



Leaner, fitter, more competitive

SI Associates, based in Glasgow in the UK and Cambridge, MA, in the US, has one aim: to help organisations become fitter and leaner – an ambition that rings all too true for companies operating in today's healthcare arena. *PharmaTimes* Magazine talks to SI's Managing Director, Harry Clark.

article history
 Septemver Deadline 20/8
 Text supplied: 2/8 - FOR COPYFIT/SALES ONLY - AWAITS CLIENT APPROVAL AT SOURCE (see notes)
 Editorial design for cir: 3/8
 Photographer trying to arrange shoot for ASAP after client returns from leave.
 Edited text supplied 10/8
 Ediorial design 10/8
 changes 11/8 - 16/8
 harry added quote 16/8
 pics added 16/8

'Bringing a new drug to market can cost anywhere between \$900 million and \$1.7 billion, depending on marketing costs,' explains Harry Clark, managing director of SI Associates. 'This figure has more than doubled in the past five years and is particularly concerning when it is realised that, of all commercialised drugs, only 30% generate revenues that meet or exceed their average development cost. In addition, despite companies ploughing significantly greater proportions of their income into R&D, there has been a significant slowdown in the number of New Chemical Entities brought to market.'

'However, this situation looks set to change with a plethora of opportunities promised via proteomics and genomics, and the pharmaceutical industry must therefore combine its focus on science with an unambiguous concentration on competitiveness to become more efficient and effective in its development and

manufacturing,' claims Harry. 'Phrases that have been routine in sectors such as electronics, automotive and aerospace – 'concurrent development,' 'design for manufacture,' 'lean manufacturing and six sigma,' and 'time to market' – will enter the everyday vocabulary of pharmaceutical companies. In fact, this is already happening.'

This is where SI Associates comes in – this is what it does.

SI is a niche organisation that was established in 1987 by The University of Strathclyde to research into and promote the adoption of best practice in manufacturing industries. Following a management buy-out in 1995, the company sharpened its focus to address three sectors – engineering, electronics and life sciences. SI now counts many top-ten pharmaceutical companies amongst its current client base.

Harry believes the pharmaceutical industry should both re-assess the way in which it identifies and manages competencies and how it



approaches competitiveness – one avenue being to make sure its functions collaborate more effectively. 'At SI, we are closely and intimately involved in the processes of development and manufacturing and – because of the link to bringing a product to market – with marketing too,' explains Harry. For SI, this means playing an integral role in forming robust and reliable management processes that enable product characterisation and development, from initial concept or synthesis through to Phase III human trials and commercialisation. 'The learning built up at the front end is designed into the later-stage development and manufacturing processes,' he says. 'This provides a means to spotlight projects that will provide a sufficient return on investment and to de-select those that don't make economic sense,' reveals Harry. 'For viable projects, it smoothes the scale-up associated with manufacture for both late-stage clinical trials and for commercial manufactur-



ing, where traditionally a lot of time gets wasted,' Harry notes. 'The earnings window for products is shrinking all the time,' he explains, 'and all that really matters is bringing safe, efficacious and profitable products to market as quickly and efficiently as possible.'

Top-end to nuts and bolts

So, down to the nitty-gritty: what does SI Associates actually do? Harry elaborates: 'Our methodology is founded on processes and can be applied throughout the spectrum of development and manufacturing functions within a pharmaceutical company, from pre-clinical to clinical, and from the strategic level of the development operation to the nuts and bolts of the manufacturing process.' Essentially, SI's consultants – who combine academic backgrounds with extensive line management experience and are therefore able to offer practical, pragmatic advice alongside client empathy – are experts at pulling apart and analysing a process, as well as streamlining and improving ►

SI Associates has been instrumental in improving the manufacturing capability of one of AstraZeneca's component suppliers by three fold, helping to ensure future supply security of a critical drug delivery device...'

Steve Metcalf, AstraZeneca

**Leaner, fitter,
more competitive**

▶ a company's capabilities. The SI philosophy is relevant both for drug products and medical devices; its application achieves tangible, measurable and sustainable improvement.

And SI has seen some impressive results: taking months out of a product's development cycle time and achieving simultaneous improvements in throughput and capacity – in some cases by as much as 25%-40%. Importantly, for a pharmaceutical company, this means precious extra time on the market and potentially many additional millions in the company's coffers.

The SI Team has brought us to a new understanding of the complexities of the product, its design and manufacture...



Execution versus science

The Industry has been aware of the need to address its approach to the drug discovery and development process for some time, so what is the benefit of employing an outside consultancy rather than handling the change internally? Explains Harry: 'The Industry's core competencies are founded in science and discovery, whereas SI's consultants have expertise in operations and process execution. Areas such as design, product development and assurance, manufacturing systems engineering, process optimisation and improvement, materials management and logistics are where we excel – a wholly different challenge. We simply complement the pharmaceutical industry's core capabilities by providing analysis and implementing solutions to issues affecting competitiveness.'

SI is a niche business and, whilst the brand is less immediately recognisable than that of some competitors, the firm certainly has a big reputation. It has worked with most of the top-ten pharmaceutical organisations. Importantly as well, 80% of its business stems from referral work within or to other client companies. And it is not hard to see why. For example, SI worked with a US-based global company to identify a 40% throughput benefit in the management of product optimisation and clinical materials. With a UK-based global pharmaceutical business, the parameters of product quality were improved by 1100% at the scale-up phase. In a US global business, development cycle times were compressed by 15% through re-engineering of the drug product optimisation and trials operation. And, at a division of Quintiles, the leading contract research organisation, SI helped implement an ambitious re-engineering plan that – on completion – revealed a projected 20% annual saving on cost of sales and 35% revenue growth.

'The pharmaceutical industry has traditionally focused on identifying blockbusters but, with just twenty-five to thirty-five New Chemical Entities brought to market over the past years, the productivity of the current model is fast diminishing,' notes Harry. Whereas discovery has previously been the rate-limiting factor to competitiveness, the Industry is seeing a complete paradigm shift in the number of targets becoming available,' he adds, 'and companies will have to move their attention to the development and manufacturing operations in a bid to cut time to market and gain a greater slice of the revenue pie.'

For companies hoping to prosper in this brave new world of pharmaceuticals, SI offers a lifeline. ▲

For more information, please contact Harry Clark, MD of SI Associates, on 0141 332 5825, or email harry_clark@si.associates.co.uk. SI's website can be found at: www.si.associates.co.uk.