DARE TO **FLY**

QC & ANALYTICAL DEVELOPMENT

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PPD

Barcelona - March 15th 2023

Galenicum 20 YEARS

University Join Industry March 15th 2023

Ismael Valverde

Marta Lorente

BRIEF INTRODUCTION

+ Vice President & Site Lead for the PPD Athlone GMP Lab (Ireland)

+ Technical background = Analytical Chemistry + DP/DS development.
20 years experience
Fine Chemistry and Pharmaceutical companies
Analytical R&D/QC labs in corporate positions.

+ Pharma executive and Innovation Director
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Marta Lorente

+ Project Manager PPD Athlone GMP Lab

+ Technical background = Analytical Development
8 years experience
Chemical Engineer

+ Scientist & Project Manager
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ROLE OF YOUR AREA WITHIN THE PHARMACEUTICAL INDUSTRY

QUALITY CONTROL ROLE

- The term quality control refers to all procedures undertaken to ensure the identity, efficacy, safety and compliance of a particular pharmaceutical by means of testing.

- Laboratory based inspection role all along the company operational chain.

- Procedures may range from simple chemical tests (infrared spectroscopy, etc.), to more complicated requirements (chromatography, microbiology).

- Activities extend to the area of quality assurance, logistics, manufacturing.

    - GMP
    - Audits/Inspections
    - Release (CoAs, LIMS)
    - Investigations/ Deviations/ Complains

SUPPLIERS

API+ Excipients+Packaging Materials
Intermediates, In Process Controls
Final Products
Retain Samples

ROLE OF YOUR AEA WITHIN THE PHARMACEUTICAL INDUSTRY

ANALYTICAL DEVELOPMENT AND RESEARCH (ARD) ROLE

- Analytical Development role is to develop tools to guide the pharmaceutical development in order to have robust, feasible and quality driven products and processes.

- Laboratory based innovation role based on high analytical and chemical knowledge.

- Different chemical test with different purpose (IP, quality, clinical driven) which some of them need to be transferred to QC as part of product specification.

- Activities extend to the area of regulatory department, galenical and manufacturing departments and usually uses external company knowledge (p.e, CROs).

ONE DAY IN THE QC OFFICE

- Planning daily activities with your team (resources allocation)
- Suspervision and ´release´activities (CoA generation, raw data revision..etc)
- Troubleshooting
- Company team discussions (investigations, audit preparations, projects being transfered..etc)

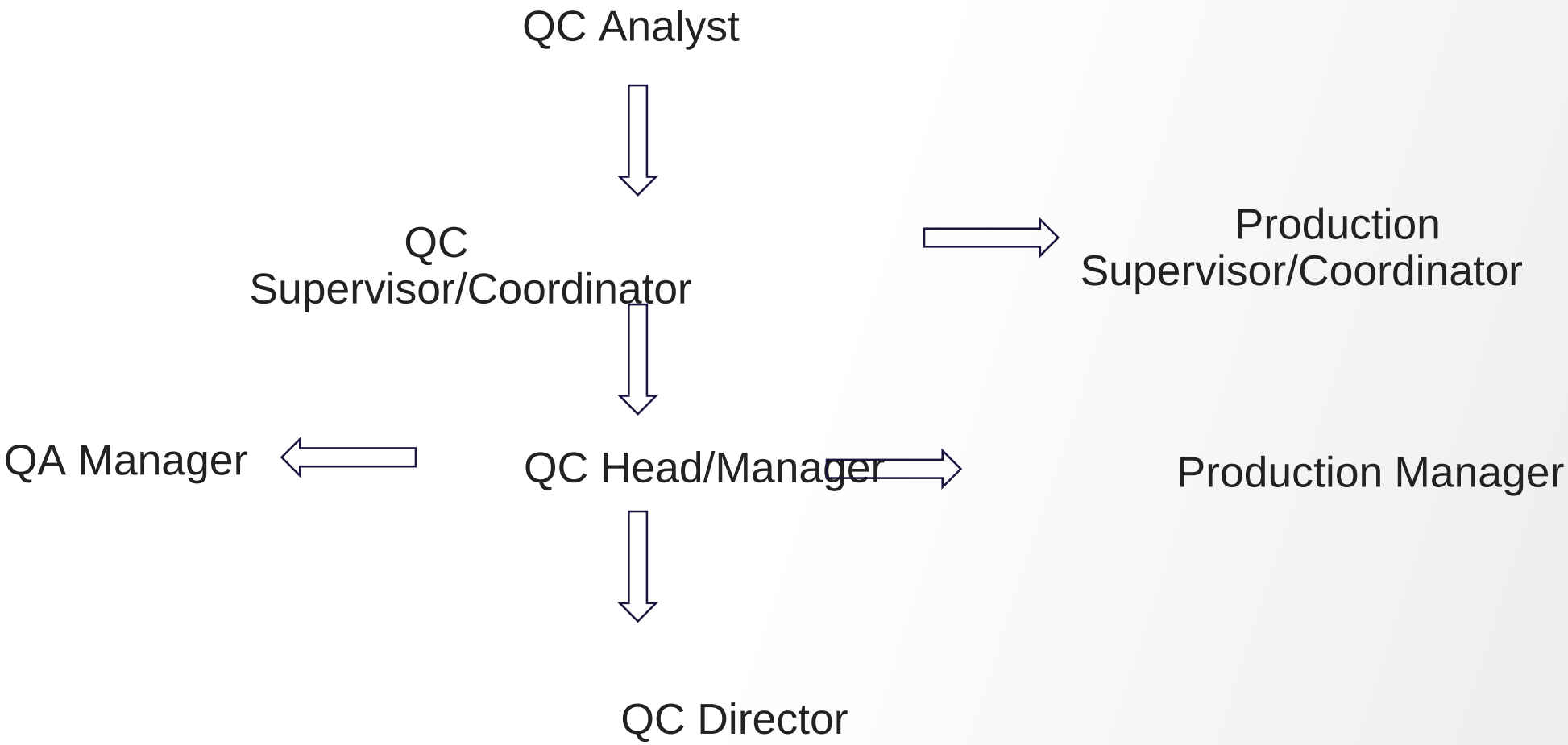
ONE DAY IN THE ARD OFFICE

- Planning daily activities with the analyst and the pharmaceutical project leader
- Observation, Conclusion, Fine-tuning, Reanalysis, Observation, Conclusion…
- R&D team discussions (What does this result mean?, next steps..)
- Questions from authorities
- Reporting

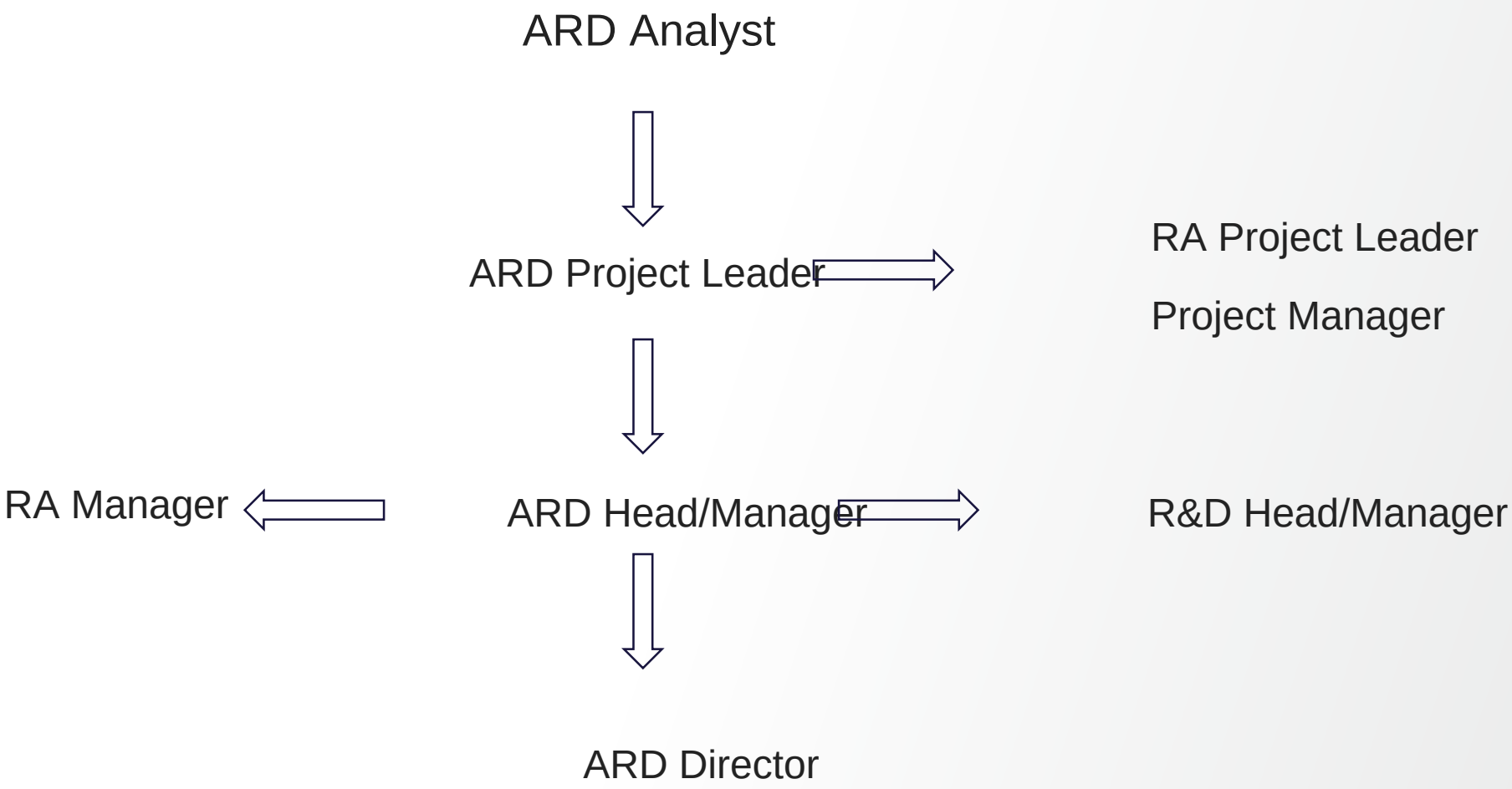
WHAT IS THE MARKET LOOKING FOR?

	ARD	QC
Hard Skills	Pharmacy, Chemistry Degree	Pharmacy, Chemistry, Biology Degree
	Analytical techniques	Analytical techniques
	Instrumentation	GMP, ISO Standards in Laboratories
	Pharmaceutical Process Knowledge	Statistical Knowledge
	English	English
Soft Skills	Result Oriented Person	Detailed Oriented Person
	Sound judgement / Decision maker	Analytical Skills
	Communication skills	Ability for multitasking
	Project Management	Teamwork

QC CAREER DEVELOPMENT

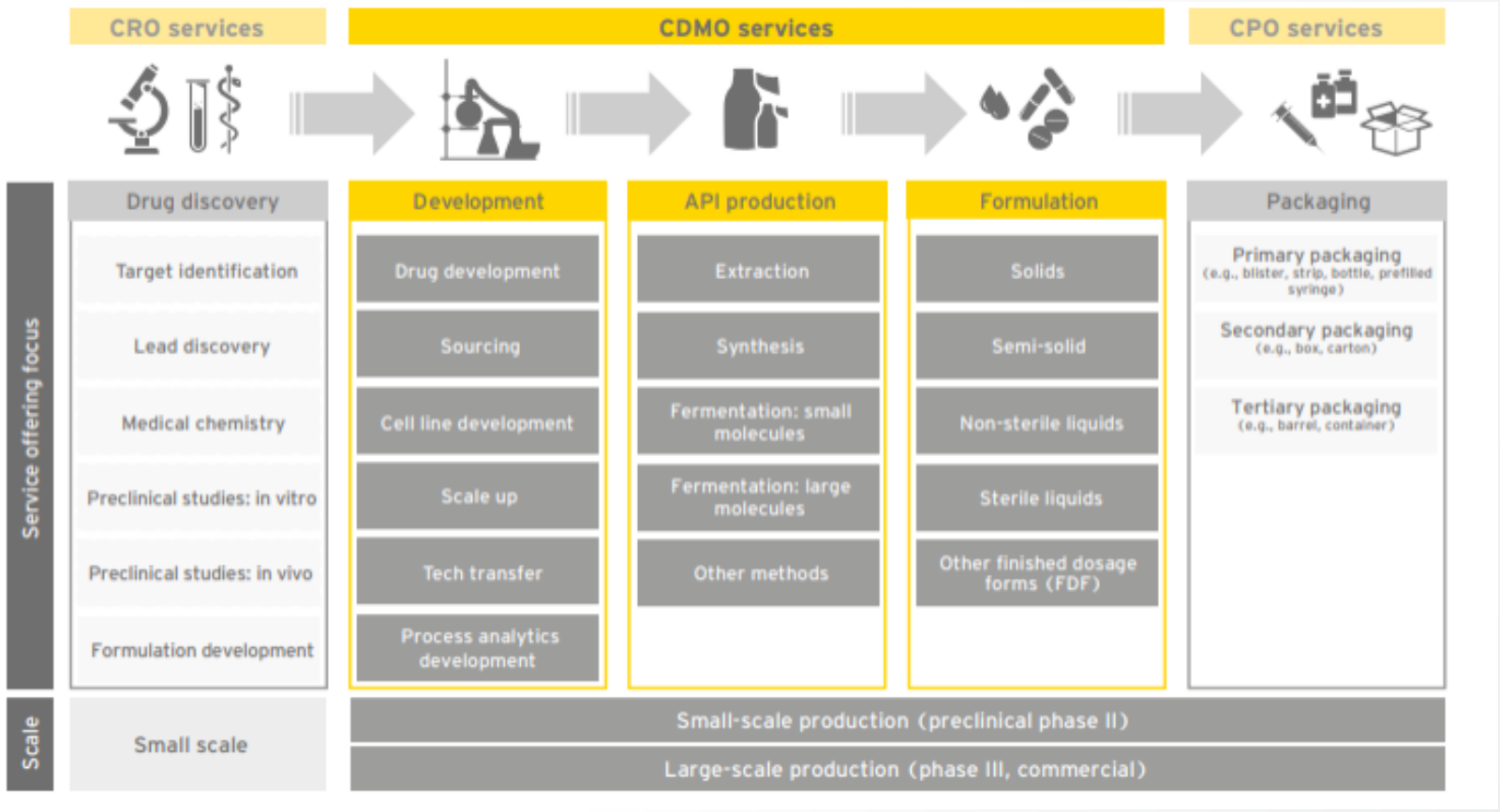


ARD CAREER DEVELOPMENT



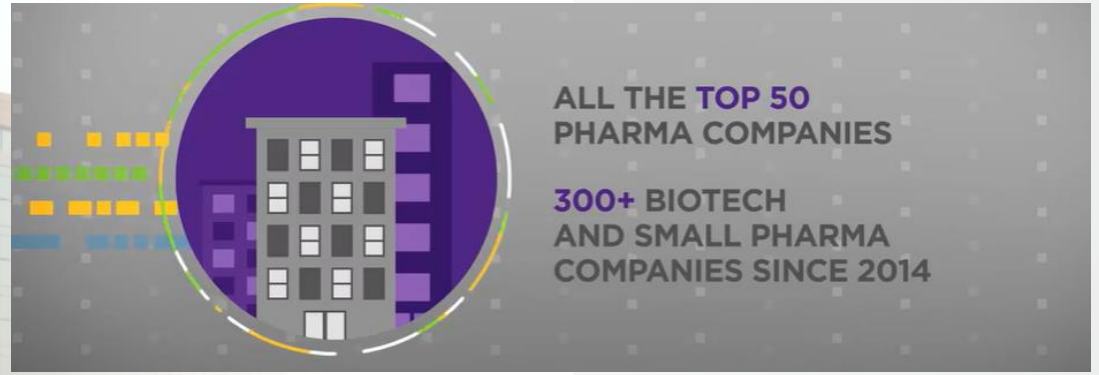
CRO/CLO/CMO/CDMO concept

A contract manufacturing organization (CMO), sometimes called a contract development and manufacturing organization (CDMO), is a company that serves other companies in the pharmaceutical industry on a contract.



CLO (Contract Laboratories Organization) is a company specialized in providing analytical services to pharmaceutical companies

PPD Overview



25,000+ Professionals **worldwide**

93 Offices, clinics and labs in **46 countries**

ATHLONE GMP LAB - Expansion Completed July 2022

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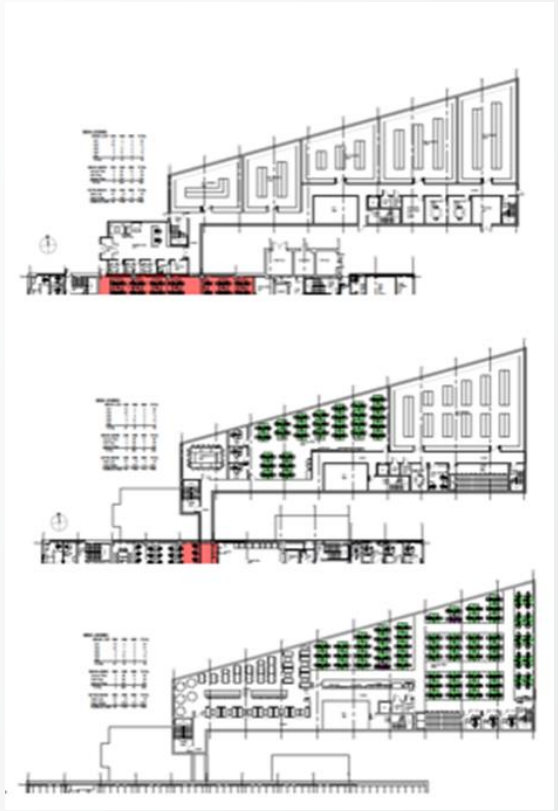
Building C Annex

34000 ft²



Building C 50000 ft²

CAREERS – Why PPD part of Thermo Fisher Scientific?

https://www.ppd.com/careers

Recruitment Team

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LIFE SCIENCE MARKET EVOLUTION