Biotechnology

OLG is a progressive engineering, validation and project management company offering a comprehensive technical and professional service to the Bioprocessing Industries.

Our range of services covers the following key areas:

- Project Design Lifecycle
- People and Material Flows
- Technology Transfer/Scale Up
- Pilot Plant through to Production Scale
- Process Equipment
- CIP and SIP
- Control Systems
- Process Utilities and Effluent Treatment
- Facility Layout, 3D Modelling and Area Classification
- Commissioning and Qualification
- Regulatory Guidance

Our Expertise

OLG has expertise in the process, mechanical and control engineering aspects of media preparation, fermentation, extraction, downstream processing and purification including microbial, fungal and mammalian cell cultures, extracts from live tissues, mRNA and vaccines.

End-to-end expertise in re-usable and single use technologies, covering upstream, downstream, bulk filling, freeze and thaw, drug product formulation and final sterile filtration systems and filling assemblies.

Client Benefits

- Wide cross-sector industry knowledge brings new ideas.
- Trusted professionals who can confidently assume ownership of client processes from Upstream Processing to Drug Substance and Drug Product.
- Full understanding of the regulatory environment enabling compliant facility design features.
- Full project delivery service from inception through to installation and validation.

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Experience Base

- Wide range of process design, scale-up, optimization, troubleshooting and engineering experience across the industry sector
- Thorough understanding of the Regulatory environment and its practical application to the design process.
- Knowledge of the equipment availability and design of bespoke solutions.
- Complete process validation from URS/VMP through to protocol generation and execution.
- Identification of process risks and provision of solutions to unproven technology.
- Introduction of QbD – full integration of systems into the process environment.

Engineering Services

Engineering of all process steps including:

Drug Substance Manufacture

Upstream

- Media preparation, cell culture (bioreactors and fermenters) with control of process environment. Pipework and instruments to GMP and ASME BPE standards. Aseptic transfers and integration of single-use technologies.
- Cell disruption and separation techniques such as high speed homogenization, heat treatment and chemical lysis.
- Harvest by centrifugation or filtration systems to maximise recovery.

Downstream

- Capture, virus inactivation, filtration, purification and polishing via a variety of processes and techniques.
- Bulk filling / freeze and thaw.

Drug Product Manufacture

- Formulation of Drug Product, Sterile Filtration (including PUPSIT), Filling, Freeze Drying, Inspection, Packaging and Labelling

CIP

- Selection and detailing of techniques and systems. Automation of sequences.

SIP

- Design of systems for repeatable validatable operation. Air elimination systems and appropriately placed fittings for Temperature Transmitter and BI's for Validation activities.

Facility Design

- Classification of areas and design of Clean Rooms to EU GMP Annex 1 and ISO14644-1. Process and equipment layout.

Regulatory Guidance

- Design reviews for GMP, Safety, DSEAR/ATEX and containment assessments.

Process Utilities

- Clean services including steam, air, WFI and Purified Water.

Containment Systems and Facilities

- Protection of the process/personnel by appropriate use of RABS and Isolators. Biowaste decontamination systems and effluent treatment. Fumigation and mycoplasma monitoring.

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Whatever your biotechnology challenge why not call OLG to discuss how we can help.

Engineering Today.
Inspiring Tomorrow.