DARE TO FLY

PROJECT MANAGEMENT

MARTA CAMARASA STRATEGIC PROJECTS MANAGER GALENICUM AXIUM

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1. PROJECT MANAGEMENT ROLE

Set up & execute Right product Secure successful the strategy & cost product launch

Develop and maintain an agreed project plan and detailed stage plans. Understand and apply business case and risk management processes.

1. PROJECT MANAGEMENT ROLE

Product Selection Pharmaceutical Development

Validation Batches

Clinical Studies

Dossier submission

- Product development is unpredictable and therefore it is critical to have a realistic expectations for any given project.
- Inherent difficulties in running a development successfully and the larger product the more numerous potential problems can be.
- Taking into account the factors that block the success of a project and being able to take an **objective view** of the necessary strategies is a demanding and necessary task.

COST

QUALITY

TIME _____ SCOPE

Dossier Approval

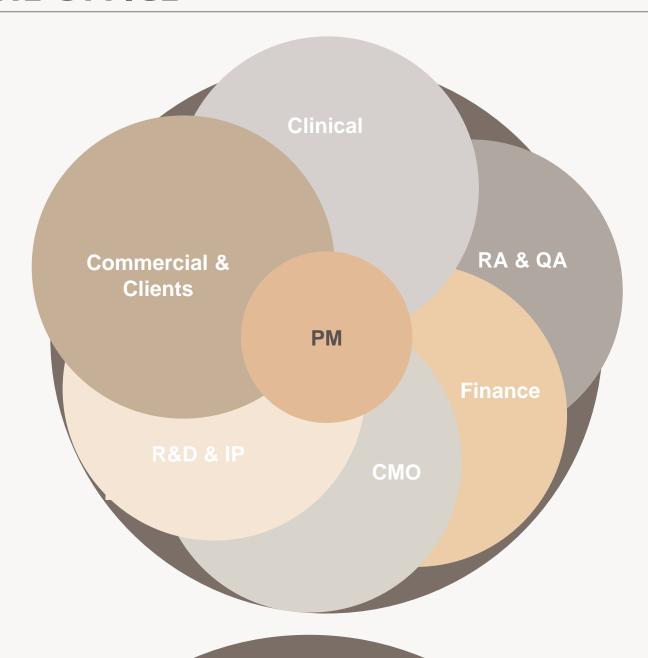
Product

Launch

2. ONE DAY IN THE OFFICE

Red Task Responsible Start End Feb Mar Abr May Jun Jul Ago Sep Oct Nov Dic Ene Feb Mar Abr May Jun Jul Ago Sep Oct No Project Set Up 15/03/23 04/04/23 Project Kick-off Marta Camarasa 15/03/23 15/03/23 1. Initiation Marta Camarasa **Project Plan** 15/03/23 04/04/23 - Scope Budget v.0 Marta Camarasa 15/03/23 28/03/23 - TPP Pharm, Dev. - Project Charter Trials **GDV** 12/04/23 25/07/23 Pre-stability ADV 25/07/23 25/12/23 Plan T=0 (Release) ADV 25/07/23 25/07/23 - Calendar deliveries ADV 25/10/23 25/10/23 T=3 months - Define milestones T=6 months ADV 25/12/23 25/12/23 - Budget EB Manufacturing **GDV** 30/01/24 11/03/24 GDV Manufacturing 1st batch 30/01/24 05/02/24 **Execution & Control** 27/02/24 04/03/24 Manufacturing 2nd batch **GDV** - Follow-up deliveries Manufacturing 3rd batch **GDV** 05/03/24 11/03/24 Check deviation cost Pivotal bioequivalence study - Mitigate risk CLI 11/03/24 25/06/24 Pivotal BE study 1st administration pilot BE CLI 11/03/24 11/03/24 - Stakeholders reporting Draft report pilot BE CLI 25/06/24 25/06/24 Stability Studies 4. Closing - ICH ICH 01/04/24 28/10/24 - Evaluate the plan vs reality in terms Samples into the Climatic ICH 01/04/24 01/04/24 Chambers of cost, time and scope T6M ICH 28/10/24 28/10/24 - KPIs (Key Performance Indicators) Documentation Submission 29/10/24 Dossier submission (NCE-1) 29/10/24

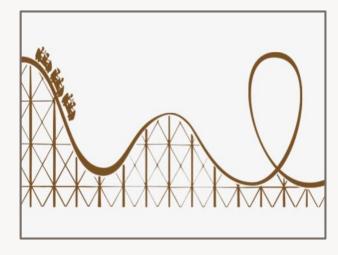
2. ONE DAY IN THE OFFICE



2. ONE DAY IN THE OFFICE













3. WHAT IS THE MARKET LOOKING FOR



Soft Skills

- Tolerance to pressure
- Leadership
- Goal & detail oriented
- Team work
- Good communicator (verbal & written)
- Problem solving and decision making
- Strategic thinking
- Proactive



Technical Skills

- Drug development understanding
- Technical background (Pharmacy, Chemistry, Biology, etc.)
- Master in Project Management (PMP methodologies, Agile, Risk Management)
- PhD is appreciated
- Knowledge in Pharmaceutical / Chemical installations and utilities.
- Data analysis (KPI's)



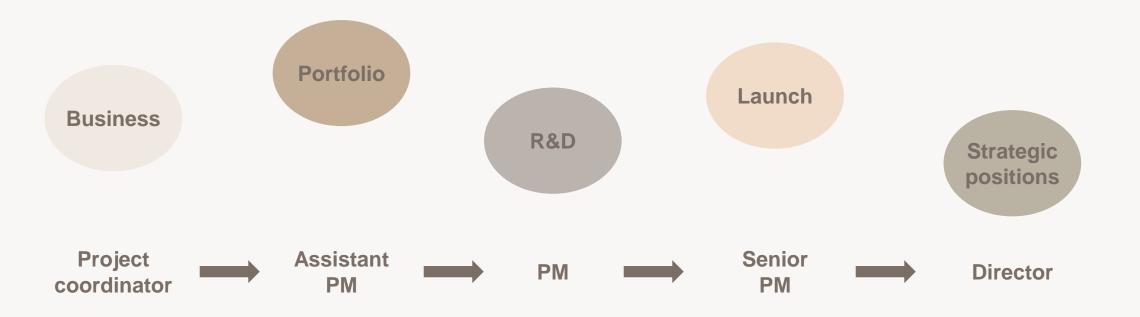
Languages

- Fluent in English
- Microsoft Office including MS Project or other PM tool
- Schedule and control of duties, cost and resources (human and materials).
- Gantt, cost curves, matrix of responsibilities

4. CAREER **DEVELOPMENT**

- No set career path for becoming a PM
- Advancement generally occurs incrementally
- PM responsibilities expand as you move up the organization hierarchy
- Great position to learn and personally develop

- / PM is not the 1st job in the Pharmaceutical Industry
- √ 2-3 years in technical position or previous experience as PM trainee
- √ Rewarding career choice → variety in the workplace
- √ Demanding position in the market
- √ Expected salary for junior/senior positions
- ✓ Do not choose your professional profile for the salary



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THANK YOU
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