

SCRIP

A woman with short, light-colored hair is shown in profile, looking out a window with horizontal blinds. She is wearing a dark jacket and holding a clipboard with papers. The scene is brightly lit, suggesting an office or laboratory environment. A potted plant with white flowers is visible in the lower-left foreground.

SUPPLEMENT SEPTEMBER 2008

Your Career in Pharma

INSIDE

The choosy candidate

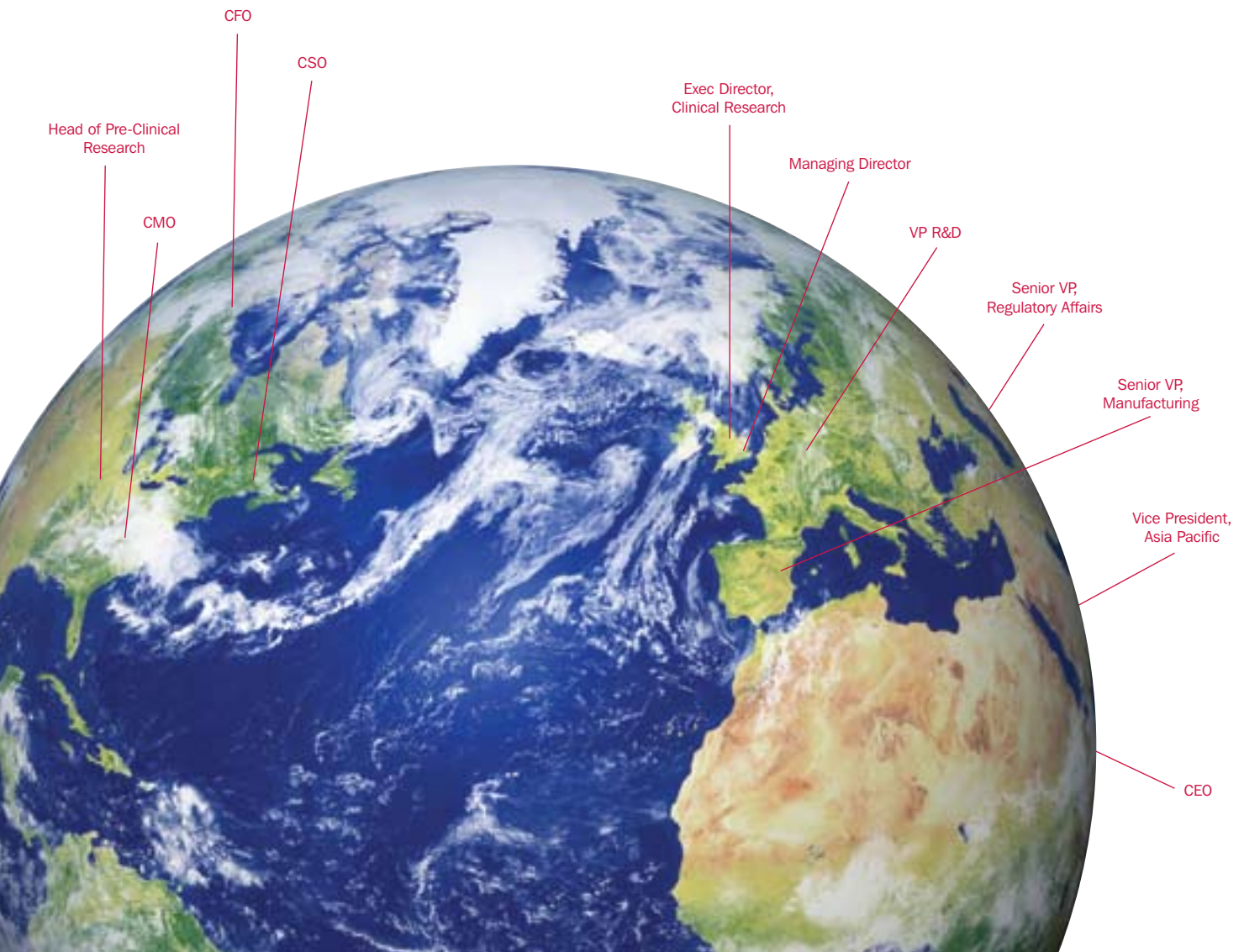
Can translational medicine deliver?

MHRA in the frame

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SCRIP'S YOUR CAREER IN PHARMA

A SUPPLEMENT TO SCRIP WORLD PHARMACEUTICAL NEWS

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New world rules: marrying opportunity with preparedness

It is widely acknowledged that pharma faces a list of challenges as long as your arm, but how should the industry's future leaders respond? Use the increasingly complex landscape to look for opportunities, says **Nick Stephens**

Careers in the pharmaceutical industry are no longer what they used to be. Times have changed and so too have recruitment patterns and career paths. So why is this?

The industry has faced considerable challenges over the past few years, and it has been compelled to adapt. Some of the issues are well known and enduring, for example: patent expiries, pricing pressure, the rising cost of discovery and development, increasingly stringent regulatory hurdles, product withdrawals, generic competition, and the broken link between product sales and sales force spend.

Efficiency and cost-cutting measures have inevitably driven the trend towards consolidation. Cue widespread M&A deals, as well as downsizing, companies shedding surplus capacity, and the trend to outsource wherever possible.

Today, companies and their employees face new challenges created by the emergence of a truly global industry, Asia-Pacific's "mega" markets, the requirements of the global stock market/investor community, and the escalating need for outsourcing. It's my personal view that the cycle time for adapting to change in the industry is shortening as well. This imposes further pressures on us all.

15 years ago, I heard that career development was "a marriage between opportunity and preparedness". This statement came from a wise friend and top executive in a major pharma company. He went on to say that most large companies promised, but crucially could not deliver, opportunity. This is even more evident today.

Opportunities arise from success or failure in the marketplace. The most important opportunities, especially when our industry faces a crisis, arise from the biggest changes. These are the challenges that leaders of the future will need to tackle: how can you best prepare yourself for what lies ahead?

To help you prepare for the "new world", we should examine how we need to address its challenges. How will they affect you and others in our industry? After all, it will still be our task to deliver value to patients, to

healthcare providers and to shareholders.

In 2004-05 we identified a major challenge for industry leaders. The tide of power had surged back towards headquarters, particularly those in the US. To take a leadership role you had to spend at least a part of your career in that country. This is still true, but the future lies in the world's emerging markets – this is where the global industry will invest.

In my opinion, the people who will add the most value in the future are those who are prepared to make themselves the pioneers of today. They will be pioneers in new markets, pushing back new frontiers. They will pioneer new approaches in, for example, addressing drug discovery and development, as well as customers and patients. So, look for opportunities to learn more about the "new" world. Look for opportunities to change the way your company (or another) does its business. When you spot such opportunities seize them enthusiastically and focus on delivering results.

Many of the new opportunities will come from the emerging Asia-Pacific markets. They are changing the face of our industry. They are changing the way we deal with discovering, developing, selling, marketing and manufacturing medicines. The emerging South American and Eastern European markets are doing the same thing – albeit to a lesser extent.

These markets are challenging and we currently only vaguely understand their rules and pitfalls. On the other hand, the rewards for those who get it right will be huge. Remember too that new competition for jobs will come from those markets. People from those regions will bring attractive experience and attitudes to employers wherever they are. A recent CEO long-list of mine contained candidates from the US, Canada, the UK, Northern Europe and, notably, India, China, Singapore and Australia. That's something you would not have seen a decade ago.

In our own marketplace, returns to shareholders are falling while the perceived risk of failure is rising. For companies of all sizes this means more M&A activity, internal

cost control, outsourcing and downsizing, and in-licensing/partnership activity.

Other industries (for example the automobile, technology and music sectors) have faced similar challenges. To lead in the future you need to learn from their mistakes as well as their successes. You then need to apply them to your own situation. You'll also need finely honed financial, influencing and remote management skills. Most of all, you'll need the ability to hear and understand the needs of others. You may think these are skills all leaders need today and you would be right. At the same time you would be surprised how much you can improve your own skill set. You might then be astonished at the enormous impact that has on your results.

There are other factors too. The outsourcing and generics sectors are growing at around double the rate of the overall industry. We expect that trend to continue and intensify. So, there will be new opportunities in these sectors. They are much less sheltered than the ethical pharmaceutical industry, and cycle times are quicker while profit margins are lower.

To succeed here you'll need to focus on output and what needs to be done. You'll also need to make decisions more quickly and address failure vigorously.

To conclude, a long-term career with a single employer is no longer an option for most (ambitious) employees. What you have is a portfolio of valuable skills – transferable across a range of opportunities in the healthcare sectors. Your strategy should be to hone them so you are prepared to take advantage of every opportunity that occurs.

The old world and its outdated ways of doing business are broken, giving way to the new. Focus on delivering what the patient needs. Know who the customer really is. You will then grow and thrive in the new world.

Good luck! **SCRIP**

Nick Stephens is the CEO of RSA.





WILLIAM BURNS

Cross-functional thinking brings benefits all round

Safety concerns, slowdowns in productivity, P&R pressures, patent expiries. The R&D-based industry today is facing an unprecedented array of challenges. Ian Schofield spoke to **William Burns**, CEO of Roche Pharmaceuticals, about the kinds of people needed to help tackle them

Getting a new drug to market has never been easy. And rightly so: all new medicines should have to clear high regulatory hurdles before they are given to patients in the wider clinical setting.

But over the past few years those hurdles have been getting higher: Regulators are demanding greater evidence of safety and efficacy, which often means more complex clinical trials and longer development times, especially for novel biotech drugs. Post-approval safety programmes are now a routine requirement. And national pricing and reimbursement authorities increasingly want more comparative data on which to base their decisions.

Addressing these challenges will require new approaches, new technologies and new ways of thinking. More and more, it will also require people who can work across different disciplines.

William Burns, CEO of Roche's pharma division, says there is an "enormous need" for people right across the industry, and plenty of opportunities, particularly in cutting-edge sciences such as molecular biology.

A major problem facing companies today is how to maximise a new product's chances of making it through a tougher regulatory system and then onto the market. One way is to ensure that it stands out from the rest. "Differentiation" is the key, says Mr Burns. For Roche, "innovation is the degree of clinical differentiation we bring for the patient".

Differentiation can be achieved by using new technologies such as monoclonal antibodies to target molecules more precisely to their site of action. It can also be done by finding subsets of patients who are more likely to respond to the drug. More companies now are looking to molecular biology techniques to allow them to better predict how new substances will act in the body.

"Scientific knowledge is still going up exponentially," says Mr Burns. "It's a question of having a group of people who can absorb all that and still think outside the box, and

find a new understanding of molecular biology that could be translated into an intervention with the potential for clinical differentiation."

Industry needs "extraordinarily bright people in research", Mr Burns says. This is particularly true in areas such as biomarker development and *in silico* testing, which have received a substantial boost from public-private partnerships such as the Critical Path Initiative in the US and Europe's Innovative Medicines Initiative.

These initiatives, says Mr Burns, are a positive step towards enhancing relations between academia and industry, particularly in Europe where, unlike in the US, such links have often been viewed with scepticism.

The IMI has opened up "a whole burgeoning area... different skills, enhanced skills, new opportunities for graduates, for people coming into industry," Mr Burns says. Moreover, some of those people are coming from "a more unusual angle, for example a combination of medicine and informatics, or biostatisticians with a medical rather than a scientific background".

Having multidisciplinary skills can be a valuable asset. "There is an increasing number of cross-functional jobs in our industry," says Mr Burns. "If you want to be the life cycle leader for one of Roche's products, you could come with a commercial or development background, or a research background. What we need are good people with leadership qualities who can work cross-functionally and who are able to influence an organisation. They may be business people but they should have no fear of science, they may be scientists but be able to work in the commercial arena."

Once a new product has been approved, it faces the next big hurdle: pricing and reimbursement. As health authorities seek more cost-benefit data, health technology assessments are becoming more widespread, and this is another area where knowledge of more than one discipline can bring dividends.

When NICE was created in the UK in 1999, Roche set up a special in-house group to deal with it. Some of the people who

joined this group came out of the National Health Service, with very different skills and disciplines from those Roche had had in the past. In this area, "it's not just a matter of being a pure economist", according to Mr Burns, "but of understanding the cost of illness and how you understand the intricacies of patient care within a healthcare system".

Being able to work in a team is another valuable asset. In drug development, for instance, clinical trials are increasingly being conducted in emerging markets such as India, China and Latin America, and this requires the ability to work as a team on a global basis. "That team work can increasingly be across national boundaries, so you need people who are prepared to deal with the Far East in the morning and California in the evening. There are no longer small national teams working in a corner."

Some areas require another skill set altogether. In sales and marketing, for example, a delicate balance needs to be struck between overselling and underselling a product. "We generate a huge amount of data to satisfy the regulatory authorities, and then we ask the sales and marketing organisation to translate that into a rather short interaction with the customer," Mr Burns observes. Sales people "must do full justice to both the benefits and the risks of the molecule, because that is where their credibility will come from".

So for people with the right qualifications and experience, there are clearly many openings into the industry, and across a whole range of functions. Are there any sectors where Roche itself expects to either increase or reduce staff levels in the near future? Mr Burns is reluctant to say. "It's not really a numbers game. I'd rather not somehow predict that here is an area that's growing and here's one in decline. I think there is still an enormous need across the industry." **SCRIP**

Ian Schofield is a principal analyst for Informa Pharma.



DR JACQUI GATEHOUSE

Small sponsors, big voices?

Scrip asked **Dr Jacqui Gatehouse**, director of outsourcing and contract management at biotech Genmab, to give some insight into her experience of the smaller company/CRO relationship – in particular that between the people involved

Pharma and biotech's growing reliance on CROs is well documented and much discussed. While there is convincing evidence that CROs provide a high quality, speedy service to sponsors, some have criticised the companies' procedures as well as the motivations and skills of their staff. Furthermore, smaller companies in particular are concerned that they may not get the best from the multinational CROs that dominate the industry; that big pharma's dollar is more attractive than their own.

Q. Is industry's increased reliance on CROs a good thing?

I don't think it's either good or bad: it's just different. What we are seeing is the evolution of drug development companies into specialised firms that focus on their core competencies. And for pharma and biotech, the core competencies are science and development. This leaves service and operational tasks, and these are the core competencies of other companies: CROs. Increasingly, many pharma companies and biotech don't want to pay to run what they see as "basic" tasks in-house.

And I doubt this is a short-term trend. Most successful companies focus on the areas where they have the most expertise. They say: "We don't want to be able to do everything. We'll do the bits that are valuable and farm out the rest."

Q. Are smaller companies more reliant on CROs than is big pharma? If so, does this have an impact on the smaller sponsor/CRO dynamic?

Many big pharma companies are just as reliant on CROs as are smaller pharma and biotech firms, if not more so when you consider the size of some of the deals CROs sign with big pharma.

However, it is easy to think that small sponsors don't even have the option to run studies in-house, which could potentially leave them "over a barrel" in their relationship with a CRO. But although they may not be able to take a study back from a

CRO and run it internally, they can move to another CRO.

The difficulty that does exist with small company/CRO relationships is that you don't often have the depth of experience in a small firm to manage your CROs. If you work in a company that has no data management department, meaning that you have to outsource all of that function, and you don't have anyone in your company who knows about data management and who can set specifications for the services you require, then you have a problem. And this problem tends to hit smaller companies harder than larger ones as big firms have more employees and a more diverse set of skills at their disposal.

Many big pharma companies are just as reliant on CROs as are smaller pharma and biotech firms, if not more so when you consider the size of some of the deals being signed

Q. So are we going to see more jobs created similar to your own, in which people are employed specifically to manage CRO relationships?

I think that is certainly happening more and more. At the recent PCMG [Pharmaceutical Contract Management Group] conference, which took place in Prague in June, the thing that came up time and time again was relationships, relationships, relationships! This signifies recognition of the fact that managing CRO relationships is a job and skill in itself. Indeed, contract and outsourcing managers are seeing their roles develop into that of a "relationship manager". We manage relationships directly and advise operational teams on how to work successfully with their CRO contacts.

Q. How many such people are there in Genmab?

This time last year, we had one – me! Now we're a team of four [as of June 1st] and I see that growth continuing because Genmab

has really seen the value of this role to the organisation.

Q. Does it make sense for a small sponsor company to use a small CRO rather than a multinational organisation? Does the management of a big CRO value their business as much as it values big pharma's?

There is often a reticence on the part of small companies to employ a big CRO because, when it comes down to it, we are talking about business, and money talks. So, a big CRO is going to care more about big customers, with big pipelines and multiple studies. When a small sponsor says: "We don't want to work with the big CROs; they don't care about us," you have to answer: "Well, why should they?"

And this is where it gets difficult for small companies. A small firm doesn't necessarily mean a small study. For a small company like Genmab that wants to take drugs through to registration, you might need the expertise of a large CRO: its geographical reach, its therapeutic experience. As a small sponsor, you can shoot yourself in the foot by using a small CRO that isn't fit for purpose because it could end up subcontracting your project, which isn't what you want.

But there are things you can do. I think that small sponsors need to sell themselves to the CRO. You need to explain what you are driving for, to make them interested, to make them realise your potential, to make you a company that the CRO wants to work with. This is especially true in the current market where it feels like the big CROs can go out and get new business tomorrow.

Q. Will you get the best CRO staff on your project if you're a smaller company?

Regardless of the type of sponsor company, you have to realise that you need to motivate your CRO's staff. You have to take your vision, take the value that the study has, and impart that to the people involved. They need to feel committed to a worthwhile cause. At Genmab, we focus on oncology, and on unmet medical need, so we are developing drugs to give hope to patients with no hope left. And we don't have

anything on the market right now. So, our current studies are important for so many reasons, and we have really had to impress this on our CRO partners. Furthermore, we have to show our appreciation of what they do.

Q. Have you been successful at this?

I've only been with Genmab for 15 months or so. But looking back, Genmab has not been good at this. We have been particularly poor at transferring our vision for a study, at reinforcing its importance. But we're definitely changing now!

Q. Are CRO employees in general as skilled and experienced as in-house researchers?

I know certain companies that say: "We will always do a better job ourselves than would a CRO", but if you look at what they do, you have to ask: "Are you sure?"

I think there are excellent people on both sides. It can be difficult to work on the CRO side though; not all people are built to be there. You have to be very service-minded. It's very different from being on the sponsor side.

In addition, the CRO industry is growing

incredibly fast. These companies need to get new staff from somewhere. But then sponsors can criticise them, saying: "That person has only just joined your company. They don't have enough experience."

Because sponsors are paying, we expect to have the best people, but we have to accept that CROs have to develop their staff. This in turn will generate skills and growth for the whole industry.

We have been particularly poor at transferring our vision for a study, at reinforcing its importance – but we're definitely changing now!

Q. So, the need for more CRO staff is being driven by pharma's reliance on CROs, therefore sponsors should take some responsibility for any skills gap that might exist?

Exactly!

Q. With all this in mind, what do you think is the key to a successful CRO/sponsor relationship?

Whatever your size, make sure you choose the right type of CRO for you at the start. Before you even submit your Request For Proposals, determine what you need. Do you need a big CRO with a huge reach that will take your study, run it and hand the data back to you at the end? Or, should your CRO be an extension of yourself; one that becomes part of your team?

I think that many companies just throw out their RFPs, saying it's this many sites, this many patients, in these countries; tell us what it will cost. They don't think about the concept behind their outsourcing decision. Find a CRO whose people understand what your people are trying to do. The chemistry has to be right.

Don't forget that no CRO is going to tell you that they are the wrong fit for you. They will find a way to take your business! If a sponsor says: "Can you do this?" they will invariably say: "Yes!" **SCRIP**

Dr Jacqui Gatehouse is director of outsourcing and contract management at Genmab.

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Double-digit growth and solid career opportunities

While clinical research professionals once had a clear choice between large pharma and small biotech career paths, the evolving nature of the industry overall is creating robust opportunities in the clinical outsourcing sector for recruits of all levels, says **Laura Thomas**

The pharmaceutical industry is at a pivotal stage in its evolution. A decline in R&D productivity is central to all of its other problems, including rising sales and marketing costs, poor financial performance and a battered reputation. In 2006, North American spending on biopharmaceutical R&D reached a record \$55.2 billion. In the same year, the US FDA approved only 22 new molecular entities and biologicals – significantly less than the 53 it approved in 1996 when R&D expenditure was half the sum it is now.

If the industry is going to survive, changes will need to be made to the traditional business model. The pharmaceutical industry needs to move away from a reliance on “blockbusters” and focus on the development of products for more “niche” markets. The necessity to strengthen pipelines is well documented, as is the need to reduce fixed costs by introducing a more flexible way of working. To achieve these goals, both large and small companies are re-focusing their in-house efforts on basic R&D and innovation, and they are increasingly outsourcing many of the more operational aspects of drug development, including clinical research.

The greater reliance on the outsourcing model has sparked a major growth in the number of CROs offering clinical development services. The global CRO market is valued at \$16.3 billion and is expected to grow at an annual rate of 12.6% to reach \$29.4 billion by 2011, according to data from Goldman Sachs. Demand for CRO services is coming from both large and small companies. Furthermore,

as pharmaceutical and biotech companies become more reliant on CROs for their drug development activities, the nature of the relationship between the company and the service provider is likely to evolve. For instance, we are likely to see a move away from simple transactional arrangements to more strategic partnerships.

For CROs to be able to meet the growing requirements of their clients, they have an almost constant need to bring in new staff – from fresh graduates all the way up to senior level executives. Thus, since 2004, the six largest CROs have increased headcount by 57% to 37,300 employees and these major players are making strategic investments to expand globally as well as to augment their clinical capabilities with preclinical and early-phase development services.

The massive growth of this sector has had a significant effect on career development opportunities for clinical research professionals, all the way from entry level CRA up to Senior VP. CROs offer clinical research staff a fantastic breadth of experience – the opportunity to gain experience across a wide range of therapy areas and exposure to a vast variety of product types. By working with many sponsor companies, the clinical research professional also gains a good insight into different product development strategies to achieve registration.

Sponsor companies want to place their business with CROs which not only demonstrate a successful track record, but provide a high-quality, flexible service. Key to

the success of any sponsor/CRO relationship is the calibre of staff the CRO is able to bring to the project team. Experience in the appropriate phase of clinical development, therapeutic area and geographical regions are all important, but in an era where relationships between sponsors and CROs are evolving, this is not always enough.

Our CRO clients are demanding candidates who can bring a wide range of skills above and beyond simple operational experience. Good customer service, an ability to build relationships and a flexible mindset are all critical attributes. Candidates who have previously occupied senior level positions on the client side are particularly attractive to CROs as they bring experience, credibility and a great insight into the expectations of the sponsor company.

To conclude, while there was once a clear choice for most clinical research professionals between large pharmaceutical companies and small biotechnology organisations, the CRO sector now represents a real alternative. A career in a CRO was historically regarded as “second tier” but as this sector continues to grow, it offers exciting career development opportunities for clinical development professionals at all levels. **SCRIP**

Laura Thomas is Director of Executive Search for RSA Singapore.



Safeguarding public health

Medicines and Healthcare products Regulatory Agency (MHRA)

The MHRA logo is a dark blue oval with the letters 'MHRA' in white, bold, sans-serif font.

The MHRA is the UK government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.

No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and we take any necessary action to protect the public promptly if there is a problem. We aim to make as much information as possible publicly available.

We enable greater access to products, and the timely introduction of innovative treatments and technologies that benefit patients and the public.

We encourage everyone – the public and healthcare professionals as well as the industry – to tell us about any problems with a medicine or medical device, so that we can investigate and take any necessary action.

Look out for the MHRA at the following events:

October 12th-13th: Pharmacy Show, Birmingham, www.thepharmacyshow.co.uk

November 11th-12th: GMP & GDP Symposium – Best Practice for QPs and RPs, Crowne Plaza Hotel, Liverpool, www.mhra.gov.uk/conferences

November 14th: Seventh National Liaison Officer Conference, Manchester Conference Centre, www.mhra.gov.uk/conferences

November 26th-27th: PharMIG Annual Conference, Nottingham, www.pharmig.org.uk/pages/meetings

Employment Opportunities

As the regulator of all UK medicines and healthcare products and a key player in EU regulation, we offer an exciting opportunity for you to work at the leading edge of regulatory decision-making in Europe.

All our assessors and inspectors are mentored through a training programme, so prior experience of assessment or inspection is not a necessity, but we do need people who are passionate about their area of expertise and would like to apply their knowledge to the task of protecting the public.

As part of the Department of Health, the MHRA offers an attractive benefits package including a Civil Service Pension and 30 days holiday PLUS 10.5 privilege days/bank holidays per year. The MHRA also recognises that personal development and work/life balance are key to maintaining a happy workforce.

We have up-coming recruitment campaigns in the following areas:

Medical Assessors

We employ a number of qualified and experienced medics from NHS and pharmaceutical industry backgrounds to carry out the assessments of medicines for UK and EU markets. As the number of drug licensing applications grows, we are keen to expand our recruitment in this area.

Pharmaceutical Assessors

At the MHRA we have a range of pharmacists from different backgrounds, such as the pharmaceutical industry and community pharmacists, assessing products ranging from parallel imports to chemical products. Entry level pharmacists are also considered in some areas.

Scientific Assessors

From entry level to experienced scientists we look for people with scientific degrees and relevant experience. Statisticians and scientists who specialise in specific fields are a key part of the Agency's workforce.

Inspectors

The MHRA has inspectors working across the UK and overseas to ensure safe practice through compliance to legislation and guidelines. From a pharmaceutical industry background, inspectors will have GMP/GDP/GCP/Pharmacovigilance/GLP experience in a regulated environment.

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PROF KENT WOODS

Strength through diversity

Professor Kent Woods talks to Scrip about the diverse MHRA workforce, recent challenges and his thoughts for the years ahead

Q. Can you outline the role of the MHRA?

The MHRA was formed in April 2003 from the merger of the former Medicines Control Agency and the Medical Devices Agency. Today, the Agency is responsible for the regulation of medicines, medical devices, blood and blood products, clinical trials and a number of other related areas, within the UK. The MHRA is an executive agency accountable to the Department of Health. Because we oversee the safety, efficacy and quality of medicines and medical products, everything we do is very much part of the national public health infrastructure.

Q. Tell me about your experience before you joined the MHRA.

I'm a cardiovascular physician by background; I spent 20 years as a consultant in a coronary care unit and teaching clinical pharmacology. When I came to the MHRA regulation was a relatively new field for me. I'd done some work in pharmacovigilance, but I was new to the senior civil service. That was helpful in many ways because it gave me the opportunity to look afresh at the role of the Agency.

Q. What types of people work for the MHRA?

We currently have around 900 staff representing a great variety of disciplines. For example, we have hundreds of scientists of various kinds, pharmacists and medical staff. We also have IT and legal staff as well as specialists in finance, HR and communications. In addition, our team of policy specialists is heavily involved in the development of future UK and European regulation.

Q. What is the upside to having such a diverse staff?

Diversity is our strength. If we're faced with a new task we can draw on this broad range of experience. It's surprising how often someone

within our organisation has very detailed past experience of a challenge we're facing today.

Q. What attracts people who already have successful careers elsewhere to come and join the MHRA?

The work is very varied and issues are constantly arising completely afresh. You never know quite what your week is going to hold. Also it's clear that the work is of high public health importance. People can see the relevance the work has to clinical practice and to public health, and that stimulates them.

Q. What has been the most demanding issue you have had to deal with at the MHRA?

The most recent was the TGN1412 incident of 2006. That was challenging because it was necessary to find the right balance between over-regulating clinical trials, and therefore impeding medicines development, and being too arms-length in relation to patient protection and patient safety, and running the risk of serious incidents recurring. The message to get out to the public was that all clinical research will carry with it some component of risk; there is no way you can absolutely remove every element of risk, particularly when you're talking about first-in-man trials. Despite that, the safety record of clinical trials is excellent.

Q. Looking ahead, what do you think are going to be the major developments within the MHRA?

We must be able to respond to new science so that as new technology comes over the horizon and becomes ready for clinical application, our system can come up with a sensible, balanced regulatory structure to deal with it. We need people who understand the science and the technology, and who can make informed judgements about how they should be assessed.

Another challenge is our working relationship with European member states. We need to work well with the European network, to be efficient and to make sure that we deliver the best value for public health. It's a big

complex network with 27 member states and we need to ensure that we're not duplicating things, and that we're using our collective resource in ways that deliver.

Q. What are the benefits of working within the civil service infrastructure?

MHRA staff are all civil servants – I think public accountability is a very proper government structure for medicines and medical devices regulation. Another considerable advantage is that we have no vested interest other than the protection of public health. We can make informed judgements based entirely on what is going to deliver the best outcome for public health.

We are not concerned with the affordability of treatments, their relative cost-effectiveness or the competitive issues in industry.

Q. How would you describe the Agency's work ethic?

Our people have a shared enthusiasm for what they're doing, and there is a strong tradition of teamwork. The MHRA environment specifically encourages people to work together on shared problems. More and more of our work is done in a cross-agency way; that is to say we're drawing skills from wherever they may be in the organisation appropriate to a particular task.

Q. Where do people who leave the Agency go on to next?

People may choose to go to other areas of central government, industry or academia. We have a healthy turnover that enables us to maintain continuity but at the same time bring in fresh skills.

Q. If you had to summarise why the Agency is a great place to work, what would you say?

The work is important and it is intellectually challenging. Those two things together are hard to beat. **SCRIP**

Professor Kent Woods is CEO of the MHRA.

When an inspector calls

The working life of the MHRA inspector includes lots of international travel, good career prospects and a real opportunity to assure the quality of medicines,

Mark Birse tells Pete Chan



MARK BIRSE

Mark Birse used to work for GlaxoSmithKline, auditing companies and suppliers, so his move into the MHRA's Inspectorate was a natural career progression. Becoming a regulator has changed his relationship with industry: "It's not like a conventional business relationship; we're inspecting companies against regulatory standards. If they fall short, we have to ask what they are going to do to resolve the issue, and if necessary take action to ensure compliance," explains Mr Birse, currently Operations Manager GMP and Senior GMP Inspector.

Inspecting pharmaceutical manufacturers is a legal requirement of the Agency. However, since 2005 the UK government has been seeking to reduce the regulatory burden across multiple industries, not just pharmaceuticals, through the implementation of the "Hampton principles". These principles aim to create a "risk-based approach to regulation", so that resources are focused where they are most needed. As then Chancellor Gordon Brown commented, this approach should result in "only a fraction of forms, a fraction of information requirements and a fraction of inspections needed".

The MHRA has consulted with industry to get feedback on its proposed risk-based inspection approaches, and the Agency is currently looking at how to take them forward. Under the new model, risk will determine how often inspectors visit sites, as well as when they visit, how long they spend there.

This is good news not just for the inspected, but also for the inspectors themselves, given the wide scope of the work involved. Mr Birse is one of over 60 MHRA inspectors (collectively known as the GXP Inspectorate) working not just in the UK, but also carrying out inspections at companies in other countries. Last year, overseas inspections were performed in Bangladesh, Brazil, China, Colombia, Japan, India, Indonesia, Thailand, Mexico and the US.

Currently, there are seven teams of inspectors based at the London head office at Market Towers, as well as at offices in Welwyn Garden City and York. Three teams focus on Good Manufacturing Practice

(GMP), and the other four individually focus on Good Distribution Practice (GDP), Good Pharmacovigilance Practice (GPvP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP).

The remit of the GMP Inspectorate is broad and includes inspections of manufacturers of sterile and non-sterile dosage forms, and active pharmaceutical ingredients, through to companies producing investigational medicinal products for clinical trials, biological and blood products, and vaccines.

New developments, current hot topics and trends are fed back to industry through symposia. For example, the GMP and GDP teams are currently busy preparing for one such event taking place in Liverpool this November on 'Best Practice for Pharmaceutical Industry QPs (Qualified Persons) and RPs (Responsible Persons)'.

Mr Birse estimates that the GMP inspectors spend over 80 days per year on site, of which around eight weeks are spent overseas. In planning the workload of GMP inspectors, work/life balance considerations need to be made. "Inspectors are given a lot of freedom to arrange their own inspection schedules, so people travel in the UK or abroad when it's most convenient."

Those that become inspectors will have gone through an incredibly rigorous selection process. For the past seven years, inspectors have been recruited through Assessment Centres, which check the applicants' ability to put specific competencies into practice. Some of the tests utilised include psychometric profiling, numerical and critical reasoning challenges, motivation questionnaires, practical exercises and technical interviews. "Some people may be very good technically, but they might not be the right person for the job, or indeed the job may not be right for them. We take recruitment into the Inspectorate very seriously," says Mr Birse.

Inspectors are recruited from a variety of backgrounds. A typical applicant would be a science graduate with management or strong technical experience in the pharmaceutical industry, "so they've taken responsibility for quality within an organisation," says Mr Birse.

Mr Birse recalls his own career path, prior to joining the Agency six years ago. While at GlaxoSmithKline, he studied part-time for a Masters degree, trained to be a QP, worked in an audit group and ensured he had experience of clinical trials. "All that was about making sure I was marketable, so I would be in a position to apply for a job such as this." He may not be unusual in this respect. "We've had people in the past who have known even before a job in the Inspectorate was advertised that this was what they wanted to do."

As for the attraction of joining the Inspectorate from an industry background, Mr Birse offers: "You're closer to the patient; your decisions impact more directly on the safety of medicines." Some of his colleagues previously had senior management positions within industry, with significantly higher salaries. "But they are at a stage in their career when they want something else. They want to do something that can make a real difference."

Over time, an inspector can expect to work their way up to Senior and Expert Inspector grades and, even for the most experienced staff, there is always scope for learning. Every type of activity covered by GMP has a different set of sign-off criteria, so even someone with over 20 years' service would not be qualified in every area of inspection, explains Mr Birse.

For such an internationally-focused group, it is fitting that the Inspectorate has very close ties with organisations worldwide. For instance, it is represented at EMEA meetings and the Pharmaceutical Inspection Co-operation Scheme (PIC/S), and carries out inspections on behalf of the EMEA, EDQM and WHO.

Mr Birse himself has recently been on a week-long inspection tour of Mexico and the US. "You get to see the world," comments Mr Birse, "...or at least the world's airports!" **SCRIP**

Mark Birse is Operations Manager GMP/Senior GMP Inspector at the MHRA. He is based at, and manages, the Welwyn Garden City Office.



DR DANIEL O'CONNOR

The front line of drug assessment

Medical assessor **Dr Daniel O'Connor** tells Pete Chan about the attractions of working at the cutting edge of drug discovery

For a medical assessor in the MHRA's Licensing division, there is no such thing as a typical working day. But two years into the job, Dr Daniel O'Connor can pull a few common features out of the numerous responsibilities his role entails. He spends a significant amount of time in meetings with pharma companies – typically those that have submitted a dossier for a clinical trial, and are looking for comments on the study design, the end-points, or the UK regulator's opinion as to whether a comparator arm reflects current clinical practice.

At these meetings, applicants receive scientific input from a small team of MHRA specialists, generally a clinician, a pharmacist, a statistician, a toxicologist and a unit manager, each offering their own expertise and the ability to view the application from a unique perspective. The team works in groups called "PLATs" or product lifecycle assessment teams. There are six speciality-driven PLATs in total; Dr O'Connor's group is focused on oncology and musculoskeletal (the former being his own area of expertise), but there are also equivalent teams devoted to cardiovascular disease/diabetes, respiratory/ENT/endocrinology/dermatology, CNS/anaesthetics, GI & nutrition/blood, anti-infectives/obs & gynae/GU tract, Clinical Trials and Biologicals/Biotechnology.

Company meetings involve constructive dialogue, says Dr O'Connor: Regulation does, of course, place a financial demand on industry, but "if a company has made the effort to come and see us, they're clearly keen to understand our perspective and seek advice in order to avoid unnecessary or inappropriate work".

When he's not in face-to-face meetings with companies, Dr O'Connor can also be found assessing the clinical details of new drug applications, and that could mean anything from a generic product to a new indication for an established drug or a product containing an entirely new active substance (NAS), possibly first in its class.

"Diverse" is a good description of the

typical PLAT team. While Dr O'Connor's clinical background was in histopathology, some of his colleagues had already enjoyed successful careers in the pharmaceutical industry or as hospital doctors in a variety of specialities. "Everyone is quite different in terms of the stage of their clinical career when they come to the MHRA," he explains. "Some come 3-4 years after qualifying, whereas some have worked as consultants on hospital wards for many years. Others have reached senior positions in the pharmaceutical industry and now need a different challenge. Everyone brings something slightly different."

Regardless of background, medical assessors have a few things in common. One is the analytical ability needed "to look at complex clinical data and form a risk/

Some people will have come from industry, some will have joined from wards, and assessing is a skill to be learnt over a period of time

benefit decision as to whether a particular product is going to be approvable," says Dr O'Connor. Assessors also have to be "exceptionally organised", he continues. "The volume of emails can be significant. We have a lot of European procedures on the go – there are many timetables to keep track of, data coming in and data having to go out."

Despite this challenging workload, a good work/life balance is important to the Agency and its assessors. And Dr O'Connor is clear about the parts of the job he enjoys the most. He finds it stimulating to work at the "cutting edge of drug discovery". He also enjoys the freedom of making decisions based on evidence, without having to worry about any of the "commercial pressures" that exist in industry. In addition, he likes the responsibility of making licensing decisions that determine the availability or otherwise of a drug in the UK, or indeed Europe as a whole. But working in Europe can also be a challenge, says Dr O'Connor. "There are 27

member states, and every clinician has an opinion. Somehow you have to reach agreement."

On his first day at the Agency, Dr O'Connor was assigned an experienced mentor. "Some people will have come from industry, some will have joined from wards, and assessing is a skill to be learnt over a period of time," he says. "So, whatever your background, mentoring provides essential support in the first year or so."

In the case of medical assessors, mentors are there, among other things, to offer advice on how dossiers should be assessed, guidelines to be used, and the type of data needed to make risk/benefit decisions. Dr O'Connor was mentored for a year, and he is keen to take on similar responsibilities himself. In fact, at present he is mentoring a visiting doctor from Spain. "It's a really rewarding part of the job," he says.

professional development

At the MHRA, learning doesn't just take place on the job; the Agency is also a keen proponent of the continuous professional development of its staff that takes place outside its walls. Dr O'Connor takes advantage of a day release from his assessor responsibilities to study part-time for an MSc in oncology. "Things move so quickly in the industry that you need to maintain your skills as much as possible. We're very much encouraged to keep up to date, so we're using the best of our abilities."

Dr O'Connor hopes to build up his experience and progress within the Agency's well defined career structure. For him, the next rung on the ladder will be the position of senior assessor, for which he will have to demonstrate a specialist level of knowledge and contribute to regulatory guidelines.

Dr O'Connor sums up the job as "combining the best of science and clinical medicine, but in an academic framework. If you're interested in science and medicine and want to see them being used in a practical sense, looking at the end of drug discovery is a really interesting way of doing that". **SCRIP**

Dr Daniel O'Connor is a medical assessor in the MHRA's Licensing division.

The problem with big pharma

Madeleine Armstrong interviewed **Chris Molloy**, vice-president of corporate development for ID Business Solutions, and **Adrian Hardy**, group director of strategic development at Huntingdon Life Sciences, on the advantages of larger and smaller players, and the issues impacting the people who work for them



CHRIS MOLLOY



ADRIAN HARDY

Q. With the “blockbuster” era seemingly over and big pharma companies raiding biotech firms to bolster their pipelines, it looks like the pharmaceutical giants could have a few things to learn from their smaller counterparts. So, what is the problem with big pharma?

Chris Molloy: One of the issues that big pharma has had over the past 5-10 years is its sheer size. Companies have become bigger and have had to focus on process, in other words, managing people across the world and trying to make sure that things are done in a uniform manner. But this activity is very difficult to square with a discovery organisation whose goals are often based on innovation and risk-taking. Process, on the other hand, is ultimately about risk management.

The consequence of this can be a reduced attitude to risk. Because discovery is all about taking risks, these two drivers may often work in opposition to one another, leading to the inability to innovate at many levels.

One of the issues facing big pharma now is rapidly learning how to remain innovative, flexible and agile within a process-dependent organisation with its key goals of efficiency and low unit cost.

Adrian Hardy: Big pharma has many problems at the moment! For many years the pharma industry has seen success primarily through the blockbuster model, which recently has certainly not been paying dividends. Industry has struggled to find new blockbusters and, as the patent cliff gets closer, big pharma is looking at significant holes in its revenue stream.

Big pharmaceutical firms are also seeing R&D costs going up, an increase in compliance issues, and increased regulatory scrutiny post-Vioxx. There are also a lot of pricing and reimbursement pressures in most of the key western markets.

And of course they've got very large fixed-cost infrastructures which they are perhaps not making efficient use of. So a lot of big pharma right now is looking at how to reduce these costs.

Q. How do small companies manage to avoid these problems?

CM: Smaller companies have the advantage of focus, which I would say is biotech's watchword. This focus seems to breed the innovation that has unfortunately, to an extent, been reduced in big pharma. A smaller firm can remain extremely committed to a relatively narrow spectrum of activities compared with large pharma, which is active across many therapeutic areas.

Large pharma is now experimenting with “biotech-like” centres within their organisations. While this is a creditable idea, the gravity of the larger organisation and the desire for cultural uniformity often restricts the actual flexibility of these smaller centres. The “arm's length” ownership by pharma of small biotechs, separately and independently managed, may at one level incur some duplication of effort, but in many cases win hands down in terms of innovation and focus.

AH: Smaller companies don't build big fixed-cost asset infrastructure. Obviously, some of the biotechs do get into manufacturing so they can do their own production. But generally they tend to virtualise the R&D process, and make much greater use of outsourcing.

As larger companies start to downsize more, this might be a model for the future – virtualising more and not having all these very expensive R&D assets in house. This is a complete paradigm shift from where big pharma started.

Also, the larger the company, the further the distance between the decision-makers and their understanding of what's happening on the shop floor. So it often makes larger firms less flexible and less responsive.

Q. Is the greater flexibility of smaller companies advantageous when it comes to progressing compounds from preclinical into clinical trials?

CM: There is a different attitude to risk at an early stage at small companies. They are often more inclined to try different approaches at an early stage than a large firm might be.

Criteria for moving compounds from

preclinical into clinical may differ in large and small organisations. The energy required to push forward a partially validated target in large pharma is far greater than that needed in a small company. That doesn't mean that small players are progressing unsafe candidates into clinical trials inappropriately – that is certainly not the case. However, venture-backed firms do have a different attitude to commercial risk – and particularly that first-in-man risk – than larger companies perhaps do.

There are examples of biotech companies that have persisted with, and successfully commercialised, compounds that big pharmaceutical firms have at one time rejected.

However, it is difficult to compare which type of organisation is more effective in this area. They operate on completely different scales. For example, for a smaller firm to have a 30% success rate, they could have progressed just a couple of compounds from a focused portfolio, but with the number of drug discovery programmes a big pharma company typically has, it couldn't possibly move 30% into the clinic!

AH: In response to your question, I would say traditionally no, because one of the critical elements at this stage is a very strong understanding of the regulatory requirements to move you from bench to clinic. Certainly one of the things we've seen most often with biotech and smaller companies is that this is the stage where they get stuck.

Q. How do the working environments in smaller and larger firms compare?

CM: I have experience of both: I spent 14 years with GlaxoSmithKline, and four years at MerLion.

Working for a small company, one can feel one's impact much more closely. Responsibility and accountability are much more easily measured, although of course these are present in big pharma too. Everybody's impact is much more noticeable; one's responsibilities are perhaps broader and more horizontal than you would see in a larger firm. But the benefits of seeing a positive impact of what you do also come with the responsibility to make sure that impact is positive. The flexibility and agility of a small company is another attraction.

Having said that, working for a multinational pharma company remains an exciting, challenging, interesting and intricate job. There is such a broad scope within large pharma, and the resources available are enormous in comparison. For any industrial scientist, to work within a large pharma company is an education, a great experience... in terms of understanding drug discovery and development, there's nowhere better:

AH: Biotech is a hugely exciting environment but you're often standing on quicksand; I think the average biotech has about two years of cash left, if it's lucky. So, there's the excitement and usually the high level of remuneration that goes with that. But it's quite a stressful

environment, because you don't know if you'll have a job in two years, or even six months.

In a very large company, you can be pigeon-holed, and only see your part of the business, whereas in a medium-sized organisation, you get the chance to understand what's happening in the company as a whole. Increasingly, this middle ground is more stable than a large company.

Q. Do smaller companies have problems retaining the best people, who may prefer the more obvious attractions of working for one of the bigger firms?

CM: Smaller companies do continue to attract quality people who wish, and are able to, make an impact – and they do retain these people.

These companies have been able to sustain a strong belief in their organisation. In an area like drug discovery, where you spend most of your time failing, having a strong belief in what you're doing is a vital way to motivate people, and to retain them. I think small organisations are increasingly able to do that more effectively than large multinationals.

People know that the success or failure of their technology or compounds has a very,

very big, and immediate, impact on everybody within the company. Everyone feels very strongly about their handful of compounds or discovery programmes – these are the lifeblood of the company, and everyone in it.

In larger firms there can be quite a degree of separation between the preclinical segment and the goal of the organisation, to commercialise medicines. This can affect the workforce's belief in an organisation.

AH: I think that very much was the case, and I think it's very much changing. We're seeing more and more people draining the other way, out of big pharma and into companies like ours; both for stability and the variety that's on offer. And I think as CROs have grown up and matured over time, they've become a far more attractive place for people to build a career.

I think the single most important factor in the CRO industry, and probably the pharma industry at large, is the ability to attract, retain and train the right people. It's absolutely critical. **SCRIP**

Madeleine Armstrong is senior science reporter for Clinica, a sister publication to Scrip.



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Stand firm against the perfect storm

Dr Renu Vijh and **Dr Kay Wardle** explain how pharma's numerous challenges, alongside the rise of CROs, are triggering important shifts in industry mindsets

The worldwide demand for medicines has appreciably increased over the past few decades. Significant levels of centralised investment from the pharmaceutical industry has delivered major blockbuster products that have resulted in much improved levels of healthcare and good profit margins within the sector. However, this business model is now looking stagnant when viewed in the context of the global commercial climate of rising costs and decreasing returns.

Streamlining operations to reduce the costs and time-to market of a drug is becoming the main focus for the industry. The pressures facing pharmaceutical companies have never been greater: the number of patent expirations (and increased generic competition), the need to eliminate drug candidates at an earlier and less costly stage of drug development, the move away from the traditional blockbuster model, increasing regulatory constraints, rising R&D costs and a lack of blockbuster drugs are all having a profound effect on the industry's shape and future direction.

The successful transition of a drug candidate from the preclinical setting to the clinic is particularly challenging and costly, with up to 90% of all promising candidates failing at the development stage. These harsh economic conditions are forcing companies to implement cost reduction strategies such as "fail early, fail cheaply". Therefore companies are under extreme pressure to improve the preclinical stages of drug development; to eliminate fixed costs and develop a more flexible business model.

This has fuelled the growth and the number of CROs across the world. Pharma company spend on CRO services has shown double-digit growth in recent years, highlighting the importance of this fast-growing market.

The unprecedented growth of the CRO industry is showing no signs of slowing and outsourcing will undoubtedly continue to be the primary mechanism utilised by pharmaceutical companies to sustain their rising global capacity needs and reduce their fixed R&D costs.

As the CRO industry continues to grow at a phenomenal rate, the need for a highly

skilled scientific workforce has also increased to the point where demand exceeds supply. Most companies are facing what can only be described as a "war for talent".

Historically, individuals working within the pharmaceutical sector would rarely consider a move into the service sector. However this trend has changed markedly over recent years and as the marketplace redefines itself, CROs, biotechs and pharma are turning to more strategic partnerships in order to gain a competitive edge. The fact that they are moving away from the historical "master/slave" relationship has captured the interest of individuals who would not have previously considered opportunities outside of mainstream pharma, including senior level staff.

The number of university and college students enrolled in science related subjects is declining, while demand for their skills and knowledge in the pharmaceutical, biotech and CRO research community is increasing

Today, it seems that in the main, senior executives are interested in opportunities that will allow for personal growth and development, while developing and building on new skill sets. Gaining commercial experience seems to be a top priority, thus making the CRO sector a very attractive alternative proposition.

Pharma, biotech and CROs have a major challenge on their hands – the size of the skilled scientific workforce is declining at an alarming rate (for instance, a wave of retirement is sweeping across the "baby boomer" generation, and companies are increasingly trying to recruit from the same finite talent pool). The most worrying point of all is that these individuals are not being back-filled. The number of university and college students enrolled in science related subjects is declining, while demand for their skills and knowledge in the pharmaceutical,

biotech and CRO research community is increasing.

So, we have entered what some have described as the "perfect storm", in which acquiring and retaining top-tier talent is becoming difficult within an increasingly competitive and challenging environment.

The impact of globalisation is being felt throughout the industry and is driving the structural and regulatory changes that are becoming increasingly evident. A global marketplace for talent is developing as R&D migrates to Asia and other emerging growth centres. This requires the industry to reassess its HR strategies to ensure it can attract and retain the best talent. Increasing fluidity between the different industry sectors will help to invigorate and refresh the existing gene pool within a particular organisation.

PricewaterhouseCoopers' recent *Pharma 2020* report highlights the need to go back to grass roots level. Companies need to consider how to make science more exciting and attractive as a career choice and how they can build better alliances with schools, academic institutions and with each other.

Companies have to be more visionary, to look beyond the recruitment strategies that have worked in the past and to re-evaluate what defines a good candidate. The industry needs to focus on expanding and developing its pipeline of scientific professionals. Fishing in the same finite talent pool is unsustainable in the long term and unless managed appropriately, the future success of what is one of the most important, exciting and dynamic industries in the world will be adversely affected. **SCRIP**

Dr Renu Vijh is a Senior Consultant in the Non Clinical R&D Practice and Dr Kay Wardle is Practice Leader for Non Clinical R&D and Managing Director of RSA Executive Search.





SMART CHOICE: In a crowded patient pool being able to target those most likely to respond to treatment provides good justification for companies to charge high prices

Translating promise into delivery

Tom Moberly spoke to **Dr Harsukh Parmar**, global early clinical development director for the Respiratory and Inflammation Therapy Area at AstraZeneca, about the future prospects for translational medicine

Q. You head a specific early development division of AstraZeneca. Do you think that early development, or translational research, needs to be seen as a special part of the drug discovery and development process?

At AstraZeneca we deliberately chose to create an early development group in each therapeutic area. We wanted to give the enterprise the right focus and the right expertise and I think giving it a name that identifies it properly helps to achieve that. Even though we have a single team, all companies will have different ways of solving the same problem.

Even if they do not all call it "early development", there will always be individuals working in these areas. This involves people who design clinical studies, those working on the basic science and research area, people developing biomarkers and prognostic markers, people looking at methodology and considering how to conduct a particular study in a targeted patient population, and how those groups will be identified. You need to have the whole methodology worked out. And that includes a team of statisticians; experts in pharmacology and toxicology; physicians with clinical experience, in the disease area being studied and in basic clinical

science; safety physicians with experience of reporting safety data; specialists in statistics, data monitoring, dose-response, modelling and simulation.

Organisations are constantly changing though because there is a need to change. Pressure on pipelines is clearly a driver for some of the changes that are occurring as we try to become more effective at discovering and developing new medicines.

People's expectations were undoubtedly very high, probably higher than the technologies involved could reasonably be expected to deliver

Unfortunately, one of the paradigms of drug development in the past few decades has been a move to split people working in drug discovery from those working in drug development. That has resulted from things becoming more reductionist.

The thinking was that if you looked at the mechanisms and undertook some *in vitro* and some *in vivo* experiments, you would then be able to take the drug into the clinic and see the same effect, measure patient outcomes and hope that everything will work out. That

is rarely the case, and that assumption has led to an over-reliance on reductionism in drug discovery, which has been a problem for the past 20-30 years.

Q. What do you think needs to be done to change that?

We need to go back and understand patients much better. We need to go back and take a holistic view of the action of a drug on a patient, with the myriad of interactions taking place *in vivo*, rather than reducing it to the science that has been studied *in vitro*. Things like micro-dosing, microdialysis, exploratory methodology studies, use of biologicals, etc, can help with that, and can give an idea of what will happen in patients when you give a drug with a specific mode of action.

What we really want to be able to do though is to target therapies more effectively, so that we only see drugs acting in a beneficial manner, with no significant adverse effect, in selected patient populations. That may seem very futuristic at the moment, but it will come with the advent of personalised medicine. We may need to lower our expectations, in the short term, but 20-30 years down the line, we should see therapies of that sort making a real difference to patients.

Patient selection is absolutely critical to

safety and efficacy. You need to choose the patients who will respond, so you limit exposure to patients where you will see a benefit, meaning you get a better safety and efficacy profile.

The over-emphasis on the reductionist approach has also had an impact on the people working in drug discovery and drug development. People have tended to "salami-slice" the whole process, and so researchers have become experts in one field or another, but are often not able to work across different fields. To be able to understand the action of a drug on a patient as a whole, you need very strong scientists who understand the molecular basis of therapies, who understand patients as human beings and who understand different aspects of the disease. We need physicians who have both those sets of skills and are able to link those two areas. There will always be demand for people of that sort and those will be the individuals for the future. If there were more people like that involved in drug development, the industry would be in better shape.

Q. How is the early development environment in which you work changing?

The industry has worked off very high margins for a long time, but that was never going to last forever. There is an ongoing and ever-present pressure on margins and companies need to change. There are big hopes that things will improve and that we will be able to find new drugs. The unmet medical need continues into many common and chronic diseases. There are drugs being produced that, individually, will never make billions, but if a company has enough such smaller drugs then it would be able to recoup its R&D costs and turn a decent profit. For example, there are companies doing different things and looking at specific patient populations. For instance, Genzyme is looking at creating a blockbuster by charging

a high price for a drug for a smaller but very specific patient group.

That is what Roche has managed to do with Herceptin [trastuzumab]. Researchers were able to identify a group of patients – those with HER2-positive breast tumours – who were most likely to respond to treatment. The population size for a targeted therapy like that may not be large, but because you can show it works and target it at very specific patients, you can charge a very high price and create a blockbuster product for a niche population. The use of biomarkers and imaging methods is helping us to identify patient populations who may benefit from particular treatments in a wide range of therapy areas – in oncology, in acute leukaemia, non-Hodgkin's lymphoma, lung cancer, colon cancer, as well as in immunology, rheumatoid arthritis, cardiovascular disease and diabetes.

With an ageing population, the need for effective treatments for diseases like cancer, Alzheimer's and diabetes is only going to carry on increasing. But the difficulty we face is that we'll always be seen to be not doing a good enough job, even though the pharma industry has contributed considerably to the betterment of human life. Such is the scale of the task facing us to improve our public image.

A number of other events have also had an impact on the drug development environment, especially the safety problems surrounding Merck's Vioxx [rofecoxib] and Tegenaro's TGNI412 clinical trial. In response to those events and other influences, regulators have taken the path of least resistance and become more conservative, which in turn means we have to work harder to bring innovative medicines to patients.

Q. For some time people have had very high hopes for breakthroughs arising from early development or translational medicine. Do you think people were over-

optimistic about what might be achieved?

People's expectations were undoubtedly very high, probably higher than the technologies involved could reasonably be expected to deliver. That was especially the case in some areas, such as with high-throughput screening and the sequencing of the human genome. So, it is really about setting the right level of expectation. But that is what happens with scientific developments. Scientific knowledge feeds into itself and is then hyped by newspapers into immediate expectations. Sometimes that produces real substantial benefits in dramatic leaps, but more often it happens in slow, incremental developments.

For instance, at the moment some biomarkers can only be measured on fresh blood, which means that samples cannot be shipped. That places limits on the way in which trials can be undertaken. But when a marker is developed that can be measured in stored blood samples, that will change the way in which trials can be conducted, where they can be conducted globally and which patients can be studied.

You can also go through a period where people see exciting changes and have very high expectations for progress. But when that happens there is never a very clear vision of when those changes will come. So people tend to assume that those changes will come in a very short time. They assume that there will be new, safe, effective drugs developed in the course of two or three years. But these developments will take 20 or 30 years. That is the sort of timescale we should be looking at. So, we need to keep in mind that any benefits of any new discovery will take time, but that does not mean that benefits will not come. Some benefits may be more immediate, while others may take a lot longer. **SCRIP**

Tom Moberly is a science reporter for Scrip.

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The evolving face of translational medicine

Translational medicine is about bridging technologies and discoveries in the laboratory with their application in clinical research and practice. Although the available candidate pool for this discipline is relatively limited, **Nicola Harding** outlines some of the key attributes sought in those looking to work in this area

Recruiting physicians for the pharmaceutical/biotechnology industries is never without its challenges – the nature of which can vary according to exactly where within the organisational structure the individual is to fit, and therefore the requisite skills, experience and personal characteristics that this demands. Identifying and screening physicians to work within the area of translational medicine brings with it its own distinct set of challenges, as the nature of the discipline demands a diverse breadth of skills and expertise, coupled with a less tangible set of softer skills centred around breadth of vision and communication.

There are many different definitions of translational medicine, but essentially it focuses on bridging technologies and discoveries in the laboratory with their application in clinical research and practice. This involves a global approach to extracting clinically useful information from advances in basic science, and bringing this directly into clinical care. The same principles apply in the academic, biotech and pharmaceutical environments, and understanding translational medicine is crucial for all professionals involved in research from “bench to bedside”.

Translational medicine is still an emerging field and, in search terms, the candidate pool is relatively limited. Centres of excellence in translational medicine, often involving collaborations between universities, hospitals and pharmaceutical companies, are increasingly becoming established in a number of markets, and many universities offer MSc courses in this discipline. However, many physicians appointed to industry posts in this field still come direct from academia, which yields experts keen to move into an environment that will afford them a broader overview of the whole value chain. Clearly, as the discipline continues to evolve, the size of the candidate pool in industry will increase – which will be an undeniable advantage to us as search consultants!

The US is generally seen as a major source of talent in translational medicine. However, Dr Graham McClelland, former head of clinical pharmacology at Roche, commented that: “in the past decade, Europe and the US have in some respects suffered from a reduction in the education and academic career opportunities relating to clinical pharmacology, as training has

become more and more disease-focused. In contrast, the Asia-Pacific region, particularly countries such as Singapore and China, has been developing an increasingly stronger presence in the fields of clinical pharmacology and translational medicine”.

The most obvious physicians to participate in translational medicine are MD PhDs, but what are the characteristics and specialist skills that recruiters should look for when searching for individuals in this area? According to Dr Graham Price, vice-president of clinical science for Takeda's Global Research & Development Centre, “the individual needs to be sufficiently experienced in clinical development to assess the level of risk of going into man on limited information”. Dr Price thinks they need to offer the following key components:

- Skills and experience in the interpretation of non-clinical data, and an understanding of the significance of the key findings;
- A good understanding of clinical pharmacology and its relationship to non-clinical;
- Knowledge of later stage clinical development, in order to identify and define clinically relevant parameters for the disease state studied in a relevant population; and
- An understanding of safety monitoring and early signal reception.

Physicians in translational medicine need to think globally, operate successfully within a multi-disciplinary matrix and work effectively across cultural/geographic boundaries. A priority is to be able to communicate with both scientific and non-scientific stakeholders, such as ethics committees, internal review boards, regulatory agencies and, importantly, research subjects. Strong leadership skills are also a prerequisite, and collegiality is critical. A solo operator has no place in translational medicine – the field requires energetic, enthusiastic and highly communicative individuals.

While the need for an understanding of contemporary translational research tools, including imaging and biomarkers, is a prerequisite, so too is the ability to think beyond current paradigms of care. And, importantly, as stated by Dr Harsukh Parmar in his interview, in addition to being strongly scientific, people working in this field need to “understand patients

as human beings” and to have a passionate interest in the ultimate benefits of the compounds to the end-user.

With this in mind, does the ideal candidate actually exist? Matthew Edwards, senior researcher in RSA's Medical Practice, comments: “Searching in translational medicine provides its own unique set of challenges. Often clients come to us looking for a breadth of expertise, coupled with the need for what is, in effect, a particular mindset, which is challenging to even the most experienced recruiter! However, RSA's success in this area is achieved through regular and open dialogue with our clients and a clear agreement with them as to which aspects of the ‘wish list’ we are able to compromise on, if the other ‘boxes’ are ticked. We have to rely on a good level of realism from our clients, to avoid being asked to search for the impossible.”

How important is specific therapeutic expertise? A translational medicine team should ideally comprise individuals with a range of therapeutic backgrounds, that will not only include those therapeutic areas where the company is planning to move compounds through into entry-into-man, but also therapy areas that are most relevant for adverse drug effects (such as cardiovascular and CNS), and drug handling (ADME). Dr Price says: “Some areas require specialist knowledge, for example, CNS may demand specific imaging expertise. However, in many instances such knowledge can be ‘bought in’ by involving KOLs, and therefore expertise within a specific therapeutic area becomes less critical.”

In summary, translational medicine is a fascinating and evolving discipline that is increasingly attracting some of the leading medical talent. Intellectually stimulating and scientifically challenging, it requires a unique combination of experience, skills and mindset, overlaid with the ability to visualise the bigger picture. In search terms, it certainly represents a challenge – one that we in RSA's Medical Practice are always happy (and able!) to rise to. **SCRIP**

Nicola Harding is Head of RSA's Medical Practice and Director of RSA London.



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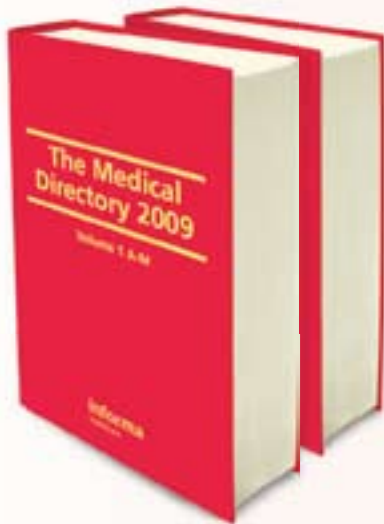
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VIC EDY



JO NUNN

Where process is key

Becky Debens spoke to **Jo Nunn**, director of programmes at Avecia Biologics, and **Vic Edy**, managing partner of Newland GxP Consultancy, about some of the unique staffing challenges that define the biologics manufacturing space

Q. Can you describe the particular challenges associated with manufacturing biologic drugs?

Jo Nunn: The complexity and control requirements of the biologics manufacturing process are major challenges, and they are becoming even more so because complex molecules and new biologics – such as fragments of antibodies, cell therapies, stem cell therapies and conjugates of proteins – are all quite difficult and expensive to fully categorise.

There is a very significant amount of reliance on process. Consequently, you need very good process and molecule understanding and control, and this takes a great degree of skill, expertise and experience. While companies may have relied on manufacturing teams that were not particularly highly-skilled in the process of, say, the chemistry of small molecules, when you're making biologics it's different – you need an extremely strong process science team. They need to understand the protein, the chemistry and the process, as well as know what that process is doing. Finding that capability can be a challenge.

Vic Edy: Beyond the inherent difficulties associated with operating a complex process, the main challenge my clients have experienced is the difficulty in identifying contract manufacturing organisations (CMOs) with appropriate equipment (in terms of both type and scale), experience of processes, and production slots that can be made available within a reasonable timeframe. There can also be the issue of communication – of ensuring that the contractor keeps the client completely up-to-date on progress – or the lack thereof.

Q. Do you think there is a skills gap in the biologics manufacturing area? If so, where does the gap lie and why has it come about?

JN: Yes I do. There is an experience gap in quite a few skills areas, such as process development, biologics analytical development and characterisation, as well as

in Quality Assurance (QA) and quality control. Using quality as an example, there are some excellent experts from the pharmaceutical industry with vast knowledge of small molecule products, but they don't necessarily have the same level of understanding of the relatively new biologics field.

Recruiting new graduates into biomanufacturing roles can be a challenge too. The very word "manufacturing" can sometimes conjure up images of being dreary and dull, and the calibre of recruits may suffer as a result. But this perception of the biologics manufacturing arena is wrong; it just needs to be sold better, especially to the top tier of new graduates.

The very word "manufacturing" can sometimes conjure up images of being dreary and dull, and the calibre of recruits may suffer as a result

VE: There is a concern about the lack of experienced QA personnel – that is to say staff who come into QA after a successful period working either in production or quality control. (In my opinion, such people often make better QA staff than those with no practical experience). This may be because QA is not seen as an interesting or challenging job; effectively just checking other people's work in a reactive capacity. While this is indeed a component of the job, a larger part is concerned with proactively working with development teams to ensure proper systems that are both compliant and workable are in place.

Q. Are there national differences in the quality of biologics manufacturing, and if so, what are the causes of this variation?

JN: At the moment, companies in India and China are setting up and very quickly establishing themselves as manufacturers that can use established processes, for example, to make launched or generic molecules,

eventually including biopharmaceuticals. My perception is that European and US companies are taking the lead in quality process development, but that situation could potentially change if India and China aggressively take up this mantle.

Some customers are not yet ready to move to China or India because quality processes, increasing yields and the ability to take the whole process through to clinical trials aren't yet established there. Nor are the skilled teams they need – these are still in development. On the other hand, people have more trust in UK and US companies because they have established expertise. But once a process is established, fully understood and characterised, manufacture may well move from the West, and I expect countries like India and China will try to make this happen in the next five to 10 years.

Just look at the speed at which these countries have managed to establish facilities that are now starting to be recognised by regulatory authorities – they are investing heavily in this area. However, at the moment, I believe they still need expertise in the process development of biologics.

Q. As the use of biologics has grown, how do you perceive this to have affected the skills base of the manufacturing sector?

JN: People have adapted their skills as the sector has grown – many staff come from the traditional pharmaceutical space and have honed their knowledge to include biologics. For example, traditional chemical engineering has been adapted to the requirements of biochemical engineering. For us this transition has been happening gradually for over 30 years, but for large pharma companies it seems to have been a more recent change. From my discussions, it seems that the larger companies are becoming increasingly focused on biologics as next generation drugs. Their teams are changing, as is the way they manage their portfolios. In many cases, companies are using contract manufacturing while historically this has not been the case.

VE: The earlier mentioned lack of QA staff is a skills-based problem, but with the growth

of the sector, I've noticed junior staff in production and QC often appear to come from academic training courses in biotech. As biotech processes become more complex, then I do foresee greater skills levels are going to be required in all areas, although I'm not aware of any requirements for completely new skills or skill sets which have emerged just yet.

Q. What should be the first steps in solving the problems you have mentioned today?

JN: In terms of the skills gap in biologics manufacturing, I'm not sure that we, as an industry, are proactive enough at making people recognise this as an interesting career path. Manufacturing is generally not a well promoted category.

We have highly intellectual people at university studying biosciences, and I think they're probably more inclined to pursue a career in drug discovery, but the manufacturing sector also needs high-quality people. Some work is already going on to promote manufacturing, and I would draw particular attention to bioProcess UK which has been very successful at building the bioscience community and getting more talent into the sector.

This effort has included working as a network to support and encourage new people to take an interest in manufacturing biologics, for example, by running road shows at universities. It's the kind of thing pharma companies used to do, and it's now the sort of activity we should be doing too. There's still a long way to go to make sure universities offer the right courses, and we need to target undergraduates, so that higher calibre scientists are attracted to our industry. Greater press coverage is also vital. We basically need to get a better understanding of biomanufacturing into the education chain.

VE: Somehow we need to promote QA as a valuable and fulfilling career path. The British Association of Research Quality Assurance [BARQA] has a working group looking for ways to address this problem – and interestingly, this isn't an issue limited to biotech or GMP QA.

In terms of the availability of contract manufacturers, it is difficult to see what can be done; development of any pharmaceutical is a high-risk enterprise, and coupled with the high costs of building and running a contract biotech

manufacturing facility, this means there will always be a shortage of organisations willing to invest in contract operations.

It is very unlikely that the thresholds new medicines have to clear will be lowered, and therefore drug development will always be a long and drawn out process. The simple answer to reduce risk of failure is to stop drugs earlier in development, when lower costs have been incurred, but often small companies are completely dependent on one or a very small number of drug candidates, so dispassionate review can be difficult.

In addition, investors in the biotech sector historically have not fully appreciated that the vast majority of drugs in development do not make it through to market, but I hope this is no longer the case. Short of government intervention, for example tax advantages for biotech investment (and I cannot see how this could be justified), I think the only thing that will boost biotech investment is a period during which a few biotech drugs succeed, and very few fail, particularly in late-stage development. **SCRIP**

Becky Debens is a reporter for Scrip.



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Biopharma manufacturing capabilities to the fore

The industry's increasing reliance on biological compounds is creating some unique recruitment challenges. And in the biologicals manufacturing space, potential candidates' requirements can sometimes be as complex as those of their prospective employers, explain **Dr Kay Wardle** and **Ian Broadway**

Despite the cheaper costs of manufacturing overseas, particularly within the emerging markets of India and China, the pharmaceutical industry has a major investment in the UK and Europe as manufacturing locations. This success has been built on the high quality of staff and technical expertise available within Europe, but recent industry trends suggest that problems may be looming for the future.

The global pharma industry is constantly changing. In addition to the growth in the number of companies establishing themselves in India and China, there has been a major shift away from the development of traditional small molecules to more complex biologicals, including antibodies, gene therapies and protein conjugates. A casual glance at any of the large pharma companies would suggest that this trend is here to stay, with many of the traditional NCE organisations moving into the biologics area, through acquisition, partnership or organic growth.

This shift in strategy has put extra pressure on the manufacturing industry. A recent report by SEMTA (the Sector Skills Council for Science, Engineering and Manufacturing Technologies in the UK), produced in collaboration with the major industry players, highlights widespread concerns about the shortage of trained staff to operate the growing number of bio-production facilities around the world, as well as localised concerns that the UK is losing its competitive edge.

Earlier this year, research conducted by SEMTA reported that 29% of UK bioscience companies lacked scientific expertise in certain areas. The research also concluded that one in four companies in the UK was looking overseas to recruit skilled staff. This skills shortage could have a major impact on the UK biopharmaceutical industry as companies will invest in countries with a strong skill base.

A separate ABPI initiative on 'Sustaining the Skills Pipeline in the Pharmaceutical and Biopharmaceutical Industries', first published in 2005, and due to be updated later this year, also highlighted skills shortages within bio-manufacturing. Specific areas for concern

included antibody fermentation, separation sciences, up and down-stream processing, quality assurance and analytical chemistry. In several of these disciplines, manufacturing appeared to struggle more than R&D to recruit good candidates – a fact which may be attributed to negative perceptions and a lack of awareness among graduates about careers in manufacturing.

If the UK and Europe are to sustain their skills pipelines and respond to the increasing competitive pressures from emerging countries, action needs to be taken now. Within the UK, the ABPI has worked closely with Government departments to coordinate and enhance delivery of careers information in schools and universities. Specific degree courses, aimed at careers in the biopharmaceutical industry have been developed. Companies themselves must be prepared to invest in staff training – to develop the skills of their existing staff to meet the changing needs of the business.

These solutions are all long-term and do not necessarily help bio-manufacturing companies solve their immediate resourcing requirements. Over recent years, RSA has seen a shift in the recruitment briefs it receives from clients – away from candidates with backgrounds in traditional NCE manufacturing and quality and towards candidates with a strong background in biopharmaceutical process development, manufacturing and control. We too face the challenge of identifying individuals possessing a unique cocktail of technical skills, leadership skills, innovation and drive in the right quantity and balance to satisfy our clients' needs. Often the perfect balance is not found in a single individual and, together with our clients, we will make a considered decision on an individual with the strongest fit and potential in the role at that point in time.

Our recruitment challenge is to find a strong short list of interested and qualified candidates for any given role that the client can interview and assess, subsequently making a hiring decision in a timely manner that ensures business continuity. In a competitive marketplace where high value candidates are being proactively approached and courted about their next career move,

relying on that individual to decide in your favour requires more than just the offer of a new role!

Flexibility in outlook and a little bit of creativity can also go a long way. A candidate's decision-making criteria are often as complex and multi-layered as the recruitment requirements laid down in the client brief. Career development and training opportunities can be of equal consideration as company profile, location and benefits package. Companies must consider how to make their opportunity stand out and be the most compelling for a candidate. And, once you have your chosen candidate on board, can you deliver? Can you fulfil the promises made at interview and retain your employee long term?

While searching for the ideal candidate or up-skilling their existing staff, many of our clients make use of a highly experienced interim manager – someone who can keep their processes running or bring valuable expertise or experience into their business when they need it. An interim manager can manage an efficient hand-over to the new recruit or be available to mentor that individual in a specific area of knowledge or expertise they lack.

In conclusion, with overseas countries aggressively building their biopharmaceutical manufacturing capabilities, the UK and European industry will need to invest heavily in training, technology and specific incentives to maintain their present position. Companies must consider how to attract candidates and, equally importantly, retain these valuable assets and maximise their lifetime value to their organisations.

Dr Kay Wardle is Managing Director of RSA Executive Search and Ian Broadway is Managing Director of RSA AG.



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OCEANS APART: Europe's P&R landscape is quite complex compared with the US with each country behaving like a unilateral island



STEVE TURLEY

P&R: views of a country manager

Steve Turley tells Pete Chan how the growing influence of health economics considerations is impacting on market access for innovative new drugs

Q. How influential has NICE become in determining access to the UK market? What do you think of the institute's recent decision not to recommend four innovative anticancers for the treatment of renal cell carcinoma on the NHS in England and Wales?

I think the role of NICE has evolved quite dramatically to the point today where it really is the reimbursement body for the UK pharmaceutical industry. There is no doubt that NICE is trying to link medicines prices to cost-effectiveness.

A clear challenge for the pharma industry is the fact that the hurdle deemed to be cost-effective is somewhat subjective. Different countries or different markets will position that hurdle in different places.

Consider that uptake of medicines in the UK compared with most other European markets is already low. Combine that low uptake with a NICE hurdle for cost-effectiveness, which in itself is also challenging, and you're going to have decisions like NICE's rejection of those four cancer drugs.

Interestingly, we have also seen some disconnects in cases where NICE has rejected a drug that the Scottish Medicines Consortium (SMC) has accepted. This is why you sometimes read stories about patients in Scotland getting access to a new drug, whereas the same medicine is denied to English and Welsh patients.

The real sadness in this is that patients are missing out on access to medicines that will make a real difference to their lives.

Q. Can we expect NICE's decisions to impact on market access to medicines in other countries?

Undoubtedly yes. We know that other countries, especially some of the smaller markets, look to NICE to a great degree. In addition, you only need to look at some of the early development decisions being made by global pharma companies to understand that they see NICE as being important not just because of the UK market, but because of the spill-over effect on other countries.

Q. In August, two US senators introduced legislation proposing the establishment of a non-profit "Health

Care Comparative Effectiveness Research Institute" to assess the cost-effectiveness of drugs. What impact do you think this would have on the US market?

It depends whether it's a back-door mechanism to reduce medicines prices or whether it's about getting transparency with regards to cost-effectiveness.

There's no doubt that some pharmaceuticals are more expensive in the US than elsewhere, so from a political point of view, reducing prices has to be fairly high on the agenda. If this is the motivation, and if the cost-effectiveness threshold is set at a low level, it could lead to huge downward pricing pressure in the US and a huge shift in medical practice in the country. From a business perspective that would probably be the main concern for industry.

At the same time, bringing transparency over cost-effectiveness decisions could be a good thing. It would mark a shift from the current situation in the US where there are many managed care organisations, each doing their own cost-effectiveness calculations to determine whether they're going to put a particular drug onto tier 1, tier 2 or tier 3 of their reimbursement schedule.

Q. To what extent do pricing and reimbursement environments differ from one market to the next?

From a pricing and reimbursement perspective, there's no doubt that the US and Europe are currently unrelated, so you may see different pricing strategies in these two continents.

A company's US pricing strategy will of course reflect the prevailing trend within that marketplace. On the other hand, the European pricing strategy is a much more complex beast altogether. In some ways Europe operates as one state, but in other respects it works as a collection of unilateral organisations.

Europe can be viewed as one homogenous body with respect to products being granted regulatory approval in the first place, and also in terms of free trade, which allows drugs to move across different European countries' borders. From a pricing perspective, however, each country behaves as a unilateral body, and that poses massive challenges for pharma. Most firms want to say that they're putting medicines on the market that provide value for money. But with different countries having different ideas as to what value for money exactly looks like, it's very difficult to decide on a price that will be appropriate for every single market.

Q. What effect do you think the proposed price cut in the UK PPRS will have on the pharma industry?

The initial impact of the PPRS scheme will be to reduce the prices of drugs that are currently on the UK market. From that perspective, the scheme to some extent will be a "one hit" for pharma companies.

But the future pricing setting in the UK will be determined more by NICE than by the PPRS. As we've already discussed, NICE relates price to cost-effectiveness. UK companies and their global parents will have to charge prices that demonstrate cost-effectiveness if they want access to the UK market.

But there will also be an impact on other markets. It's going to pose problems for those multinationals that perhaps see different cost-effectiveness margins in different markets, especially if the UK is at the low end of both the medicines uptake model and the pricing model.

Global pharma companies are going to have to make some strategic decisions about where the UK sits in their world. That might have a long-term impact on access to innovative medicines in the UK, but also the UK as a centre of innovation in its own right.

Aside from the changes associated with the PPRS, it is encouraging to see NICE being prepared to enter into dialogue and provide insight and advice to companies through the development phase. We're talking about huge

multimillion-pound decisions being made here. It's good to have that advice rather than make decisions blind. Ultimately, one would hope there is a common objective, namely developing and providing access to innovative, differentiated drugs that are cost-effective and make a real difference to patient care.

Q. Are there any remaining issues to be resolved with regards to working with NICE?

If NICE is increasingly going to take this role as the reimbursement body of the UK, we have to see systems put in place that allow the assessment of medicines in an expeditious manner. In Scotland, the SMC employs a three-month process, which allows a company to submit a dossier before product launch, and to know within a month or two of launch whether the medicine is going to be endorsed.

Companies in the past have taken their compounds all the way through to the end of Phase III, only to realise that some of the data did not support the P&R message they want to give out

On the other hand, if access to a medicine in England is to be restricted until it gets NICE's endorsement, it's frankly unacceptable for a company to have to wait 12-18 months after launch for that to happen. While NICE is well respected, and while it's moving in the right direction with respect to conducting single rather than multiple technology appraisals, speed is key. I would very much like to see a system that allows innovative medicines to be used much more quickly after approval.

Q. Is the first wave of blockbuster patent expiries going to impact price?

Looking back to some of the big primary care blockbusters of the 1980s, the patents covering those products have already expired. Interestingly, what we're going to see around 2010-12 is the first wave of patent expiries for high-value biological compounds.

In future, we can expect procurement groups – mainly hospital procurement bodies, because most of the drugs concerned are administered in the secondary care setting – to see biosimilars as a very easy way of freeing up funding to pay for future innovation.

But the biosimilars debate is about much more than just pricing. A biosimilar is not a generic product in the conventional sense; it's not an exact copy of the original drug. So, there are also going to be complexities around

the legal situation and patient safety issues that need to be answered.

Q. Companies have suggested various risk-sharing schemes to get their products recommended by NICE. Should we expect to see more arrangements of this type?

Because of the different reimbursement requirements in different markets, I think this trend will have to increase. But if risk-sharing schemes are going to be successful, they have to be simple to administer. If every pharma company went away and developed its own risk-sharing proposal in order to demonstrate cost-effectiveness, then hospital groups and PCTs would complain about them being too complicated. If we got it right though, risk-sharing could be a major boost for the uptake of innovation.

Q. At what stage in the development of a new molecule should companies begin to factor in health economics considerations?

It has to be early; at the very least it has to be a core consideration of Phase III design. All too often companies in the past have taken their compounds all the way through to the end of Phase III and then started thinking about pricing and reimbursement, only to realise that some of the data from the Phase III programme did not support the message they want to give out.

So, there's a delicate balance to be struck between making decisions before good data are available, and leaving it too late in the development cycle. Logically, when taking a molecule from the end of Phase II and moving into Phase III, a company shouldn't just be making a go/no-go decision around a clinical endpoint; they should also be asking what the Phase III trial needs to look like to achieve pricing and reimbursement in the core markets.

Q. What other issues are we likely to be talking about over the next few years?

We need to separate cost-effectiveness from affordability; that's a key challenge in the UK. At present NICE determines whether a certain price combined with a particular outcome makes a drug cost-effective. Yet even if NICE decides that a drug is cost-effective, there is still the question of whether the healthcare system can actually afford to pay for it. That could be our next challenge; ensuring affordability as well as cost-effectiveness, and hence making the UK a place where uptake of new medicines is world class in its appropriateness. **SCRIP**

Steve Turley is general manager for the UK and Ireland of Actelion Pharmaceuticals UK.

The global touch

The growing influence of health economics considerations in determining market access for innovative new products is creating healthy demand for professionals tuned in to the pricing and reimbursement landscapes of the world's major markets, says **Susan Macdonald**

Steve Turley makes some telling points on this subject. His perspective as a UK managing director is a valuable one, particularly in relation to NICE. The challenges its decisions present continue to grow for all stakeholders, be they the pharmaceutical industry, payers, clinicians or patients.

From RSA's perspective as a global service provider we see additional considerations across the broader international arena.

When you type 'pharmaceutical pricing and reimbursement' into Google, the search engine returns 277,000 results from all points of the globe in 0.18 seconds. Had we done the same five years ago, would the return have been so great, or so widespread?

Setting the price of a new product has never been the easiest task. Nor has finding the people with the skills to do it well, but more on that later.

Historically it is perhaps fair to say that companies have based pricing in part on what they judged the market would bear. The process of price-setting has now become increasingly more challenging and complex. There is an ever-growing squeeze on pharmaceutical companies from healthcare providers to develop products that offer value for money as well as innovation.

While a product may be able to gain approval this no longer means that it will necessarily secure reimbursement. As a consequence, pharmaceutical and medical device companies are having to implement strategic pricing assessments across global markets and product life cycles.

When formulating product pricing at an international level, companies also have to consider:

- Pricing differentials between countries;
- Cross-border trading and currency fluctuations; and
- Local considerations, such as market size and the competitive landscape.

As Mr Turley mentioned, companies have to take into account the value of their product to both payers and clinicians much earlier in the product development phase. They have to ensure that clinical and health

economics data support their future pricing and reimbursement aspirations.

International pricing comparisons are becoming more common, as is collaboration in health technology assessments. In 2006, the UK's NICE, Germany's IQWiG and HAS of France agreed to meet regularly and share their latest findings and methods.

Their aim is to cite each other's research when reaching decisions.

It remains to be seen what impact the outcome of the impending US Presidential election will have on this issue. If a Democrat is elected could this mean that the US will also be looking to adopt similar assessments?

Within the European market alone, there is much diversity of approach to assessment,

If a Democrat President is elected could this mean that the US will also be looking to adopt similar assessments?

drug pricing and reimbursement among member states. For example, some countries will allow companies to set their own launch prices. Others require formal economic evaluations to support a product's pricing dossier.

The considerations above are only a few, and they represent just the tip of the iceberg when it comes to reconciling the different challenges that companies now face. Sound pricing and reimbursement strategies are harder and harder to develop and the landscape is changing rapidly.

An additional challenge is finding the right personnel who understand the complexities of pricing and reimbursement. They need to be able to work with and influence colleagues throughout product development and life cycle management to ensure all are working to the same endpoints.

Over the past three years, RSA Executive Search has undertaken a number of global searches on behalf of client companies. We have sought to identify and attract to these companies high-calibre individuals with the required knowledge and skills in this specialist area. The desired candidates are

individuals who understand pricing and reimbursement across all or some of the major markets, ie, the US, Europe and Japan. They have to be able to demonstrate their success in the preparation and approval of pricing and reimbursement dossiers.

As these are strategic roles, these individuals have to work at either corporate headquarters or within one of the major markets. More often than not this will require candidates to be geographically flexible as well as prepared to travel. Fluency in a language other than English is desirable, though not always necessary.

Candidates have to demonstrate a full understanding of the drug development process. They may come from an educational background of life sciences or health economics, but the majority will have additional advanced qualifications, such as PhDs, Masters degrees or MBAs. Whatever their credentials, they tend to have strong commercial acumen.

The softer skills these individuals possess are also key as they spend much of their time communicating with key decision makers both internally and externally.

As you would expect, demand for these candidates tends to outstrip supply. Companies may therefore decide to use specialist consultancies to supplement their in-house teams in the development of their pricing and reimbursement strategies.

This area is one that will become increasingly important for the future success of product portfolios and ultimately company profitability. The question is therefore: do you have the people within your organisation in the right positions with the necessary skills and knowledge to support your product development investments?

There is an old saying that "money and facilities make things possible; only people make things happen". If you need help finding those people, speak with RSA and let us use our global network to find them for you.

SCRIP

Susan Macdonald is the Practice Leader for Sales and Marketing at RSA Executive Search.





DR CHAS BOUNTRA

The best of both worlds

Dr Chas Bountra, chief scientific officer of the Structural Genomics Consortium, explains to Dr Peter Charlish how public-private consortia look for exactly the same types of people as those that typically excel in pharma

The Structural Genomics Consortium (SGC) was set up in 2004 as a partnership between the Wellcome Trust, GlaxoSmithKline and several Canadian and Swedish research-funding agencies/charities. It now also receives funding from Merck & Co and the Novartis Research Foundation. The SGC is based at the Universities of Oxford and Toronto, and at the Karolinska Institutet. Its aim is to determine the three-dimensional structures of proteins of medical significance, and to provide unrestricted public access to them. So far it has released 724 structures, including enzymes and other proteins involved in cell signalling, drug metabolism and toxicology, neurobiology, parasitic diseases and cancer.

The SGC is in the process of establishing a major new collaboration with GSK, the US National Institutes of Health and two academic groups in Oxford (with funding for these two academic groups in the Chemistry and Biochemistry departments, and the additional SGC staff coming from the Wellcome Trust) to solve the structures of three important "epigenetic" protein families and, in a significant extension of its activities, to generate chemical probes for them.

Chas Bountra was appointed chief scientist of the SGC's laboratory at the University of Oxford in January of this year. During a career of almost 20 years with Glaxo and its successor companies he was involved in bringing more than 30 candidates to the clinic. Talking to him, it is immediately obvious that he is passionate about what the SGC is trying to achieve. Part of that passion springs from his belief that drug discovery has two broad scientific challenges: establishing target validation (ie, which target out of a plethora of proteins when modulated will deliver a clinically useful therapeutic) and once a clinical candidate is identified, how clinical proof-of-concept (what patient sub group, dose, clinical readout, etc) can be established. He firmly believes that the public-private model is in many respects a new organisational

experiment to tackle these challenges.

There are certain things that the industry is very good at, Bountra explains, and certain things that academia is very good at: the beauty of a public-private partnership is that you can get the best of both worlds. For example, pharma is brilliant at managing large-scale projects, especially processes like high-throughput screening, lead optimisation, large-scale trials, gaining regulatory approval and launching new products. Biotechs can offer a greater sense of urgency, more focus, less process and potentially more ownership.

Just as in industry, networking is massively important in the public-private sector

And academia brings its own strengths to the party, such as the freedom to allow people to be more innovative (without some of the restrictions experienced in a purely commercial environment, which is perhaps more milestone-driven), easier access to patients and a more long-term horizon for tackling some of these difficult intellectual problems. Many of his colleagues relish taking on complex, technically demanding and scientifically challenging problems – drug discovery certainly fits into all these categories.

If public-private consortia are good at addressing the challenges of drug discovery, does it follow that they are also good places to work? Without a doubt, Bountra says.

"I work with some immensely smart people, I have the opportunity to collaborate with world leaders in targets, technologies, disease... I am learning and I get paid well! The opportunities are limitless. I have to focus because there is never enough time and resources are always limited."

And what types of people and what types of skills do public-private consortia such as the SGC look for? "Exactly the same types of people as the pharma industry," Bountra says. "They should have creativity,

energy, the determination to succeed, the ability to be a good team player, and a good track record in their individual field of endeavour."

Just as in industry, networking is massively important in the public-private sector, he adds, something to which his own contribution to the SGC bears testament. "Ultimately, it's all about relationships, both within the organisation and beyond. The secret is to pick the right people, create the right culture, support their aspirations, have confidence in them and provide a clear direction – in other words, exercise good leadership."

Asked what the possible drawbacks to working in the public-private sector are, Bountra doesn't hesitate. "There are none," he says.

Bountra sees a trend in the growing number of public-private partnerships like the SGC. "In the past, there were some people who spent their entire careers in pharmaceutical companies, while others tended to circulate among the biotechs. Still others chose a purely academic career path. But all that is changing as the traditional barriers to career mobility start to fall, and this is leading to the growing number of inter-relationships and indeed inter-dependencies between the various sectors." And as these various groupings realise the benefits of working together, then the number of such partnerships will increase further.

One consequence of this greater mobility is that the boundaries between industry and academic research will blur in the public's perception, which will help improve the image of the pharmaceutical industry. The latter is an unfair reputation for an organisation pursuing such a laudable endeavour, he says.

Bountra has already been in his post six months, but he says it feels like five minutes. "I'm privileged to be working with a team of such clever, decent, passionate people – I'm learning so much," he says. What better recommendation could there be for working within a public-private partnership? **SCRIP**

Dr Peter Charlish is a principal analyst for Informa Pharma.

Recruiting in the NFP sector: are there differences?

Elsewhere in this publication we have read much about recruitment in the commercial pharma sector. But can careers in the not-for-profit arena be equally rewarding? Where do the differences lie and who benefits from such a move? **Kevin Young** discusses

Dr Chas Bountra is a prime example of someone who has succeeded in his industry career in new drug discovery and development and is now applying his commercial experience more broadly. This illustrates an increasing trend for high quality executives being attracted into senior not-for-profit (NFP) roles, where their skills are truly transposable.

The "entry criteria" for such roles in the public sector or public-private partnerships usually include:

- A strong academic background in medicine or the biomedical sciences;
- Clear evidence of personal achievement within the business world;
- Ability to think laterally and outside the commercial "box";
- Outstanding interpersonal skills (eg. a collegial style, a good listener yet also authoritative, good communication skills, goal-oriented);
- Resilient under pressure and often, these days, with media presence; and
- Leadership skills.

When searching and interviewing for candidates for key NFP positions, RSA focuses on these and related skills. It can be revealing, for example, when candidates over-embellish their personal achievements. Since many decisions in pharmaceutical R&D are handled by interdisciplinary project teams, we endeavour to dissect out which particular part(s) of a given project they have been truly responsible for; in other words, what would not have occurred had they not been involved. References are sometimes (but not always) useful in this respect, so careful interviewing is important in order to present candidates in the most appropriate light.

process

All clients – companies from the private sector and NFP organisations – want to attract high calibre people. But the routes to achieving this do vary. The single biggest difference in the NFP sector is that a Selection Committee is usually established to provide the initial recruitment brief, to

subsequently review the long list of interested candidates, then interview the best short list, and select and appoint the preferred candidate. Frequently this can involve professorial-level experts, based internationally, and this can impact on timelines – arranging meetings can be time consuming and delays ensue. Candidates therefore need to be kept informed and reassured by us, sometimes for several weeks or months, so that they do not lose faith or interest. We strive to give them all genuine feedback on what is happening behind the scenes, without breaching our terms of reference to the Selection Committee(s).

In consequence, recruiting at the level of research director, chief scientific officer or CEO can take between 6-9 months, depending on availability of the Committee members and the potential candidates.

So, more patience can perhaps be required in applying for NFP roles (however frustrating this may be). The corollary, of course, is that good people are in demand and won't wait forever, so RSA applies pressure where possible to minimise delays.

terms and conditions

There was a time when there was no level playing field between the industry and the NFP sectors in terms of compensation packages. Over the past five years, international market forces have partly redressed this imbalance. Now it is not uncommon for base salaries in the NFP sector to be similar to those in the industry (or at least 80-90%), and for merit-related bonuses to be payable. Pension arrangements can also be attractive.

The main area of discrepancy is clearly the loss of major company benefits such as stock options. In the minds of some candidates, this differential is "compensated" by a greater degree of operational freedom and by increased security: senior NFP roles are often offered for a minimum term of five years, with the opportunity for renewal. There may be additional benefits that will accrue if a particular technology or operating company can be "spun out".

Perhaps the candidates best suited and most successful in transferring from industry to the NFP sector are:

- Those who have hit a glass ceiling in the private sector; or
- Those who, for example, are confronting their second or third merger, and are limited or frustrated in their ability to fully apply their skills in the emerging organisation.

They seek fresh challenges that capitalise on their extensive experience in biomedical R&D. They are generally motivated by an improved quality of life and perhaps increasing personal influence on corporate strategy and direction. Dr Bountra is an example of someone who has successfully made this transition and, significantly, is enjoying the new challenges.

This is not to underestimate the issues that senior executives have to confront in the NFP sector: often these include raising finance and keeping multiple stakeholders on side.

The end game for all – in industry and the NFP arena – is the improved understanding of disease mechanisms and development and application of new diagnostics and therapies. This requires high quality executives with the foresight and mental agility to identify and pursue the rich seams of research that offer the best prospect of delivering improvements.

RSA relishes the challenges of finding candidates around the world to fill key senior roles. It is continually enjoyable and a privilege for us to engage people at the top of their science or sub-specialty, introducing them to other avenues where they can apply their experiences and make an impact. **SCRIP**

Kevin Young is Director of RSA Science & Medicine.





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Company profile

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BMS in the UK is always interested to hear from top talent from both within and outside the pharmaceutical industry, especially in the following areas:

- Marketeers
- Disease Area Specialists or Medical Science Managers
- Healthcare Managers/Payor Management Specialists
- Sales Representatives, Key Customer Managers & Regional Sales Managers
- Regulatory Affairs Specialists
- Health Economists

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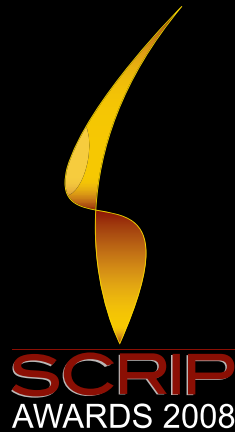
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