



**DEEP TISSUE
CHARACTERIZATION
CENTER (DTCC)**

Cell and Tissue Characterization Services

Cells, tissues, and organs are challenging products to manufacture and even harder to characterize. Quite often, the mechanism of action is not known or well understood. Despite the biologic complexity, regulatory authorities still expect innovators to identify product attributes (purity, potency, identity, and safety) that drive the clinical outcome. ARMI | BioFabUSA has established a Deep Tissue Characterization Center with the capabilities to provide innovators with the critical information that they need to manufacture high-quality products and meet safety and therapeutic efficacy requirements.

THE DEEP TISSUE CHARACTERIZATION CENTER CAN HELP INNOVATORS:

- Shorten development timelines by determining critical product attributes and process parameters and applying Quality by Design (QbD) principles to process development
- Reduce risk by providing regulatory authorities with the information that they expect to see
- Establish robust, cost-effective processes by developing a control strategy based on a detailed understanding of the critical process parameters that drive the critical quality attributes

EXTENSIVE CAPABILITIES

- Metabolomics, lipidomics, proteomics analysis
- Flow cytometry
- Confocal microscopy
- Gene expression analysis

ADVANCED DATA ANALYTICS

- Machine learning
- Predictive analytics

APPLICATION OF QBD PRINCIPLES

- Correlation of product characteristics to clinical outcomes
- Identification of potential CQAs and CPPs

Cell and Tissue Characterization Services

Establishing critical quality attributes (purity, identity, and potency)

PROTEOME (LC-MS/MS)

- Protein identification
- Non-targeted proteomics
- Molecular weight determination
- Quantitative protein profiling
- Post-translational modifications

METABOLOME (LC-MS/MS)

- Non-targeted metabolomics
- Targeted metabolomics

LIPODOME (LC-MS/MS AND GC-MS/MS)

- Non-targeted lipidomics
- Targeted lipidomics

DATA ANALYTICS (PREDICTIVE ANALYTICS/MACHINE LEARNING)

- Data collection, storage, and transformation
- Unsupervised, supervised, and deep machine learning
- Exploratory data analysis
- Descriptive and inferential statistics

ADDITIONAL ANALYTICAL CAPABILITIES

- Gene expression
- Common ELISA and qPCR analyses
- Client-specific assay development
- Flow cytometry
- Confocal microscopy

MECHANICAL TESTING (ELECTROFORCE MECHANICAL TESTING MACHINE)

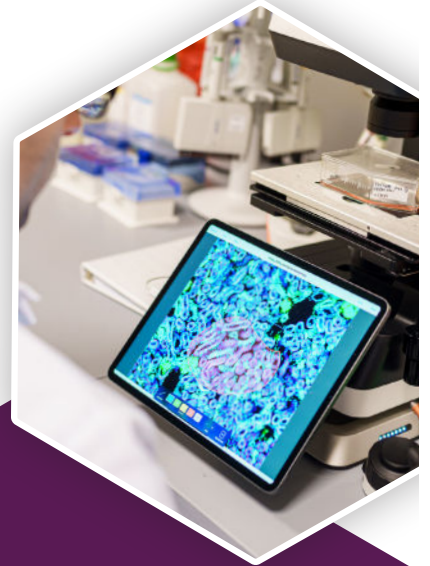
- Tissue and biomaterial characterization

GEL PERMEATION CHROMATOGRAPHY (HPLC WITH RID AND ELSD)

- Molecular weight determination
- Separation of sugar, proteins, peptides, etc. based on size

EXTRACTABLES & LEACHABLES (GC-MS/MS AND GC-FID)

- Testing per ISO 10993 procedure



In-depth characterization of cell and engineered tissues to draw correlations between measured quality attributes, manufacturing conditions, and clinical outcomes.

To learn more about ARMI | BioFabUSA's DTCC capabilities, contact outreach_membership@armiusa.org

WHO WE ARE

The Advanced Regenerative Manufacturing Institute (ARMI) is a membership-based, non-profit organization. The Department of Defense awarded ARMI more than \$100 million in grants to operate BioFabUSA. BioFabUSA is a public-private partnership with more than 170 members, including companies, academic institutions and not-for profit organizations working to manufacture cells, tissues and organs.

