

DARE TO FLY

QC & ANALYTICAL DEVELOPMENT

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PPD

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PPD



Barcelona - March 15th 2023

Galenicum | 20 YEARS



University Join Industry March 15th 2023

Ismael Valverde

Marta Lorente

BRIEF INTRODUCTION



LinkedIn profile card for Ismael Valverde Martin. The background image shows a hand pointing at a whiteboard with various business icons like a lightbulb, puzzle pieces, and a thumbs up. The text on the card includes his name, title, and company logos for PPD and Esade.

Ismael Valverde Martin, PhD/MBA
Site Lead | Innovation Management | R&D Strategy |
Pharmaceutical Director | Fine Chemicals | Generics | CRO |
CMC | Analytical Expert

PPD PPD
Esade Esade

- + 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
Ismael.ValverdeMartin@ppd.com



Marta Lorente

- + Project Manager PPD Athlone GMP Lab

- + Technical background = Analytical Development

8 years experience

Chemical Engineer

- + Scientist & Project Manager

Marta.lorente@ppd.com

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

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)
- Supervision and 'release' activities (CoA generation, raw data revision..etc)
- Troubleshooting
- Company team discussions (investigations, audit preparations, projects being transferred..etc)

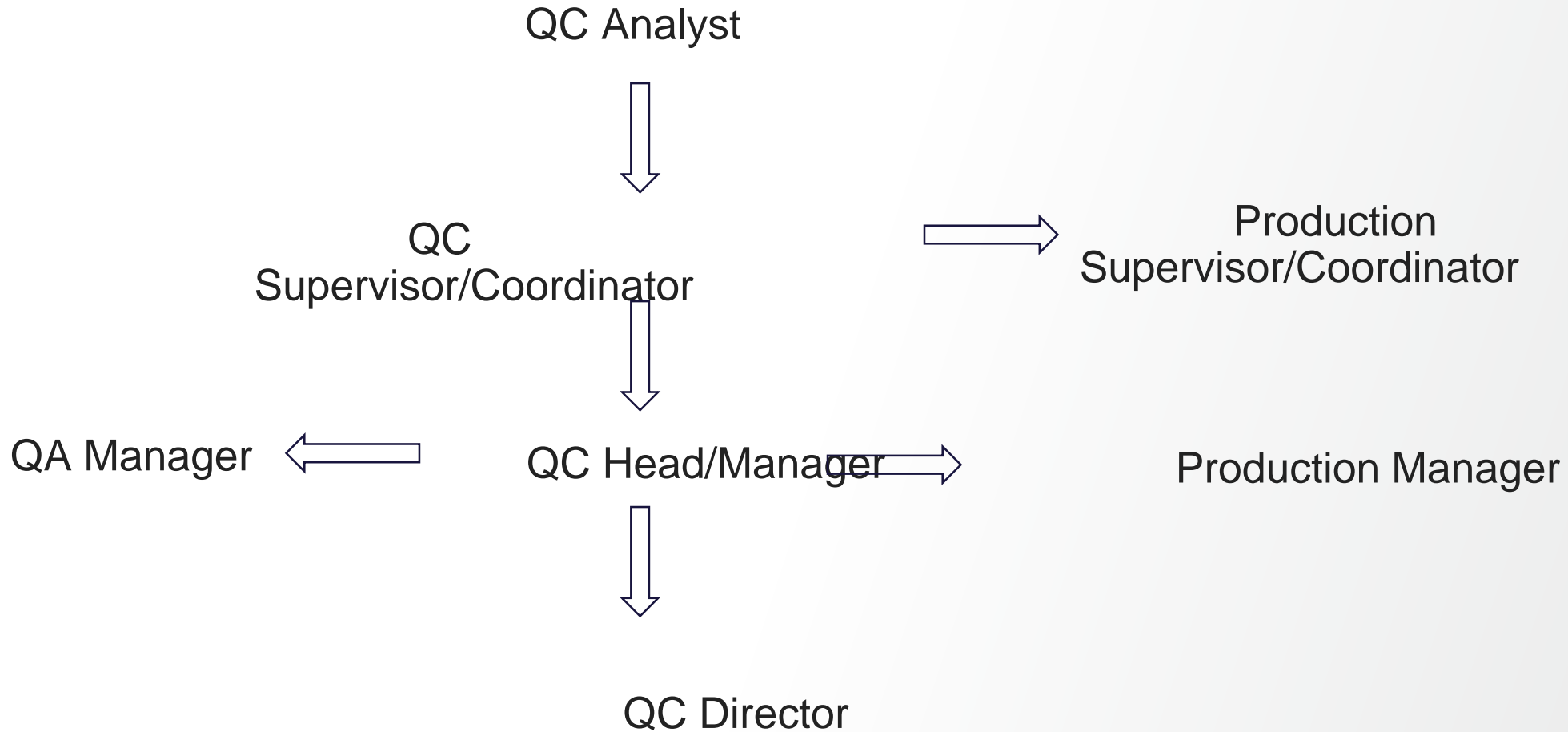
ONE DAY IN THE **ARD** OFFICE

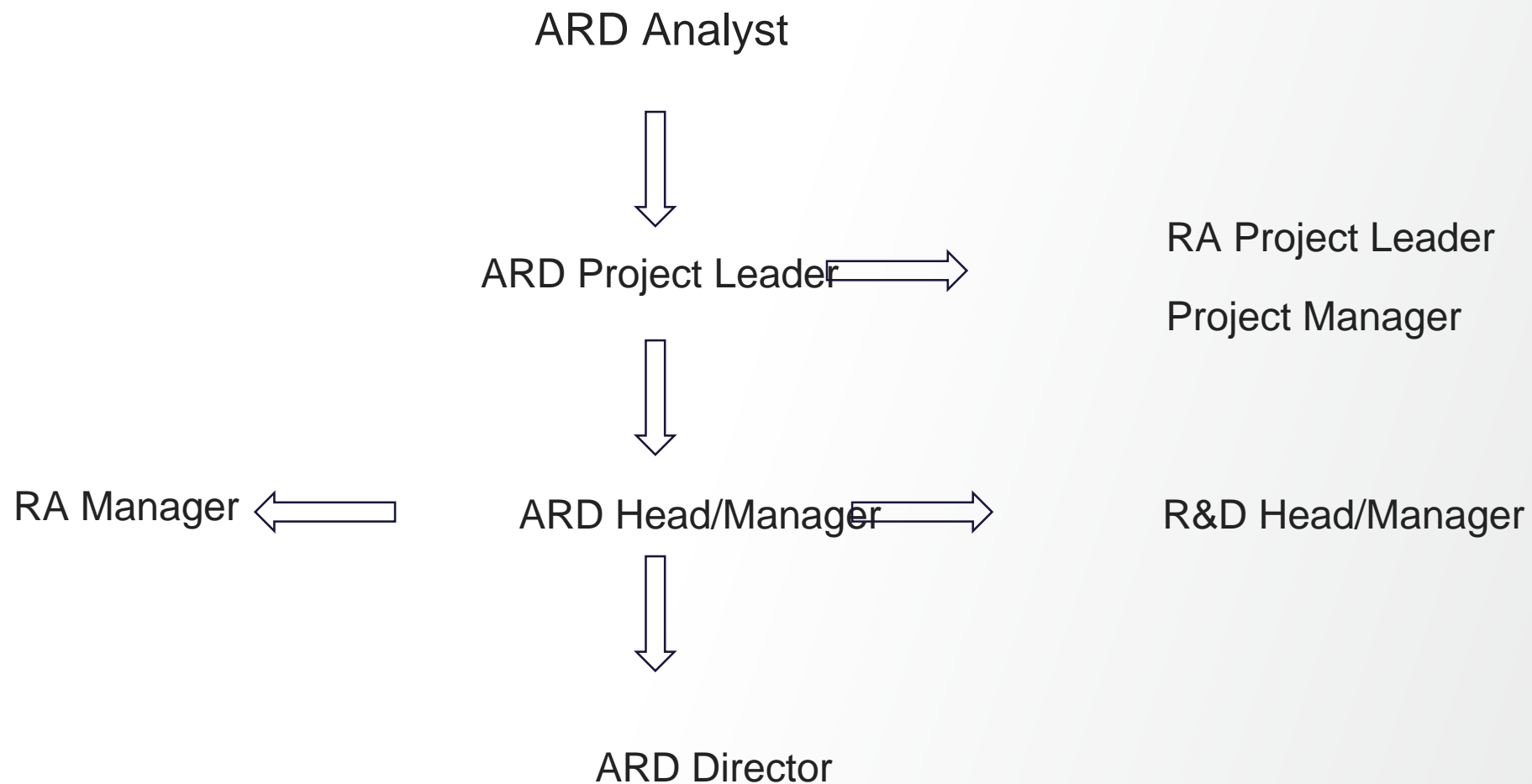
- Planning daily activities with the analyst and the pharmaceutical project leader
- Observation, Conclusion, Fine-tuning, Reanalysis, Observation, Conclusion...
- R&D team discussions (What does this result mean?, next steps..)
- Questions from authorities
- Reporting

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

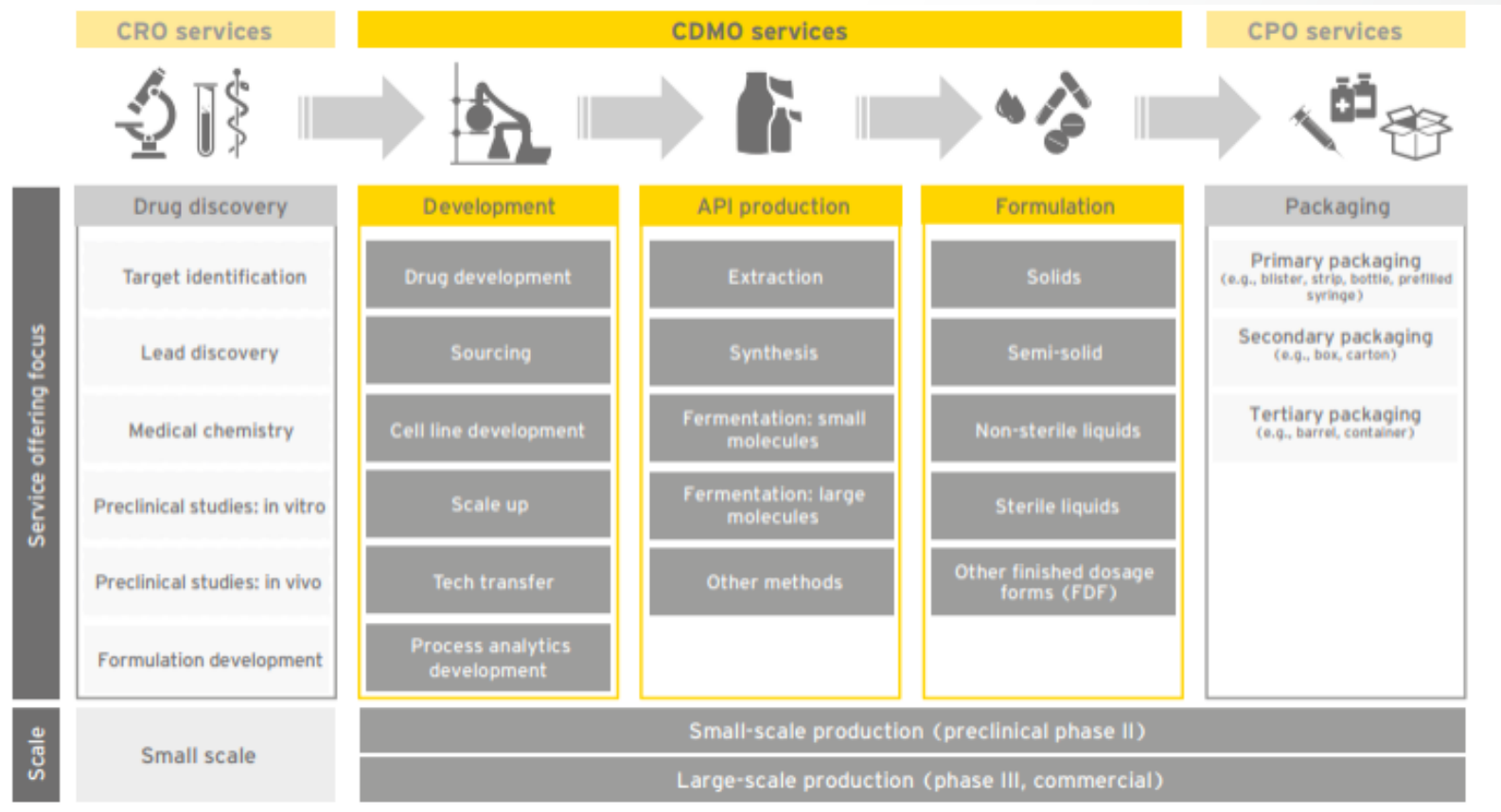
QC CAREER DEVELOPMENT





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



ALL THE TOP 50
PHARMA COMPANIES

300+ BIOTECH
AND SMALL PHARMA
COMPANIES SINCE 2014

A GLOBAL PROVIDER
OF CLINICAL DEVELOPMENT
AND LABORATORY SERVICES

Forbes | 2019
AMERICA'S
BEST LARGE
EMPLOYERS

TOP
125

CIO100
AWARDS

cdc

**CRO
LEADERSHIP
AWARDS**
2012 2013 2014 2015
2016 2017 2018 2019

The CenterWatch Monthly
2018 Top
Innovators

InformationWeek
Elite 100

PharmTimes
CLINICAL
RESEARCHER
OF THE YEAR 2019
20 YEARS

PharmTimes
INTERNATIONAL
CLINICAL
RESEARCHER
OF THE YEAR 2019

ViE
AWARDS

PharmTimes
CLINICAL
RESEARCHER
OF THE YEAR 2019
THE AMERICAS

[25,000+]

Professionals
worldwide

93

Offices, clinics and
labs in 46 countries]

**ATHLONE
GMP LAB -
Expansion
Completed
July 2022**

**ThermoFisher
SCIENTIFIC**



Athlone, Ireland - Laboratory Expansion

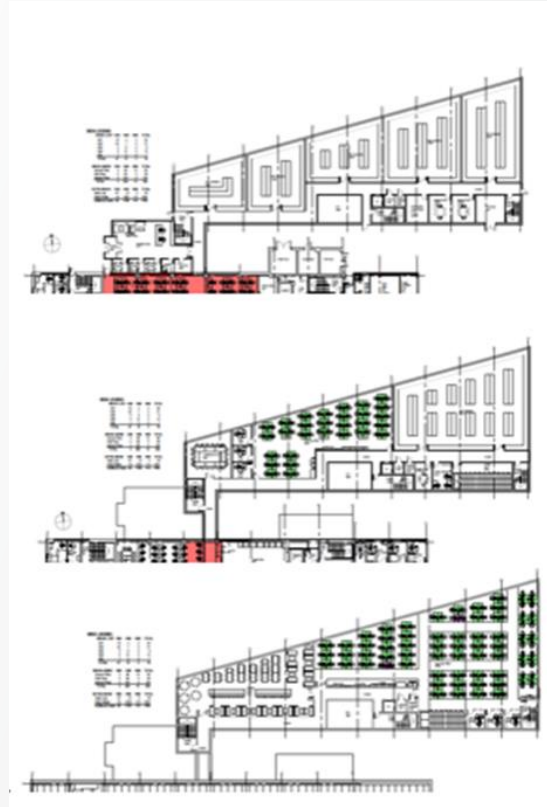
PPD[®] LABORATORIES

**ATHLONE
GMP LAB -
Expansion
Completed
July 2022**



*Building
C Annex*

34000 ft²



Building C 50000 ft²



- Best in class training
- Excellent culture of teamwork and collaboration
- Diversity of work – multiple clients and products
- Opportunities for employee growth and development
- Extensive Technical Expertise
- Excellent Quality Standards
- Work/Life Balance
- Rewarding - contribution to bringing life changing therapies to market
- Proud to be part of PPD



Partner with PPD Laboratories.
Together we can deliver life-changing therapies.

Recruitment Team

<https://www.ppd.com/careers>

Marguerite.Gately@ppd.com
Michelle.Hand@ppd.com

LIFE SCIENCE MARKET EVOLUTION

The screenshot shows a web browser window with the URL <https://www.thermo.com/profesionales/calculadora-salarial>. The page title is 'CALCULADORA SALARIAL'. Below the title, there is a navigation menu with 'Inicio', 'Calculadora', 'Info de tu sector', 'Descargar', and 'Contacto'. The main content area features a large thermometer graphic with a blue fill at the bottom. To the left of the thermometer, there are labels 'Máximo DE' and 'Mínimo DE' with horizontal lines. Below the thermometer is a blue button that says 'Ver ofertas de Life Sciences'. To the right of the thermometer, there is a text link 'Compara tus resultados'. On the far right, there is a white sidebar containing a form with the following fields: 'Sector' (with 'Ind. Ciencias' selected), 'Subsector' (with 'Industria Farmacéutica' selected), 'Departamento' (with 'Selección' selected), 'Años de experiencia' (with 'Selección' selected), 'Localidad' (with 'Selección' selected), 'Salario anual' (with 'Indica aquí tu salario anual'), and 'Email' (with 'Indica aquí tu correo electrónico'). Below the form is a checkbox for 'Al rellenar este formulario, confirmo que he leído y aceptado los Términos y Condiciones. Del mismo modo, confirmo que he leído y aceptado la Política de Privacidad'. At the bottom of the sidebar is a blue button labeled 'Recalcular' and a link 'Descargar Guía Hays 2023'.