



SCM Pharma is a dedicated Contract Manufacturing Organization (CMO) that provides a wide range of specialized sterile development, manufacturing, fill and finish services to current Good Manufacturing Practice (cGMP) regulations.

And we're a CMO with a difference. Open up and read on to find out why...



Hello North America

We're SCM Pharma and we specialize in the custom manufacture of novel, difficult and dangerous drug products for clinical trials and commercial supply. So if you've got a tricky manufacturing project on the cards, let's talk.

Our corporate HQ and manufacturing facilities are located in Northumberland in the UK with a commercial office in New Jersey, USA. We're a privately-owned business that operates from an MHRA-licensed facility and work with pharmaceutical, biotechnology and medical device companies in North America and Europe.

If you're anything like our lovely clients, you'll have an unusual product, a complex manufacturing process and/or need a European-based manufacturing hub to support gateway testing, release and distribution into Europe. And if you've got something completely off the wall, then our technical team are really going to love you!

We're a bit like a CMO yoga guru. Flexible and always stretching to adapt to our clients' product manufacturing needs. So if you're after the sterile filling of a clinical batch of vials or the regular supply of a few thousand ampoules, then we can help. And if your product is Carbon-14 (^{14}C) radiolabeled or a potent, that's fine too.



"SCM Pharma has played a critical role in the manufacturing of our products, particularly for our clinical trials. We have worked with the SCM team for a number of years and their expertise and ability to meet the manufacturing challenges associated with our novel dosage form has been extremely useful."

Charles Potter

CEO at specialty medical device developer, Glide Pharma

"We were very impressed with the manner and speed in which SCM Pharma was able to deliver the fill/finish of our radiolabeled cytotoxic compound. The team showed great willingness to meet the tight deadline and was able to come up with solutions to solve the challenging production requirements. We've had no hesitation in appointing SCM Pharma for a repeat project to deliver our product in time for our scheduled Phase III clinical trials."

Head of production at top five big Pharma, Sanofi-aventis (UK)



Our shiny facilities

www.scm-pharma.com info@scm-pharma.com

SCM Pharma operates from a state-of-the-art, purpose-built 17,000 sq. ft. facility, specifically designed to meet cGMP standards and satisfy the needs of clients that require Investigational Medicinal Products (IMPs) or commercial supplies of niche licensed medicines. Our expanding facility will be inspected by the FDA in Q3 2011 and includes –

- Seven cleanrooms – all Grade C (class 10,000)
- Aseptic processing isolators
- Dedicated suites for handling potent materials
- Formulation, analytical and microbiology laboratories
- Batch sizes up to 200 Liters
- Inspection areas
- A range of packaging areas
- Temperature controlled warehousing

Watch this space. To cater for new client projects and the scale-up of existing contracts, we are also planning to invest in the opening of a second facility and additional filling equipment in 2011/2012. So if you got something in the pipeline, let's get it booked in.

Our bread and butter

Whether you're looking for product supply for clinical trials or a commercial market such as orphan drugs, we provide a range of services to meet your specific needs. These include –

- Process development
- Aseptic processing (using isolator technology)
- Non-aseptic processing followed by terminal sterilization
- Fill/finish of ^{14}C radiolabeled compounds
- Fill/finish of highly potent products including cytotoxic and cytostatic formulations
- Drug/medical device filling and assembly
- In-house testing including sterility, endotoxin, microbiology and analytical chemistry
- ICH stability testing
- Clinical packaging and distribution
- QP release

Generally, we manufacture liquids, gels and powders in a range of final dosage forms including ampoules, vials, cartridges, syringes and bottles. But if you've got something a bit unusual that's causing a bit of head scratching, then let us take a look. If we can help you, hurrah! If not, our team's industry knowledge means we will be more than happy to at least point you in the right direction.



All projects are not created equal



Our manufacturing services are custom designed and adapted to meet individual client requirements. So if you have a product or device that has special requirements such as short runs or a complex process, that's right up our bright orange-lit street. Novel, difficult and dangerous...now you're talking. So if that fits with what you're after, then give us a call.

Radiopharma – fill/finish of ^{14}C radiolabeled compounds

OK, now the seriously smart bit. We are licensed to handle, process and fill ^{14}C radiolabeled compounds to cGMP. This specialized in-house capability allows us to provide you with the option of combining radiolabeled drug products with aseptic processing for injectable presentations.

We have worked with some of the world's largest pharmaceutical companies on such projects, providing finished products to enable them to carry out absorption, distribution, metabolism and excretion (ADME) studies at pre-clinical and clinical trials stages.



"SCM Pharma were very insightful, professional and helpful from start to finish. Even when the project required changes, they were able to guide us through the process, while being flexible to adapt to the new requirements. I was very pleased the team was able to guide us through the project and run this element of the study in a smooth, trouble-free manner."

Frances C. Hall

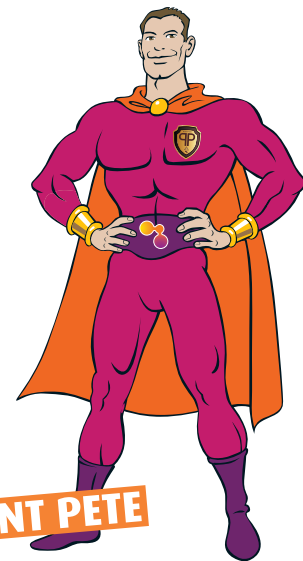
Lecturer and Honorary Consultant in Rheumatology, University of Cambridge

Potents – fill/finish of highly potent drugs

The clever stuff doesn't end there either. We are also licensed to handle highly potent products, for example cytotoxics and cytostatics, which can be produced aseptically, terminally sterilized by autoclave, dry heat or irradiation.

Our cleanrooms include dedicated suites with their own air handling systems, designed specifically for the manufacture of such products and to minimize the risk of any cross contamination. Our patient-friendly facility also provides an ideal solution for clients requiring the containment and development of new formulations.

The disposable isolator technology used at SCM Pharma has provided several clients with a cost-effective solution to complex potent processing as it also offers full environmental controls such as humidity, temperature and light. The use of disposable technology for equipment dedicated to a process can minimize your investment and time to market. Dangerous products and fast-tracked delivery. What a potent combination.



POTENT PETE

A person wearing a blue protective suit, hood, and mask is working in a laboratory. They are holding a small vial and a red pipette tip. The background is slightly blurred, showing other laboratory equipment and another person in a similar suit.

Your gateway to Europe

Like many North American firms, one of the issues you may face is that of the EU approval required for distributing any drug products from North America into Europe. So whether you have a product for clinical trials or commercial supply, we can be your pal across the pond for gateway testing and QP release to give your drug the approval it needs for European distribution.

And if you're planning a clinical trial in Europe, even better, as we're well placed to help you out. Our talented team will provide rapid tech transfer, manufacturing, testing and release all under one roof. This helps reduce your costs and time to market. Compelling stuff we think.

Clever techy folks

As you can see by the pictures, we do have a pretty fancy facility. Yet, in truth, clients tend to select us again and again for our expertise and experience in devising creative solutions for difficult processes. Our people are the really clever bit. And we smile a lot too.

When you work with SCM Pharma, you get a team of commercial, technical, production and quality experts that have varied and in-depth experience in clinical trial and commercial manufacturing. You also get an account management group dedicated to managing your project to ensure it is on track and in budget.

Every project is conducted under stringent quality standards. Regular client audits, biennial MHRA inspections, internal quality reviews and staff training ensure we comply with cGMP at all times and maintain our focus on continuous improvement to enhance our quality performance. SCM Pharma is also anticipating and actively preparing for an inspection from the FDA in 2011. We hear they're pretty tough. Don't worry, we're in training and will be more than ready.

Whether you're in big pharma, specialty pharmaceutical, emerging biotech or a virtual company, our goal is to always add value. Coming up with new ideas or technical solutions for a novel process, expanding your existing capacity, increasing productivity, ensuring a continuous supply of product or quite simply to reduce your time to market or overall cost – that's just what we do.



“SCM Pharma has been our partner in an oncology project over the last two years. 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 commercial batches are on the market in Scandinavia, Holland and Germany.”

Mads Renlef Henningsen

Vice president at specialty pharmaceutical company, NordMedica A/S



Working with the orange ones...

At SCM Pharma, we ensure all enquiries and discussions are dealt with in an open, professional and pro-active manner. Whatever your requirement, you can expect the highest level of service from our passionate and friendly team. And if you're at AAPS, Interphex or Contract Pharma, that's us with the bright orange ties!

Even though we're a vibrant business that proudly differs from the rest of the CMO crowd, one thing we have always taken very seriously is confidentiality. So if you partner with us, rest assured, it'll be our little secret. Due to the nature of the projects we undertake, things don't always go to plan. But no matter what unforeseen issues arise, we aim to be transparent and stick to what we quote you, avoiding the dreaded 'additional costs'.

We also do what we do to ultimately help people and improve healthcare. We understand our moral obligation to meeting patient needs and never underestimate the importance of delivering quality medicines on-time. Late nights. Early mornings. It doesn't matter. Whatever it takes. We'll do all we can to deliver your product.

Whether you're looking for a preferred partner, supplementary supplier or contingency vendor, we always look to build long-term relationships with our clients. Tactical outsourcing or looking for something more strategic? Either way, let's get together for a coffee or at least a quick chat over the phone.



Challenge us

Here at SCM Pharma, we like a challenge. We're also good at solving problems. As far as contract manufacturing goes, we know we're different. And hope now, you do too.

So, if you've got an unusual clinical trial manufacturing project on the horizon such as the aseptic processing of a radiolabeled product, a small batch of vials needing to be filled and terminally sterilized, or maybe you need a partner for commercial supply of a licensed potent product, then get in touch as we'd like to talk to you.

Whatever your requirements, we invite you to challenge us.

"With regular demand for our product Ketensin in the Netherlands, we required a contract manufacturing partner that could not only sterile fill into various sizes of vials and test the finished products, but that could reliably deal with smaller commercial quantities. We have been impressed by the customer interaction, willingness and technical ability demonstrated by SCM Pharma and look forward to working with the team on an ongoing basis."

David Traynor
Senior VP manufacturing and pharmaceutical sciences at specialty pharmaceutical company, ProStrakan

Let's talk...

North American enquiries

SCM Pharma Ltd
197 Route 18 South
Suite 3000
East Brunswick, NJ 08816
Tel: 732-214-2541

All other enquiries

SCM Pharma Limited
Unit 6 Regents Drive
Low Prudhoe Industrial Estate
Northumberland
NE42 6PX

Tel: +44 (0) 1661 833 693
Fax: +44 (0) 1661 835 010
info@scm-pharma.com
www.scm-pharma.com