

University Meets Industry March 2022

Quality Control & Analytical Development Functions

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Brief Introduction



- + Executive Director for the PPD Athlone GMP Lab (Ireland)
- + Technical background = Analytical Chemistry + DP/DS development. 20 years experience Fine Chemistry and Pharmaceutical companies managing Analytical R&D/QC labs in corporate positions.
- + Pharmaceutical R&D Executive and Innovation Director

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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 AREA 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 OFFICE

QC

- 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 transfered..etc)

ARD

- Planning daily activities with analyst and galenical 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?

•

QC

Technical skills: Pharmacy, Chemistry, Biology Degree
Analytical techniques
GMP,ISO Standards in Laboratories
Statistical Knowledge
English

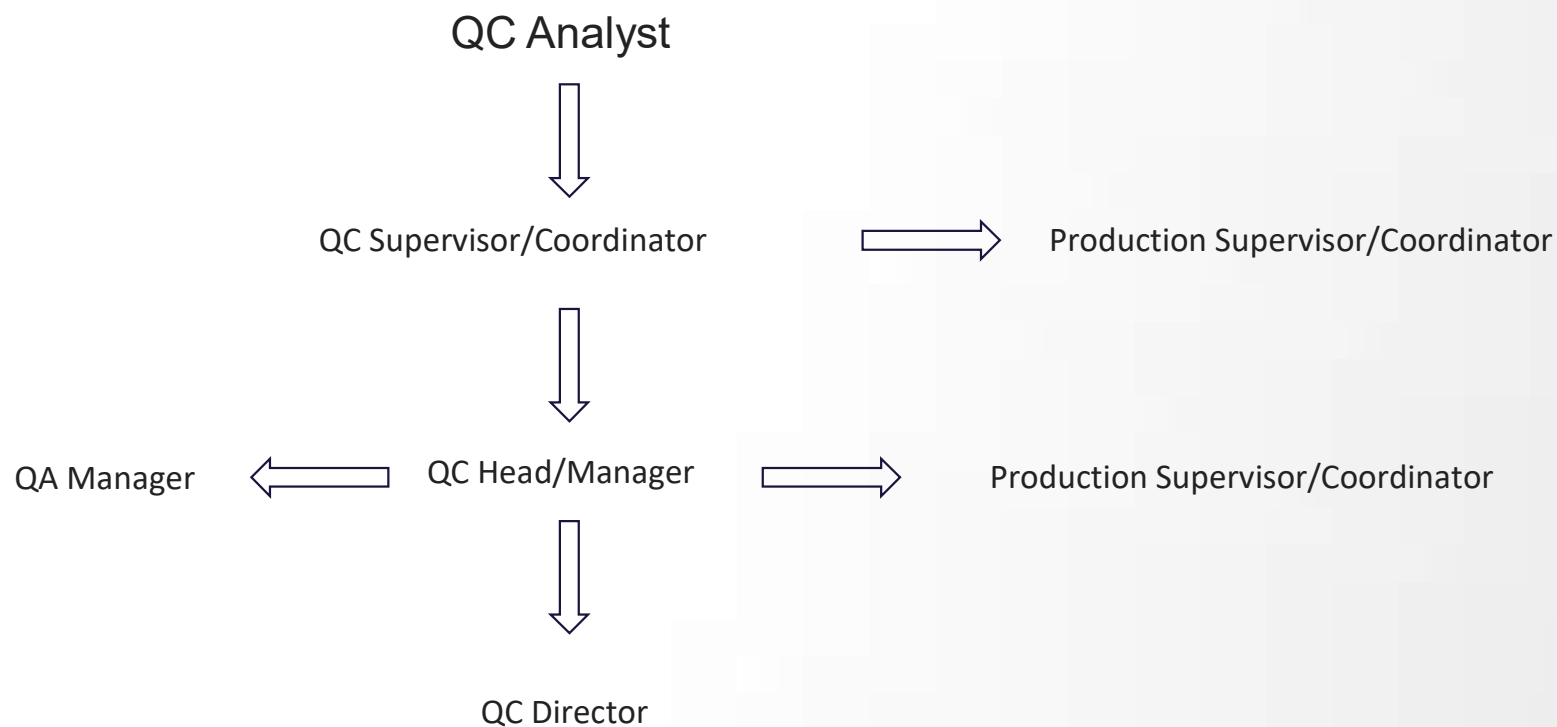
Soft Skills: Detailed oriented person
Analytical and research skills
Ability for multitasking
Teamwork

ARD

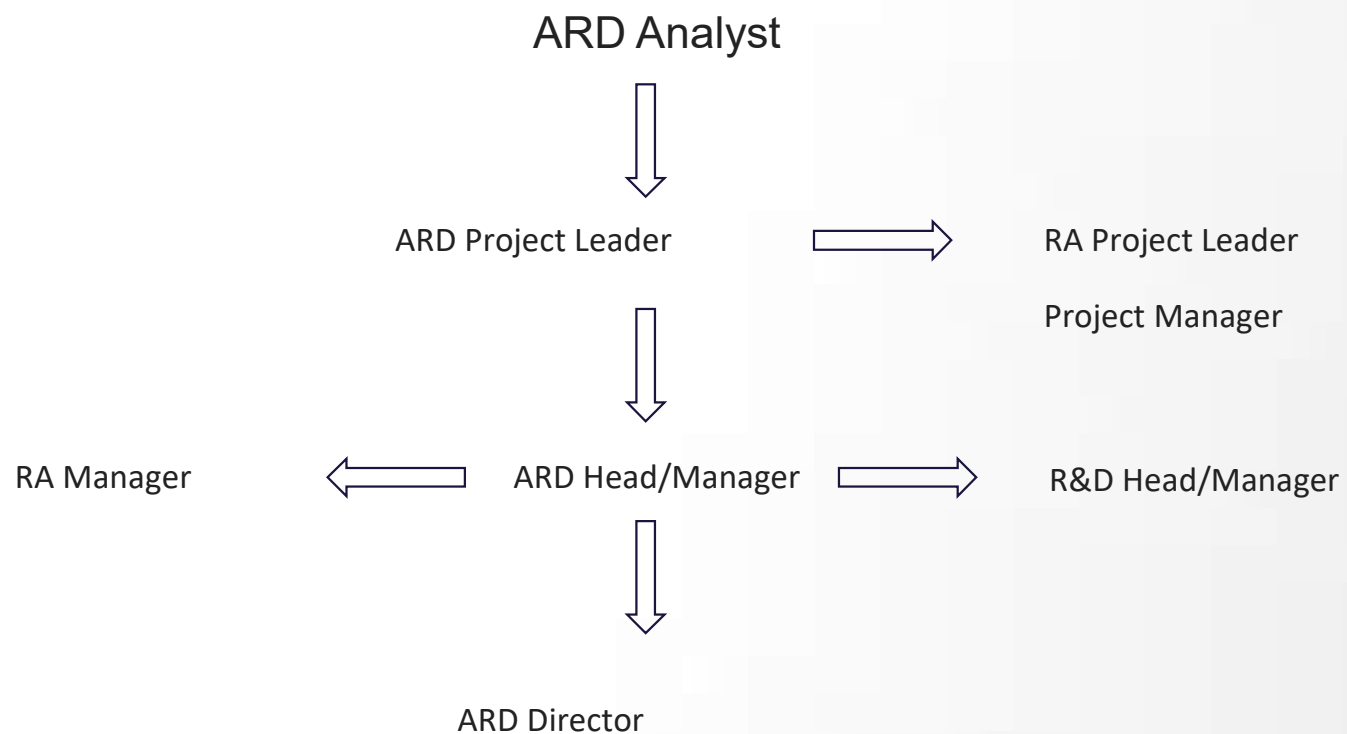
Pharmacy, Chemistry
Analytical techniques
Instrumentation
Pharmaceutical Process
English

Result oriented person
Sound judgment and decision making
Communication skills
Project Management

QC CAREER DEVELOPMENT

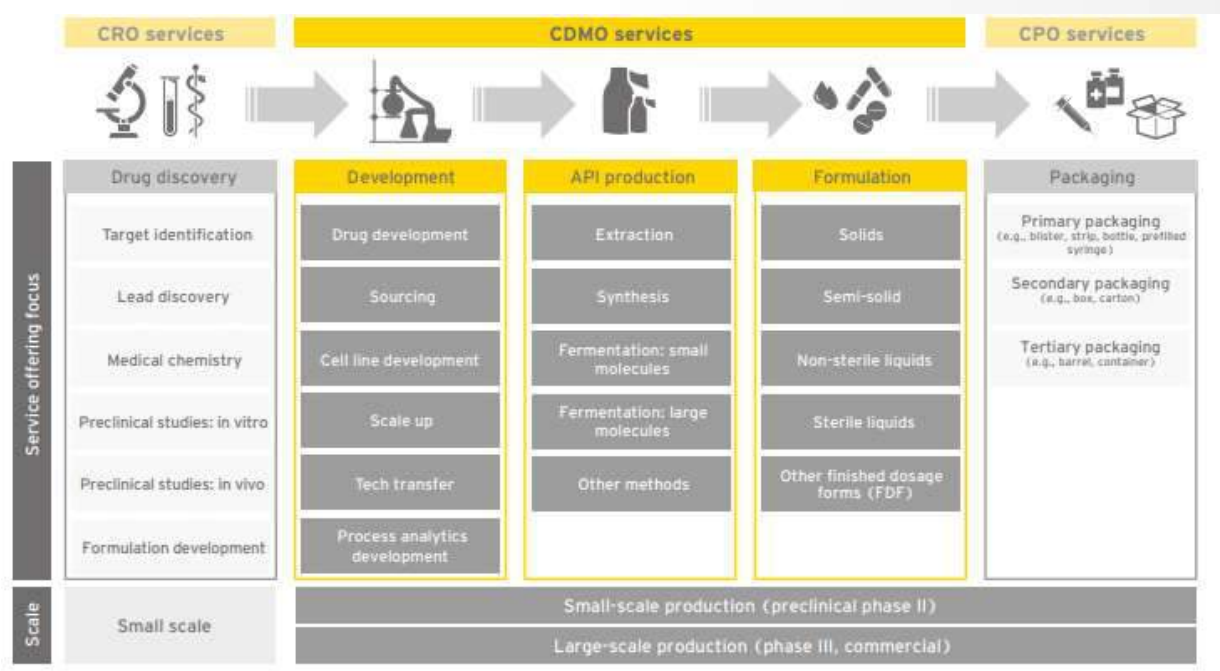


ARD CAREER DEVELOPMENT



CRO/CMO/CDMO concept

A contract `development and manufacturing organization (CDMO), is a [company](#) that serves other companies in the [pharmaceutical industry](#) on a [contract](#). Services offered by CDMOs include, but are not limited to: [formulation](#) development, stability studies, method development/validation, pre-clinical and Phase I [clinical trial](#) materials, late-stage clinical trial materials, scale-up, registration batches, packaging activities and commercial production/testing.



CROs are companies specialized in research activities for pharmaceutical companies.

- PPD became a Thermo Fisher group company



+



- Integration is on going
- Business/client driven and intended to exploit synergies
- PPD continues to be a brand and a legal entity (PPD development Ireland)

PPD Overview



25,000+

Professionals
worldwide

93

Offices, clinics and
labs in 46 countries

A Global Network of Laboratories to Support All Phases of Drug Development



Bioanalytical lab

Biomarker lab

Central lab

GMP lab

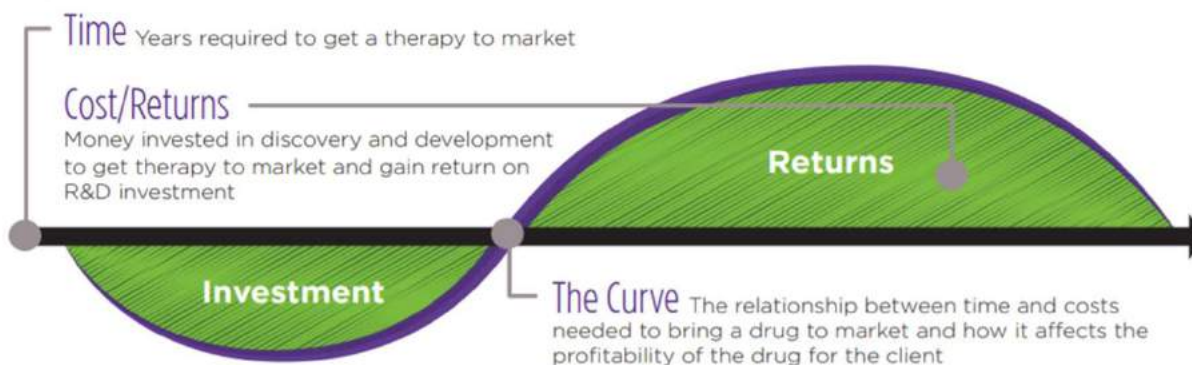
Vaccine sciences

Bending the Time and Cost Curve



The Challenge

Time and costs for drug development influence the profitability of a drug. PPD has a vested interest in reducing time and costs.



The Solution

If we reduce the time and costs to bring a drug to market, our clients have higher returns. PPD is moving the curve in the following ways:

Creative solutions

Innovative technology

Continuous process improvements

Faster site activation and recruitment

GMP Lab: One Lab, Multiple Locations

ATHLONE, IRELAND

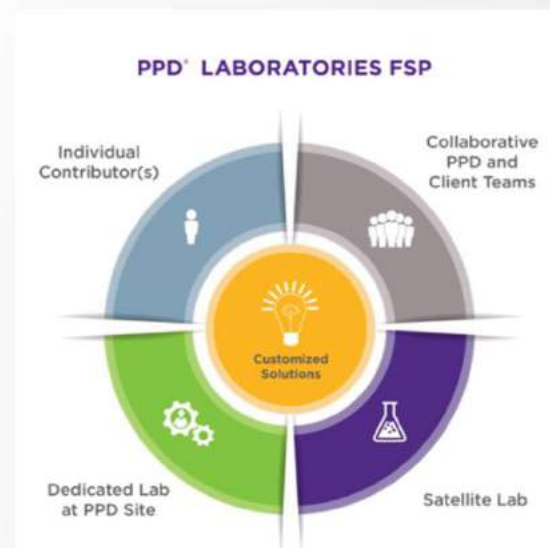
More than
47,000 sq. ft.
and **245 staff**

MIDDLETON, WISCONSIN, USA

More than
435,000 sq. ft.
and **1,600 staff**

FUNCTIONAL SERVICE PARTNERSHIPS

Multiple client locations in the
U.S. and Europe
with more than
300 staff



Athlone- A convenient location in Ireland





Athlone, Ireland – Laboratory Expansion

PPD® LABORATORIES



Current Athlone Laboratory Footprint



- Thermo Fisher Scientific officially acquired PPD on 10th December 2021
- PPD became a Thermo Fisher group company

PPD has confirmed our new group and division names as part of Thermo Fisher.



David Johnston



Senior Vice President and President
Clinical Research Group



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Careers – Why PPD?

- 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

6. LIFE SCIENCE MARKET EVOLUTION

<https://guiasalarial.hays.es/trabajador/home>

The screenshot shows the Hays website's worker portal for the Life Sciences sector. The header includes the Hays logo with the tagline 'Recruiting experts worldwide', social media icons for LinkedIn, Twitter, Facebook, and YouTube, and a navigation bar with links for 'Quiénes somos', 'Busca candidatos', 'Inicio', 'Calculadora', 'Plan de carrera', 'Info de tu sector', 'Encuestas e infográficos', 'Descargar', 'Videos', and 'Contacto'. The main content area features a large blue banner with the text 'Bienvenido al área de trabajador del sector Life Sciences' and a brief description of the portal's purpose. Below this, there is a blue box with the question '¿Quieres saber cómo evolucionarán los salarios del sector Life Sciences en los próximos años?' and a 'Ver más' button. To the right, there is a 'Descargas' section with a download icon and a link to 'Guía Hays 2019'.

HAYS Recruiting experts worldwide

in | | | | Empresa | Trabajador Life Sciences

Quiénes somos Busca candidatos Inicio Calculadora Plan de carrera Info de tu sector Encuestas e infográficos Descargar Videos Contacto

Bienvenido al área de trabajador del sector Life Sciences

Desde aquí podrás conocer de primera mano las tendencias del sector, la evolución de los sueldos, los puestos de trabajo más demandados y una visión general de todo el mercado laboral.

¡Adelante!

¿Quieres saber cómo evolucionarán los salarios del sector Life Sciences en los próximos años?

Descubre cómo han evolucionado los salarios en los últimos años y qué tendencia de futuro se espera.

Ver más

Descargas

Guía Hays 2019

- Salary Estimation per position/location/experience
- Career plans
- Reasons for talent retention

QUESTIONS- Choose the right one

1. Do QA and QC department perform the same activities in the pharmaceutical industry?

- a. Yes, they do. Therefore, both departments work under the same unit
- b. No, QA assures you are doing the right things, the right way while QC assures that the results of what you have done are the expected ones
- c. No, QA and QC are totally two independent departments in every single pharmaceutical industry
- d. No, because QC is the responsible department for releasing the product to the market

2. Analytical Research and Development Department...

- a. never participates in quality investigations for commercial products
- b. only develops the methods/tests that are finally used in the QC department
- c. needs to understand the process and the formula changes to correctly guide the development
- d. implies the use of limited analytical techniques

3. Why do Pharma industries use CDMO/CROs?

- a. CDMOs/CROs allow them to have access to new technologies, knowledge, markets
- b. CDMOs/CROs may help them in quick workload ramp ups and/or being more efficient
- c. CDMOs/CROs may help them in mitigating financial risks
- d. All above