reviews.

4.9.2. Delivery of Training Sessions

On-boarding Sessions: Conducted for all new PMs to introduce PMO standards and the central document repository.

Workshops: Mandatory sessions focusing on proactive uncertainty prediction to move risk management from reactive to proactive.

Case Study Application: PMs will practice risk analysis using historical project data to learn from past "unpredictable losses".

4.9.3. Competency Assessment

PMs must demonstrate proficiency by accurately identifying risks and mitigation strategies for project.

Training attendance and performance scores must be tracked to ensure 100% adoption.

4.9.4. Continuous Support & Mentoring

The PMO will provide "help-desk" support to assist PMs in using the Risk Escalation Matrix for enterprise-level threats.

One-on-one mentoring sessions will be available for PMs navigating complex compliance gates.

4.9.5. Documentation & Records

All training materials, attendance logs, and evaluation records must be stored in the Centralized Project Repository.

Training content will be updated annually based on feedback and lessons learned from completed projects.

4.10. Risk Management Policy

To establish a proactive culture and ensure GMP compliance, Horizon Healthcare (Pvt) Ltd. operates under a formal Risk Management Policy. This policy transitions the company from reactive problem-solving to a structured, supportive PMO -led governance model.

4.10.1. Policy Statement

Horizon Healthcare is committed to identifying, evaluating, and mitigating risks that may impact product quality, patient safety, or project success. The company adopts a "Proactive Uncertainty Prediction" approach, where risk management is an integral part of every project life cycle, ensuring that all manufacturing and operational activities remain compliant with DRAP and WHO -GMP standards.

4.10.2. Core Principles

Supportive Governance: The PMO shall act as the central authority for risk methodology, providing the tools and training necessary for Project Managers (PMs) to manage risks effectively.

Proactive Mitigation: Risks must be identified at the earliest possible stage (Initiation/Planning) to prevent "unpredictable losses."

Mandatory Standardization: All projects must utilize the standardized PMO Risk Register and adhere to the defined Risk Management SOPs.

Risk-Based Decision Making: No project shall proceed through critical "Stage Gates" without a formal risk assessment and Quality Assurance (QA) sign-off

4.11. Roles and Responsibilities

Steering Committee / COO: Accountable for approving high-level risk strategies and providing resources for mitigation of enterprise-level threats.

Supportive PMO: Responsible for maintaining the risk framework, hosting the centralized "Lessons Learned" library, and escalating critical risks to the Sponsor.

Project Managers (PMs): Responsible for the daily identification, monitoring, and updating of project-specific risks within the Risk Register.

Quality Assurance (QA): Responsible for validating risk assessments to ensure they meet pharmaceutical regulatory and safety standards.

4.12. The Risk Management Process

Every project within Horizon must follow the under mentioned risk process:

Plan Risk Management

Identify Risk

Qualitative Risk Analysis

Quantitative Risk Analysis

Plan Risk Responses

Implement/ Control Risk

Risk management process depicted in below picture.



4.13. Compliance & Audit Readiness

All Risk Registers and Stage-Gate approvals must be stored in the Centralized Repository.

This documentation serves as the official organizational record for internal audits and external regulatory inspections.

4.14. Policy Review

This policy shall be reviewed annually by the PMO Lead and the Head of QA to incorporate new regulatory requirements and lessons learned from the previous year's

Standard Operating Procedure (SOP) Risk Management Procedure Horizon Healthcare (Pvt) Ltd.

PMO-RISK-SOP-001

Effective Date: To be Assigned

Revision Number: 00

Department: Project Management Office (PMO) / Quality Assurance (QA)

1. Purpose

This SOP defines a standardized and proactive risk management process to ensure compliance with DRAP, WHO -GMP, and PMI standards.

2. Scope

Applies to all projects, programs, and initiatives managed under the Supportive PMO.

3. Definitions

Risk: An uncertain event impacting project objectives.

Risk Register: PMO -controlled document to record risks.

Stage Gate: Formal approval point requiring risk assessment.

4. Roles and Responsibilities

Steering Committee/COO: Approves enterprise-level risk strategies.

Supportive PMO: Maintains risk framework and lessons learned.

Project Manager: Identifies and manages project risks.

Quality Assurance: Validates regulatory and GMP compliance.

5. Risk Management Process

- Plan Risk Management
- Identify Risks
- Qualitative Risk Analysis
- Quantitative Risk Analysis
- Plan Risk Responses
- Implement and Control Risks

6. Stage-Gate Risk Review

Projects cannot proceed without QA-approved risk assessment.

7. Documentation & Audit Readiness

All risk documents must be stored in the centralized PMO repository.

8. Training

Mandatory training for Project Managers.

9. Review and Revision

Reviewed annually by PMO Lead and Head of QA.

10. Approval

PMO Lead
Head of QA
COO

Risk Matrix (Probability × Impact)

Legend:

Green = Low Risk | Yellow = Medium Risk | Orange = High Risk | Red = Critical Risk

Impact ↓ / Probability →	1 Rare	2 Unlikely	3 Possible	4 Likely	5 Almost Certain
5 Catastrophic	Yellow	Orange	Red	Red	Red
4 Major	Yellow	Orange	Orange	Red	Red
3 Moderate	Green	Yellow	Orange	Orange	Red
2 Minor	Green	Green	Yellow	Orange	Orange
1 Insignificant	Green	Green	Yellow	Yellow	Orange
	Green	Green	Yellow	Yellow	Orange

Impact \ Probability	1	2	3	4	5
5 (Very High)	5	10	15	20	25
4 (High)	4	8	12	16	20
3 (Moderate)	3	6	9	12	15
2 (Low)	2	4	6	8	10
1 (Very Low)	1	2	3	4	5

Methodology

We applied the PMI recommended Risk Matrix approach, involving:

- Probability Scale: 1 (Very Low) to 5 (Very High)
- Impact Scale: 1 (Very Low) to 5 (Very High)
- Risk Score: Probability × Impact
- Risk Rating Classification:
- Low Risk: 1–6
- Medium Risk: 7–14
- High Risk: 15–25

Horizon Healthcare: Supportive PMO Governance Policy

Policy Statement:

To ensure that the newly established PMO remains a value-adding partner rather than an administrative hurdle, Horizon Healthcare (Pvt) Ltd. operates under the following Supportive PMO Governance Policy. This policy defines the "rules of engagement" for how the PMO interacts with departments to manage risk and maintain GMP standards.

1. Purpose

The purpose of this policy is to establish a governance framework that provides standardization, oversight, and support to project teams. It aims to eliminate fragmented documentation and reactive risk management, ensuring all projects align with Horizon's strategic goals and DRAP/ WHO -GMP regulatory requirements.

2. Governance Model: The "Supportive" Approach

Horizon Healthcare adopts a Supportive PMO Model. Under this model:
The PMO does not take direct control of projects.
The PMO provides templates, best practices, training, and a centralized repository.
The PMO acts as a consultant and a guardian of the "Project Life Cycle."

3. Core Governance Pillars

A. Methodology Standardization

Every project must utilize the PMO Unified Life Cycle (Initiation, Planning, Execution, Monitoring, and Closure).

Use of the mandatory Template Suite (Project Charter, Risk Register, and Status Report) is non-negotiable for all manufacturing and IT projects.

B. Risk-Based Stage Gate Control

The PMO governs mandatory Stage Gates. A project cannot move to the next phase without a formal review.

Quality Assurance (QA) must co-sign on gates involving Design Qualification (DQ), Installation Qualification (IQ), and Operational Qualification (OQ).

C. Centralized Knowledge Management

All project artefacts must be stored in the PMO Central Electronic Repository.

A "Lessons Learned" session is mandatory at the end of every project to prevent the recurrence of "unpredictable losses."

4. Escalation Authority

Governance dictates a clear path for resolving conflicts and addressing risks:

Project Level: Managed by the PM and functional leads.

PMO Level: The PMO Lead intervenes when templates are bypassed or risks cross-departmental lines.

Executive Level: The Steering Committee and COO have final authority on budget changes, resource reallocation, and project cancellation.

5. Compliance & Performance Audit

The PMO will conduct quarterly "Process Audits" to ensure PMs are following the established SOPs.

Success is measured by the Reduction in Audit Deviations and the Adoption Rate of standardized tools.

The PMO will conduct quarterly "Process Audits" to ensure PMs are following the established SOPs.

Success is measured by the Reduction in Audit Deviations and the Adoption Rate of standardized tools.

6. Policy Maintenance

This policy is owned by the PMO Lead and must be reviewed annually by the Steering Committee to ensure it evolves with the company's manufacturing maturity and regulatory changes.

SOP for Governance

1. Purpose

To establish a standardized process for project initiation, execution, and closure within Horizon Healthcare, ensuring that all projects are managed with proactive risk oversight and remain compliant with GMP and DRAP standards.

2. Scope

This SOP applies to all project-based activities at Horizon Healthcare, including manufacturing setup, IT implementations, and regulatory compliance projects.

3. Responsibilities

Supportive PMO Lead: Responsible for maintaining the template repository and ensuring the project life cycle is followed.

Project Manager (PM): Responsible for executing project tasks and providing mandatory documentation.

Quality Assurance (QA): Responsible for validating risk-based stage gates and compliance artefacts.

Project Sponsor (COO): Responsible for final approvals at critical milestones.

4. Procedure

4.1. Project Initiation

The PM must submit a Project Charter using the official PMO template.

The Charter must define the scope, objectives, and high-level risks.

Gate 1 Review: The PMO and Sponsor must approve the Charter before any resources are allocated.

4.2. Planning and Risk Setup

The PM shall develop a detailed project plan and a Risk Register.

All identified risks must be categorized by probability and impact.

Gate 2 Review: A mandatory review of the Risk Register and project timeline.

4.3. Execution and Monitoring

PMs must submit a Bi-Weekly Status Report to the PMO.

The PMO will consolidate these reports into a Project Dashboard for the Steering Committee.

Any risk scoring "High" must be escalated immediately according to the Risk Escalation Matrix.

4.4. Stage-Gate Control

Projects must pass through mandatory "Checkpoints" (e.g., Design Qualification, Installation Qualification).

The PMO Lead and QA Head must sign off on the Stage-Gate Approval Form before the project moves to the next phase.

4.5. Closure and Knowledge Capture

Upon completion, the PM must submit a Project Closure Report.

A "Lessons Learned" session is mandatory to document what went well and what failed.

All documents must be uploaded to the Centralized Electronic Repository.

5. Compliance and Audit

Failure to adhere to the standardized templates or bypassing stage gates will result in a project "Hold" status.

The PMO will perform a quarterly internal audit of project files to ensure 100% compliance with this SOP.

6. PMO Templates at Horizon Healthcare

To support its functions and ensure standardization. The PMO at horizon health care will create and manage a comprehensive set of templates. These templates will guide project manager and teams through various project activities, ensuring consistency, compliance and efficiency

List of Key Templates the PMO must create.

- Project Charter Template.
- Stakeholder Register.
- Risk Register.
- Stage Gate Approval.
- Closure Report.

1. Project Charter

Project Title: Establishment of Supportive PMO for Risk Management

Project ID: HH-PMO-001

Department: Corporate / Quality / Operations

Sponsor: Chief Operating Officer (COO)

Project Manager: PMO Lead

Start Date: 01-Jan-2025

Planned End Date: 30-Jun-2025

1. Project Purpose & Justification

The purpose of this project is to establish a Supportive Project Management Office (PMO) focused on proactive risk management to ensure consistent compliance with DRAP and WHO-GMP requirements. The project addresses current gaps in risk identification, documentation, and governance, shifting the organization from reactive issue handling to structured risk-based decision-making.

2. Project Objectives

- Establish a standardized risk management framework across all projects
- Ensure early identification and mitigation of GMP and regulatory risks
- Improve audit readiness and documentation consistency

- Provide governance, tools, and training through a Supportive PMO

3. Project Scope

In-Scope:

- PMO structure definition
- Risk Management SOP development
- Risk Register and templates
- Stage-gate governance model
- Training of Project Managers

Out-of-Scope:

- Direct operational execution of manufacturing processes
- ERP or system automation

4. Key Deliverables

- Risk Management Policy & SOP
- Standard Risk Register and templates
- Stage-Gate approval framework
- Lessons Learned repository

5. High-Level Risks & Assumptions

Risks: Resistance to change, limited PM maturity

Assumptions: Executive support and QA engagement are available

6. Stakeholders

COO, QA Head, PMO Team, Department Heads, Project Managers

7. Milestones & Stage Gates

Milestone	Target Date	Stage Gate
PMO Design Approval	Feb-2025	Gate 1
SOP & Templates Approval	Apr-2025	Gate 2
Training Completion	Jun-2025	Gate 3

8. Approval

Sponsor: COO

Date: _____

2. Stakeholder Register

Project Name: Supportive PMO Establishment

Project Manager: PMO Lead

Date: _____

Stakeholder	Role	Dept	Influence	Interest	Engagement Strategy
COO	Sponsor	Management	High	High	Steering meetings
Head of QA	Compliance Authority	QA	High	High	Reviews & approvals
PMO Team	Execution	PMO	Medium	High	Weekly meetings
Dept Heads	Users	Operations	Medium	Medium	Progress updates
Project Managers	End Users	Cross-Functional	Low	High	Training & support

3. Risk Register

Project Name: Supportive PMO Establishment

Revision: 01

Date: _____

Risk ID	Description	Category	Probability	Impact	Score	Owner	Mitigation Plan	Status
R-01	Resistance to PMO adoption	Organizational	Medium	High	6	PMO Lead	Awareness & training	Open
R-02	Incomplete GMP alignment	Compliance	Low	High	3	QA Head	QA review & validation	Mitigated
R-03	Limited PM competency	Resource	Medium	Medium	4	PMO Lead	PM training program	Open
R-04	Audit findings due to poor records	Regulatory	Low	High	3	QA Head	Central repository	Controlled

4. Stage Gate Approval

Project Name: Supportive PMO Establishment

Stage Gate: Gate 2 – SOP & Framework Approval

Review Date: _____

1. Stage Summary

Risk Management Policy, SOP, and templates have been developed and reviewed.

2. Deliverables Status

Completed

3. Key Risks & Mitigation Status

- Change resistance – Training planned
- Documentation gaps – Central repository implemented

4. Quality & Compliance Review (QA)

All documents comply with DRAP and WHO -GMP requirements.

5. Decision

Approved

6. Approvals

Role	Name	Signature	Date
Project Manager	PMO Lead		
PMO	PMO Lead		
QA	Head of QA		
Sponsor	COO		

5. Project Closure Report

Project Name: Supportive PMO Establishment

Project Manager: PMO Lead

Sponsor: COO

Closure Date: _____

1. Project Summary

The project successfully established a Supportive PMO to govern risk management across Horizon Healthcare projects, enhancing compliance and proactive decision-making.

2. Achievement of Objectives

All defined objectives were achieved, including SOP development, template standardization, and stakeholder training.

3. Final Deliverable & Acceptance

All deliverable approved by QA and Sponsor.

4. Schedule & Cost Performance

Project completed within approved schedule and budget.

5. Risk & Issue Summary

No critical residual risks remain open at project closure.

6. Lessons Learned

Early QA involvement significantly improves regulatory alignment.

7. Regulatory / GMP Compliance Confirmation

All activities complied with DRAP and WHO -GMP requirements.

8. Formal Closure Approval

Sponsor: COO

Date: _____

Form-PMO-01: Project Charter

Form-PMO-02: Risk Register

Form-PMO-03: Stage-Gate Approval

Form-PMO-04: Project Closure Report

Chapter 5

Project Closure

5.1 Post Review

The post-implementation review for the Supportive PMO establishment project assesses the overall effectiveness of the new governance framework and its success in achieving GMP -aligned risk management. we both evaluates the 100% adoption rate of standardized templates, such as the Risk Register, and verifies that mandatory stage gates have been successfully integrated into the project life cycle to improve audit readiness. By analyzing feedback from Project Managers and the Quality Assurance department, the review identifies opportunities to further refine Standard Operating Procedures (SOPs) and captures critical lessons learned in the centralized repository. Ultimately, this process confirms that the PMO has successfully shifted the organization toward proactive risk handling, effectively reducing "unpredictable operational losses" and providing senior leadership with the visibility required for informed decision-making

5.2 Revision

The revision of the supportive PMO at Horizon Healthcare (GHP) focuses on shifting from a reactive operational stance to a proactive risk-governed framework that ensures strict alignment with Good Manufacturing Practice (GMP) and DRAP regulatory standards. This refinement transforms the PMO's role into a strategic support unit that provides a unified project life-cycle, standardized documentation templates, and a centralized knowledge repository to eliminate the fragmentation and "unpredictable losses" identified in the initial assessment. By embedding mandatory, risk-based stage gates and formalizing the Quality Assurance (QA) sign-off process, the revised PMO establishes a sustainable governance model that prioritizes audit readiness and enterprise-level risk visibility without imposing excessive administrative bureaucracy on project managers.

5.3 Report Finalization

The finalization of the project report was conducted in strict accordance with the professional guidelines and academic standards set forth by Sir Ahsan Maqbool, ensuring that all strategic recommendations for the Horizon Healthcare PMO implementation were both technically sound and administratively robust. To ensure a cohesive and professional presentation, both team members, signifying a shared commitment to the project's quality and integrity, carried out the physical assembly and report binding as a collaborative effort. This meticulous attention to detail in the final formatting and binding phases reflects the high standards of the proposed PMO framework, providing a polished and comprehensive document ready for executive review and organizational implementation.

5.4 Report Submission

The finalized report for establishing a Supportive PMO at Horizon Healthcare has been formally bound and submitted to the Bahria University Lahore Campus for final perusal

and academic evaluation. This submission represents the culmination of extensive research and strategic planning; adhering strictly to the professional guidelines provided by Sir Ahsan Maqbool to ensure the proposed framework meets both industry standards and institutional requirements. The physical preparation and binding of the document were carried out as a collaborative effort, symbolizing a dedicated commitment to quality and the successful conclusion of the project management lifecycle. This report now stands as a comprehensive blueprint for transforming GHP's operational landscape through standardized governance and proactive risk management.

5.5 Viva

Following the formal submission, a comprehensive viva voce examination for the report was organized by Bahria University to evaluate the strategic and academic depth of the proposed PMO framework. The examination panel was composed of both internal and external examiners, providing a rigorous and balanced assessment of the project's feasibility and alignment with industry best practices. During the session, the team defended the PMO's structure, specifically highlighting its role in enhancing risk governance and GMP compliance at Horizon Healthcare. The examiners provided critical perusal of the methodology, and the successful completion of this viva marks the final validation of the project's contribution to the field of project management.

5.6 Lesson Learned

The collaborative journey of developing this report proved to be an invaluable educational experience for both Allah Bakhsh and Muhammad Shabraiz Butt, bridging the gap between theoretical project management concepts and their practical application within the pharmaceutical industry. Through the detailed analysis of Horizon Healthcare operational landscape, both students gained a profound understanding of how a Supportive PMO functions as a centre of excellence rather than just an administrative layer. Learning to navigate the complexities of PMBOK standards, the integration of GMP-compliant stage gates, and the design of proactive risk management frameworks has equipped them with the professional skills necessary to lead structured initiatives in a real-world corporate environment. This project has not only deepened their academic knowledge but has also provided them with a functional blueprint for establishing organizational discipline and driving continuous improvement in the field of Project Management.

5.7 Sign Off

The formal sign-off of this report signifies the official acceptance and approval of the proposed Supportive PMO framework for Horizon Healthcare. By endorsing this document, the Project Sponsor and the executive leadership acknowledge that the transition toward a standardized, risk-governed environment aligned with PMBOK and GMP standards is strategically sound and ready for operational deployment. This sign-off confirms that all project deliverable, including the refined scope, mandatory stage-gate checklists, and proactive risk management protocols, have been thoroughly reviewed and

meet the organizational requirements for enhancing audit readiness and reducing unpredictable losses. With this final authorization, the project is officially transitioned from the planning and establishment phase to sustainable PMO operations, marking a milestone in Horizon's journey toward project management excellence.

APPENDIX:

Appendix 01:

1. Project Charter Template

Project Title:

Project ID:

Department:

Sponsor:

Project Manager:

Start Date:

Planned End Date:

1. Project Purpose & Justification

Briefly describe why the project is being initiated, including regulatory, quality, operational, or business drivers.

2. Project Objectives

List clear, measurable objectives aligned with organizational and GMP requirements.

3. Project Scope

In-Scope:

-

Out-of-Scope:

-

4. Key Deliverables

-

-

-

5. High-Level Risks & Assumptions

Key Risks:

Key Assumptions:

6. Stakeholders

List key internal and external stakeholders.

7. Milestones & Stage Gates

Milestone	Target Date	Stage Gate
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8. Approval

Sponsor Name & Signature:

Date:

Appendix 02:

Lessons Learned Register						
ID	Date Identified	Owner	Name	Category	Situation	Recommendation

Appendix 03:

Risk Register											
Date											
Project Name:											
ID No.	Rank	Risk	Description	Category	Root Cause	Triggers	Potential Responses	Risk Owner	Probability	Impact	Status

Appendix 04:

Project Closure:

General Project Information

Project Name	
Project Description	
Project Manager	
Project Sponsors	
Key Stakeholder	
Date of Closure	
Team Members	

	Goal	Actual	Variance
Start Date	Charter Signed X/XX/XX		
Finish Date	Go Live X/XX/XX		
Days			

Project Scope Retrospective

Now that the project has been completed, look at the scope as defined in the original project charter and evaluate it.

Upon reflection, the original project scope was:

Too narrow	<input type="checkbox"/>	Too broad	<input type="checkbox"/>	Too large	<input type="checkbox"/>	On Target	<input type="checkbox"/>
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Comments:

Management Effectiveness

This section should contain an overall summary of the project from start to finish.,

Lessons Learned

This section should contain a summary of the project's pain points and the steps taken to mitigate them.

Administrative Closure

The following items were deliverable from this project:

Include a summary of the project's successes, concerns, additions as needed

Contract Closure

Include a list/description of any contracts that were initiated and closed because of this project. An answer of "There were no contracts involved with this project." is perfectly acceptable.

Appendix 05:

STAGE-GATE APPROVAL CHECKLIST:

Project Information

Project Name & ID:

Gate Number & Stage:

Review Date:

Sponsor / Gatekeeper:

1. Project Overview

- Objectives and business context defined
- Strategic alignment confirmed
- Status and schedule reviewed
- Previous gate actions closed

2. Deliverables & Milestones

- Stage deliverables completed
- Milestones achieved
- Supporting documents available
- Deviations approved

3. Business Case

- Cost estimates updated
- Revenue and ROI validated
- Market and customer data reviewed
- Business justification approved

4. Risk & Opportunity

- Risk register updated
- Key risks mitigated
- Compliance reviewed
- Opportunities identified

5. Technical & Execution Readiness

- Technical feasibility confirmed
- Testing/prototype reviewed
- Operational readiness confirmed
- Resources available

6. Financial & Resourcing

- Budget vs actual reviewed
- Next-stage forecast approved
- Vendor readiness confirmed

7. Stakeholder Alignment

- Sponsor approval
- Cross-functional alignment
- Customer validation completed

8. Lessons Learned

- Successes documented
- Issues analyzed
- Improvements identified

9. Gate Decision

Decision: Go Hold Redirect Terminate

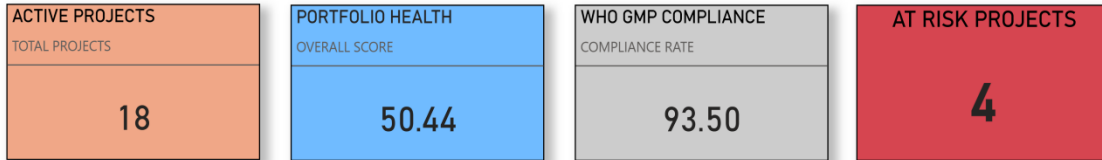
Conditions/Actions:

Approved Next Stage Timeline:

Gatekeeper Signature:

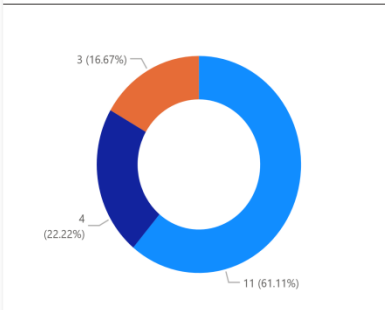
Appendix 6:

PMO PROJECT DASHBOARD



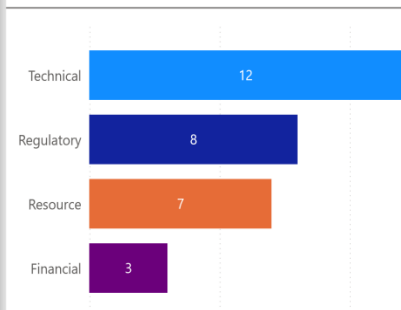
PROJECT STATUS DISTRIBUTION

ON TRACK, RISK & DELAYED



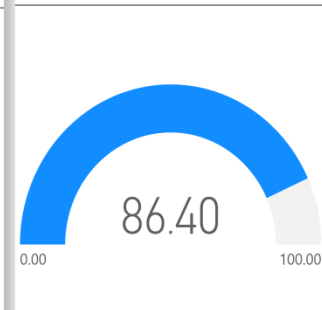
RISK CATEGORIES

AVG. RISK SCORE



AUDIT READINESS %AGE

READY FOR AUDIT



ACTIVE PROJECTS OVERVIEW

Project_Name	Phase	Status	Risk_Level	Sum of Progress_Percentage	Year	Quarter	Month	Day	Owner
API Manufacturing Line	Execution	On Track	Low	72	2025	Qtr 1	February	5	Bilal Hussain
Clean Room Certification	Execution	On Track	Medium	65	2025	Qtr 1	January	18	Nadia Akhtar
Clinical Trials Management	Design	At Risk	High	40	2025	Qtr 1	January	17	Dr. Saima Riaz
Cold Chain Optimization	Execution	On Track	Low	81	2024	Qtr 4	December	28	Dr. Ahmed Khan
DRAP Documentation System	Initiation	Delayed	High	28	2025	Qtr 1	January	5	Imran Siddiqui
Energy Management System	Execution	On Track	Low	76	2025	Qtr 1	January	30	Tariq Mehmood
ERP System Integration	Planning	At Risk	High	35	2025	Qtr 1	January	12	Ayesha Khan
GMP Compliance Upgrade	Planning	At Risk	High	42	2024	Qtr 4	December	30	Sarah Malik
Laboratory Equipment Upgrade	Design	On Track	Medium	48	2025	Qtr 1	January	28	Zainab Malik
Manufacturing Unit-3 Expansion	Execution	On Track	Low	68	2025	Qtr 1	January	15	Ali Raza
Packaging Line Automation	Design	On Track	Low	58	2025	Qtr 1	February	8	Rashid Mahmood
Quality Control Automation	Design	On Track	Medium	55	2025	Qtr 1	January	8	Fatima Noor
Quality Management System V2	Initiation	At Risk	High	22	2025	Qtr 1	January	10	Kamran Shah
Regulatory Training Program	Execution	Delayed	Medium	52	2025	Qtr 1	January	15	Usman Ali
Safety & Security Enhancement	Planning	On Track	Medium	50	2025	Qtr 1	January	23	Aamir Siddique
Supply Chain Digitalization	Planning	On Track	Low	45	2025	Qtr 1	January	20	Sana Tariq
Vendor Management Portal	Planning	Delayed	Medium	33	2025	Qtr 1	January	25	Farah Noor
Warehouse Expansion Phase 2	Design	On Track	Medium	38	2025	Qtr 1	January	22	Hassan Ahmed

Total

908