

Information sheet

Project Management at Quotient Sciences – A True Partnership

Quotient is an innovative drug development and manufacturing partner supporting clients from candidate selection to commercial launch. With expertise in end-to-end Project Management and integrated project teams, we make drug development easier for our customers and dramatically reduce the time and cost of getting new medicines to patients.

Introduction

The pharmaceutical industry has changed significantly over the last decade. Big pharma is transitioning to a leaner business model that relies heavily on external partners and a sharp increase in the number of biotech companies actively engaged in research is now fueling the industry pipeline of drug candidates. Across the industry, the R&D process is not getting any easier; drug developers are working with tightening R&D budgets, aggressive timelines, capacity constraints and rising patient expectations. An increasing reliance on collaborating with partner companies to access capacity and innovation is now the norm. But with the right development partner, there are opportunities to succeed in this highly competitive environment.

Quotient Project Management can guide you on this journey and help you reach your destination:

- > **Together, we will build your program**
- > **Together, we will solve problems**
- > **Together, we will deliver a project tailored to you and your molecule.**

30⁺
project
managers
at Quotient

200⁺
years of collective
project management
experience

60⁺
employees
working
in project
management

90%⁺
clients plan
to work with
Quotient again

300
projects
ongoing at
any given time

90%⁺
projects
delivered to
budget

200
customers
globally

Why Quotient Sciences? What makes us different?

We deliver a One Business, One Customer Experience Approach

Quotient is a global business with over 900 employees across six operating sites in the US and UK. Our organizational design is built around global functioning groups and are committed to delivering “one business, one experience” to our customers irrespective of where a project is performed. The integration of our sites, capabilities and project teams is designed to deliver an exceptional service for our customers.

We have Expertise from Early Phase Development to Commercial Manufacture

We will support you all the way through development, from candidate selection to commercial product supply, and any stage of development in-between. Quotient Project Management will provide end-to-end support from concept and project scoping, to project delivery, to making recommendations for the next stage in development. And where projects transition across our sites, or intersect with other service providers, we'll make the process seamless for you.

We are Truly Integrated

There are no silo's at Quotient. We break these down, working in a matrix team structure where Project Management integrates across functions, across sites globally and across stages of development. Quotient Project Management are the link that connects multiple disciplines, companies and stakeholders, to form strong partnerships in a true collaboration where total integration creates a project environment of alignment, trust and togetherness, where the purpose and direction are fully understood by all. Quotient Project Management lessens the distance between us all.

We have Multidisciplinary Focus

Unlike traditional service providers who focus on one aspect of drug development, Quotient has capabilities and expertise in a broad range of scientific and technical disciplines; from discovery chemistry, biopharmaceutics, drug metabolism, formulation development, regulatory affairs, clinical pharmacology, data sciences, clinical and commercial manufacturing. Our customers can therefore access skills that they may not have in-house and we become an extension of their R&D team.

We Engage & are Responsive to Our Customers' Needs

Project Management put you, our customer at the heart of how we deliver each project. We strive to understand your way of working, your objectives and needs and we appreciate the huge responsibility and opportunity we have, to support you delivering drug products to allow people to lead healthy lives.

We are Agile and Adaptive

Project Management is no different to the rest of Quotient; operating with agility and flexibility, to optimally manage fast moving projects in the dynamic world of drug development. Quotient Project Managers will adapt along with your project to ensure your needs and the needs of your product are continuously met and all collaborators remain aligned with the objectives and end goal. Quotient Project Managers embrace changing requirements and endeavour to create simplicity amongst complexity.

We are Passionate & Dedicated

We understand that you are looking to collaborate with a partner that is as dedicated and as passionate as you are about your molecules. You put your trust in your partners hands and Quotient Project Managers are motivated to be involved in your projects and are committed to helping you achieve your targets.

We are Strong Leaders with Expertise in the Fundamentals of Project Management

We focus on delivering projects on-time and on-budget, helping you to make decisions on your molecule faster. We'll also optimally manage and mitigate the risks on your project, to successfully develop your products and help get new medicines to patients faster.

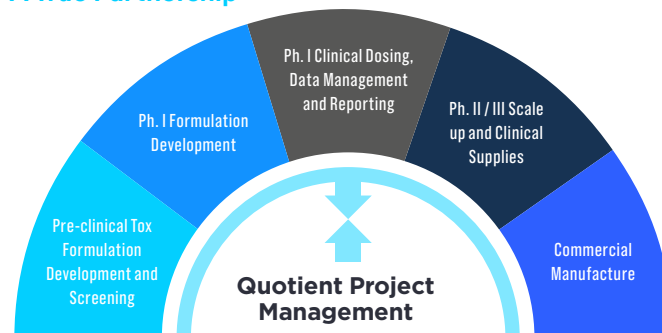
We Elevate Communication

We actively listen and hear what is important to you and adapt our communication style to fit yours. Quotient Project Managers bring everyone together, deliver the detail openly and honestly, actively encourage open discussion, feedback and criticism, to ensure the best outcome for all.

We Inspire Quality

We have a culture of continuous improvement, driving attention to detail and technical excellence. Quotient Project Management are central to this, working closely with individual team members and stretching across all functions, including our Quality Assurance department. We will provide full project oversight, managing every detail and ensure all elements are delivered to a high standard of quality.

We are all in this together: Quotient – A True Partnership



Collaboration between Quotient & DRGT (Druggability Technologies) – Phase I formulation to Commercial Ready Drug Product

Background

DRGT is a specialty pharma company that selected Quotient to support the development of a novel Celecoxib formulation for the treatment of pain.

Program Scope

1. Transition from a simple formulation to a patient friendly drug product
2. Efficiently scale the product and processes from Phase I to commercial ready

Overall Goals for the Partnership:

- > Develop the product as quickly as possible
- > Reduce the complexity of drug development
- > Simplify outsourcing and vendor management
- > Minimize risk in the program

Outcome of the Partnership

DRGT stated “Collaborating with Quotient Sciences enabled the rapid development, clinical assessment and commercial readiness of the product using integrated services across Quotient’s network of harmonized development and manufacturing sites in the UK and US”. By working with Quotient, DRGT have been able to bridge from Phase I to Commercial ready in 18 months, which is remarkable.

The impact of Quotient Project Management

DRGT captured that “Quotient has become an extension of our project team and have knowledge of our product. They are highly interactive and committed to helping us achieve our goals”. By breaking down silos and working in a matrix team structure, Quotient Project Management integrates across functions, across sites globally and across stages of development, to reduce the complexity and costs of development.

Quotient Project Management

Phase I Formulation Selection

Drug product

- > SDD granules in bottle
- > <100 units
- > ProCepT spray dryer

Project scope

- > Select formulation
- > Clinical PK study to confirm reduced food effect and improve PK profile

Develop Patient-Friendly Formulation

Drug product

- > Sachet formulation
- > 600 units
- > ProCepT spray dryer

Project scope

- > Develop sachet formulation
- > Taste masking development with flavours & sweeteners
- > Clinical taste study and pivotal PK study to select lead commercial formulation

Scale up Commercial Formulation

Drug product

- > Sachet formulation
- > 100,000 units
- > Niro Minor spray dryer

Project scope

- > Scale up spray drying & develop automated granulation process
- > DoE, process robustness, stability testing
- > Registration batches and Phase III manufacture

Feedback from our partners



Contract partners must be able to form a good interactive project team, and must deliver timely, quality work. From the outset, we were impressed with Quotient. From the outset, it was apparent that Quotient had the same kind of philosophy as Clovis; an honest and straightforward company with a very progressive attitude.



Clovis – Gillian C. Ivers-Read

Executive Vice President, Technical Operations and Chief Regulatory Officer and co-founder of Clovis Oncology



Everything ran very smoothly; we had a very good project manager who was on top of things all the time, and there were no hitches. We had weekly telephone conferences to discuss potential problems and timelines, and it worked very well... I have been in this industry for a long time; I know the reputations and capabilities of the different CROs, and I would say that Quotient offers the best balance of quality and timing versus cost of trials.



XSpray – Dr Andreas Konar

Director of Business Development at XSpray

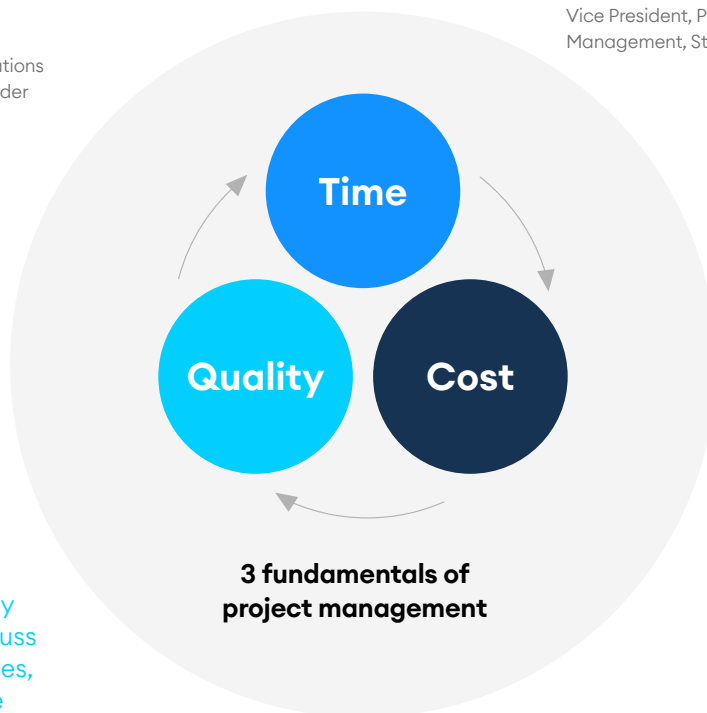


Quotient offers a unique combination – it is truly a clinical pharmacology formulation company with the added advantage of first-in-human testing. Our CMC and clinical teams found it very refreshing to work with them, developing a real understanding of parts of a project where they would not traditionally have been involved.



Stealth BioTherapeutics – Deborah Gouveia

Vice President, Program and Alliance Management, Stealth



This was our first study with Quotient and the company has been a very good partner to work with, enabling us to achieve proof of pharmacological effect more quickly than would otherwise have been possible.



Corcept Therapeutics – Hazel Hunt

Vice President of Research at Corcept



Quotient has been a great partner to work with. Their project management was top-notch and costs remained within budget throughout our collaboration. Their scheduling and execution have been impeccable; the program has run like clock-work. As a client, you can't really ask for more!



MEI Pharma – Dr Ofir Moreno

Vice President of Research and Development at MEI Pharma

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