



# AGENDA

8:00 a.m. – 8:30 a.m.	Registration & Networking Breakfast
8:30 a.m. – 9:00 a.m.	<b>Welcome &amp; Opening Remarks</b> <ul style="list-style-type: none"><li>• <b>Debbie Hart</b>, President &amp; CEO, <b>BioNJ</b></li><li>• <b>Haro Hartounian, Ph.D.</b>, CEO &amp; Founder, <b>BioCentriq</b></li><li>• <b>Teik C. Lim, Ph.D., MSc</b>, President, <b>New Jersey Institute of Technology (NJIT)</b></li></ul>
9:00 a.m. – 9:30 a.m.	<b>Setting the Stage: Industry Trends Shaping Manufacturing Strategy of the Future</b> <ul style="list-style-type: none"><li>• <b>Laurie Lanoue, MBA</b>, Partner, <b>McKinsey &amp; Company</b></li></ul>
9:30 a.m. – 10:30 a.m.	<b>The Road to Building an Agile Network: Lessons Learned from Pandemic, Post-Pandemic Cliff, Supply Chain Instability</b> <p>An industry perspective from key industry stakeholders on how they are incorporating lessons from recent events into manufacturing strategy.</p> <p><b>Panelists:</b></p> <ul style="list-style-type: none"><li>• <b>Mike Nicolazzo</b>, Senior Director, Production Portfolio Management, <b>Fisher Scientific</b></li><li>• <b>David Owen</b>, Executive Director, Engineering for Large Molecule Technical Operations, <b>Merck &amp; Co.</b></li></ul> <p><b>Moderator:</b></p> <ul style="list-style-type: none"><li>• <b>David J. Kristjanson, PMP</b>, Senior Director, Northeast Life Sciences Practice Leader, <b>CBRE Life Sciences</b></li></ul>
10:30 a.m. – 11:00 a.m.	<b>Networking Break</b>
11:00 a.m. – 11:30 a.m.	<b>Case Study: Incorporating Innovation into Manufacturing Strategy of the Future</b> <p>This case study will discuss some examples of incorporating innovation into the CMC development process and bringing manufacturing into the future.</p> <ul style="list-style-type: none"><li>• <b>John Knighton, Ph.D., MBA</b>, Vice President, Cell &amp; Gene Therapy API, Janssen R&amp;D <b>Janssen Pharmaceutical Companies of Johnson &amp; Johnson</b></li></ul>
11:30 a.m. – 12:30 p.m.	<b>A Strategy to Accelerate Manufacturing Performance and Productivity of Tomorrow</b> <p>A discussion on what is on the horizon, including potential game-changers and enablers, such as the use of digital, technology enablement, process yield improvements and talent.</p> <p><b>Panelists:</b></p> <ul style="list-style-type: none"><li>• <b>Chatthuranga "Chat" DeSilva, Ph.D.</b>, Senior Director, Business Development, <b>BioCentriq</b></li><li>• <b>David Gardner</b>, Executive Director, Master Data &amp; Digital Strategy, <b>Bristol Myers Squibb</b></li><li>• <b>Gene Schaefer, MSc, ScD</b>, Senior Fellow, <b>The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)</b></li><li>• <b>Orlando Serani</b>, Program Architect, Advanced Therapies Supply Chain, <b>Janssen Pharmaceutical Companies of Johnson &amp; Johnson</b></li></ul> <p><b>Moderator:</b></p> <ul style="list-style-type: none"><li>• <b>John Tomtishen</b>, Vice President, Operations, <b>Cellares</b></li></ul>
12:30 p.m. – 1:00 p.m.	<b>Keynote: Manufacturing Matters</b> <p>Back by popular demand, Dr. Marks will highlight the importance of quality manufacturing for biologics, the need for manufacturing capacity — both for products in development and for future surge capacity in the event of emergency — and provide guidance and resources for manufacturers.</p> <ul style="list-style-type: none"><li>• <b>Peter Marks, M.D., Ph.D.</b>, Director, Center for Biologics Evaluation and Research (CBER), <b>FDA</b></li></ul>
1:00 p.m. – 1:30 p.m.	<b>Networking Lunch</b>
1:30 p.m. – 1:50 p.m.	<b>BioNJ Closing Remarks &amp; Intro to Digital Capability Center</b> <ul style="list-style-type: none"><li>• <b>Sara Loewenthal</b>, Manager, Digital Capability Centers North America, <b>McKinsey &amp; Company</b></li><li>• <b>Debbie Hart</b>, President &amp; CEO, <b>BioNJ</b></li></ul>
1:50 p.m. – 2:30 p.m.	<b>Digital Capability Center New Jersey Event Tour (pre-registration required)</b> <p>The Digital Capability Center New Jersey is a state-of-the-art learning facility which concentrates on the impact of digital enablement across cell &amp; gene therapy related operations. It provides an immersive learning experience that simulates the journey to operational excellence — including observations of a simulated manufacturing process in its before-and-after state, digital use cases and plenaries on lean principles and enabling mindsets. Attendees will tour the facility and experience a selection of the digital use cases.</p>