# GCCL Solutions for
## Obesity & Metabolic Therapeutics

As the obesity therapeutics market evolves rapidly, advanced analyses tailored to drug-specific mechanisms has become essential to accelerating development timelines.

GCCL designs and develops optimized PK, ADA, and biomarker analytical platforms based on a deep understanding of drug mechanisms, enabling rapid clinical assay transfer and support.

## Obesity Therapeutics Landscape

▸ GLP-1 therapies have transformed obesity into a treatable disease paradigm

▸ Semaglutide patent expirations (2026–2032)
→ driving intensified global competition

▸ Expansion of dual/multi-agonists, novel delivery modes, and long-acting formulations

▸ Growing focus on complex metabolic diseases and cardiovascular risk reduction

▸ Indication expansion beyond obesity, including CNS disorders

## Why Is Obesity Drug Analysis Challenging?

Unlike conventional small molecules and large molecule protein therapeutics, peptide-based obesity drugs given at high doses over long durations present distinct analytical challenges. With proven expertise in peptide drug analysis and LC-MS/MS and LBA method development, GCCL delivers reliable solutions to these challenges.

**1 Peptide PK (LC-MS/MS)**
- Challenges in high-sensitivity peptide quantification by LC-MS/MS
- Increased analytical complexity due to structural characteristics
- Matrix effect mitigation & peptide stability control issue

**2 Immunogenicity (LBA)**
- Requirement for ELISA/ECL based ADA and NAb assays
- Drug interference mitigation issue (acid dissociation, etc)
- Need for development and validation strategies for bridging/direct assay (ADA/NAb)

**3 Biomarker Analysis**
- Diversified clinical biomarker testing requirements
- Data quality management aligned with international standards

## Biomarker Panel for Obesity & Metabolic Disease

GCCL provides biomarker analysis services to support drug development, covering biomarkers commonly used in the field.
(Additional biomarkers and customized panel configurations are available upon request.)

| | Glucose Control | Insulin Dynamics | Fibrosis | Bone Metabolism | CV / Inflammation | GLP-1 Mechanism |
|---|---|---|---|---|---|---|
| Key Markers | FPG, PPG, OGTT, HbA1c | Insulin, C-peptide, HOMA-IR/β, QUICKI | ELF, Pro-C3, CTX-3 | P1NP, BALP, OC, CTX-1 | Lipid panel, ApoA/B, Lp(a), IL-6, hs-CRP | Adiponectin, Glucagon, Paracetamol test |
| Purpose | Glycemic control | Insulin secretion·insulin resistance | Presence of liver fibrosis | Bone metabolism changes associated with weight loss | Cardiovascular· inflammatory risk | Mechanistic evaluation |

# GCCL Key Services

**Key Services 1**

### PK analysis (LC-MS/MS)

✓ High-sensitivity peptide drug quantification using LC-MS/MS

✓ Extensive experience with peptide and modified peptide analysis

✓ Method development and validation with rapid initiation based on prior expertise

✓ Analytical conditions optimized for GLP-1 analogues

**Key Services 2**

### Immunogenicity Analysis

✓ Development and validation of ADA assays using ELISA/ECL platforms

✓ Proven experience in improving drug tolerance

✓ Statistical analysis support for assay development and validation

✓ High-quality analysis and data management tailored to GLP-1 and related modalities

**Key Services 3**

### Regulated Clinical Bioanalysis Support

✓ Experience analyzing clinical samples from obesity and metabolic disease studies

✓ Quality management aligned with GCLP and ISO 15189 standards

✓ Full sample traceability and chain-of-custody management

✓ Support for analysis initiation aligned with each clinical trial phase

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