Title: Challenges and Complexities in Medical Device Testing In Vitro: From 2D to 3D Models

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Abstract:

The evaluation of biocompatibility is pivotal for ensuring the safety and efficacy of medical devices. Traditional testing methods, which primarily utilize animal models and basic in vitro cytotoxicity tests as prescribed by ISO 10993, are foundational yet often inadequate in mimicking the complex biological interactions of human tissues. This shortfall becomes increasingly significant as medical devices grow more complex, integrating various materials intended for diverse application scenarios. Standard biocompatibility assessments such as cytotoxicity, irritation, and sensitization are mandated for most devices, but additional evaluations like genotoxicity, systemic toxicity, hemocompatibility, and implantation studies may be necessary based on the device's nature and intended use. Despite these requirements, the medical device industry continues to rely heavily on animal testing, with a slower adoption of alternative methods compared to other sectors.

The field of tissue engineering has seen significant advancements leading to the development of three-dimensional human reconstructed tissue models, including spheroids, organoids, and planar systems. These innovative models have been incorporated into regulatory assessments for chemicals, cosmetics, and pesticides, and are increasingly recognized in the medical device sector. The recent integration of the 3D human epidermis model into ISO 10993-23, following successful validation trials, marks a pivotal development. The use of sophisticated in vitro models, enhanced by technologies such as microfluidics and 3D printing, suggests a potential shift in medical device safety assessments. These technologies enable the creation of physiologically relevant models that closely replicate human organ structures and dynamics, thus improving the accuracy of biocompatibility tests. This presentation will discuss the challenges and complexities of MD testing, but also an urgency for evolving regulatory frameworks to facilitate the adoption of these advanced methodologies, promoting more accurate, ethical, and scientifically rigorous biocompatibility testing.

Literature:

H. Kandarova, P.Pôbiš. (2024). The “Big Three” in biocompatibility testing of medical devices: implementation of alternatives to animal experimentation—are we there yet? Front. Toxicol., Sec. Regulatory Toxicology. Volume 5 - 2023 | https://doi.org/10.3389/ftox.2023.1337468