

## Your Integrated Bioanalytical Partner for Translational and Clinical Success

Syngene's Translational and Clinical Research (T&CR) unit offers end-to-end bioanalytical solutions for large and small molecules. Backed by 20+ years of experience, specialized scientific teams, and globally recognized quality systems, we support programs from discovery through late-stage clinical development. Our bioanalytical labs operate under GLP, GCLP, EMA & USFDA guidance, with a proven history of successful inspections.

**1 Million +**

samples analysed

**500+**

methods developed

**360+**

molecules approved

**200+**

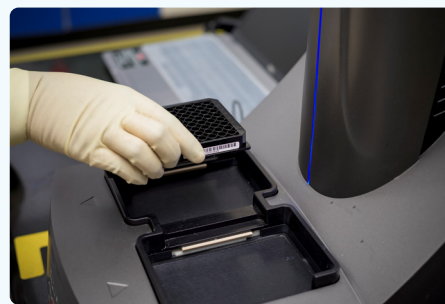
global clinical trials supported with PK/PD and ADA

**35+**

successful audits by global regulatory authorities USFDA, PMDA, ANVISA

### End-to-End Bioanalytical Study Support

- Non-GLP Preclinical Phase I/II/III PMS studies
- Sample analysis at scale for global multicentric clinical trials
- Expertise across modalities: small molecules, mAbs, bispecifics, fusion proteins, nanobodies, vaccines, oligos, ADCs



### Large Molecule Bioanalysis (PK/PD/ADA/NAb)

- ELISA, MSD/ECL, Luminex, Flow, SPR, cell-based bioassays
- Drug-tolerant and target-tolerant assay designs
- Multi-tier ADA workflows with confirmatory & neutralization tiers
- Assay optimization for sensitivity, specificity & selectivity

## Immunogenicity & Mechanism-of-Action Expertise

- Transient vs. persistent ADA characterization
- Biomarker-aligned strategies for oncology, immuno-oncology metabolic, neuro-inflammatory & autoimmune indications
- Platform familiarity with VEGF, HER2, PD-1, LAG-3 bispecifics, SLAMF family, TNF- $\alpha$ , PCSK9, CGRP, and more

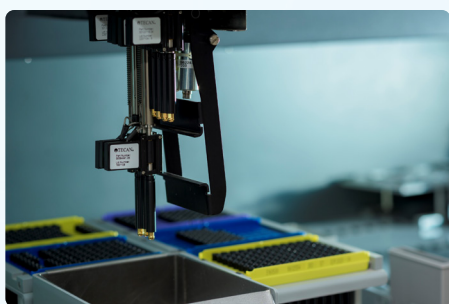


## Small Molecule Bioanalytical Services (GCP Laboratory)

- Analysis of drugs & metabolites in biological matrices (blood, plasma, serum) supporting TK, PK, BA/BE & TDM studies
- 260+ validated small-molecule methods (USFDA-aligned)
- Scientific data management via Watson LIMS

## Method Development, Validation & Transfer

- Fit-for-purpose and full validation per global regulatory guidelines
- Rapid development cycles (20–25 methods/year)
- Smooth method transfers with minimal re-optimization
- Troubleshooting and matrix-effect mitigation strategies



## Automation, Data Integrity & Sample Management

- Automated liquid handling (Tecan Freedom EVO)
- GLP-validated data capture and analysis systems
- WATSON LIMS 7.5 and Revvity ELN 18.1 workflows
- Global-study-ready sample logistics and traceability

## From Reagents to Readouts with Experience Accuracy and Confidence

Partnering with Syngene's bioanalytical services gives your program access to scientific excellence, advanced technology, and globally compliant quality systems. Our integrated large- and small-molecule platforms deliver precise, rapid, and audit-ready data, enabling you to de-risk development and advance molecules confidently toward key milestones with efficiency and scientific rigor.



### LET'S ADVANCE YOUR PROGRAM

For collaboration inquiries, study discussions, or a capabilities briefing contact [bdc@syngeneintl.com](mailto:bdc@syngeneintl.com)  
[www.syngeneintl.com](http://www.syngeneintl.com)



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