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Challenges and successes of measuring antigen specific immune responses

Assessing immunogenicity is a challenge in the biopharmaceutical industry, as an increasing number of new drugs and vaccines aim to elicit a response from the cellular components of the immune system. Antigen specific responses for white blood cells such as T, B, NK and others, is of paramount importance throughout the drug/vaccine development cycle in both the preclinical and clinical phases. It is often the case that cell responses are studied based upon population levels that presume outcomes, but do not clearly enumerate the products individual cells have released. Lack of sensitivity in these assays can lead to misinterpretation of results. Therefore, it may be of key importance to employ an assay that produces high sensitivity based upon single cell responses. For this reason, assays such as ELISA and flow cytometry should be complemented with a single cell assay such as ELISPOT. Measurements of antibodies in bodily fluids (e.g., by ELISA) have provided robust and reproducible results for decades and such assays have been validated for monitoring of B cell immunity. While T cells play a critical role, reliable measurements of antigen specific T cell responses *ex vivo* remain seemingly problematic, as typically, T cells occur in very low frequencies in test samples, such as peripheral blood with the need to test live cells in functional assays *ex vivo*. Early considerations to the standardization of specimen processing, cryopreservation, sample management and assay systems are vital steps for the successful design and execution of pre-clinical and clinical trials that deliver consistent and regulatory acceptable immune monitoring data. Examples of such successful T cell monitoring in vaccine evaluations will be presented.

Biography

Magdalena Tary-Lehmann is an Adjunct Associate Professor of Case Western Reserve University (CASE) Department of Pathology, Co-Founding Scientist and Chief Scientific Officer for Cellular Technology Limited (CTL). She has published more than 75 papers in peer-reviewed journals. She provides guidance and oversight for technical operations in the GLP laboratory, ensuring the ongoing scientific excellence of CTL. Over the past decade, she has worked with clients and regulatory agencies to develop and validate reference samples and controls for use in regulated immune monitoring assays.

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