C L S

Complete Laboratory Solutions

MedPharma

integrity without compromise

CLS is the leading provider of **sampling and analysis** to the food, environmental, pharmaceutical and medical device industries. Founded in 1994, CLS has developed a reputation for delivering high quality laboratory data with a customer focused service in a timely manner.

Clients & Quality The CLS group of laboratories has the accreditations and approvals required to allow us work in partnership with our clients.

Staff We view our staff as our most valuable asset. We have a complimenting mix of highly qualified laboratory analysts, supported by CLS staff recruited from the environmental, food, medical device and pharmaceutical industries.

Sample collection We have focused on being the best in the market in the areas of collection, turnaround of results and responsiveness. To ensure this position, we have a fleet of refrigerated vehicles nationwide and CLS staff based in Galway, Dublin and Cork.

Reporting At CLS we have developed a bespoke in-house Laboratory Information Management System (LIMS) and an Enterprise Resource Planning System (ERP). Results of tests are available online. Clients can securely download their results and trend their data and or apply limits for compliance. The system complies with GAMP guidelines and FDA 21 CFR part 11.

Sampling and analysis at CLS or Client sites: We can provide clients with an option to outsource their testing requirements to CLS state of the art laboratories & technology or CLS's analysts can work from client sites on contract and conduct the sampling and or testing there.

Our centres of excellence include the following:

Water / Environmental

Microbiological
Chemistry
Sampling / Training
Supply analysts on contract
Pipe & Tank Sterilisation
Noise / Vibration

Pharmaceutical/ Medical Devices

Microbiological
Analytical / Stability
Sampling / Training
Supply Analysts on Contract
Air / Validation
Healthscreening

Food/Beverages

Microbiological
Food chemistry
Sampling / Training
Pipe & Tank Sterilisation
Air / Validation

Experienced

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CLS MedPharma

CLS, a long established market leader in laboratory services, has dedicated facilities to lead its centre of excellence to service the Pharmaceutical and Medical Device Industries. CLS's cGMP approved testing facility works in partnership with leading manufacturers of medical devices and pharmaceutical products. CLS's MedPharma is managed by senior experienced personnel who understand the industry. CLS has invested in state of the art facilities and technology to deliver the most up to date and appropriate solutions to their clients. For CLS this ensures that they continue to work in partnership with leading companies and for their clients this helps to ensure they support their current products and help create their future business and next generations of products.

CLS provides cGMP approved Analytical Chemistry and Microbiology testing using Compendial test methods / Customer specific test methods, ICH /FDA Guidelines or relevant ISO Standard.
In addition, its capability includes stability storage and subsequent testing as per ICH guidelines and also includes provisions for performing batch release testing and subsequent QP release as per EEC Directive 75/319/EEC.

CLS continues to offer strategic supports to their cleanroom and pharmaceutical clients by providing **sampling**, **testing** and **product release** services.

CLS MedPharma supports and works in partnership with the following:

- Pharmaceutical
- Medical Device Manufacturers
- Biotechnology Companies
- Hospitals (Sub group's operating theatres, chemo, IVF, Bloodbank, & Maintenance)
- Electronics
- High Risk Industries

Client Benefits

CLS MedPharma provides Relationship Management to all of its clients, sharing information, and endeavouring to facilitate their requirements quickly using an experienced team who are committed to our quality systems.

CLS MedPharma provides flexibility, innovative technology, cutting edge solutions, nationwide collection service and the ability to adapt and meet our client's business requirements leading to long term partnerships.

Analytical

A Sample range of our Analysis:

- Full range of raw material testing (API / Excipients- including cytotoxic drugs) in accordance with USP, BP, EP and JP
- Batch release testing (chromatography, dissolution, spectroscopy, wet chemical analysis and physical testing)
- Validation and subsequent routine monitoring of water systems
- Analytical method validation as per ICH Guidelines
- Process and Cleaning validation analysis
- Storage of retain samples as per GMP
- Oral dosage forms (tablets, capsules, sachets, liquids)
- Injectables and Ophthalmics
- Topicals and ointments
- Medical Devices /Combination products

CLS MedPharma leading Technology offers a complete independent testing service to its clients including:

- Chromatography –(HPLC, TLC, GC)
- Spectroscopy – (UV Vis, FTIR)
- Dissolution testing
- Wet chemical techniques
- Physical testing of tablets
- Microbiological tests (Microbial limit test, Endotoxin, Bioburden)
- Environmental Monitoring
- Water testing as per USP /EP
- Full generator and UPS back up

Analytical Microbiology:

- Microbial limit testing of raw materials and finished products
- Endotoxin test method development, validation and subsequent testing using gel clot and kinetic turbidiometric methodologies as per FDA /AASMI Guidelines
- Bioburden method development, validation and subsequent testing as per ISO 11737
- Validation and subsequent routine monitoring of water systems
- Identification of micro organisms (API,VITEK)
- Detergent and disinfectants testing as per USP

Analyst performing reverse phase chromatography at CLS MedPharma

Non viable monitoring (Particulate counts) of a cleanroom by a CLS technician

Cleanroom Classification

Cleanrooms are Classified A-D; classifications are awarded in accordance with the number and size of particles per volume of air.

Validation Projects

CLS Pharma can conduct a wide range of customised validation projects. This can be an already prepared project that has been specified and scoped out by our client or in consultation with CLS. There is a valuable resource of expertise and knowledge that can be shared within our team and programmes can be drawn up and agreed. The following are examples of validation projects. An extended example of one of the areas 'cleanroom validation' is given below in more detail.

- Method Transfers from client sites to CLS Pharma
- Methods developed to client specification, international guidance or non specific
- Process Validation
- Process Simulation
- Purified Water Systems e.g. Operational Qualification (OP) and Production Qualification (PQ) Purified to water for injectables
- Various classification validations
- Cleaning / Detergent efficacy
- Training / Comparative validations
- Pilot Validation studies
- Material Integrity Validation

Cleanroom Validation (an extended example of a validation project)

- Design the validation programme in accordance with the clients requirements
- Draw up specifications and compliance requirements
- Specify testing requirements and accreditations
- Compile a working document and report structure
- Include interpretation and compliance discussion
- Follow and design monitoring programmes and set up warning and action limits
- Trained technicians conduct environmental sampling
- Viable sampling and analysis of surfaces, air, personnel and water
- Non viable sampling and reporting of non viable counts
- On site recording of environmental conditions, number of personnel present, etc
- Following through on over action results: Gram stains and Api identification
- Setting up of a company library of strains identified
- Troubleshooting for recurring issues

Microbiology Department Scope includes:

Environmental monitoring:
- Particulate
- Viable
- Surface /contacts
- Finger swabs
- Gowning

Product testing:
- Endotoxin
- Bioburden

Water:
- Endotoxin
- TVC filtration

Identifications:
- API
- Gram stains
- Bbl crystals

Stability Testing & Storage

Our range of services includes ICH Stability storage facilities that are fully supported by our GMP operating Analytical Chemistry and Microbiology Laboratories. We have extensive experience in working with many dosage forms, drug substances and excipients.

CLS MedPharma stability facility includes:

- Fully qualified facilities with associated operation and control documentation
- Trained and experienced staff
- Standard reach in rooms operating at :
  25 +/- 2 /60 % RH+/- 5%
  30 +/- 2 /65 % RH+/- 5 %
  40 +/- 2 /70 % RH +/- 5%
- All conditions logged to provide continuous record of compliance
- All temperature and humidity conditions alarmed with 24 hour / 7 day call out response
- Preparation of stability protocols as per ICH Guidelines
- High security facility
- Full generator back up in the event of power failure
- Comprehensive preventative maintenance program

Bacteriological plate analysis at CLS

Routine analysis at CLS MedPharma

Instrumentation:

Along with a state of the art facility CLS MedPharma houses all of the most up to date technology available, ensuring we have the capabilities and equipment to meet your specific requirements

- HPLC with UV and PDA Detection systems
- GC with FID /MS Detection systems
- FTIR Spectroscopy
- UV Spectroscopy
- TOC Analyzer
- Dissolution testing
- Particle size analyzer
- Karl Fischer
- Muffle furnace
- Containment unit for cytotoxic drugs
- Kinetic turbiometric analyzer
- Vitek ID System

Outsource to CLS MedPharma or CLS analysts test at Client sites?

CLS are the exclusive suppliers of analysts on contract to client sites. This involves CLS providing fully trained CLS personnel to migrate to client sites for an agreed period of time. Typically this can be during peaks in testing, covering projects, validation, and providing cover for example maternity. Some clients use it for cost effectiveness to keep head count down, no employer add on expenses for sick pay, holidays, training, recruitment or redundancy. It acts as a mobile pool of technical capability and resources and provides flexibility for ever changing production and laboratory demands.

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