



## Center for Devices and Radiological Health Resilient Supply Chain Program

### Background:

The SARS-CoV2 (COVID-19) pandemic demonstrated that by the time there is an emergency, it is often too late to prevent shortages of critical devices. Supply chain disruptions were beginning to occur even before COVID-19 cases were identified in the U.S., as outbreaks of the disease in other nations created unprecedented need for personal protective equipment (PPE), testing supplies, and other medical devices. Moreover, there can be situations, including but not limited to recalls, cyberattacks, hurricanes and other natural disasters, that may not rise to the level of a public health emergency (PHE), but for which device shortages could significantly impact patient care.

The FDA has a unique and critical role in establishing a resilient supply chain that ensures patients and health care providers throughout the U.S. have reliable access to safe and quality medical devices.

### Resilient Supply Chain Program (RSCP):

*The mission of the RSCP is to strengthen public health supply chains and promote availability of medical devices by proactively monitoring, assessing, and communicating risks and vulnerabilities.*

The RSCP will provide technical leadership and assistance to enable rapid interventions to prevent, mitigate, and provide situational awareness of the impacts from supply chain disruptions and shortages. The Program will develop and apply supply chain monitoring capabilities for predictive modeling and early signal detection for critical devices. Additionally, the RSCP will work with stakeholders across the medical device ecosystem and government partners to foster a more resilient medical device supply chain and advance resiliency practices.

To accomplish this, the RSCP will:

- Develop strategies, analyses, and informational products to prevent, and when appropriate and possible, mitigate medical device supply chain disruptions and shortages
- Identify risks and provide actionable information to medical device stakeholders and government partners
- Develop communication channels across the medical device ecosystem to engage in developing risk reduction strategies and enhance supply chain visibility
- Collaborate with government partners and medical device stakeholders to triage supply chain interruption, discontinuance, and/or shortage signals; determine potential impacts of these disruptions; and provide public health information to support an informed mitigation response

For any questions related to the RSCP, please contact the program by email: [RSCPWorkshop@fda.hhs.gov](mailto:RSCPWorkshop@fda.hhs.gov).