



Could you give us an overview of the phase-dependent solutions that CatSci offer?

The phrase 'perfect-for-purpose process research and development' neatly summarises this. We recognise that the speed/quality/cost triangle typifies the balance that needs to be struck in the chemical process research and development (PR&D) of a potential new small molecule therapeutic.

Why is it important to consider different PR&D solutions for different phases?

Understanding what solutions can be used at different phases is essential; doing the right thing at the right time enables the timely and cost-effective progression of a drug candidate. For each phase, we need to manage the technical risks associated with the need for safe and secure supply of material on time, in full and to the desired quality (OTIFTDQ).

Could you talk through what you need to consider at each phase when supporting the customer? What are the differences and similarities between phases?

Specific objectives will differ at each stage of the overall drug development process. Earlier on in the pipeline, it is more important to progress projects into the clinic as quickly as possible, thus requiring relatively small quantities of the candidate drug. As the project progresses, attention then turns towards a longer-term, economically and environmentally sustainable manufacturing process that may need to deliver tonnes of drug substance every year.

What tools/approaches do you use to understand varying customer needs?

The key is our consultative approach: we take the time with our customers to fully explore the broader project context, timelines and objectives. We ask lots of questions in order to solicit the requisite information for formulating a tailored solution that is project-specific and phase-dependent. We listen and learn about the particular chemical and other technical challenges facing a project.

Our experience and expertise mean that we are very familiar with different potential scenarios. It is important to reassure our customers that we can draw on this knowledge to devise a precise solution for their needs. Trust is therefore also important, as we need to develop that understanding between us and our customers.

How do customer requirements vary between getting support on a single phase or when they require support from lead optimisation through product launch?

Customer requirements for each phase are broadly similar, whether taken individually or combined into a single project. The timelines for the overall drug development process inevitably lead to points where PR&D activities can be parked, so the effort to develop a manufacturing process is not continual from pre-clinical through to launch. One influential factor is that the greater the line of sight we have, then the greater the opportunities are to operate with enhanced efficiency and effectiveness.

What are the challenges you might face at each phase when supporting the customer and their product?

Early: Route assessment and selection (chemistry)

Mid: Safe and robust scale-up onto pilot plant (chemistry) to requisite quality (analytical)

Late: Commercial scale manufacturing (engineering)

How does effectively managing the speed/quality/cost triangle vary between stages?

As you move through the drug development timeline, the emphasis starts on speed, where the priority is whether you have a potential therapeutic. It then moves through quality to cost, where the focus is on whether you have an economically and environmentally viable process. Nonetheless, at every stage, the balance of the three factors is crucial with the relative co-efficient of each of the three factors varying as the project progresses. For example, the long-term economics of a drug substance manufacturing process (often referred to as the cost of goods) will only be important if the therapeutic makes it to market. However, there are elements of the process development programme that will need to consider this objective way before launch. If an assessment of the synthetic route reveals that it will not make the grade from an economic viewpoint, then thought must be given as to how and when to develop an alternative.

Do you think how you approach phase-dependent PR&D will change in the future with emerging manufacturing technologies?

This will, of course, depend on the nature of the emerging technologies. Process analytical technology (PAT), for example, has had a significant beneficial impact on process research, development and manufacturing. Valuable PR&D will always be founded on rigorous understanding of reactions and processes. Laboratory techniques and analytical technology have revolutionised the data that we can obtain about a chemical reaction and the way in which we are able to collect and interrogate it. However, that in itself has not changed the need for tailored solutions. It has instead rather improved our ability to meet the objective of timely process development in an efficient and effective manner. The critical element that underpins the need for phase-dependent solutions is cost-effective risk management, so the real question becomes 'how will emerging technologies enable better alignment of investment with project risk?'

How do you ensure that providing material of the right quality to feed the corresponding phase is done in a timely manner?

My favourite topic – risk management powered by process understanding! If you know how the steps in a manufacturing process will perform at the required scale, then you can put together a project plan with confidence that you will deliver OTIFTDQ.

Could you summarise what you need to find out from a customer to create highly specific phase-dependent solutions?

- Precise objectives
- Background process knowledge (chemistry, analytical, engineering, safety, etc.)
- Quality targets
- Technical challenges and priorities
- Budgetary scope
- Timelines
- Attitude to risk

Simon obtained an MA in Natural Sciences (Chemistry) from Hertford College, Oxford in 1995 and earned a PhD in 1998 after research on asymmetric synthesis in the group of Prof. Laurence M. Harwood. Then followed a two-year post-doctoral stint with Prof. Barry M. Trost at Stanford University, studying the catalysis of the Claisen rearrangement. In 2001, Simon returned to the UK to join Process R&D in AstraZeneca, gaining experience and understanding of the multi-disciplinary needs of drug development to lead significant process development projects ranging from candidate selection to Phase III, therein establishing a record of exploiting innovative synthetic and catalytic chemistry for the manufacture of drug candidates. After ten years in big pharma, Simon played a pivotal role as a co-founder of CatSci Ltd, negotiating the financial terms for the asset transfer and service agreement with AstraZeneca. After an initial operational role during the establishment of the new start-up, he subsequently took on commercial responsibility for the company, overseeing growth to a multi-million pound business. He currently serves as Chief Operating Officer, focused on unleashing the talents of staff across the organisation to exceed the expectations of customers. As a dynamic leader, he is committed to the development of others through vision, participation and affiliation.

Want to find out more about our phase-dependent process R&D solutions?
Contact us at technical_enquiries@catsci.com or visit our website catsci.com