# Wickham Laboratories

Contract Analytical Services

## 50 Years of Global Experience

## Your Partner of Choice


**Over the past ten years, we have focused our service offerings, moved to a new facility and nearly doubled our revenue.**

**Our Hoeford Point location is a 4,000 square metre facility segregated into independent microbiology and toxicology laboratories.**

**In addition to the main building shown above which contains our laboratories and administrative offices, we also have ample space on site to build and expand.**

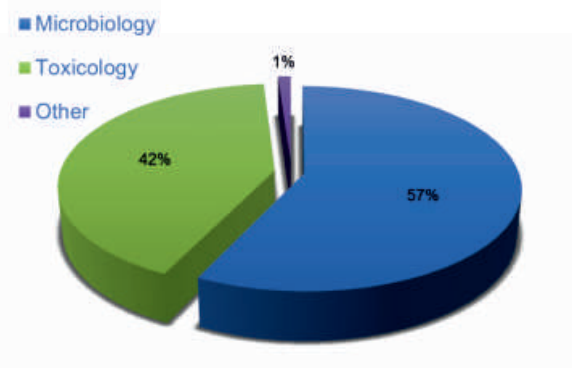
# Company Overview

**Outstanding Contract Testing Facility**

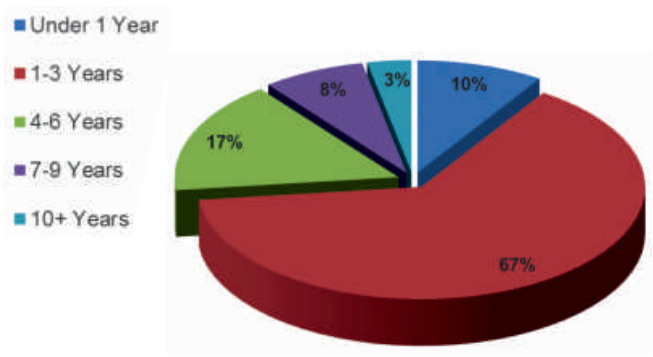
With five decades of global experience in contract testing behind us, you can be assured of a reliable, confidential and cost-effective extension to your in house capabilities.

Our mission is to be the partner of choice for contract research outsourcing and we aim to offer only the highest possible level of quality and standards for our customers.

We are routinely inspected by the MHRA, FDA and Home Office, and offer the opportunity for clients to conduct audits on a regular basis.




We provide microbiology and toxicology services to a wide spectrum of clients and have worked with 500+ companies in the last decade.




70% of our clients work with us year after year, including several of the top global pharmaceutical and medical device companies.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SOP No. MM110.14
KQCL LAL TEST FOR BACTERIAL ENDOTOXINS USING FUJIFILM ASSURANCE MICROPLATE READER
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ORIGINAL IN RED
SECTION 2 - PRINCIPLE
1.1 Principle
1.2
1.2.1 Risk Assessment
1.2.2 Hydrochloric Acid
1.2.3 Sodium Hydroxide

# Quality Assurance

We are a GMP, GLP compliant laboratory and are regularly audited by the MHRA and FDA.

We are proud our services are recognised in the industry and of our ability to deliver consistent and high quality testing.

Core to our business is Quality Assurance which oversee our test facility activities. Our QA unit details four main functions:

- **Study plan checks for GLP compliant work**
- **Procedural inspections**
- **Report reviews**
- **Facility inspection and audits**

We maintain an audit ready facility at all times and both regulatory and client inspection agreed recommendations are instituted promptly.

**GMP** Compliant Laboratory

**GLP** Compliant Laboratory

**FDA** Audited Laboratory

# Consulting

In addition to laboratory services, we offer global support and consultancy relevant to a wide range of pharmaceutical and medical devices.

- **Clean room qualification and monitoring**
- **Water system validation**
- **Process validation**
- **Identification of contamination sources in manufacturing**
- **Manufacturing cleaning practices**
- **Assay development**
- **Regulatory pathway support and advice**

# Pharmaceutical Testing

We offer a range of testing services for the routine quality control, method development and validation of pharmaceutical products, as well as testing for cytotoxic and pyrogenic responses with both in vitro and in vivo methods.

Using industry standard harmonised methods compliant with Ph. Eur, USP and JP guidelines, our testing services have produced data to support NDAs, MAAs and other global regulatory applications.

We conduct testing on active pharmaceutical ingredients, excipients and products as well as biological preparations and fluids for a wide client base consisting of:

- **Pharmaceutical manufacturers**
- **Discovery & biotechnology companies**
- **Clinical research organisations**
- **Other contract testing laboratories**

# Medical Device Testing

We are able to undertake development work to confirm proof of concept and handle routine analysis required for sterilisation and bioburden testing. Our services meet the stringent requirements of regulators, with our reports supporting claims for CE marking at various notified bodies and 510K submissions in the United States.

We are experienced with the microbiological requirements and practices of:

- **ISO 11135-1: Sterilization of health care products-ethylene oxide-Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices**

- **ISO 11737-1 & 2: Sterilization of medical devices-microbiological methods**

- **ISO 10933-5: Biological evaluation of medical devices-tests for in vitro cytotoxicity**

# Microbiology Services

# Quality Control Testing

Our QC section undertakes microbial examination of non-sterile products on a routine basis and we have expertise in many formulations and dosage forms.

**Total aerobic microbial counts**

- **Total bacterial count**
- **Yeasts & mould count**

**Tests for specified microorganisms**

- ***Escherichia coli***
- ***Salmonella spp***
- ***Pseudomonas aeruginosa***
- ***Staphylococcus aureus***
- ***Bile tolerant gram-negative bacteria***
- ***Burkholderia cepacia***
- ***Candida spp***
- ***Clostridia spp***

**Bioburden determination**

- **ISO 11737-1 - sterilization of medical devices**

**Sterility testing**

- **Steritest® enclosed filtration system**
- **Membrane filtration**
- **Direct inoculation**

# Validation Projects

Our validation department regularly performs identification and methodology work as well as engaging in a wide range of bespoke R&D projects such as claims support regarding antimicrobial efficacy, proof of concept, and challenge testing.

We offer the following routine testing:

- **Biological indicator enumeration (11138 series)**
- **Method validation/suitability**
- **Integrity testing**
- **Log reduction testing for antimicrobial effectiveness**
- **Media quality control tests**
- **Microbial identification (rapid & traditional methods)**
- **Preservative efficacy**
- **Quality control methodology**

# Cytotoxicity Testing

The ISO 10993-5 and USP 87 cytotoxicity tests for medical device biocompatibility are in vitro methods for assessing cytotoxic effects on living cells using cell culture techniques. This type of testing is used as a precursor to toxicology work, assessing materials for an initial cytotoxic response in an effort to avoid unnecessary in vivo testing.

Depending upon the nature of the medical device material we can perform cytotoxicity tests by extraction, suitable for devices which may be tested as composite or individual components, or by agar overlay, an indirect method suitable for transparent materials such as contact lenses.

# Bacterial Endotoxin Testing

We utilise the Limulus Amebocyte Lysate (LAL) to screen for harmful endotoxins in parenteral medicines, irrigation fluids, dialysis solutions, and purified water as well as to assess the safety of medical devices designed to come into direct or indirect contact with blood and body tissues.

We offer three standard methods for bacterial endotoxin testing, the gel clot method, kinetic chromogenic method, and kinetic turbidimetric method.


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D

# Toxicology Testing

Our toxicology department has considerable expertise in biological testing. We work with the human and veterinary pharmaceutical and medical device industries, providing quality control of existing products, registration of new formulations, and research into new medicines and technologies.

The types of toxicology tests that we offer are as follows:

- **Abnormal toxicity (general safety) tests**
- **Potency bioassays**
- **Rabbit pyrogen testing**
- **USP Plastic Class I-VI tests**
  - **Acute systemic toxicity**
  - **Intracutaneous reactivity**
  - **Tissue implantation**

We are also dedicated to the development, qualification and refinement of in vitro test methods and have established a separate research division for the investigation and implementation of non animal alternatives.

# Animal Welfare

We are a designated animal testing facility by the Home Office under the Animals (Scientific Procedures) Act of 1986, enforcing and adhering to the principles that animals are only to be used where alternative testing methods do not exist.

Our animals are well cared for with structured routines to meet their environmental, dietary and enrichment needs. An independent Named Veterinary Surgeon (NVS) is available 24/7 and we also have our own Animal Welfare and Ethical Review Body (AWERB) comprised of the Establishment License Holder, the NVS, Named Animal Care and Welfare Officer (NACWO), a lay member, scientists and licence holders.

We are signatories to the Concordat on Openness on Animal Research and support the guiding principles on ethical use of animals in testing, the 3Rs:

**Reduction**

**Refinement**

**Replacement**

# Research & Development

Research initiatives at Wickham Laboratories are split into three separate areas:

**Client Projects**

We are regularly involved in method and process validation, bespoke validation work such as proof of concept claims, and other research projects on behalf of our clients.

**New Technologies**

To support our endeavours to provide the best services for our clients, we have a dedicated research and development department focused on identifying and validating new technologies which may provide additional benefits or alternative methods to those we currently offer.

**In Vitro Methods**

We have established a separate research division for the investigation and implementation of non animal alternatives as part of our dedication to the development, qualification and refinement of in vitro test methods.

Wickham Laboratories
Contract Analytical Services

**General Enquiries & Quote Requests:**
mail@wickhamlabs.co.uk

**Quality Assurance:**
qa@wickhamlabs.co.uk

**Careers:**
hr@wickhamlabs.co.uk

Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England

Phone:+44 (0)1329 226600

mail@wickhamlabs.co.uk

**www.wickhamlabs.co.uk**