

# Ensuring Sufficient Manufacturing Capacity for COVID-19 Therapeutics

## Our Goal

Accelerate and increase the availability of COVID-19 therapeutics (Tx) by addressing the industry’s most critical capacity bottlenecks and regulatory concerns

## Our Approach

We interviewed ~20 companies developing COVID-19 Tx to identify priority capacity bottlenecks and key policy/regulatory concerns. The companies represent a broad range of sizes and technologies, from small molecules to biologics, blood products and cell/gene therapies

We are now developing a detailed view of the capacity landscape (needs & availability) to help companies find the capacities they need and to inform BIO’s engagement with policymakers, in order to advocate for solutions that can expand and accelerate manufacture of COVID-19 Tx

## Key Findings

While there are several potential bottlenecks in the end to end manufacturing and supply chain, we have identified three key steps that could stand in the way of large-scale COVID-19 Tx production and potentially require cross-industry solutions:



**Biologics Drug  
Substance  
Production**



**Sterile Fill &  
Finish Capacity**



**Lyophilization  
Capacity**

On the policy side we also identified shared concerns in two key categories (*see next page for details*):

**Industry  
Regulation**

**Trade Policy &  
Competition Regulation**

# Collaboration Between Industry & Regulators Is Critical for Success

## Industry Regulation concerns include:



Importance of rapid response from industry regulators on development questions



Need to accelerate manufacturing technology transfer & facility registration processes to expand available capacity



Need for international regulatory harmonization

## Trade Policy & Competition Regulation concerns include:



Prevention of potential export restrictions



Unintended consequences of compulsory licensing



Financial risk & inefficiencies of locking up speculative capacity

## Contact Info:

### Tom Dilenge

[tdilenge@bio.org](mailto:tdilenge@bio.org)

**President, Advocacy, Law & Public Policy Division,**  
*Biotechnology Innovation Organization*

### Phyllis Arthur

[parthur@bio.org](mailto:parthur@bio.org)

**Vice President, Infectious Diseases and Diagnostics Policy**  
*Biotechnology Innovation Organization*

### Philip Berk

[Berk.Philip@bcg.com](mailto:Berk.Philip@bcg.com)

**Managing Director & Senior Partner**  
*Boston Consulting Group*

### Jon Williams

[Williams.Jon@bcg.com](mailto:Williams.Jon@bcg.com)

**Project Leader**  
*Boston Consulting Group*