SUMMER INTERNSHIP PROGRAM

At

FRESENIUS KABI ONCOLOGY Ltd.

1 MAY 2024 – 28 JUNE 2024

A REPORT BY

DIVYANSHU BHANDARI

Master of Business Administration

PHARMACEUTICAL MANAGEMENT

2023-2025

under the Mentorship of

RAHUL SHARMA

FRESENIUS KABI

Fresenius Kabi Oncology Limited
Echelon Institutional Area, Plot No. 11,
Sector-32, Gurugram - 122 001,
Haryana, India.
T+91 124 488 5000, +91 124 332 5000
F+91 124 488 5003
www.fresenius-kabi-oncology.com

FKOL/HR-Trng/24
July 02, 2024

TO WHOM IT MAY CONCERN

This is to certify that **Mr. Divyanshu Bhandari** has done his training in Project Management (R&D-Formulation) department of Fresenius Kabi Oncology Limited, Gurgaon.

During his association with us he has done his training under the guidance of Mr. Amit Sharma, Vice President, Project Management (R&D-Formulation) from May 01, 2024 to June 28, 2024.

We wish him success for a bright future.

For **Fresenius Kabi Oncology Limited**

Parul Singh
Sr. Manager-Human Resources

IIHMR UNIVERSITY

IIHMR University Faculty Mentor Approval

This is to certify that Mr. DIVYANSHU BHANDARI of academic year 2023-25 of School of Pharmaceutical Management has prepared a poster with respect to his summer internship held during May-June 2024.

He has carried out work as per the guidelines. His poster is approved for presentation.

Date: 20/07/2024

(Signature of Faculty Mentor)

Name: Rahul Sharma
Designation: Assistant Professor

1, Prabhu Dayal Marg, Near Sanganer Airport, Jaipur- 302029, Rajasthan, India.
Ph.: 0141- 3924700, 2791431- 32, Fax: 0141 3924738, E-mail: iihmr@iihmr.edu.in, Web.: www.iihmr.edu.in

Global Project & Launch Management

Divyanshu Bhandari
Roll no. 0498
Batch- PM 15

Organization Mentor - Amit Sharma (VP)
Faculty Mentor - Rahul Sharma

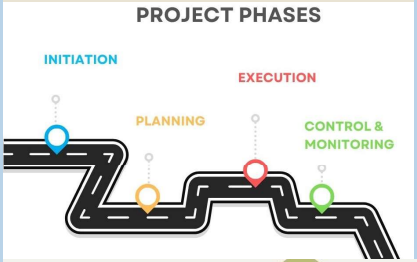
Mission &Vision

"Caring for life"

Vision 2026! expand our global business offerings & market position, improve access to high-quality healthcare around the globe.

Fresenius Kabi at a glance

Fresenius Kabi Oncology Limited, a subsdiary of Fresenius Kabi AG, Germany. Operates as a specialized division commited to addresing the unique challenges posed by cancer care to treat chronically,critically ill cancer patients. Primarilly operating in the field of Research & Development of world- class oncology drugs. Their product portfolio comprises a range of highly complex biopharmaceuticals, clinical nutrition, medical technologies & I.V. generics drugs. The company logo represents compassion, knowledge, insight & integrity.



Learnings during internship

- Learned SOP of the PM and role of Manager.
- Basic introduction & brief learning of different departments in FKOL.
- Project costs, Stage gates, & how they are being managed.
- Phases project goes in development at FKOL.

Theoretical & Practical

Theoretical understanding-
- Provides a broad perspective & fundamental knowledge.
- Often lacks context & real-world applicability.
- May not cover the latest industry developments or challenges.

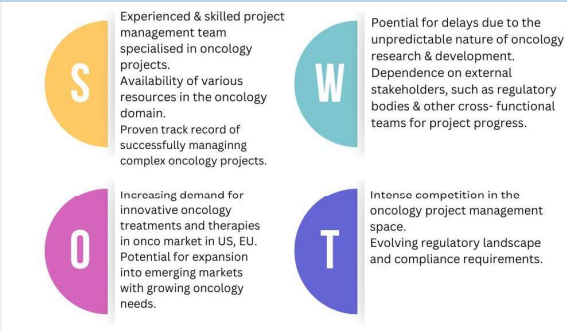
Practical Exposure-
- Provides hands-on experience & skill development.
- Exposes you to industry-specific chllenges, technologies, best practice.
- Enhances problem-solving, critical thinking, & decision-making abilities.

Challenges faced in internship

- Adapting to industry- specific processes.
- Took time to get familier with PM technical tools.
- Communication barrier because of unaware terms of PM.
- Team dynamics.

Usefulness of internship

- Practical industry experience.
- Networking opportunity
- Skill development
- Professionalism & work ethic.



CONTENTS


Organization Structure
Global Project Management
Vice- President
Joint Director
Project Manager
Project Manager
Project Manager

INTRODUCTION TO ORGANIZATION

Fresenius Kabi Oncology, a subsidiary of Fresenius Kabi AG, operates as a specialized division committed to addressing the unique challenges posed by cancer care. Focus manufacturing, and delivering high-quality oncology medications, the company plays an integral role in the treatment and management of a myriad of cancers. Situated in the bustling city of Gurgaon, India, the facility serves as a cornerstone of the broader Fresenius Kabi network, which spans across various continents and is recognized for its dedication to healthcare excellence.

FRESENIUS KABI AT A GLANCE

Their product line includes a variety of IV generic medications, clinical nutrition, medical technologies, and extremely complicated biopharmaceuticals. Kabi is a biopharmaceutical company that specializes in biosimilar medications for oncology and autoimmune illnesses. A large assortment of enteral and parenteral nutrition items is included in the clinical nutrition portfolio. Fresenius Kabi is a provider of essential disposables, infusion pumps, apheresis machines, cell therapy devices, and other medical technology.

Approximately 42,000 individuals work for Fresenius Kabi worldwide. As part of their "caring for life" company goal, they provide vital medications and technologies to those who assist patients and identify the most effective solutions for their problems.

In keeping with "Vision 2026," they are also dedicated to boosting patient care and therapy efficiency and improving access to first-rate medical care anywhere. They want to dominate the world in our product categories, serving patients, clients, and other stakeholders in the process.

They declared sales of almost €7.8 billion in 2022. A fully owned subsidiary of the German healthcare company Fresenius SE & Co. is Fresenius Kabi AG.

ESTABLISHMENT

1995

Originally incorporated as “Fresenius Mafatlal Medicals Private Limited.” – Joint venture with Mafatlal Group and name changed to “Fresenius Mafatlal Medicals Limited.”

2000

Became subsidiary of Fresenius Kabi AG name Changed to Fresenius Kabi India Private Limited.

2008

After acquiring Dabur Pharma, Fresenius Kabi increased its business into oncology medications in addition to growing its IV generics division.

2012

By acquiring Fenwal, a leader in transfusion technology, Fresenius Kabi established a global presence.

2013

Manufacturing Unit of Goa Formulations Limited in Goa was acquired by Fresenius Kabi India Pvt Ltd.

2016

Fresenius Kabi India Pvt Ltd launched 2 new divisions - EN Outside Market (Enteral Nutrition Products for Outside Hospital Market) and Kabi Criticare (I.V.Drugs).

BUSINESS AREA'S

THERAPY OF INFUSION

Fresenius Kabi distributes fluid for infusion therapy and solutions for replacing blood volume. The product portfolio from Fresenius Kabi also includes a large selection of disposables and infusion technologies for the administration of medications to be delivered by vein.

INTRAVENOUSLY ADMINISTERED DRUGS

Fresenius Kabi provides a large selection of bio- similar medications for intravenous administration in a number of therapeutic areas, including critical care, anesthetics and analgesics, cancer, and antibiotics. The associated equipment is supplied by the firm for the administration of these products.

CLINICAL NUTRITION

Fresenius Kabi is among the few firms in world that provides nutrition pumps and infusion disposables along with nutrition for parental (given intravenously) and enteral nutrition (given via tube feed in the gastrointestinal system) in the context of clinical nutrition.

BIOSIMILARS

We concentrate on oncology and autoimmune illnesses in the field of biosimilars. Fresenius Kabi launched its first biosimilar medicine in 2019.

DEVICE

We provide infusion therapy, clinical nutrition supplies, and equipment for injecting generic medications intravenously.

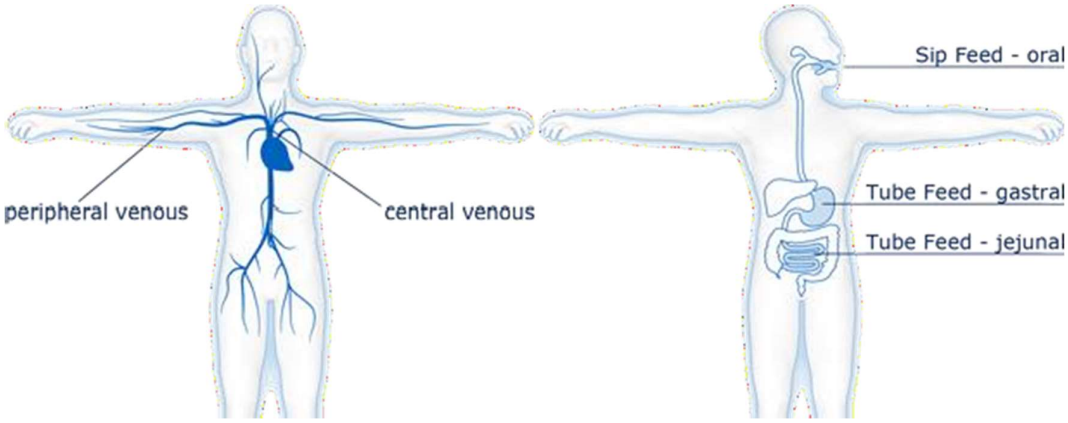


Figure : Enteral nutrition (right image) uses the gastrointestinal route, whereas parenteral nourishment (left image) is given intravenously.

Both serve to help patients who cannot eat any, or sufficient, normal food. This is especially the case for patients in intensive care units, for patients who are seriously ill and with malnutrition. When the patient leaves the hospital the ambulatory services of Fresenius Kabi can care for the patient and provide him with the necessary products.

PROJECT MANAGEMENT ?

A comprehensive profession, project management is used to manage projects in a variety of sectors, including the production of medicinal drugs.
Can be defined as planning and organizations of company's resources to make move a specific task, towards the completion without any deviation in cost, time and quality.

Principles that define the scope of Project Management

1. Management of scope
2. Project planning, carrying out, and overseeing projects
3. Planning a timeline & budget
4. Managing stakeholder
5. Overseeing compliance & regulatory plans
6. Safety in environment
7. Managing the risk
8. Group supervision

Project management is the process of starting, planning, carrying out, supervising, and endorsing the appropriate course of action at the appropriate moment to accomplish particular objectives within particular limitations and success standards, such as meeting deadlines, adhering to budgetary constraints, and producing a high-quality product. As seen in Figure, these three factors are referred to as the project scope triangle. Ensure proper balance of project and controlling resources planning and managing them to ensure that the project is finished within the fixed cost & time.

Figure. Project Scope Triangle.

"These constraints form an interdependent set - a change in one constraint can require a change in another constraint in order to restore the equilibrium of the project. In this context the set of three parameters form a system that must remain in balance for the project to be in balance"

Pharmaceutical R&D and PMgt's Induction into the Pharmaceutical Sector. The process of finding, creating, producing, and bringing medications to market is known as pharmaceutical research and development (R&D). The five phases established by the regulatory (FDA) are typically followed in the pharmaceutical industry's drug development process.

1. Product discovery & production
2. Preclinical research
3. Research & studies
4. Evaluation of regulations
5. Following approval post-market monitoring

PHASES OF PROJECT MANAGEMENT

1. INITIATION

The project's scope has been discussed during this phase. Requirement details are discussed, exchanged, and clarified. The projected pharmacy product is contrasted with competing products. The project's viability in light of the requirements is examined. Numerous business scenarios are examined based on prior encounters. Before the project is really started, professional counsel is sought. During this phase, all the information needed to start the project before planning is gathered.

2. PLANNING

One of the most important steps in reaching goals. Data from the start phase is used as the basis for analysis. One strategy doesn't always work, therefore having a backup plan is crucial. The effective distribution of work is primarily dependent on the resource planning of the project manager. The manager arranges meetings with key team members and stakeholders to discuss cost budgeting. The management board's estimated budget and the actual budget are contrasted. It is attempted to keep the predicted cost as low as possible in relation to the fixed actual budget. A project manager assigns the tasks to the resource once each activity has been analyzed. A project manager divides up the work among the main team members according to their qualifications and expertise. The manager also makes sure that there are adequate resources available for all of the project's tasks. The project manager addresses uncertain risks as well and develops a plan to solve them.

3. EXECUTION

This stage marks the beginning of planned execution. With regard to time and resource allocation, the manager creates the activity chart, which is closely adhered to. As agreed upon throughout the planning stage, deadlines are adhered to. The range of activities includes scientific research, laboratory testing, management, plant operation (which involves transforming pharmacological active ingredients into medications), finance and accounting, marketing, and IT. Under the direction of the pharmaceutical project manager, activities are carried out as tasks and handled by the appropriate teams. The project manager receives daily team updates from the team. The management keeps an eye on the report and keeps track of its performance. In order to update the leads of each team on the status of the projects, a manager also arranges weekly meetings. In the event that the manager discovers that tasks are not being done in accordance with activities as scheduled, the appropriate action is taken to address the issues. A manager also handles unforeseen alterations to the project flow.

4. MANAGE AND CONTROL

Project surveillance is necessary all the way up final stage close. Project budget was established in the planning stage, within the pharmaceutical manager's authority. The manager has an obligation to complete high-quality projects on schedule and within budget, using all available resources. Since there is a maximum amount of potential for unknown developments, project operations must be closely watched and managed. Numerous initiatives that were successful in the beginning have frequently collapsed during project execution as a result of inadequate oversight and management.

6. CLOSURE

Closure is the last stage that comes after all of the previously listed stages are finished. The project is deemed finished when it produces a high-quality output within the allotted resources and budget within the specified time frame. During this stage, lessons are learned regardless of the project's success or failure. There is seldom a flawless project that satisfies every criterion. Future enhancements are added for the upcoming version of the system if certain features are still missing from the present project version. A pharmaceutical manager also keeps project documentation up to date for reference.

here's a more detailed methodology breakdown of the stages of pharmaceutical project management in industry:

PRE-FEASIBILITY

- **Conceptualization:** Identify the need or opportunity for a pharmaceutical project,considering market trends, patient needs, and business goals.
- **Preliminary Research:** Gather initial data to assess the potential feasibility of theproject, including market demand, competition, and technical feasibility.
- **High-Level Cost Estimation:** Estimate the potential costs and resources required for the project.

FEASIBILITY

- **Technical Feasibility:** Conduct in-depth technical analysis to determine if therequired technology, expertise, and resources are available to develop the product.
- **Financial Feasibility:** Create a detailed budget by estimating costs for research,development, manufacturing, regulatory compliance, and marketing
- **Market Feasibility:** Conduct comprehensive market research to

understand potentialdemand, target audience, and competitive landscape.

NPA (NEW PRODUCT APPLICATION) PREPARATION

- **Research and Development:** Perform laboratory research to develop the pharmaceutical product's formulation, optimize dosages, and conduct initial safety and efficacy tests.
- **Regulatory Compliance:** Ensure that the product's development follows Good Laboratory Practices (GLP) and other relevant regulations.
- **Documentation:** Prepare detailed documentation of the formulation process, experimental results, safety assessments, and preliminary stability studies.

APPROVAL

- **Regulatory Submission Preparation:** Compile all required documentation, including formulation details, preclinical studies, safety data, and proposed labelling, for submission to regulatory authorities.
- **Regulatory Review:** Regulatory agencies review the submission to ensure compliance with safety, efficacy, and quality standards.
- **Responses and Negotiations:** Address any questions, concerns, or requests for additional information from regulatory authorities.

KICK-OFF

- **Project Team Formation:** Assemble a cross-functional team with expertise in research, development, manufacturing, regulatory affairs, quality assurance, and project management.
- **Project Charter:** Design a proper project plan that describes tasks, milestones, timelines, resources, and responsibilities.
- **Resource Allocation:** Allocate personnel, facilities, equipment, and funds accordingto the project plan.
- **Communication Strategy:** Establish communication channels and protocols toensure effective information sharing among team members.

LAB DEVELOPMENT

- **Formulation Development:** Continuously refine the product's formulation based onlaboratory testing and analysis.
- **Analytical Method Development:** Develop and validate methods to test the product'squality, potency, and purity.
- **Stability Testing:** Conduct stability studies to determine the product's shelf life andstorage conditions.

SCALE-UP PREPARATION

- **Pilot Manufacturing:** Produce small batches of the product using scaled-upprocesses to ensure consistency and quality.
- **Process Validation:** Verify that production procedures consistently yield the desired level of product quality.
- **Raw Material Sourcing:** Identify and secure reliable sources for raw materials andcomponents required for large-scale manufacturing.
- **Documentation:** Compile comprehensive documentation of the scaled-up

processes,equipment specifications, and validation reports.

EXECUTION

- **Product Development:** Begin the process of manufacturing, testing, and refining thepharmaceutical product.
- **Quality Control:** Adopt strict quality control procedures to guarantee that the product satisfies legal requirements & specifications.
- **Project Monitoring:** Continuously monitor progress, budget, and resources to ensurealignment with the project plan.
- **Stakeholder Engagement:** Keep stakeholders informed about project progress andaddress any concerns.

CLOSURE

- **Product Completion:** Complete all manufacturing, testing, and quality controlprocesses for the pharmaceutical product.
- **Documentation and Reporting:** Compile comprehensive documentation about theproduct's development, testing, and quality control measures.
- **Regulatory Compliance:** Ensure that all regulatory requirements have been met forthe product's release.
- **Project Evaluation:** Conduct a final assessment to ensure all project objectives have been achieved.

Each of these stages is essential for the successful development and launch of a pharmaceutical product. Effective project management, strict adherence to regulations, robust quality control, and open communication among all stakeholders and collaboration among cross-functional teams are critical throughout the entire process.

PROJECT CHARTER

A one- or two-page document that is co-written by the project manager is called a project charter. Project goals including timetable, target value, and build approach are outlined in a project charter. It also delineates the ideals that team members will strive to uphold as they strive toward common project objectives and creates more individualized standards of satisfaction. While it should be concise enough to be written on the wall, it should also be specific enough to keep everyone in the integrated project team on the same page.

A project charter is necessary for each pharmaceutical project. It is formally authorized or approved by the project owners and names the project team, including the project leader. It is drafted early in the project's life. A project charter is a synopsis of the new pharmaceutical plant's establishment. It acts as a contract that establishes a common vision and understanding of the desired result between the team, stakeholders, and the owner of the project. The pharmaceutical project charter includes a thorough work plan, important presumptions, dependencies, stakeholders, project benefits and risks, deliverables, schedules, and milestones.

Reporting Format

(Weekly)

Name of the Organisation: Fresenius Kabi Oncology Ltd.

Area/ Department/ Project of Summer Internship Program: Project Management

Name of the Student: Divyanshu Bhandari

Roll no: 0498 **Stream:** Pharmaceutical Management

Week no: 1 **From:** 1 May **to** 10 May

Activity Done	Introduction to the Project Management team. Introduction to the Organization ethics and code of conduct by the Organization Mentor. Brief go through about the topics like R&D, API, Formulation development. Got to know about the working procedure of R&D and how all the departments are involved in this procedure.
Linking theory (Classroom learning) with practice at your organisation	Learned about how the theory topics like Drug API, R&D, Formulation development & Regulatory compliance are managed in industry.
Gaps identified on the working area.	No gaps identified on the working area.
Suggestions for improvement	No suggestions for improvement.
Plan for the next week	Introduction and discussion on the SOP of Project Management department.

Signature of the Student

Approved by the IIHMR University's Mentor

Reporting Format

(Weekly)

Name of the Organisation: Fresenius Kabi Oncology Ltd.

Area/ Department/ Project of Summer Internship Program: Project Management

Name of the Student: Divyanshu Bhandari

Roll no: 0498 **Stream:** Pharmaceutical Management

Week no: 2 **From:** 13 May **to** 17 May

Activity Done	Introduction & working procedure of the formulation development. Discussion on SOP in Project Management department. Got introduced about the working procedure of R&D and how all the departments are involved in this procedure. Introduced to the Microsoft Notebook where the Data management is done of the projects. Worked on the API planner project links in Microsoft Notebook.
Linking theory (Classroom learning) with practice at your organisation	The role of SOP in industries. Importance of Data Management in managing the project status. R&D Management
Gaps identified on the working area.	No, gaps identified on the working area.
Suggestions for improvement	No, suggestions for improvement.
Plan for the next week	Introduction & learning to the guiding document SOP of project management. Introduction about the Project cost.

Signature of the Student

Approved by the IIHMR University's Mentor

Reporting Format

(Weekly)

Name of the Organisation: Fresenius Kabi Oncology Ltd.

Area/ Department/ Project of Summer Internship Program: Project Management

Name of the Student: Divyanshu Bhandari

Roll no: 0498 **Stream:** Pharmaceutical Management

Week no: 3 **From:** 20 May **to** 24 May

Activity Done	Learned and discussed on Guiding document SOP. Got to know about the Project cost and its types. Worked on the links for API Planner. Streamlined the projects databases for better tracking of project information. Co- ordination with various stakeholders to move the project smoothly and meet the deadlines for the completion of task.
Linking theory (Classroom learning) with practice at your organisation	Types of project cost and how they are used in managing the project. Organizational behaviour.
Gaps identified on the working area.	Lack of coordination among the departments due to which proper efficiency is not in the work.
Suggestions for improvement	Coordination could be improved by maintaining the proper flow of information among the departments.
Plan for the next week	To design the structure of project phases methodologies followed in the organization.

Signature of the Student

Approved by the IIHMR University's Mentor

Reporting Format

(Weekly)

Name of the Organisation: Fresenius Kabi Oncoology Ltd.

Area/ Department/ Project of Summer Internship Program: Project Management

Name of the Student: Divyanshu Bhandari

Roll no: 0498 **Stream:** Pharmaceutical Management

Week no: 4 **From:** 27 May **to** 31 May

Activity Done	Task to design a structured phases through which a project passes from the Feasibility to the Market Launch on Microsoft Excel. Introduction & discussion in global alliance management Their key role in Global Business Development, Scouting, Negotiation, in- licensing, out- licensing, CMO, Product acquisition's, Co-development etc. Supported in developing Project Management tools for better management of projects.
Linking theory (Classroom learning) with practice at your organisation	Business Development in the pharmaceutical industry. Project Management phases. Supply chain management
Gaps identified on the working area.	No, gaps identified on the working area.
Suggestions for improvement	As the Global Alliance Management gets regulated from the global management they can appoint a management head in Indian market.
Plan for the next week	Discussion & introduction to the Formulation development department & Regulatory department.

Signature of the Student

Approved by the IIHMR University's Mentor

Reporting Format

(Weekly)

Name of the Organisation: Fresenius Kabi Oncology Ltd.

Area/ Department/ Project of Summer Internship Program: Project Management

Name of the Student: Divyanshu Bhandari

Roll no: 0498 **Stream:** Pharmaceutical Management

Week no: 5 **From:** 3 June **to 7** June

Activity Done	Introduction to the Formulation Development department. Their working on three phases like Pre – feasibility, Feasibility, Risk- assessment and Product development. Understanding of the tools being used in the department. Got involved in different stage gate meetings for smooth delivery of managing development projects by addressing different issues. Under the guidance of the project manager prepared the project charter for the projects got NPA.
Linking theory (Classroom learning) with practice at your organisation	Formulation Development in pharmaceutical industry.
Gaps identified on the working area.	Lack of coordination & understanding between the formulation department and project management department.
Suggestions for improvement	Formulation development department can work on improving their communication regarding the production issues with the project management department so that smooth delivery of the project may done.
Plan for the next week	Discussion on the Regulatory dossier done of the drug with the regulatory department.

Signature of the Student

Approved by the IIHMR University's Mentor

Reporting Format

(Weekly)

Name of the Organisation: Fresenius Kabi Oncology Ltd.

Area/ Department/ Project of Summer Internship Program: Project Management

Name of the Student: Divyanshu Bhandari

Roll no: 0498 **Stream:** Pharmaceutical Management

Week no: 6 **From:** 10 June **to** 14 June

Activity Done	Introduction to the Regulatory department by the department head and learned about their different divisions like CMC team, Labelling team, Regulatory Intelligence. Dossier submission process, TTD document, publishing and submission to the regulatory body of the EU, US market. Created the core team members list that are also as a stakeholder to the projects. Involved in meeting for Global Kick off of feasibility project that has got NPA approval by the management board.
Linking theory (Classroom learning) with practice at your organisation	Dossier submission, TTD document, dossier compilation.
Gaps identified on the working area.	No, gaps identified on the working area.
Suggestions for improvement	Integrated tools of the organization being used by the regulatory department could be more accurate, & interface could be more easy to understand.
Plan for the next week	To calculate a time being utilised in a phase and the cost utilised.

Signature of the Student

Approved by the IIHMR University's Mentor

Reporting Format

(Weekly)

Name of the Organisation: Fresenius Kabi Oncology Ltd.

Area/ Department/ Project of Summer Internship Program: Project Management

Name of the Student: Divyanshu Bhandari

Roll no: 0498 **Stream:** Pharmaceutical Management

Week no: 7 **From:** 17 June **to** 21 June

Activity Done	Learned to calculate a time being utilised in a phase and the cost utilised. Red, Yellow, Green signal basically used for the project status and with the comparison to the standard budget cost and time duration planned for each project who got NPA. Analyse the cost and time deviation from the actual budget and time duration kept for the project to the time and cost being utilised. Involved in a meeting for the Global market project to know the status of the project and find the cost and time deviation.
Linking theory (Classroom learning) with practice at your organisation	Cost & Time management Operations management
Gaps identified on the working area.	No, gaps identified on the working area.
Suggestions for improvement	No, suggestions for improvement.
Plan for the next week	Introduction to Analytical Development & Chemical Research department. Global launch SOP for project managers.

Signature of the Student

Approved by the IIHMR University's Mentor

Reporting Format

(Weekly)

Name of the Organisation: Fresenius Kabi Oncology Ltd.

Area/ Department/ Project of Summer Internship Program: Project Management

Name of the Student: Divyanshu Bhandari

Roll no: 0498 **Stream:** Pharmaceutical Management

Week no: 8 **From:** 24 June **to** 28 June

Activity Done	Introduction & discussion Analytical Development department & Chemical Research department & learned about working procedure how the testing & validation is done in Analytical department when some API can't be outsourced then the API is being made in lab in-house API. This in- house API is being manufactured under Chemical research labs. Under the guidance of Vice President the meeting of the Global Launch SOP for Project Managers so easy launch of product can be done in a target market like EU, US.
Linking theory (Classroom learning) with practice at your organisation	Global market strategies. Strategic Management
Gaps identified on the working area.	Potential for delays due to the unpredictable nature of Oncology research and development.
Suggestions for improvement	Potential expansion into emerging markets with growing oncology needs.
Plan for the next week	8 week's Summer Internship training completed.

Signature of the Student

Approved by the IIHMR University's Mentor

Compiled Reporting Format

Name of the Organisation: Fresenius Kabi Oncology Ltd.

Area/ Department/ Project of Summer Internship Program: Project Management

Name of the Student: DIVYANSHU BHANDARI

Roll no: 0498 **Stream:** Pharmaceutical Management

Activity Done	Introduction to the Organization ethics and code of conduct by the Organization Mentor. Introduction to the Project Management department, team introduction. Briefing on the topics like the R&D, Formulation Development, Analytical Development, Regulatory Department, Global Alliance Management department. Got to know about the working procedure of R&D and how all the departments are involved in this procedure. Supported in developing Project Management tools for better management of projects. **Learned about the Formulation Development and its role in R&D.** Brief discussion on the Standard Operating Procedure of the organization and the Project Management department. Got introduced to the **Microsoft Notebook where the Data management is done of the projects.** Worked on the links for API Planner. Streamlined the projects databases for better tracking of project information. Co- ordination with various stakeholders to move the project smoothly and meet the deadlines for the completion of task. Got the **Standard Operating Procedure controlled document of the Project Management department.** After thorough reading of the SOP involved in the meeting discussion about the procedures being

	followed in the Project Management department by the organization mentor. Then learned about the Guiding document SOP. And then the **Project Cost document which states about the type of cost are being managed. (Internal, External, Investment, Cap Ex.)** Projects data consolidation for management reviews. **Introduction to the Formulation Development department** under the guidance of Organization mentor and the Senior manager from the formulation development department. Their working on three phases like Pre – feasibility, Feasibility, Risk- assessment and Product development. Understanding of the tools being used in the department. Got involved in different stage gate meetings for smooth delivery of managing development projects by addressing different issues. Got a **task to design a phases through which a project passes from the Feasibility to the Market Launch on Microsoft Excel.** To calculate a time being utilised in a phase and the cost utilised. **Red, Yellow, Green signal basically used for the project status and with the comparison to the standard budget cost and time duration planned for each project who got NPA.** **Red**- denotes that the project is much deviated from the planned cost budget and time and the project need a re- approval from the management board whether to discontinue the project or to continue it. **Yellow**- denotes that the project may deviate from the planned cost budget and time due to which the project may take more time to launch than its launch date , here the project manager needs so be on alert regarding the project and necessary steps need to be taken. **Green**- denotes that the project status is healthy and is going according to the planned cost and time planned on the project charter and NPA by the management board.

	Calculate and analyse the cost and time deviation from the actual budget and time duration kept for the project to the time and cost being utilised. **Involved in a meeting for the Global market project to know the status of the project and find the cost and time deviation.** Worked on the MS Notebook for project data management like project direct links for all department and API planner. Under the guidance of the project manager prepared the **project charter for the projects got NPA**. **Introduction in the Global Alliance Management** department by the department head. Involved in the discussion about the working of the GAM department and their role in the Global Business Development, Scouting, Negotiation, in-licensing, out- licensing, CMO, Product acquisition's, Co-development etc. Created a new notebook for the projects that are under the feasibility phase and worked on their data management from their status to the NPA. **Introduction to the Regulatory department** by the department head and learned about their different divisions like CMC team, Labelling team, Regulatory Intelligence, Administration. Their Dossier submission process, TTD document, dossier compilation, publishing and submission to the regulatory body of the EU, US market. Created the core team members list that are also as a stakeholder to the projects. **Involved in the meeting for the Global Kick off of the feasibility project that has got the NPA approval by the management board.** **Assigned some projects that are already being under the phase development of the Project Manager.**

	Worked along the project manager and learned about the phases in detail from where the project gets started to the market launch phase. Involved in meetings with Global clients regarding the project status, API sourcing. Got introduced to the Fresenius Kabi integrated master tool that plays a very important role for a project manager to manage all the inputs details and manage data of each project that is assigned to that project manager and only that project manager has access to that tool. Involved with the team in preparing the meeting minutes on the the basis of the discussion done with the global clients to prepare the record and manage the data. **Under the guidance of Vice President attended the meeting for the Global Launch SOP for the Project Managers so that the easy launch of a product can be carried in a target market like EU, US.** **Introduction to the Analytical Development department and Chemical Research department** and learned about their working procedure how all the testing and validation is done in Analytical department and how when some API can't be outsourced then the API is being manufactured in the lab in-house API. This in- house API is being manufactured under Chemical research labs. Involved in a meeting conducted by the management board just to check that the projects that are being under development, are they in aligned to the COST and TIME and if not, then how much deviation is their then the project re- approval is done. Attended the meeting for core team members and worked on core team presentations. Attended the weekly meeting with the team to track the status report of the project and inform the team leads.

Linking theory (Classroom learning) with practice at your organisation	**Organizational Behaviour-** Observed organizational culture, ethics, and code of conduct. Saw how teams collaborate and communicate effectively. Experienced the importance of Leadership, Mentorship and Guidance. **Project Management-** Worked on projects from feasibility to market launch. Learned to manage project timelines, resources, and cost. Coordinated with cross- functional teams, ensuring effective project delivery. **R&D Management-** Gained insight into R&D Processes, formulation development, analytical development. Saw how innovation and risk assessment are managed. Understood the importance of regulatory compliance. **Operations Management-** Observed departmental workflows, process optimization and efficiency. Learned how resources are allocated and managed. Experienced the importance of effective supply chain management. **Supply Chain-** Learned about API sourcing, outsourcing and supply chain optimization. Got to know how relationships with vendors and partners are managed. Understood the importance of logistics and distribution. **COST & TIME Management-** Analysing the COST & TIME deviations, identifying areas for the improvement. Experienced how budgeting and resource allocation impact project timelines. Got to know the importance of effective cost and time management.

	Global Business Development- Gained exposure to Global market projects, regulatory submissions, and business development strategies. Saw how market research and competitive analysis inform business decisions. **Data Management-** Worked with Microsoft Notebook and other tools for project management. Saw how data analysis informs business decisions. Experienced the importance of effective data management. **Team Management-** Collaborated with cross-functional teams, including project managers, regulatory experts. Learned how effective communication and collaboration drive project success. **Strategic Management-** Attended meetings with senior management, observing strategic decision-making. Saw how organizational goals and objectives are set and achieved. Understood the importance of aligning projects with organizational strategy. **Global Market Strategies-** Discussions with global clients and involvement in global projects provide insights into market strategies and international marketing theories, emphasizing market entry and product launch strategies in different regions.
Gaps identified on the working area.	Limited resources/ Resources constraint results in burden over the team. Potential for delays due to the unpredictable nature of Oncology research and development. Dependence on external stakeholders, such as regulatory bodies, and other cross functional teams for project progress. Lack of coordination among the departments due to which proper efficiency is not in the work. Lack of proper knowledge about the tools being used to the other department core team members.

Suggestions for improvement	Coordination could be their among the departments for the clear flow of information regarding the project. Changes can be done in data being manage in MS Notebook and tools for easy tracking of the projects that are under the development. Projects and be classified on the basis of the status like feasibility, product development and regulatory. Coordination can be improved with the EU, US market core team members so that project delivery can be easy. Potential expansion into emerging markets with growing oncology needs.

Signature of the Student

Approved by the IIHMR University's Mentor