



**Commercial Production of In Vitro Human Epithelial Models at MatTek Corporation: A Survey of Available Models and Applications.** P. J. Hayden, J. Kubilus, S. Ayehunie, Y. Kaluzhny, H. Kandarova, P. Kearney, M. Klausner and J. Sheasgreen. MatTek Corporation, Ashland, MA 01721. Email: phayden@mattek.com

Abstract 1562630 (Podium Presentation):

Techniques for in vitro reconstruction of 3-D epithelia from isolated human cells have become more refined and widely utilized in recent years. These epithelial models are cultured on microporous membranes at an air-liquid interface to produce highly differentiated 3-D cultures that possess many of the physical and biochemical properties of in vivo epithelium. The in vivo-like characteristics and barrier properties allow application and evaluation of test chemicals, candidate therapeutic compounds and finished formulations in a more realistic manner compared to cultures submerged in media. Examples of models currently produced from normal (nontransformed) human epithelial cells by MatTek Corporation include dermal (EpiDerm™), ocular (EpiOcular™), airway (EpiAirway™), gingival (EpiGingival™), buccal (EpiOral™) and vaginal EpiVaginal™ epithelium. Second generation models provide additional levels of complexity by incorporating multiple cells types including fibroblasts (EpiDerm-FT™, EpiAirway-FT™, (EpiVaginal-FT™), melanocytes (MelanoDerm™) and/or dendritic cells (DC-100). The ultimate utility of in vitro epithelial culture models for widespread use in research applications and for regulatory purposes depends upon their performance and validation with respect to interlaboratory transferability, long-term reproducibility, and the extent to which in vitro results can be extrapolated to in vivo human results. An overview of the Good Manufacturing Production (GMP) process, long-term reproducibility data and status of validation programs for ocular irritation, dermal corrosion, irritation and phototoxicity, airway irritation and vaginal irritation will be presented.

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