

GLOBAL SPECIALISTS IN PHARMACEUTICAL,  
MEDICAL DEVICE & COMBINATION  
PRODUCT TESTING AND CONSULTING



**CORMICA<sup>®</sup>**

**GMP | GLP | ISO 17025**

[www.cormica.com](http://www.cormica.com) | [sales@cormica.com](mailto:sales@cormica.com)



# ABOUT CORMICA

*Cormica's mission is to improve patients' lives by providing comprehensive testing services, enabling clients to launch and release their products safely and rapidly across the world.*

We are industry experts dedicated to partnering with hundreds of medical device and pharmaceutical innovators, providing essential support for the launch and release of their products.

Our unique capability to assist both medical device and pharmaceutical clients, positions us as the preferred CRO for combination product testing.



## Our Values

- **We Do What Is Right** – We uphold ethical standards, delivering accurate and reliable results with integrity.
- **We Have Ownership** – We take pride in our work, exceeding client expectations with commitment and accountability.
- **We Work Together** – We support each other and celebrate our collective success.
- **We Continually Improve** – We strive for excellence, always enhancing our expertise and services.
- **We Are Our Community** – We give back, supporting initiatives that improve patients' lives.



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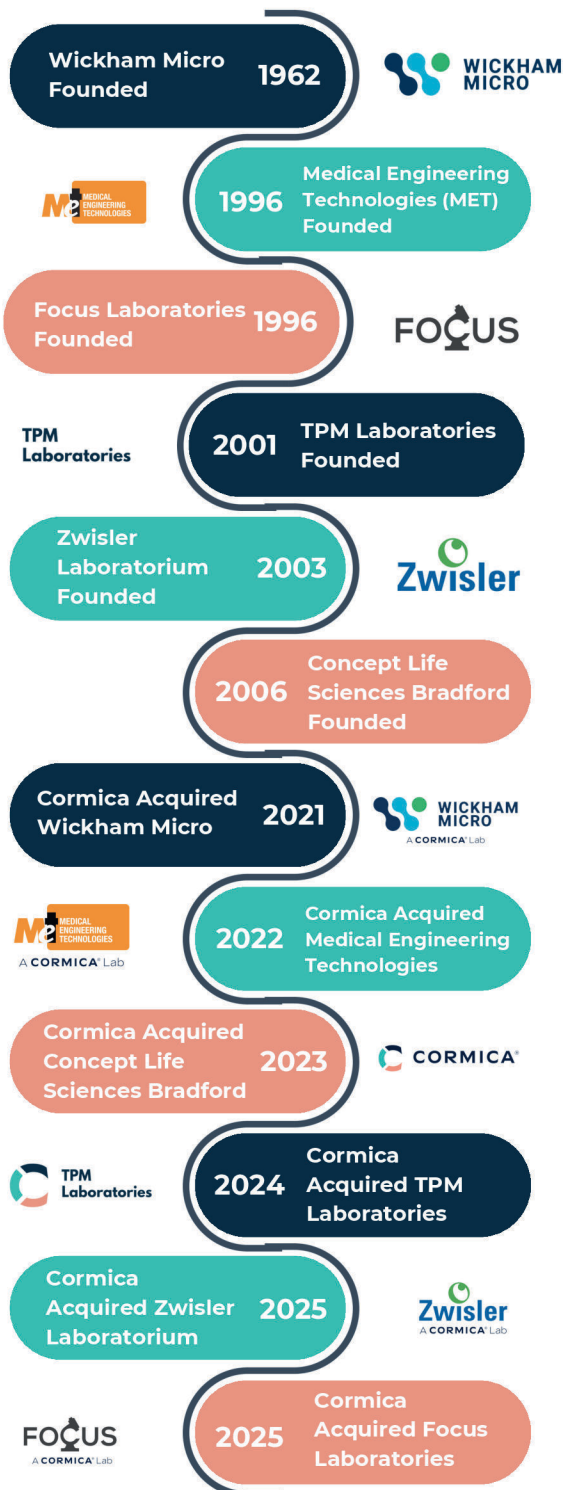
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# OUR HISTORY



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Cormica is one of the world leaders in GMP (Good Manufacturing Practice), GLP (Good Laboratory Practice) and ISO accredited testing services dedicated to the Pharmaceutical and Medical Device sector. Cormica was established in 2021 but can trace its roots back to the 1960s through its laboratories.

Cormica is proud of the heritage that all of our laboratories bring to the group and we continue to build on the heritage of each site by operating with the same principles, on the same site, whilst we continue to evolve our processes and team to respond to growing customer and regulator needs.

Cormica is a name that reflects our expertise and focus. It's made up of three Latin words that capture what we do:

'cor' from corporalis (physical)  
'mic' from micro (small or microscopic)  
'ca' from chemica (chemical)

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# CLIENT SUCCESSSES

“

The exceptional team at Cormica have been amazing at supporting our needs in both terms of testing, sterility predominantly, and advice in completing our projects. Their knowledge and focus on doing what is correct for the customer is second to none and the range of testing services they provide is exceptional....

**KIMAL - Technical Manager**

**KIMAL**  
delivering healthcare innovation

”

“

After speaking with Cormica at a trade show it became immediately evident that they were the 'go-to' group for the services we required. Their professionalism, clarity and honesty made them an easy choice to work with and working with them has most definitely optimised our business opportunities.

**Cantor & Nissel - Managing Director**

**CANTOR-NISSEL**

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“

We collaborate with Cormica on several pharma projects, they have consistently demonstrated a high level of expertise, professionalism, and attention to detail in all aspects of CMC related work, including formulation development, analytical method validation, and routine testing for stability studies...

**Clinical Research Leader**

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“

We're very pleased with the testing conducted for us. Cormica demonstrated exceptional professionalism and efficiency, and the results were delivered exactly as promised. They made the entire process seamless. We will be returning for future testing projects.

**Prosys International Ltd**

**ProSys**  
International Ltd

”

“

Cormica was able to carry out specialised testing for odour control and gas permeability services that no other testing laboratory were able to offer. The team was knowledgeable, professional, and easy to work with throughout the process. Their support made the experience smooth and efficient.

**Ostique - CEO**

**ostique**

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“

Working with the Cormica was a real pleasure. We had a very urgent matter for an extensive study with a critical schedule. Cormica's handling of this challenge was outstanding!

**Gerresheimer Bünde GmbH -  
Manager Regulatory Affairs**

**gerresheimer**

”

# QUALITY

Quality is at the heart of everything we do, and a non-negotiable bedrock in all of our operations. We are committed to providing high quality GMP/GLP/ISO and other regulated services to our partners for today and the future. As part of our commitment to providing a high quality testing service, our aim is to achieve the highest levels of client satisfaction whilst operating to the highest standards demanded by our customers and regulators.

Our sites are accredited as a facility for contract analysis in compliance with GMP / GLP (or ISO where appropriate) with regular inspections from our customers as well as local and overseas regulators.

We are extremely proud of our heritage and exceptional high standards we set for ourselves for quality and welcome a high number of client and regulatory audits each year. As part of our continual improvement our aim is to recruit, train, and retain our staff to deliver exceptional service to our clients and the community as a whole.



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## Microbiological Testing

### Bioburden & Microbial Enumeration Testing

- Bioburden testing, recovery & validation
- Non-sterile product quality control testing
  - Absence of specified organisms & pathogens
  - TAMC & TYMC
  - Microbial limits testing
  - Water testing (potable, WFI, purified)
- Growth promotion testing of media

### Endotoxin & Pyrogen Testing

- Bacterial endotoxin testing (BET) – Limulus Amebocyte Lysate (LAL)
  - Kinetic turbidimetric
  - Kinetic chromogenic
  - Gel-clot method
- Recombinant testing
- Monocyte activation testing (MAT)

### Other Microbiology Testing Services

- Antimicrobial & preservative efficacy testing
- Disinfectant efficacy testing
- Microbial identification
  - MALDI-ToF, MicroSEQ & VITEK
- Antibiotic microbial assay
- Biological indicator enumeration
- Reprocessing validation
- Method validation & batch release testing
- R&D support
- Bespoke & client specific testing protocols

### Sterility Testing

- Sterility testing (including Millipore Steritest™)
- Rapid sterility testing
  - Celsis Bioluminescence
    - Celsis Advance for nonfilterable therapies
    - Celsis Adapt for cellular therapies
  - Scan RDI Chemiluminescence
- Particulate testing
- Container closure integrity testing (CCIT)
- Media fill incubation and analysis

### Environmental Monitoring

- Cleanroom environmental monitoring support
  - EMPQ (performance qualification) & risk assessment
  - Sampling, incubation & enumeration
  - Reporting and trending
  - Culture preservation
- Cleaning validation support
- Total organic carbon (TOC) analysis

### Regulatory Standards Including

- **USP:** <51>, <60>, <61>, <62>, <63>, <71>, <85>, <87>, <643>, <645>, <788>, <789>, <1072>, <1116>, <1911>
- **Ph. Eur.:** 2.2.44, 2.6.1, 2.6.12, 2.6.13, 2.6.14, 5.1.3, 5.1.6, 5.1.11
- **ISO:** 10993, 11137, 11737,
- **ICH / GMP:** ICH Q7, EU GMP Annex 15

## Physical & Packaging Testing

### Device Verification, Functional & Physical Testing

#### Injection & Delivery System Testing

- Prefilled syringe testing
- Needle-based injection system testing
- Break loose & glide force testing
- Needle cap removal force testing
- Injection force testing
- Dose accuracy testing

#### Device Performance & Functional Testing

- Catheter performance testing
- Infusion set testing
- Wound dressing performance testing
- Small-bore connector testing

### Regulatory Standards including

- **USP:** <1207>
- **EN:** 12439, 13726, 13868
- **BS:** 6196

### Packaging & Distribution Testing

#### Transit Simulation & Distribution Testing

- Pre-conditioning
- Drop & compression testing
- Random & sinusoidal vibration testing
- Concentrated impact testing
- High altitude (vacuum) testing

#### Packaging Integrity Testing

- Container closure integrity testing (CCIT)
- Dye penetration testing
- Contaminant migration studies
- Seal testing (peel strength & burst)

#### Ageing & stability testing

- Accelerated ageing
- Real-time ageing

- **ISO:** 10555, 11040, 11070, 11607, 11608, 20695, 20696, 20698, 23907, 80369, 8871, 8536, 7864
- **ASTM:** D4169, D4332, D4728, D5276, D6344, D642, D6653/D6653M, D7386, D999, F88, F1140, F1886, F1929, F1980, F2054, F2096, F2338
- **ISTA:** 2A, 3A



## GMP Validated Analytical Equipment

### Gas Chromatography (GC)

- PerkinElmer GC-FID
- Thermo Trace 1310 GC-FID
- Thermo TSQ EVO GC-MS/MS
- Thermo ISQ GC-MS
- Direct Injection, headspace & SPME
- SPME-GC-QQQ

### Elemental & Other Analysis

- Agilent 7900 ICP-MS
- Thermo iCAP 6500 Duo ICP-OES
- Jasco FTIR 4600 CFR
- Netzsch Kinexus Ultra+ Rheometer
- PerkinElmer Lambda 365 UV/Vis
- Metrohm 852 Combined Karl Fischer with Oven
- Metrohm 904 Titrando
- SEM-EDX

### Nanoparticle Sizing

- Zetasizer Ultra Red
- Nanosight NS300

### Particle Size & Shape Analysis

- Malvern Mastersizer 3000
- Morphologi4-ID
- Sympatec HELOS / RODOS BR
- Microtrac S3500 with ASVR & USVR
- Malvern Spraytec
- Optical Microscopy

### Solid State Analysis

- Bruker D8 & Empyrean S3 XRPD
- APSS Light Obscuration for Sub-visible Particles
- Micromeritics TriStar 3020 BET SSA
- Perkin Elmer DSC 4000 & TGA 8000
- SMS Discovery Aqua DVS
- Scanning Electron Microscopy

### HPLC Systems

- Agilent 1260 HPLC
- Thermo Ultimate 3000 uHPLC
- Thermo Vanquish uHPLC
- Thermo Altis & Fortis TSQ LC-MS/MS
- Thermo ISQ LC-MS
- uHPLC-QTOF/ DAD

### Detectors

- UV / DAD / PDA
- Refractive Index (RID)
- Charged Aerosol (CAD)
- Fluorescence (FLD)
- Electrochemical (ECD)

### Additional Techniques

- Metrohm 940 Pro IC
  - CD, PAD, Cyanide, Sugars
- Dissolution Testing:
  - USP Apparatus I, II, IV

## Our Analytical Testing Services

### GXP Fundamentals

- Method development, validation and transfer
- QC release testing
- ICH, GMP, GLP and R&D storage stability
- physico-chemical properties
- Product safety registration

### Physical / Materials Characterisation

- Particle size, shape, composition & association
- Generics support and IVBE
- X-ray diffraction
- Specialist solid state analysis
- Subvisible and visible particulate matter testing
- Nanoparticle analysis

### Chemical Characterisation

- Extractables & leachables (E&L)
- Organic impurities
- Elemental impurities
- Residual solvents
- Volatile organic compounds (VOC & VOS)
- Nitrosamine analysis
- Carbonyls analysis

### Manufacturing & Commercialisation

- Cleaning validation & verification
- Occupational hygiene
- Contaminants & foreign bodies
- Contaminant migration studies

## Consultancy

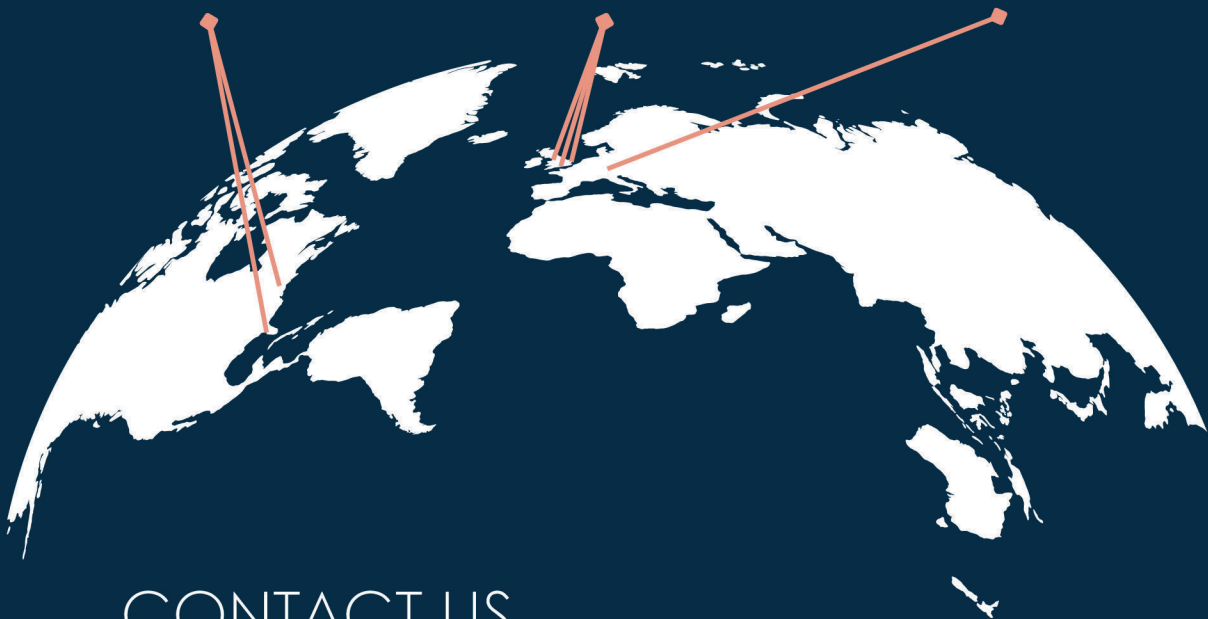
- Biological evaluation plans & reports
  - BEP & BER
- Clinical evaluation plans & reports
  - CEP & CER
- Submission support
  - US FDA
  - UK & EU MDR
- Toxicological risk analysis
- Biological gap analysis
- PSUR (Periodic safety update report)
- Post market surveillance

## ISO 10993 & 18562 Biocompatibility Testing

- Extractables & Leachables
  - Organic & elemental impurities
- Leachables in condensate
- Particulate Emission
- Volatile Organic Substances (VOC & Carbonyls)
- Cytotoxicity
- Irritation
- Sensitisation
- Material mediated pyrogenicity
- Acute Systemic Toxicity
- Subacute, Subchronic & Chronic toxicity
- Genotoxicity
- Carcinogenicity
- Hemocompatibility
- Implantation
- Reproductive / developmental toxicity
- Degradation studies



# GLOBAL COVERAGE



CONTACT US

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ANALYTICAL CHEMISTRY



PHYSICAL & PACKAGING



MICROBIOLOGY & STERILITY

