



The Immune System and the Journey to CAR-T Therapy

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Abstract: This presentation will provide a comprehensive overview of the immune system, detailing its fundamental components and intricate mechanisms from the perspective of over two decades of experience in biopharmaceutical development and manufacturing. We will explore the two primary arms of the immune response: innate immunity, offering rapid, non-specific defense, and adaptive immunity, characterized by antigen-specific responses involving antibodies and lymphocytes. Key cellular players such as macrophages, B cells, T cells (including CD4+ Helper T cells and CD8+ Cytotoxic T cells), and dendritic cells will be discussed.

The presentation will then transition to the field of immunotherapy, a therapeutic approach harnessing the body's immune system to combat diseases, particularly cancer. Various immunotherapies will be outlined, leading to a significant focus on adoptive cellular therapies, particularly Chimeric Antigen Receptor (CAR) T-cell therapy. Drawing on direct experience in advancing the manufacturing of next-generation cell therapies, we will examine the evolution of CAR T-cell constructs, the critical role of viral vectors, and the complexities of designing and deploying robust manufacturing processes for these innovative treatments. The discussion will cover the journey of CAR T-cell therapy from process development to clinical and commercial operations, including an overview of FDA-approved therapies and the management of potential side-effects. This exploration aims to elucidate the scientific advancements and the critical manufacturing considerations that drive progress in this rapidly evolving field.

Bio: Dr. Semsi Ensari, a distinguished alumnus of the University of California, Irvine, where he earned both his Master's and Ph.D. degrees in Biochemical Engineering. Dr. Ensari is currently a Senior Director at Kite Pharma, a Gilead Company, where he leads the Process Technology and Materials Development team. In this role, he is at the forefront of developing and implementing cutting-edge technologies and materials, playing an instrumental part in advancing the manufacturing processes for next-generation cell therapies.

With over two decades of leadership in the biopharmaceutical industry, Dr. Ensari has a profound track record in the design, optimization, and deployment of robust manufacturing processes. His expertise spans cell and gene therapies, therapeutic proteins, and monoclonal antibodies, consistently integrating advanced biochemical engineering principles across the entire product lifecycle – from initial process development and technology transfer to large-scale clinical and commercial production. Notably, he established and led Kite Pharma's Southern California MSAT team, providing critical technical oversight for cell therapy and viral vector manufacturing.

Prior to his impactful work at Kite, Dr. Ensari held significant roles in Research, Process Development, and Manufacturing at leading companies including Genentech, Ambrx, and Schering-Plough, contributing to the successful development and commercialization of numerous biologics. His innovative leadership and deep technical expertise continue to drive substantial progress in the rapidly evolving and critical field of cell and gene therapy manufacturing.

Hosted by: Prof. Vasan Venugopalan