

SCM Pharma - Radiopharma Services

Radio-labelling

- Radio-labelling relates to the attachment of a radioactive portion to a drug molecule
- SCM's UK-based state-of-the-art facility is fully MHRA licensed and the company has the in-house capability to handle and process Carbon 14 radio-labelled compounds – for intravenous (IV) presentations and other dosage forms
- After taking delivery of the radio-labelled compound, SCM can develop and manufacture, and fill this into a usable dosage form, under GMP conditions to allow clients to carry out absorption, distribution, metabolism and excretion (ADME) studies at the pre-clinical or clinical trials stage
- The process is extremely beneficial in terms of speeding up the drug development cycle as both cost and lead time are shortened. Identification of drug distribution and metabolite identification becomes possible at this early stage in the development of the drug molecule

Pre-clinical trials (Phase 0)

- SCM's innovative manufacturing and filling radiopharma services can be invaluable at this very early stage in terms of helping clients gather vital information about their drug, therefore limiting significant expenditure by screening a range of potential drug candidates earlier in the drug development process
- As SCM is able to provide small scale quantities in low dosage forms, clients are able to microdose a small number of patients. This limits the potential risk to the patient when compared to standard dosing which is often carried out later in the clinical trials process with a greater number of volunteers

Clinical trials (Phase I-III)

- SCM's radiopharma offering can also be useful later in the development process, to gain greater insight into the action of a drug whilst in the clinical phase. This again can help eliminate potentially harmful drugs at an earlier stage of development and reduce expenditure on unsuitable drug candidates

Given current industry trends and the rising costs associated with developing new drugs as well as fewer new drugs coming through to launch, radiopharma is an area where SCM can deliver huge benefits to its clients. By providing handling, compounding, filling and packaging services for radio-labelled materials, SCM can add true value to a project by enabling clients to carry out the types of studies mentioned above.

SCM's pioneering facility and highly experienced quality team allows it to process a range of different radiolabelled drug dosage forms, including cytotoxic and biological materials and those requiring sterile and aseptic processing. The company's exceptionally high quality standards can provide an ideal contract solution for clients looking to outsource this element of their project whether in the pre-clinical trial or clinical trial stage.

If you currently provide a similar radiopharma service and are operating at maximum capacity and are considering contracting-out an element of your radiopharma manufacturing, then feel free to get in touch with SCM. In addition, if you're in the business of labelling or 'tagging' drug molecules, then SCM would like to hear from you to see whether it can help progress your or your clients projects to the manufacturing and development stage.

Aside from its radiopharma services, SCM provides a wide range of small-medium scale manufacturing, development and packaging services to meet both clinical trial and commercial needs. Working with companies ranging in size from top 20 pharma to small virtual development companies, SCM operates as a centre for excellence and caters for clients in the pharmaceutical, bio and healthcare sectors. Its specialist offering also includes sterile and non-sterile manufacturing, aseptic processing, biologicals, cytotoxics and clinical packaging services.

cGMP Manufacture of C-14 Radio-labelled Investigational Medicinal Products

- Sterile IMP's are manufactured in an isolator sterilised with vaporised hydrogen peroxide which affords a greater level of sterility assurance for aseptically manufactured products. The isolator is situated in a grade C cleanroom (Class 10,000)
- Oral IMP's, such as hard gelatine capsules or powder in vial for reconstitution in the clinic are manufactured in a containment isolator in a grade C cleanroom
- Cold chain storage and worldwide shipment available (e.g. 2 to 8°C or -25°C monitored)

The Process

- > Technical agreement and product specification file prepared detailing the responsibilities of each party and documents all technical information necessary to manufacture, pack and QP release the IMP.
- > Risk assessment performed on the process for sterility assurance. Short term stability study initiated to provide a usable shelf life.
- > API manufacturer synthesises the radio-labelled API to cGMP in its MHRA approved facility and provides a certificate of analysis.
- > The compound is securely transported to SCM Pharma and then securely stored under the correct and monitored storage conditions (e.g. -25°C).
- > QA/QC receipt checks are performed and the compound released for IMP manufacture together with all components and excipients required.
- > Components and equipment are prepared and the isolator sterilised with vaporised hydrogen peroxide. Bulk solution compounded to the required specific activity and sterile filtered then filled into type I glass vials to the required fill volume and then sealed with stopper and aluminium overseal. 100% visual inspection performed.
- > Batch tested to the product specification detailed in the IMPD/IND including but not limited to sterility, endotoxins, assay, related substances and specific activity.
- > Label text approvals obtained and the batch clinically labelled and packaged in accordance with client requirements.
- > Qualified Person release of the product to the clinic - cGMP release and Regulatory Release (the latter can be performed if the sponsor supplies the Clinical Trials Authorisation and the ethics committee approval).
- > Ship to the clinic worldwide with certificate of cGMP Compliance and Certificate of Analysis.

Other Services

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