Ann Lee is vice president for process development at Genentech, responsible for the development, implementation, and support of clinical and commercial production processes and technologies. She leads cell culture, purification, formulation, devices, packaging, analytical development, project management and pilot plant operations teams. Lee was previously employed by Merck & Co., where she held several leadership positions in vaccine development and then served as vice president of chemical technology and engineering, responsible for global chemical technical support and process engineering in the manufacturing division. Lee is an author on more than 35 scientific articles and an inventor on three issued patents and numerous patent applications. She is a fellow of the American Institute of Medical and Biological Engineering and serves on several academic and scientific advisory boards. She is Associate Editor of Biotechnology and Applied Biochemistry. Lee holds a B.S. in chemical engineering from Cornell University and graduate degrees in biochemical engineering from Yale University.

Innovations in Technical Development and Manufacturing of Targeted Oncology Drugs

At Roche, personalized healthcare (PHC) is at the core of the company’s strategy for developing new medicines against serious diseases. PHC is based on fitting the right therapy to the right patient. Modern diagnostics and biomarkers help to identify patient sub-groups most likely to benefit from the treatment, as well as those patient subgroups who will not respond to the drug. PHC is a key enabler to increasing the efficacy and success rate in drug development, and to bringing more clinically differentiated therapies to patients. This presentation will highlight some of the technology innovations that have contributed to the development of several breakthrough novel medicines in oncology, and it will also shares insights into what it takes to make these drugs.

For monoclonal antibody therapeutics, improvements in process technologies have continued to build upon the recombinant DNA techniques that Genentech first peioneered nearly 3 decades ago. Additional manufacturing innovations have led to novel therapeutic modalities such as antibody drug conjugates. Innovations in formulation technology have resulted in increased stability and bioavailability for a targeted small molecule therapeutic. Three oncology drugs, Herceptin, Kadcyla, and Zelboraf which are excellent examples of targeted therapies will be discussed, along with mention of some exciting molecules under development in the new and promising field of cancer immunotherapy.