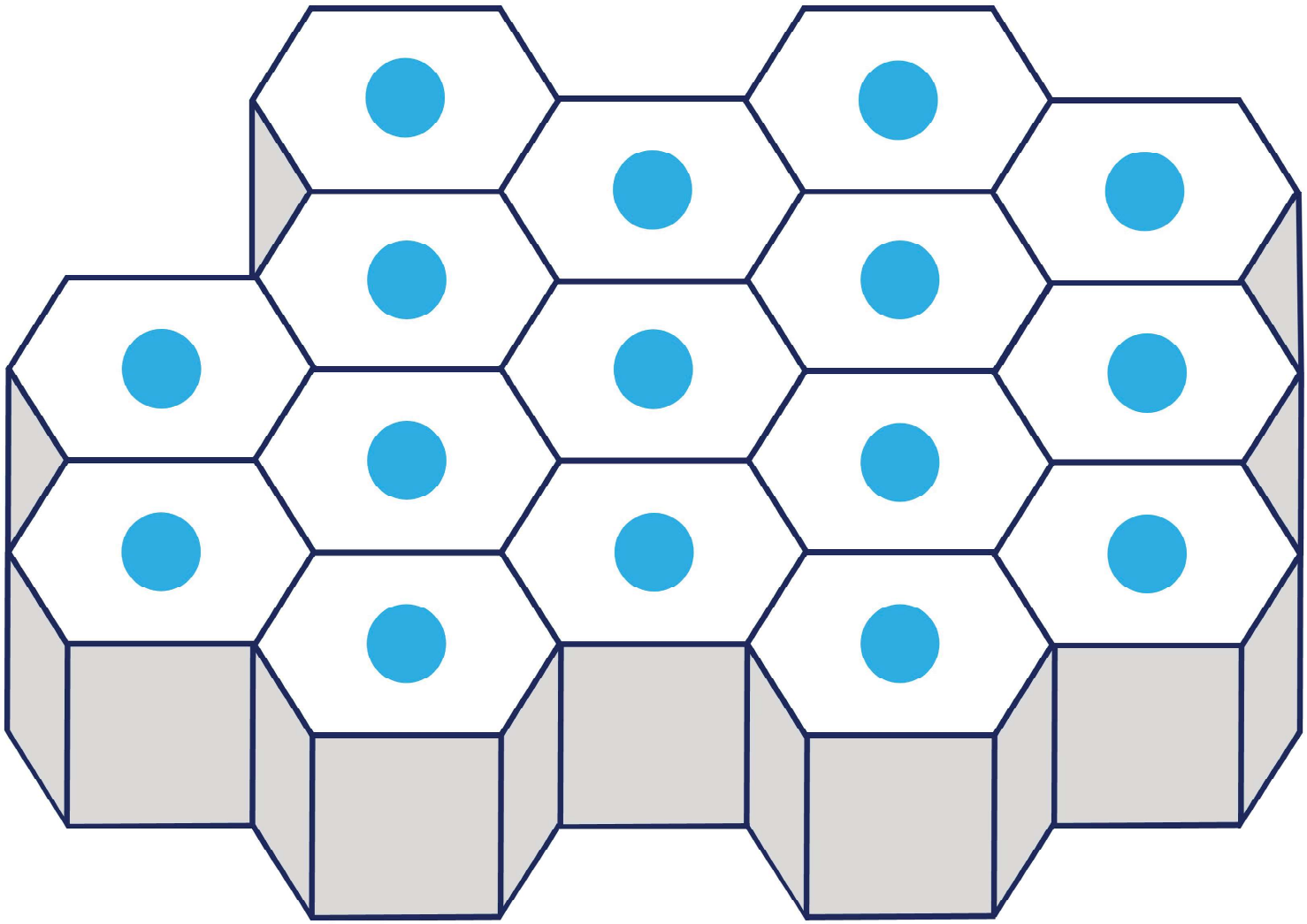
CELL guidance systems

# Primary Cell Solutions for ADME and Toxicology Assays



# Primary Human Hepatocytes

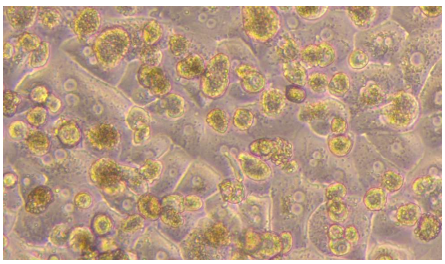
**Primary human hepatocytes are the gold standard for hepatic *in vitro* DMPK and toxicology assays**

- **Representative**
  Enable *in vivo* correlations from *in vitro* data to better evaulate a candidate drug's effect on the liver.
- **Quality-control**
  Stringent quality standards and batch acceptance criteria ensures high viability and metabolic parameters.
- **Characterization**
  Each vial is supplied with a comprehensive data sheet characterizing the product.

With a full drug metabolism and pharmacokinetics profile, primary human hepatocytes can be utilized to conduct a variety of ADME (absorption, distribution, metabolism, and excretion) and toxicity assays in drug discovery programmes. Cell Guidance Systems offer hepatocyte cells in three grades to maximize their value, dependent on your specific assay requirements. Detailed product QC is provided for each sample.

## Plateable Grade

Primary human liver cells of the highest grade for most applications. The only faithful liver model which is validated on Transporter Expression, CYP activity, Drug response and HBV uptake.



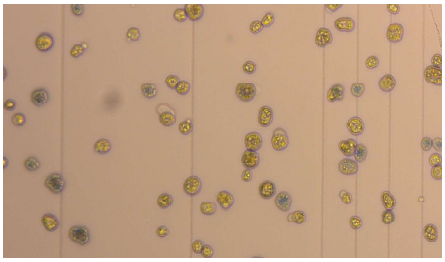
Suitable for a variety of complex assays including:

- Drug-drug interaction assays
- Extended metabolism studies
- Drug influx and efflux studies
- Compound uptake
- HBV/HCV replication assays

- ✓ Viability >85%
- ✓ Formation of a confluent monolayer at 350,000 cells/well (24 well plates) within 24 hours
- ✓ Monolayer survival up to 5 days

## Suspension Grade

Primary human liver cells of an intermediate grade. These cells are pooled from ten individuals to increase assay relevance.



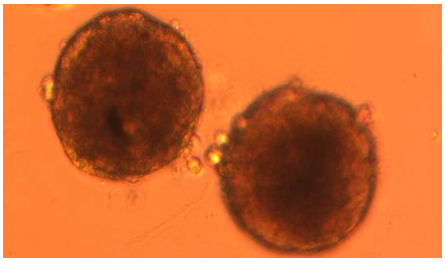
Suitable for a variety of assays including:

- Short-term metabolic studies
- Metabolic route identification
- Metabolite identification assays

- ✓ Viability >80%
- ✓ CYP and Phase II enzyme activity threshold is at least 6 hours before loss of 50%

## Spheroid Grade

Primary human liver cells suitable for generating hepatic spheroids for longer term assays.



Suitable for a variety of assays including:

- Hepatotoxicity
- Low clearance compounds
- Metabolism assessment

- ✓ Viability >80%
- ✓ Formation of a dense spheroid within 7-10 days

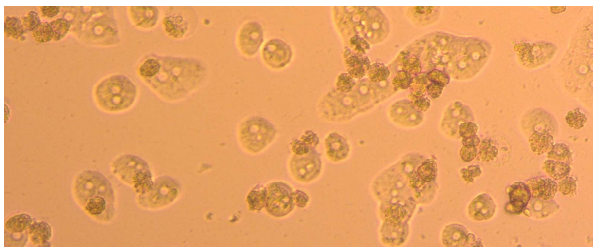
# Animal Hepatocytes

## Primary suspension hepatocytes from a range of species

Our animal cryopreserved suspension hepatocytes are prepared using the same meticulous isolation and cryopreservation techniques as the human batches. Viabilities for these cells are ≥ 80%, ≥ 5 million cells/vial and they are characterized for Phase I and Phase II enzyme activity. Perfect for *in vitro* to *in vivo* correlation experiements.

The following animal hepatocytes are available from Cell Guidance Systems:

- CD1 mouse hepatocytes
- Sprague-Dawley rat hepatocytes
- Beagle dog hepatocytes
- Cynomolgus monkey hepatocytes



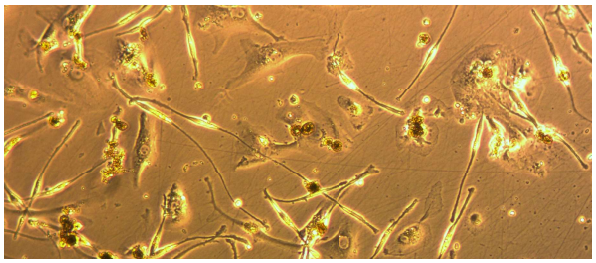
# Non-Parenchymal Cells

## Hepatocyte co-cultures for *in vitro* hepatotoxicity

Hepatocytes alone are not able to fully represent *in vivo* functionality during toxicology evaluations. Co-cultures are a liver-derived *in vitro* model system that aims to preserve liver-specific morphology and functionality beyond what is provided by pure parenchymal cell cultures.

Co-cultures can be prepared using hepatocytes and non-parenchymal cells (NPC) cultures which, has been evidenced to be one of the most successful models for maintaining functionality *in vitro* when examining drug related hepatotoxicity. Cell Guidance Systems offer NPC characterized for the co-culture with hepatocytes in basement membrane extract overlay.

- ✓ 1 million cells/vial
- ✓ HIV/HBV/HCV negative
- ✓ Microbiologically sterile
- ✓ Qualified for short-term cultures
- ✓ Applications include DMPK evaluations and toxicology assessments
- ✓ Stable for a 1 week long assay



# Microsomes

## Isolated microsomes for drug metabolism and pharmacokinetic assays

The cytochrome P450 enzyme (CYP) family play a key role in hepatic elimination that occurs in the endoplasmic reticulum. Liver microsomes are the most convenient way to investigate CYP- mediated metabolism. Microsomes are a useful *in vitro* testing system as they contain all CYP enzymes and ensure the CYP kinetic measurements are not confused with other metabolic processes or cellular uptake.

Cell Guidance Systems offer the following microsomes (CYP qualified):

- Human liver microsomes, pooled from 50 donors (balanced gender)
- CD1 mouse liver microsomes, pooled
- Wistar rat liver microsomes, pooled

Cell Guidance Systems' reagents and services enable control, manipulation and monitoring of the cell, both *in vitro* and *in vivo*

**Growth Factors**
- Conventional (unformulated)
- PODS® - Sustained release

**Exosomes**
- Exo-spin™ - Purification
- ExoLISA™ - ELISA-like detection
- Instant Exosomes™ - purified and characterized
- NTA Service
- Freeze drying service

**PeptiGel®**
- Tunable self-assembling peptide hydrogels

**Other products and services**
- Small Molecules
- Softwell™ - 2D hydrogel (Europe only)
- Orangu™ - Cell counting reagent
- LipoQ™ - Lipid quantification assay
- Primary Hepatocytes

**Cytogenetics**
- Karyotype Analysis
- Array Hybridization

**Scan for Hepatocytes product page**

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