



Chia-Chu Tsai (James Tsai)

Position : Founder and CEO

Affiliation: CellTech Innovation Studio Co., Inc

WORK EXPERIENCE:

- *Secretary General, Taiwan Association of Cellular Therapy (TACT) (2023-)**
- *Scientific Advisor Creative (2023-)**
- *IND and GMP Advisor Apexcella (2023-)**
- *Founder and CEO, CellTech Innovative Accelerator (2023-)**
- *CEO, Pharmasaga Co., Inc. (2022-2023)**
- *Founder, President and GM, Unicocell Biomed Co. Ltd. OTC-listed 6794 (2018-2021)**
- *Co-Chairman, Regenerative Medicine Dept, TRPMA (2018-2021)**
- *Founder, President and GM, Unicocell Biomed Co. Ltd. OTC-listed 6539 (now DV Biomed) (2011-2019)**
- *Research Fellow, Medical Oncology, Dana Farber Cancer Institute, Boston MA (2008- 2010).**

PROFESSIONAL EXPERIENCE:

***Cell Therapy**

- Leading cell production team to improve manufacturing processes for products to be profitable and quality benefit.
- Establishing the stem cell potency to evaluate the correlation among cell quantity, quality and clinical outcome.
- Applying The Regulation Governing the Application of Specific Medical Examination Technique and Medical Device (RASMET) for cell therapy with major hospitals

***Clinical Trials**

- Leading the first-in-class and first-in-human chemical drug against type 2 diabetes to clinical trial phase I, FDA and tFDA IND.
- Sponsoring allogenic clinical trial of mesenchymal stem cell therapy on osteo-arthritis phase I/IIa with ChangGung Hospital, tFDA IND
- Sponsoring allogenic clinical trial of mesenchymal stem cell therapy on chronic kidney disease phase I/IIa with ShuangHo hospital, FDA and tFDA IND

***GTP/GMP/ISO Facilities**

- Establishing one of the first GTP facilities in early stage of cell therapy in Taiwan and certified by Japan PMDA as oversea cell processing center.
- Acquiring the ISO/TES 17025 accreditations on cell therapy related tests granted by TAF, and

human organ bank license by Ministry of Health and Welfare.

- Establishing the first PIC/S GMP leading factory for cell therapy in Taiwan.

***Mass Production**

- Awarded by Asia-Pacific Bioprocessing Excellence Awards (ABEA) on semi-automatic production line for attached mesenchymal stem cell manufacturing including bioreactor culturing, collecting, washing and condensation, filling and finishing system under close and semi-automatic process.
- Inventing the first class-II medical device licensed cell storage container and corresponded automatic fill and close machine.
- Establishing the leading allogeneic cell bank of adipose stem cell source in Taiwan, built in accordance with ICH regulations, recently received Acknowledgment letter of DMF (Drug Master File) from US FDA .

***Company Development**

- Founding the biotech company, leading the company to obtain several government funding and certificates, and listed by OTC as IPO company.
- Establishing the brand name DV Biomed as one of the leading brands in Aesthetics Medical Clinics, Cosmetics, and health supplements aspects.
- Integrating several small businesses into single entity and creating annual income over NTD 70M.

*** Invention Patent**

- US 11389801B2, TW I673359, TW M546105. UnicoVial®, a cell storage tube.
- TW M562268. Food packaging bag structure.
- TW I555847, TW 201506162. Adipose stem cells culture and production method of secretions of stem cells
- TW 201628632. Use Of Stem Cells Secretion For Manufacturing A Medicament For Treating Liver Damage

EXPERTISE:

Cell Biology, Molecular Biology, Clinical Trial, Mass Production, Process Development, GTP/GMP Certificate, ISO Laboratory, Allogenic Cell Therapy, Mesenchymal Stem Cell, IPO, Branding, Product Development, Company Roadmap Blue map, Team Buildup, Entrepreneurship

Publish:

- Stem Cell Res Ther. 2021; 12: 562.
- J Cell Mol Med. 2022 May;26(10):2972-2980.

Award:

- Leading three of company's products awarded as one gold and two silver medals 2019.
- Leading company awarded by Awarded by Asia-Pacific Bioprocessing Excellence Awards (ABEA) 2020.