

4

- Sterile fill/finish
- Potents
- GMP radio-labelled products



Greetings and welcome to the latest issue of...

# scmpharmatimes

With lots of exciting developments at SCM Pharma over the last few months, issue 4 kicks off with a view from the top as the company's new managing director shares her views on the pharma industry and her first few months at the helm.

Along with bringing you bang up-to-date with the latest goings on at SCM Pharma, including the launch of new in-house testing services, we also bring you an exclusive Q&A from one of the top men at a leading European speciality pharmaceutical company who believes locked prices, forced price reductions for reimbursable pharmaceuticals and government spending on healthcare will undoubtedly affect the pharma industry in the years to come.

Our very own contract manufacturing connoisseur, Mr Mike Parry, chips in with his view on the changing pharma outsourcing landscape.

And finally, with some of the sector's biggest global gatherings on the horizon, we have the low down on key dates and events you can meet Team SCM if you're planning to hit the skies.

Any comments or suggestions are always welcome at [info@scm-pharma.com](mailto:info@scm-pharma.com) ...only if they're nice of course!

Enjoy....

WHO ARE THESE GUYS?



FIND OUT ON PAGE SIX...



Dianne Sharp,  
managing director

## SERVICE PLEASE...

*By Dianne Sharp, managing director at SCM Pharma*

The crucial point in any relay race is not the legs themselves but those vital few seconds of baton exchange.

Many an Olympic medal has been won or lost due to dropped batons and fumbled handovers. This was something Shirley Dann and I were keenly aware of when I joined SCM Pharma as MD earlier this year. Shirley has been key in supporting our growing client base and the business to this point and therefore Shirley's time supporting me in a business development

role for the last few months has been vital to ensure that these internal changes do not affect our service levels. Now, as Shirley moves on and I have the baton firmly in hand, SCM Pharma is entering the next exciting leg of its development.

Having developed our key services in the manufacture of novel, difficult and dangerous drugs, we are now expanding these services to deliver end to end solutions for our client partners. Since the last edition of scmpharmatimes, we have introduced sterility and BET in-house testing and are actively working on additional testing services, supported by a 50% increase in our analytical staff. Scale-up capabilities have continued to receive investment including a larger depyrogenation oven, automated aseptic ampoule filling and automated leak testing of ampoules.

*We recognise that, today, clients are looking for long-term partnerships to provide expertise and share risks. Managing outsourced relationships is costly for clients and therefore the more services that we are able to support clients with, the lower the number of relationships a client has to manage.*

Having built our expertise in the supply of clinical trial manufacturing services, the last year has seen SCM Pharma deliver and expand its commercial scale services and capabilities, thereby reducing the risks and costs for our clients associated with technology transfer at the crucial commercialisation stage.

So in this new era at SCM Pharma, what is our philosophy for maintaining long-term relationships? Service, service and service. It is that simple and that complex. Working with clients, understanding their needs, being open and honest and remembering that we will be judged on the relationship delivery and not the number of ampoules. There will always be issues; the question is not whether you have any but how you resolve them.

And so I am delighted to be part of team SCM Pharma and I look forward to meeting more of you over the coming months both on-site at our facility and at the many events we are attending – I'll be the one holding the orange baton!



## SANOFI CALLS ON CMO FOR REPEAT C14 PROJECT



FRENCH pharmaceutical company sanofi-aventis has once again selected SCM Pharma for the fast-tracked fill/finish of a radio-labelled product.

Just a year after appointing the company for the initial phase of the project, the world's second biggest pharmaceutical firm has opted to utilise the services of SCM Pharma for the aseptic manufacture and filling of a cytotoxic compound.

The potent oncology product will be filled into vials under aseptic conditions and then QP released at the CMO's facility within just two months before being packaged at sanofi-aventis and distributed to clinical trial sites.

The project is being led by sanofi-aventis' Analytical Sciences Department based in Alnwick. Head of production at sanofi-aventis said: "We were very impressed with the manner and speed in which SCM Pharma was able to deliver the project last year. The team showed great willingness to meet the tight deadline and was able to come up with solutions to solve the challenging production requirements.

"Based on its performance, we had no hesitation in approaching and appointing SCM Pharma with another project. We are looking forward to working with the team again and expect they will once again deliver the product in time for our scheduled Phase III clinical trials."

The radiopharma supply service includes the cGMP production of sterile radiolabelled products, both intravenous and other in dosage presentations.

## TESTING. TESTING. 1, 2...

SCM Pharma has launched two new testing services to complement its sterile manufacturing capabilities and reduce the risks associated with offsite testing for client projects.

The company has introduced **Sterility and Bacterial Endotoxin Testing (BET)** that supplement its existing analytical, stability and microbiological testing capabilities. Both methods are set to be rolled out for clients on a number of recently secured contracts following the full validation of both services.

Debra Hagel, QC manager at SCM Pharma, said: "The launch of these in-house testing services is a major milestone in that it allows us to fill, test and release sterilised product for our clients all under one roof.

"Not only will this reduce the potential risk of loss, breakage, documentation issues and delays associated with offsite testing but by allocating testing slots straight after sterile filling, our clients are likely to get their product even quicker," added Debra.

In-house sterility testing is performed within a validated grade A environment utilising a sterility test isolator situated within a cleanroom. BET meanwhile is performed in a designated area of the microbiology laboratory using the Quantitative Turbidimetric Assay technique and using GMP-compliant software to allow quick generation of COAs and results.

Both services are a logical addition to its established in-house aseptic processing and terminal sterilisation capabilities that allows the company to sterile fill ampoules, vials and syringes.





## SCM briefs

### SCM'S OBE

**DIRECTOR** at SCM Pharma, Fiona Cruickshank, has been awarded with an OBE following the unveiling of the Queen's annual 2010 Birthday Honours List.

One of the North-East's most popular and respected entrepreneurs, Fiona was given the prestigious title for her services to business in the region. She was one of only four pharmacists in the UK and two people in Northumberland to land such a prize.

She said: *"This really is a great honour for all the people who have worked with me. I am very pleased manufacturing and pharmaceuticals in the North East have been recognised in this way."*



Fiona Cruickshank,  
owner and director

### VIALS DELIVERED TO FAMOUS UNIVERSITY



SCM Pharma has successfully completed a quick-fire aseptic processing project for internationally-famous academic institution, the University of Oxford.

The university's team required the aseptic processing of 2000 2ml vials, which took place in a sterile isolator located in a grade C cleanroom at SCM Pharma. The vials were then packed, QP released and delivered for use in a clinical trial.

Ian Pardo, quality assurance manager at the Clinical Biomanufacturing Facility, University of Oxford, said: "We were instantly impressed with the approachable, friendly and knowledgeable nature of the team at SCM Pharma.

"When the project faced challenges, their team kept us informed and up-to-date with the status of the project timelines. More importantly, having rejected the initial batch due to a quality issue, this filled us with confidence in the sense that this was a CMO with robust quality systems that would not release a batch unless the product was 100% right.

"The products delivered were great and overall, we had a very positive experience dealing with SCM Pharma and look forward to working with them on a regular basis," added Ian.

Graham Dotchin,  
commercial director



### AND SAY HELLO TO OUR NEW DIRECTOR...

Graham Dotchin has been appointed as the new commercial director at SCM Pharma to assist with the company's current growth and future expansion plans.

He joins the team after spending an interim period with the business as its finance manager in 2009. A former professional basketball player, 12ft Graham (ha ha, just kidding Mr D!) arrives with a decade of finance experience in corporate management.

His arrival at SCM Pharma coincides with a major recruitment drive that has seen a further six new employees join the firm, taking staff numbers to 54.

Graham said: *"My aim is to grow the business by ensuring our clients' needs are constantly being met with regards to meeting product delivery timelines and providing exceptional customer service."*

# scmpharmatimes

**EXCLUSIVE**

## Q&A with... NordMedica

This issue, our exclusive Q&A comes from one of the senior team members at Denmark-based pharmaceutical firm NordMedica A/S - Mr Mads Renlef Henningsen.

### Hi Mads, can you explain what NordMedica does?

NordMedica is a privately held specialty pharmaceutical company focused on the commercialization and marketing of niche pharmaceutical products in specific therapeutic areas. Our business concept is about acquiring well established, original medicinal products from international pharmaceutical companies to be marketed mainly to hospitals within the EU.

### How did you get involved / what was the inspiration?

NordMedica was founded in 2003 and the founders possess extensive international management experience from the pharmaceutical industry, acquired in the Nordic area, Europe and Japan. In 2003 the two founders gained access to acquiring some niche hospital products from a large pharmaceutical company, and decided to start their own company in Denmark with a Nordic focus. Today NordMedica has made more than 10 acquisitions and divestments and we sell our products in more than 15 countries worldwide.

### Has the company been affected by the economic downturn?

Yes. Access to risk-willing capital for larger acquisitions was hard to obtain during 2008/2009. Luckily this has changed.

### What are your views on the challenges facing the global pharma industry?

Locked prices or even forced price reductions for reimbursable pharmaceuticals, and increased awareness on government spending on health care will undoubtedly affect the industry in the upcoming years.

### What role has SCM Pharma played in assisting NordMedica?

SCM Pharma has been our partner in an oncology project over the last year. We have worked closely together in setting up a new production line and SCM Pharma has been a solid and competent partner. We can now proudly say that the first commercial batches are on the market in Scandinavia, Holland and Germany.

### Where would you like to see NordMedica in 10 years?

Our business is based on buying mature products from big pharma companies and this is what we still will be doing in 10 years from now. But hopefully NordMedica will have expanded geographically and the acquisitions might become of a larger scale. Our aim is to be a truly global player with a wide range of niche, proprietary products.

### What's the best bit of business advice you have ever received?

"If you don't know you can't do it, you just might be able to..."

### If you could sum-up NordMedica in three words – what would they be?

Focused, ethical and dynamic.

For more info visit [www.nordmedica.com](http://www.nordmedica.com)

## NordMedica



Mr Mads Renlef  
Henningsen



NordMedica's new  
Corporate HQ

Mike Parry,  
business development  
manager



## FOLLOW THE LEADER...

by Mike Parry, Business Development  
Manager at SCM Pharma

Whilst browsing a recent article in Contract Pharma titled “The Future of Pharmaceutical CMOs, revolution or evolution for the industry?” (Dr Enrico T. Palastro), I couldn’t help but reflect both on the way the pharmaceutical industry has evolved over the last 20 years and in many ways how the CMO sector has followed this lead.

It’s easy to forget yesterday’s names once familiar to the industry that have subsequently been amalgamated into today’s major players on the back of acquisitions and mergers promising synergies, benefits of scale, increased R&D resources, shared “this” and expanded “that”. A familiarity with names such as Fisons, Evans Medical, Hoechst, Rorer, Beechams and Searle now only demonstrate just how close to retirement you might be.

During this period of time, which the industry as a whole has moved into the “mature” phase of its life-cycle, we have seen the CMO sector growing rapidly in response to the massive growth in outsourced services demanded by big pharma.

Currently in Europe alone there are more than 150 CMOs offering various manufacturing capabilities and of course the global outsourcing capacity is many times more. Perhaps this re-positioning, of what is essentially the manufacturing sector, is of no surprise since if one looks outside the pharmaceutical sector, we see similar trends where leading brands in consumer driven markets are now most frequently outsourced.

What is interesting however is that we are beginning to see the same acquisition and merger activity occurring amongst CMOs. As exciting as this may be to shareholders, one must question whether it has the same appeal to its customers.

Big can be beautiful and certainly there is an attraction of the “one stop shop” when looking at the array of manufacturing services on offer from some of the larger CMOs. Frequently I hear of outsourcing managers attempting to rationalize the number of suppliers they deal with and large CMOs with broad portfolios of services must offer a seductive option.

Big, however may not always provide the perfect solution and in his Contract Pharma paper Dr Palastro warns that CMOs wishing to meet today’s demands of suppliers should not necessarily be dazzled by growth. Amongst other attributes they should be “Large enough to matter, but small enough to care and be easy enough to manage”.

*I endorse such sentiments and would like to add a further observation regarding the subject of confidentiality, which is often heralded as the single most important aspect of the customer/supplier relationship and one that can be linked to probably the hottest topic currently facing the pharmaceutical industry - counterfeiting.*

The CMO sector is entrusted with the hard won intellectual property of its customers and as companies grow, especially spanning several continents they must be careful not to jeopardize the sector’s evolving role within the worldwide supply of medicines by losing sight of what is probably the very first commitment ever made to their clients. That client confidentially agreement signed right at the onset might just be another document, but in this increasingly global industry, it’s one of the most important.

With the busy event season about to kick-off, team SCM will be jet-setting to Paris, New Orleans and London over the next few months to spread the word about our specialist services.

## IS IT A BIRD? IS IT A PLANE? NO...

It's the latest two new additions to Team SCM...

To your right ladies and gents are... **Potent Pete** and **Radioactive Ray**.

As the world's leading CMO when it comes to the GMP filling of radio-labelled materials for ADME studies and the fill/finish of highly potent products for clinical trials or low volume commercial supply, our new extended team will be looking to speak to those requiring these extraordinary powers – helping save people across the globe from delayed drug development and the numerous challenges associated with filling life-saving potent products such as cytotoxics and cytostatics.

As you know, here at SCM Pharma, we believe people like doing business with people. And there is nothing better than a time-honoured face-to-face meeting to talk, catch-up, find out what's going on and share industry knowledge. So, if you're attending any of the following events over the next few months, drop us a line or email us at [coffee@scm-pharma.com](mailto:coffee@scm-pharma.com) if you would like to meet us for a quick cuppa...



5-7 October 2010

ICSE/BioPh (CPhI)  
Nord Villepinte Exhibition and  
Convention Centre  
Paris, France



14-17 November 2010

AAPS  
Morial Convention Center  
New Orleans, USA

## GENESIS

9 December 2010

Genesis  
Queen Elizabeth Conference  
Centre  
London, UK

Whether meeting us again or maybe for the first time, let us know where and when suits you so we can pop it in the diary.

Either way, we'll work around you. Let's get together. We'll see you soon.



# POTENT PETE

# RADIOACTIVE RAY

## Our new e-home

If you have not already, please pay a visit to our brand spanking new website that is jam-packed full of news, views and helpful information about choosing a CMO. Just Google SCM Pharma and enjoy...

You can also access this and previous scmpharmatimes issues online. To make things easier, just subscribe to our newsletter on our homepage and we'll make sure you're kept up to date with developments at SCM Pharma.

## Can we help you?

Here at SCM Pharma, we like a challenge. We're also rather good at solving problems. For instance, if you've got a tricky looking clinical trial manufacturing project on the horizon such as the aseptic processing of a potent radio-labelled product, a small batch needing to be terminally sterilised, the filling of a novel medical device, or maybe you need a specialist contract partner for ongoing commercial supply of a licensed product, then let's talk.

## Getting connected



If you're on LinkedIn then become a follower of SCM Pharma at [www.linkedin.com/companies/scm-pharma](http://www.linkedin.com/companies/scm-pharma)

## Tweet tweet



If you would like to follow SCM Pharma on Twitter, then please visit us at [www.twitter.com/scmpharma](http://www.twitter.com/scmpharma) and become a follower.

## Contact

To get in touch with SCM Pharma about any current or future projects, please contact our business development team +44 (0) 1661 833 693.



# scmpharmatimes

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