Life Science Production (LSP) is a division of Life Science Group Ltd (LSG). This division participates in the manufacture of custom cell culture sera, media, buffers and associated reagents. LSP offers a variety of bespoke buffer and media solutions for groups looking to outsource their manufacturing and production processes.

We have put together some FAQs to assist with the decision-making process.

Why outsource media production?

Outsourcing of buffer and media production has some clear advantages including savings of time, resources and robust quality systems. Production of media for a specific process is frequently a distraction from the main operation. Outsourcing offers economy of scale, independent quality control testing and expertise in formulation and raw material sourcing.

IP Protection

All buffer and media formulations remain the property of the customer. All work conducted at LSG is protected by non-disclosure agreements. Formulation information is strictly controlled through the LSG management team with access control and electronic document control ensuring that there is safe, effective and efficient use of information, protecting the interests of the customer at all times.

Documentation

LSG is an ISO 13485-registered company. The company works to cGMP for all production processes. Documentation is discussed at the start of a project to ensure that all documentary and regulatory requirements of the customer are met in full. Specifications are developed jointly and a project progresses only once the full specification has been agreed and signed off by the customer.

Traceability

LSG is an International Serum Industry Association Traceability Certified company. Whilst this certification applies only to the handling of animal-derived materials within the LSG facility, the same stringent traceability controls are maintained for all products as they move through the pipeline, allowing for full traceability of all raw materials and consumables used within a process.

Excipients

LSP is happy to use excipients as per customer's specification and can also often recommend alternative materials from trusted suppliers that may offer potential cost savings.

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Sterile fill

LSP can offer clean room production resulting in an aseptic fill. Samples are despatched for sterility testing at independent registered Quality Testing laboratories. Terminal sterilisation of products by gamma irradiation or by autoclave is also an option.

Quality Control

LSP will discuss the quality control requirements of a project with the customer at the point where the specification of the project is determined. LSP can offer a variety of quality control tests, both from our own Quality Laboratory and through external testing laboratories. The quality report will be designed to meet the requirements of the customer documentary systems.

Batch Size

We can offer batch sizes of up to 1000 litres. -. Small scale manufacturing for either small production, validation or trial batches is available.

Packaging

LSP is happy to dispense products into any commercially available closure, bottle or packaging. Common options are PET and PETG bottles (2 litre, 1 litre, 500mL, 100mL, 50mL etc), single use sterile bags (20 Litres, 1 litre, 500mL, 50mL) and 1000 litre IBCs. Dispensing can also be carried out into cryovials and other small volume closures. LSP is also happy to dispense into specific closures supplied by the customer.

Dispensing

LSP can offer dispensing at a range of bottle sizes and volumes dispensed, from 100µl up to 10mL. We have a variety of automated and semi-automated dispensing options which may be applied to a project.

Cleanrooms

LSP operates in a series of ISO Class 5 and Class 7 cleanrooms with one Grade C/Grade D cleanroom suite specifically built for cGMP manufacture of products that do not contain animal-derived material.

Logistics

We can manufacture and arrange delivery to suit individual requirements.

Labelling

We can label a product with LSP labels or with labels of customer's own design carrying specified details and logo. The design of labels is included within the project specification.

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Shelf-life Determination

LSP can assist with shelf-life determination using accelerated shelf-life studies at a range of temperatures.

Storage

LSP can offer storage at ambient, +4°C and -20°C. For very temperature sensitive items storage at -80°C and storage in liquid nitrogen is also available.

Experience

The management and manufacturing team at LSG has a wealth of experience and expertise in the contract production of serum, media and buffers. Our Quality and Regulatory Team can assist with quality testing and the preparation of technical files and other documentation required. Companies often mention how long they were contributing to the specific market - that would show our experience too.

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