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OMB Control Number: 0694-0119
Expiration Date: September 30, 2023

UNITED STATES INFLUENZA VACCINE INDUSTRIAL BASE ASSESSMENT

SCOPE OF ASSESSMENT

The U.S. Department of Commerce, Bureau of Industry and Security (BIS), Office of Technology Evaluation (OTE), in partnership with the Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA), is conducting a survey of U.S. influenza vaccine manufacturers and their suppliers providing raw or starting materials, active pharmaceutical ingredients, or other consumables required for manufacturing influenza vaccine products. The survey results will be incorporated into a comprehensive report that presents the current state of the influenza vaccine industrial base, including existing supply chain vulnerabilities, production capacities, emergency response capabilities, and other trends from the survey data analyses. Additionally, the report will give recommendations to help improve the resiliency of the influenza vaccine supply chain in the face of future public health emergencies.

RESPONSE TO THIS SURVEY IS REQUIRED BY LAW

A response to this survey is required by law (50 U.S.C. Sec. 4555). Failure to respond can result in a maximum fine of $10,000, imprisonment of up to one year, or both. Information furnished herewith is deemed confidential and will not be published or disclosed except in accordance with Section 705 of the Defense Production Act of 1950, as amended (50 U.S.C. Sec. 4555). Section 705 prohibits the publication or disclosure of this information unless the President determines that its withholding is contrary to the national defense. Information will not be shared with any non-government entity, other than in aggregate form. The information will be protected pursuant to the appropriate exemptions from disclosure under the Freedom of Information Act (FOIA), should it be the subject of a FOIA request.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number.

BURDEN ESTIMATE AND REQUEST FOR COMMENT

Public reporting burden for this collection of information is estimated to average 18 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to BIS Information Collection Officer, Room 6883, Bureau of Industry and Security, U.S. Department of Commerce, Washington, D.C. 20230, and to the Office of Management and Budget, Paperwork Reduction Project (OMB Control No. 0694-0119), Washington, D.C. 20503.

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	General Instructions
A.	Your location is required to complete this survey on the U.S. influenza vaccine industrial base. Your location has been identified as a manufacturer, distributor, supplier, or service provider of a product or input required in the manufacturing of the influenza vaccine. You must complete the survey using the Microsoft Excel-based template which can be downloaded from the secure Census Bureau portal: https://respond.census.gov/XXXX For your convenience, a PDF version of the survey and required drop-down content is available at the Census Bureau portal to aid internal data collection. DO NOT SUBMIT the PDF version of the survey as your response to BIS. Should this occur, your organization will be required to resubmit the survey in Excel format.
B.	THIS SURVEY IS LOCATION-BASED (see "Location" in Definitions tab). The majority of the information provided in this survey should be provided at the location level. Carefully read the instructions associated with each prompt and respond accordingly. Respond to every question. Surveys that are incomplete will be returned for completion. Use the comment boxes at the bottom of every section to provide any supplemental information. Make sure to record a complete answer in the cell provided, even if the cell does not appear to expand to fit all the information. Refer to the "Definitions" section while completing the survey. Fill out the survey tabs in sequential order and AVOID SKIPPING TABS. Some information will auto-generate based on responses in previous tabs. DO NOT COPY AND PASTE RESPONSES WITHIN THIS SURVEY. Inputs to the survey are to be made via keyboard or drop-down menus. The use of copy/paste can corrupt the file. If your submittal is corrupted due to copy/pasted responses your organization will be required to download an additional survey from the portal and resubmit.
C.	**Do not disclose any classified information in this survey form.**
D.	Submit your completed survey only through the secure Census Bureau portal: https://respond.census.gov/XXXX Do not email surveys to BIS.
E.	Questions related to the survey content should be directed to BIS survey support staff at XXXsurvey@bis.doc.gov Email is the preferred method of contact.
F.	For questions related to the overall scope of the industrial base survey and assessment, contact XXXsurvey@bis.doc.gov or: Jason Bolton Director, Defense Industrial Base Division BIS/Export Administration/Office of Technology Evaluation 1401 Constitution Avenue, NW, Room 1093 Washington, DC 20230 DO NOT submit completed surveys to Mr. Bolton.

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Definitions	
Term	**Definition**
Active Pharmaceutical Ingredients	The active components in a pharmaceutical drug that produce the intended effect on the body to treat a condition.
Authorizing Official	An executive officer of the organization or business unit or another individual who has the authority to execute this survey on behalf of the organization.
Biosafety Level	The level of the biocontainment precautions required to isolate dangerous biological agents in an enclosed facility, as defined by the Centers for Disease Control and Prevention.
Blockchain	A method of storing digital information on a secured, public database that allows for tracing of products through the supply chain. Each transaction is verified and recorded as a block in the blockchain ledger.
Brute Force	A method of accessing an obstructed device through attempting multiple combinations of numeric/alphanumeric passwords.
Capability	Having the ability to provide the product or service within 12 months in typical business conditions.
Capacity Utilization	The extent to which a facility is achieving its full productive capacity.
Capacity Utilization Rate	(actual output per period / full capacity per period) x 100
Capital Expenditures ()	Investments made by an organization in buildings, equipment, property, and systems where the expense is depreciated. This does not include expenditures for consumable materials, other operating expenses, and salaries associated with normal business operations.
Chemical Abstracts Service (CAS) Number	A unique numerical identifier assigned by the Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature. Find CAS registry numbers here: https://www.cdc.gov/niosh/npg/npgdcas.html
Cloud Computing	The delivery of computing services—including servers, storage, databases, networking, software, analytics, and intelligence—over the Internet (“the cloud”).
Code/SQL Injection	A type of cyberattack that looks for web sites that pass insufficiently-processed user input to database back-ends.
Commercial and Government Entity (CAGE) Code	A unique identifier used for companies doing or wishing to do business with the U.S. Federal Government. The code is used to support mechanized government systems and provides a standardized method of identifying a given facility at a specific organization. Find CAGE codes here: https://cage.dla.mil
Corporate Linkage	An identifier that reflects the relationship between different businesses within a corporate family.

Definitions	
Term	**Definition**
Cost Plus Contract	A cost-reimbursement contract that provides for payment to the contractor of a negotiated fee that is fixed at the inception of the contract. The fixed fee does not vary with actual cost, but may be adjusted as a result of changes in the work to be performed under the contract.
Customer	An entity to which an organization directly delivers the product or service that it produces. A customer may be another organization or another facility owned by the same parent organization. The customer may be the end user for the item but often can be the immediate link in the supply chain, adding additional value before transferring the item to yet another customer.
Cybersecurity	The body of technologies, processes, and practices designed to protect networks, computers, programs, and data from attack, damage, or unauthorized access.
Diagnostic Testing	The use of tests to identify a medical condition, the cause of a medical condition, and/or the progression of a medical condition.
Distributor	An independent selling agent who has a contract to sell the products of a manufacturer.
Exports	Shipments to destinations outside the United States.
External Company	A company that is not within your own organization.
External Technology Transfer	The transfer of technological products, processes, or knowledge from an original innovator to an outside entity such as a contract manufacturing organization.
Full Time Equivalent (FTE) Employees	Employees who work for 40 hours in a normal work week. Convert part-time employees into "full time equivalents" by taking their work hours as a fraction of 40 hours.
Headquarters	A location that serves as an organization's hub of operations with all branches or divisions reporting to it.
IIV3	A trivalent inactivated influenza vaccine. When referring specifically to adjuvanted vaccine, the prefix "a" is used (e.g., aIIV3).
IIV4	A quadrivalent inactivated influenza vaccine. When referring specifically to adjuvanted vaccine, the prefix "a" is used (e.g., aIIV3). When referring specifically to cell culture-based vaccine, the prefix "cc" is used (e.g., ccIIV4). When referring specifically to High-dose vs. Standard-dose vaccines, the prefixes "HD-" and "SD-" are used (e.g., HD-IIV3 vs. SD-IIV3 and SD-IIV4).

Definitions	
Term	**Definition**
Infectious Disease Therapeutics	Therapies and treatments used to alleviate or prevent specific diseases or medical conditions that spread from person to person. This includes antibiotics, antifungals, anthelmintics, antimalarials, antiprotozoals, antituberculosis agents, and antivirals, which are can used to treat infectious diseases such as HIV/AIDS, influenza, hepatitis, malaria, and tuberculosis.
Infectious Disease Vaccines	Biological preparations that improve immunity to infectious diseases such as polio, influenza, hepatitis, measles, and pneumonia.
Influenza Vaccine-Related Products	Raw and key starting materials, active pharmaceutical ingredients, consumables, and production equipment required for manufacturing influenza vaccine products, including end-use influenza vaccines. Includes but is not limited to product categories listed in the *Product Capabilities* section of this survey.
International Union of Pure and Applied Chemistry (IUPAC) Name	A systematic method of naming organic chemical compounds as recommended by the International Union of Pure and Applied Chemistry. More information here: https://iupac.org/what-we-do/nomenclature/brief-guides/
Inventory	The goods or materials an organization holds for its own use or for the ultimate goal of sale.
ISO 28000	An international standard addressing the requirements of a security management system for the supply chain. More information here: https://www.iso.org/standard/79612.html
Live Attenuated Influenza Vaccine (LAIV)	A live attenuated influenza vaccine. This vaccine is administered intranasally.
Location	A building or the minimum complex of buildings or parts of buildings in which an organization operates to serve a particular function, producing revenue and incurring costs for the company. A location may produce an item of tangible or intangible property or may perform a service. It may encompass a floor or group of floors within a building, a single building, or a group of buildings or structures. A location could include a group of related locations at which organization employees work, together constituting a profit-and-loss center for the company, and it may be identified by a unique Data Universal Numbering System (DUNS) number.
Logistics Management Information System	A system of records and reports used to aggregate, analyze, validate and display data from all levels of the logistics system that can be used to make logistics decisions and manage the supply chain.

Definitions	
Term	**Definition**
Manufacturer	An organization that uses labor and capital to convert raw materials into finished or semi-finished goods. For purposes of this survey, manufacturing includes integration, assembly, and/or fill finish.
Manufacturing Defect	Errors or contamination that occurs during the production phase that only affect certain units or batches of a product, rather than all products in a line,
Medical Consumables	Non-durable medical supplies that cannot withstand repeated use, are usually disposable, and are generally not used in the absence of illness or injury.
Non-Infectious Disease Therapeutics	Therapies and treatments for disease that is not spread from person to person. This includes treatments for noncommunicable diseases such as cancer, cardiovascular disease, diabetes, genetic disease, mental disorders, and chronic respiratory diseases.
Non-U.S. Facility	A facility that is physically located outside of the United States.
Organization	A company, firm, laboratory, or other entity that owns or controls the location capable of manufacturing or distributing influenza vaccine products.
Over the Counter (OTC) Pharmaceuticals	Medicines sold directly to consumers without need for a prescription from a medical professional.
Partnership	Any type of service or collaboration agreement between two parties under which proprietary information can be shared in either tangible or non-tangible forms.
Priority Rated Orders (Defense Priorities and Allocations System)	A rated order is a contract or order placed in support of a national defense program, pursuant to section 101(a) of the DPA. A rated order takes precedence over all unrated orders, when necessary to meet delivery dates specified in the rated order. A priority rating consists of a rating – either “DO” or “DX” – and an alpha numeric program identification symbol (PIS), such as “N3.” Between priority ratings, a DX rated order takes precedence over all DO rated orders.
Production	The process of transforming inputs (raw materials, semi-finished goods, subassemblies, fill finish) into goods or services.
Research and Development	Basic and applied research in the engineering sciences, as well as design and development of prototype products and processes. Efforts that an organization conducts towards innovating, introducing and/or improving products and processes.
RIV4	A quadrivalent recombinant influenza vaccine.
Sales	All reported and unreported sales of subject products, including sales to end-users, producers, financial entities, intermediaries, traders, distributors, et al.
Scrap	Goods that become waste or are recycled due to defects or errors during manufacturing.

Definitions	
Term	**Definition**
Sensitive Information	Privileged or proprietary information which, if compromised through alteration, corruption, loss, misuse, or unauthorized disclosure, could cause serious harm to the information's owners.
Sole Source	A supplier that is the only source for the supply of parts, components, or services. No alternative U.S. or non-U.S. based suppliers exist other than the current supplier.
Strategic National Stockpile (SNS)	The U.S. national repository of critical medical supplies used to protect the American public in case of a public health emergency, managed by the Assistant Secretary for Preparedness and Response within the Department of Health and Human Services.
Supplier	An entity from which your organization obtains inputs, which may be goods or services. A supplier may be another organization with which you have a contractual relationship, or it may be another facility owned by the same parent organization.
Supply Chain Disruption	Any event causing a disruption or delay in production, sales, or distribution of products.
Surge Capacity	Ability to rapidly mobilize and expand beyond normal service levels to meet an increased demand in the event of large-scale disasters or public health emergencies.
United States	The "United States" or "U.S." includes the 50 states, the District of Columbia, Puerto Rico, Guam, America Samoa, the U.S. Virgin Islands, and the Northern Mariana Islands.
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1. Location Information

A. Provide your location's primary point of contact (POC) for this survey. This individual will be responsible for ensuring the completion and certification of this location's survey.

Name	Title	Phone Number	Email Address	State

B. Provide the information.

Organization Name		Link: Definition of ***Organization***
Location Name		
Location Street Address		
Location City		
Location State		
Location ZIP Code (5-digit)		
Location Country		
CAGE(s), comma delineated (if applicable)		
Ultimate Parent Organization Name		
Ultimate Parent Organization Country		
Is your ultimate parent organization a public or private entity?		If Public, Stock Ticker:

C. In two or three sentences, describe the activities that take place at this location.

Comments:	

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Public
Private

AUDENZ, BCG Vaccine, BEXSERO, Biothrax, Boostrix, Cervarix, Comirnaty, DAPTACEL, DENGVAXIA, Engerix-B, ERVEBO, Fluad, Fluad Quadrivalent, Fluarix, Fluarix Quadrivalent, Flublok, Flublok Quadrivalent, Flucelvax, Flucelvax Quadrivalent, FluLaval, Flulaval Quadrivalent, FluMist, FluMist Quadrivalent, Fluvirin, Fluzone Quadrivalent, Fluzone High-Dose and Fluzone Intradermal, Gardasil, Gardasil 9, Havrix, HEPLISAV-B, Hiberix, Imovax, Infanrix, IPOL, Ixiaro, JYNNEOS, KINRIX, Menactra, Menomune-A/C/Y/W-135, MenQuadfi, MENVEO, M-M-R II, Pediarix, PedvaxHIB, Pentacel, Pneumovax 23, Poliovax, PREHEVBRIO, Prevnar 13, Prevnar 20, PRIORIX, ProQuad, Quadracel, RabAvert, Recombivax HB, ROTARIX, RotaTeq, SHINGRIX, SPIKEVAX, TDVAX, TENIVAC, TICE BCG, TICOVAC, TRUMENBA, Twinrix, TYPHIM Vi, VAQTA, Varivax, Vaxchora, VAXELIS, VAXNEUVANCE, Vivotif, YF-Vax, Zostavax, Other (write-in)

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2. Organization Information

A. Using the drop-down menu, identify the top five vaccines manufactured and/or distributed by your organization that generate the greatest sales revenue, in decending order, other than influenza. If your organization does not manufacture vaccines, please proceed to sub-section B of this tab.

1.	
2.	
3.	
4.	
5.	

B. List all entities in descending order, including individuals and governments, which currently hold 5% or more of your organization's voting rights.

Entity or Individual Name	Stake %	Street Address	City	State	Country

C. In the box to the right, record the total number of mergers, acquisitions and divestitures that your organization has been party to in the past **five years**. Include both U.S. and non-U.S. activities. Use drowpdown menu unless you select "Other, write in." If so, write your response in the cell.

Identify mergers, acquisitions, and divestures completed in the past five years that are **most relevant to your organization's influenza vaccine-related product operations.**

Organization Name	Full Address	Country	Type of Activity	Primary Objective	Year Transaction Completed

D. In the box to the right, record the total number of joint ventures that your organization has been completed in the past **five years.** Include both U.S. and non-U.S. activities.

Identify joint venture activities completed in the past five years that are **most relevant to your organization's influenza vaccine-related product operations.**

Joint Venture Name	Full Address	Country	Partner Name	Primary Objective	Year Initiated

E. Provide the total number of your organization's U.S. and non-U.S. locations currently involved in the distribution and/or production of influenza vaccine-related products, including contract manufacturing organizations (CMOs). Then, **list the locations in descending order by revenue**. NOTE: Non-headquarter locations may proceed to the next section.

Number of U.S. Locations		Number of non-U.S. Locations	

Global Locations

Location Name	Primary Product Category	Primary Influenza Vaccine-Related Function	City	Country	Zip Code

omments:

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Acquisition
Merger
Divestiture

Analytical Testing
Ancillary Equipment and Supplies
Cell Culture
Consumables
Fill/Finish
Influenza Vaccines
Raw Materials

Assembly
Distribution and/or Procurement
Manufacturing
Packaging
Research and Development
Testing and Quality Assurance
Other (write-in)
None

Access to government contracts
Access to intellectual property
Bankruptcy/restructuring
Broaden customer base
Develop new capabilities
Overcome geopolitical concerns
R&D access/coordination
Reduce Costs
Tax-related
Other (write-in)

Currently Manufacture
Currently Distribute
Both

Sole Global Source
Existing Non-U.S. Competitors only
Existing U.S. Competitors only
Existing U.S. and Non-U.S. Competitors

Yes
No

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3. Product Capabilities

Indicate if your location currently manufactures or distributes products within the influenza vaccine-related product categories listed below by selecting the appropriate dropdown menu choice for any applicable product categories.
For each product category that your location manufactures or distributes, indicate a product range description, top export country, availability of alternative providers, and whether your facility conducts research and development.

Link: Definition of ***Distributor***

Analytical Testing	Capability	Product(s) Range Description	Top Export Country (if applicable)	Availability of Alternative Providers	Research and Development
Assays - Cell Viability					
Assays - Contamination Detection					
Assays - Potency					
Assays - Stability					
Reagents					
Other Analytical Testing Products					
Ancillary Equipment and Supplies	Capability	Product(s) Range Description	Primary Export Country (if applicable)	Availability of Alternative Providers	Research and Development
Containers					
Flasks					
Jet Injectors					
Needles					
Pipettes					
Sterile Clothing (Booties, Gloves, Jump Suits)					
Syringes					
Other Ancillary Equipment and Supplies					
Cell Culture	Capability	Product(s) Range Description	Primary Export Country (if applicable)	Availability of Alternative Providers	Research and Development
Bioreactor - Single-Use					
Bioreactor - Non-Single-Use					
Cell Banking					
Growth Media and Additives - Amino Acids					
Growth Media and Additives - Calcium Chloride					
Growth Media and Additives - DNA					
Growth Media and Additives - Cell Proteins					
Growth Media and Additives - Hydrocortisone					
Growth Media and Additives - Egg, Egg Proteins (Albumin, Ovalbumin)					
Other Cell Culture Products					
Consumables	Capability	Product(s) Range Description	Primary Export Country (if applicable)	Availability of Alternative Providers	Research and Development
Aseptic Sampling Systems					
Bioreactor Bags					
Buffer/Storage Bags					
Chromatography Resins					
Chromatography Columns (pre-packed)					
Filters - Depth Filters					
Filters - Nominal Filters					
Filters - Sterile Filters					
Filters - Ultrafiltration Filters					
Filters - Vent Filters					
Flow Paths					
Manifold Assembly Systems					
Mixing Bags					
Sterile Connectors					
Tubing					
Other Consumables					
Fill/Finish	Capability	Product(s) Range Description	Primary Export Country (if applicable)	Availability of Alternative Providers	Research and Development
Filling Assemblies					
Labels					
Seals					
Stoppers (including rubber)					
Vial Adapters					
Vials					
Vial Caps					
Other Fill/Finish Products					
Influenza Vaccines	Capability	Product(s) Range Description	Primary Export Country (if applicable)	Availability of Alternative Providers	Research and Development
IIV3 - Standard dose - Egg based with MF59 (aIIV3)					
IIV4 - High dose - Egg-based (HD-IIV4)					
IIV4 - Standard dose - Cell-culture based (ccIIV4)					
IIV4 - Standard dose - Egg-based					
IIV4 - Standard dose - Egg-based with MF59 (aIIV4)					
LAIV4 - Egg-based					
RIV4 - Recombinant HA					
Raw Materials	Capability	Product(s) Range Description	Primary Export Country (if applicable)	Availability of Alternative Providers	Research and Development
Antibiotics - Gentamicin Sulfate					
Antibiotics - Kanamycin					
Antibiotics - Neomycin, Neomycin Sulfate					
Antibiotics - Polymyxin B					
a-tocopherol					
Buffer Components					
Buffer Solution, Pre-made					
Gases (Nitrogen, Oxygen, Liquid Oxygen)					
Inactivating Agents - Beta-propiolactone					
Inactivating Agents - Formaldehyde					
Preservatives - Ethylenediaminetetraacetic acid (EDTA)					
Preservatives - Thimerosal					
Protein Purifier - Sodium Taurodeoxycholate					
Salts					
Squalene					
Stabilizers - Gelatin					
Stabilizers - Monosodium Glutamate					
Stabilizers - Sucrose					
Surfactants - Cetrimonium Bromide (CTAB)					
Surfactants - SPAN 85					
Surfactants - Nonylphenol Ethoxylate					
Surfactants - Octoxynol-10 (Triton X-100)					
Surfactants - Polysorbate 20					
Surfactants - Polysorbate 80					
Surfactants - Sodium Deoxycholate					
Surfactants - Sorbitan Trioleate					
Surfactants - Other					
Water for Injection (WFI) Quality Water					
Other Raw Materials					
Comments:					

Manufacture
Distribute

inches
mm
L
g
units

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4. Product Assortment

Document your location's influenza vaccine-related products in the matrix below If your location manufactures or distributes more than ten influenza vaccine-related products, list the ten influenza vaccine-related products that were the **most vulnerable to supply chain disruptions in 2022.**
For each influenza vaccine-related product, indicate product category (generated from your response in the previous tab), capability type, unit of measurement, annual output in 2018 and 2022, revenue per unit in 2018 and 2022, planning horizon, projected annual and maximum output/delivery in 2027, the number of units contributed to the Strategic National Stockpile in 2022, and product shelf life.

Link: Definition of ***Influenza Vaccine-Related Products***

- To determine supply chain vulnerability, first consider the elements of the supply chain that increase the likelihood of disruptions, and then consider your products exposure to those elements.
- The following are examples of elements that may increase the likelihood of supply chain disruptions: Insufficient U.S. manufacturing capacity, natural disasters or force majeure events, political intervention, geopolitical instability, distortionary trade practices, lack of skilled workforce, dependence on foreign suppliers, sole-source suppliers
- Unit: A "unit" refers to a singular product. For example, for a 500mL mixing bag, you would select "L" for Measurement Unit, then indicate ".5" for Unit Size. If the product has no unit of measurement, select "units."

Click on a column title for a more in depth explanation.								Output Over Time		Revenue Over Time		Future Estimate (If Applicable) Estimate future output/delivery if planning horizon is shorter than five years		
	Product Brand Name or Trade Name	Product Category *(generated from Product Capabilities)*	Manufacture or Distribute	Measurement Unit	Unit Size (# of Measurement Units)	Strategic National Stockpile (units provided in 2022)	Typical Shelf-Life	Percentage of 2022 Output Exported	Annual Output 2018 (Units)	Annual Output 2022 (Units)	Unit Revenue 2018 ($)	Unit Revenue 2022 ($)	Typical Planning Horizon	Projected Annual Output/Delivery (Units) 2027	Projected Maximum Annual Output/Delivery (Units) 2027
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															
Comments															

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Less than 1 month
1-3 months
4-6 months
7-9 months
10-12 months
More than 12 months
N/A

Less than 1 month
1-5 months
6-12 months
1-2 years
3-4 years
More than 5 year

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5. Production Capacity

A. Does your location *manufacture* influenza vaccine related products? If no, proceed to tab 6. — Yes / No

B. Provide the production capacity information for each product identified as being manufactured at your location. To estimate your location's surge capacity, make the following assumptions:

1) Existing U.S. production facilities are to be operated at maximum practical productive capacity;
2) Labor and Material availability reflects normal local market conditions;
3) Facilities operate at the maximum rate possible given technological constraints; and
4) The product area in question is given priority over other products that may use the same manufacturing resources.

	Manufactured Products *(generated from Product Assortment List)*	Time Required to Achieve Surge Capacity	Maximum Annual Output at Surge (units)	Primary Barrier to Achieve Surge Capacity	Secondary Barrier to Achieve Surge Capacity (if applicable)	Explain
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

Time Required to Achieve Surge Capacity: 0-2 weeks; 2-4 weeks; 1-3 months; 3-6 months; 6-12 months; Over 1 year

Primary / Secondary Barrier to Achieve Surge Capacity: Critical Machinery Lead Times; Environmental/Health and Safety issue; Insufficient Sterilization Capacity; Insufficient Warehouse Space; Lack of Component Supply; Lack of Personnel; Lack of Qualified Suppliers; Lack of Raw Material Supply; Late or Delayed Supplier Delivery; Access to Capital

C. Answer the following questions regarding automation in your location's production processes. — Link: Definition of ***Influenza Vaccine Products***

1.	Is your location investing (or considering investing) in increased automation of your production process?	
	If yes, explain the automation processes in which your location is currently (or considering) investing.	
2.	Estimate the percentage of your location's production process that is automated.	
3.	Does your organization use automated software to manage your supply chain or production process planning?	
	If yes, indicate which type of software.	

Yes / No

Advanced Planning and Scheduling Systems (APS); Enterprise Resource Planning Systems (EPR); Material Requirements Planning (MRP); Manufacturing Resource Planning (MRP II); Other (write-in)

D. Answer the following questions pertaining to your location's manufacturing efficiency.

1.	Regarding influenza vaccine products only, estimate the annual cost of your location's manufacturing defects in 2022.	
2.	Estimate your location's scrap rate for influenza vaccine products in 2022. Scrap rate = (number of scrap items / total items) x 100 — *Link: Definition of* ***Scrap***	
3.	Estimate scrap recycled (in Kg)	
4.	Estimate scrap waste (in Kg)	
5.	What is the most common reason for scrapping influenza vaccine related products at your location?	
6.	Which of your location's influenza vaccine products is most vulnerable specifically to production delays/disruptions?	

Destroyed in transit; Expiration due to excess supply; Quality check failure - human error; Quality check failure - machine error; Poor storage; Product damage; Other (write-in)

Comments

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6. Manufacturing Inputs

For each manufactured product, please provide that product's ten inputs that were most vulnerable to supply chain disruptions in 2022. List the inputs in descending order, starting with the most vulnerable. For each input, please provide the following: input type, input name, reason for vulnerability, and change in sourcing difficulty since 2018. For the Sourcing Difficulty Δ prompt, indicate whether each input has become more or less difficult to source since 2018. Please include IUPAC names and CAS Registry numbers, when applicable.

Do NOT fill in grayed out cells (non-manufactured products). These should be left blank.

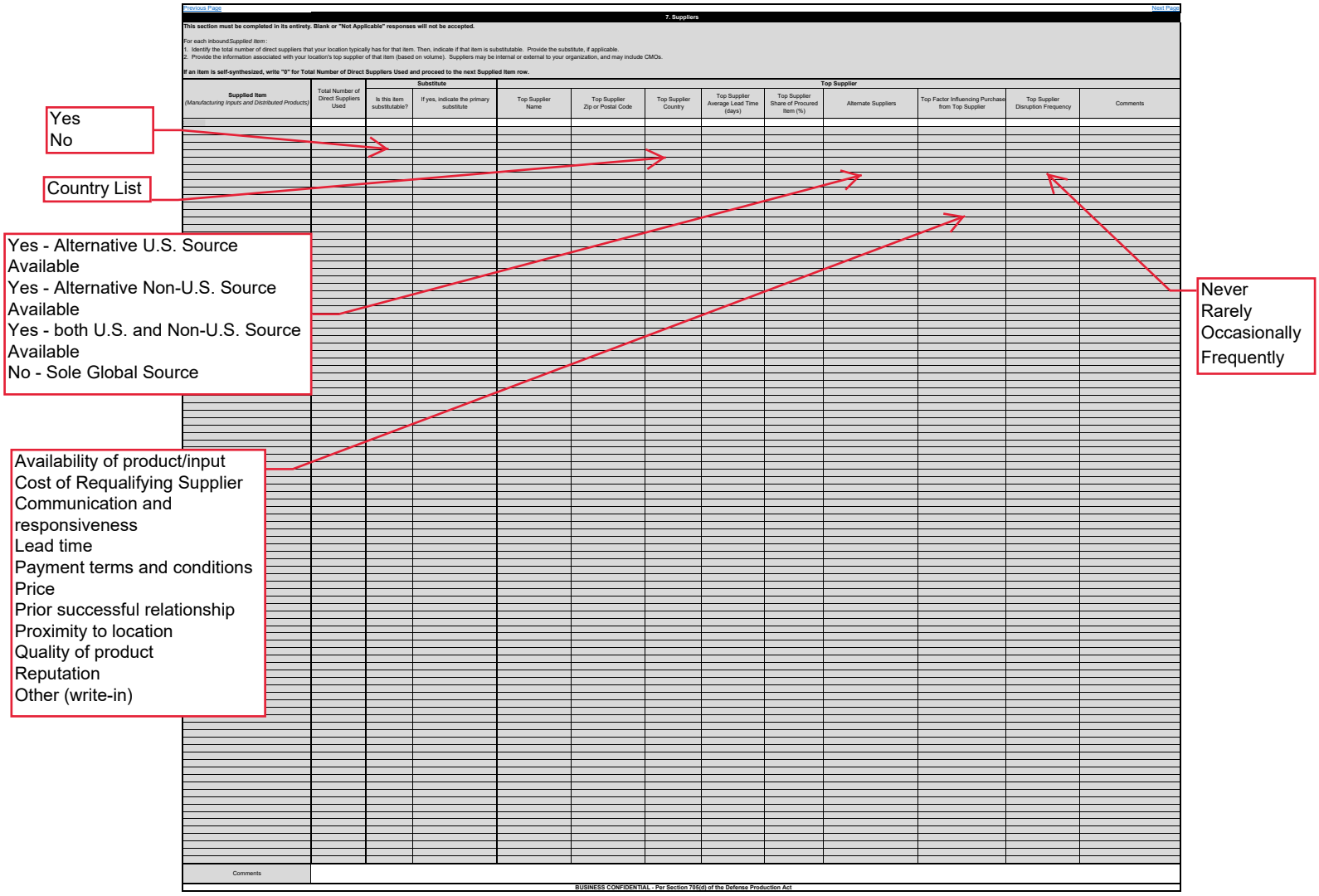
Linked Definition: International Union of Pure and Applied Chemistry (IUPAC) Name
Linked Definition: Chemical Abstracts Service (CAS) Number

	Products *(auto-generated from Product Assortment)*	Brand Name Product 1	Brand Name Product 2	
1	Input 1 Type			
	Input 1 Name			
	Reason for Vulnerability			
	Sourcing Difficulty Δ since 2018			
	IUPAC Name			
	CAS Registry Number			
2	Input 2 Type			
	Input 2 Name			
	Reason for Vulnerability			
	Sourcing Difficulty Δ since 2018			
	IUPAC Name			
	CAS Registry Number			
3	Input 3 Type			
	Input 3 Name			
	Reason for Vulnerability			
	Sourcing Difficulty Δ since 2018			
	IUPAC Name			
	CAS Registry Number			
4	Input 4 Type			
	Input 4 Name			
	Reason for Vulnerability			
	Sourcing Difficulty Δ since 2018			
	IUPAC Name			
	CAS Registry Number			
5	Input 5 Type			
	Input 5 Name			
	Reason for Vulnerability			
	Sourcing Difficulty Δ since 2018			
	IUPAC Name			
	CAS Registry Number			
6	Input 6 Type			
	Input 6 Name			
	Reason for Vulnerability			
	Sourcing Difficulty Δ since 2018			
	IUPAC Name			
	CAS Registry Number			
7	Input 7 Type			
	Input 7 Name			
	Reason for Vulnerability			
	Sourcing Difficulty Δ since 2018			
	IUPAC Name			
	CAS Registry Number			
8	Input 8 Type			
	Input 8 Name			
	Reason for Vulnerability			
	Sourcing Difficulty Δ since 2018			
	IUPAC Name			
	CAS Registry Number			
9	Input 9 Type			
	Input 9 Name			
	Reason for Vulnerability			
	Sourcing Difficulty Δ since 2018			
	IUPAC Name			
	CAS Registry Number			
10	Input 10 Type			
	Input 10 Name			
	Reason for Vulnerability			
	Sourcing Difficulty Δ since 2018			
	IUPAC Name			
	CAS Registry Number			
	Comments:			

Reason for Vulnerability Dropdown
- Changes to Laws
- Delivery Delays/Excessive Lead Times
- Dependence on Foreign Suppliers
- Distortionary Trade Practices
- Foreign Competition
- Geopolitical Instability
- Increased Cost
- Insufficient U.S. Manufacturing
- Lack of Skilled Workforce
- Limited or Sole Source
- Loss of Critical Suppliers
- Natural Disasters or Force Majeure Events
- Other (write-in)

Sourcing Difficulty Change Dropdown
- Easier to Source
- No Change in Sourcing Difficulty
- Moderately More Difficult to Source
- Substantially More Difficult to Source

Input Type Dropdown
- Antibiotics - Gentamicin Sulfate
- Antibiotics - Kanamycin
- Antibiotics - Neomycin, Neomycin Sulfate
- Antibiotics - Polymyxin B
- Aseptic Sampling Systems
- Assays - Cell Viability
- Assays - Contamination Detection
- Assays - Potency
- Assays - Stability
- a-tocopherol
- Bioreactor - Non-Single-Use
- Bioreactor - Single-Use
- Bioreactor Bags
- Buffer Components
- Buffer Solution, Pre-made
- Buffer/Storage Bags
- Cell Banking
- Chemical - Compound
- Chemical - Single Element
- Chromatography Resins
- Chromatograpy Columns (pre-packed)
- Containers
- Filling Assemblies
- Filters - Depth Filters
- Filters - Nominal Filters
- Filters - Sterile Filters
- Filters - Ultrafiltration Filters
- Filters - Vent Filters
- Flasks
- Flow Paths
- Gases (Nitrogen, Oxygen, Liquid Oxygen)
- Growth Media and Additives - Amino Acids
- Growth Media and Additives - Calcium Chloride
- Growth Media and Additives - Cell Proteins
- Growth Media and Additives - DNA
- Growth Media and Additives - Egg, Egg Proteins (Albumin, Ovalbumin)
- Growth Media and Additives - Hydrocortisone
- IIV3 - Standard dose - Egg based with MF59 (aIIV3)
- IIV4 - High dose - Egg-based (HD-IIV4)
- IIV4 - Standard dose - Cell-culture based (ccIIV4)
- IIV4 - Standard dose - Egg-based
- IIV4 - Standard dose - Egg-based with MF59 (aIIV4)
- Inactivating Agents - Beta-propiolactone
- Inactivating Agents - Formaldehyde
- Labels
- LAIV4 - Egg-based
- Manifold Assembly Systems and Tubing Sets
- Mixing Bags
- Pipettes
- Preservatives - Ethylenediaminetetraacetic acid (EDTA)
- Preservatives - Thimerosal
- Protein Purifier - Sodium Taurodeoxycholate
- Reagents
- RIV4 - Recombinant HA
- Salts
- Seals
- Squalene
- Stabilizers - Gelatin
- Stabilizers - Monosodium Glutamate
- Stabilizers - Sucrose
- Sterile Clothing (Booties, Gloves, Jump Suits)
- Sterile Connectors
- Stoppers (including rubber)
- Surfactants - Cetrimonium Bromide (CTAB)
- Surfactants - Nonylphenol Ethoxylate
- Surfactants - Octoxynol-10 (Triton X-100)
- Surfactants - Other
- Surfactants - Polysorbate 20
- Surfactants - Polysorbate 80
- Surfactants - Sodium Deoxycholate
- Surfactants - Sorbitan Trioleate
- Surfactants - SPAN 85
- Syringes
- Tubing
- Vial Adapters
- Vial Caps
- Vials
- Water for Injection (WFI) Quality Water
- Wave Bioreactor Bags
- Other Analytical Testing Products
- Other Ancillary Equipment and Supplies
- Other Cell Culture Products
- Other Consumables
- Other Fill/Finish Products
- Other Raw Materials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7. Suppliers
This section must be completed in its entirety. Blank or "Not Applicable" responses will not be accepted.
For each inbound Supplied Item :
1. Identify the total number of direct suppliers that your location typically has for that item. Then, indicate if that item is substitutable. Provide the substitute, if applicable.
2. Provide the information associated with your location's top supplier of that item (based on volume). Suppliers may be internal or external to your organization, and may include CMOs.
If an item is self-synthesized, write "0" for Total Number of Direct Suppliers Used and proceed to the next Supplied Item row.
Substitute
Top Supplier
Supplied Item (Manufacturing Inputs and Distributed Products)
Total Number of Direct Suppliers Used
Is this item substitutable?
If yes, indicate the primary substitute
Top Supplier Name
Top Supplier Zip or Postal Code
Top Supplier Country
Top Supplier Average Lead Time (days)
Top Supplier Share of Procured Item (%)
Alternate Suppliers
Top Factor Influencing Purchase from Top Supplier
Top Supplier Disruption Frequency
Comments
Comments
BUSINESS CONFIDENTIAL - Per Section 705(d) of the Defense Production Act
Yes
No
Country List
Yes - Alternative U.S. Source Available
Yes - Alternative Non-U.S. Source Available
Yes - both U.S. and Non-U.S. Source Available
No - Sole Global Source
Availability of product/input
Cost of Requalifying Supplier
Communication and responsiveness
Lead time
Payment terms and conditions
Price
Prior successful relationship
Proximity to location
Quality of product
Reputation
Other (write-in)
Never
Rarely
Occasionally
Frequently

-Less than 1 month
-1-5 months
-6-12 months
-1-2 years
-3-4 years
-More than 5 year

-< 5 years
-5-7 years
-7-10 years
->10 year

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8. Capital Equipment

Identify the ten types of capital equipment that are most critical to your location's influenza vaccine manufacturing process. List the equipment in decending order, starting with the most vulnerable to supply chain disruptions in 2023-2027.
For each equipment type, provide the manufacturer, country of origin, typical lead time to acquire, acquisition cost per unit, average useful life, number of operable units, and the average remaining useful life of operable units.

Note 1: To determine supply chain vulnerability, first consider the elements of the supply chain that increase the likelihood of disruptions, and then consider your product's exposure to those elements.

Note 2: The following are examples of elements that may increase the likelihood of supply chain disruptions: Insufficient U.S. manufacturing capacity, natural disasters or force majeure events, political intervention, geopolitical instability, distortionary trade practices, lack of skilled workforce, dependence on foreign suppliers, sole-source suppliers.

	Equipment Type	Primary Product Associated	Equipment Manufacturer	Country of Origin	Typical Lead Time to Acquire	Acquisition Cost per Unit	Average Useful Life (years)	Number of Operable Units	Average Remaining Useful Life of Operable Units
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
	Comments								

See Product list from Section 3

-Airflow Hoods
-Airlock Systems
-Biological Safety Cabinets
-Cell Separators
-Centrifuges
-Chromatography Frits
-Chromatography Pump
-Chromatography Detector

-Yes, both inbound and outbound
-Yes, inbound only
-Yes, outbound only
-No

-Cost
-Disruptions
-Import regulations
-Quality management
-Visibility
-Other (write-in)

-Cost
-Disruptions
-Export regulations
-Quality management
-Visibility
-Other (write-in)

-In-house team
-Third party provider

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9. Procurement and Logistics

Respond to the following questions and provide an explanation regarding your location's logistics visibility for influenza vaccine-related products.
Note: Inbound supply chain refers to products coming into your location from suppliers. **Outbound** supply chain refers to products leaving your location to customers.

A.	1.	Select the option that most appropriately reflects how inbound logistics are handled at your location.		Explain:
	2.	Select the option that most appropriately reflects how outbound logistics are handled at your location.		Explain:
	3.	What is the greatest challenge that your location faces with respect to its inbound supply chain?		Explain:
	4.	What is the greatest challenge that your location faces with respect to its outbound supply chain?		Explain:
	5.	Does your location track the status/location of your shipments while they are en route?	Yes / No	Explain:
	6.	Does your location utilize a control tower or Logistics Management Information System (LMIS) to manage its supply chain? Definition: Logistics Management Information System		Explain:
	7.	How can the USG assist in improving supply chain visibility?		Explain:

-Yes / No

-Guaranteed Orders
-Longer Contracts
-Other (Specify here)
-No Incentive Offered

Respond to the following questions related to your location's supply chain procurement of influenza vaccine-related products.

B. 1.	Estimate the percentage of influenza vaccine-related product inputs supplied to your location that are manufactured in the following countries:	U.S.		China		India		Pakistan		Russia	
		Canada		Mexico		Iran		U.K			
2.	Does your location source from your organization's production sites located overseas?	Yes / No		If yes, what is the primary reason for choosing to produce materials overseas?							
3.	Is your location taking steps to geographically diversify its supply chain?			Explain:							

Respond to the following questions related to your location's experienced and anticipated supply chain disruptions of influenza vaccine products.

Based on your location's products that are most vulnerable to supply chain disruption (identified in Tab 3), identify your location's most significant supply chain disruptions experienced in 2022. For each disruption, include the product most impacted by each disruption, the length and year of the disruption, whether the disruption was caused internally or externally, the reason for the disruption, and actions taken to mitigate consequences of the disruption.
NOTE: This list can include disruptions that originated outside of the U.S., as long as they had location-specific impact.

C.		Affected Product	Length of Disruption	Supplier Country	Internal or External	If Internal, Reason for Disruption	If External, Reason for Disruption	If External, Primary Input Disrupted *(Manufacturing Inputs and Distributed Products)*	Main Action Taken to Mitigate Disruption
	1.								
	2.								
	3.								
	4.								
	5.								

Internal
External

-Under 2 weeks
-2-4 weeks
-1-2 months
-2-3 months
-3-4 months
-4-6 months
-Over 6 months

Identify the three products or product inputs that your organization anticipates having the most difficulty acquiring between 2023 and 2027.

D.		Product or Input	Reason of Difficulty *(select from drop-down or write-in)*	Explanation
	1.			
	2.			
	3.			
	4.			
	5.			

Comments:

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Products listed by respondent in Section 4

-Product/Input provided by respondent

-Cyber Security Incident
-Disease/ Quarantine
-Equipment Outage
-Financial Constraint
-Labor Disruption
-Quality Control Issue
-Regulatory/ Environmental
-Restrictions
-Other (write-in)

-Changes to Laws
-Delivery Delays/ Excessive Lead Times
-Dependence on Foreign Suppliers
-Distortionary Trade Practices
-Foreign Competition
-Geopolitical Instability
-Increased Cost
-Insufficient U.S. Manufacturing

-Customs or Ports Issue
-Cyber Security Incident
-Disease/Quarantine
-Geopolitical Instability
-Labor Disruption
-Natural Disaster
-Supplier Ended Production
-Supplier Production Delays

Disrupted input listed by respondent

-Designed-Out Input
-Developed Captive Capability
-Identified Another Supplier
-Stockpiling
-Substituted Input
-Waited Until Disruption Passed
-Other (write-in)
-Designed-Out Input

-Burdensome regulations
-Distance from raw material suppliers
-High CapEx investment costs
-High labor costs
-High material costs
-Lack of government investment
-Limited labor availability
-Not enough tax incentives
-Political instability
-Other (write-in)

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10. Customers

This section must be completed in its entirety, blank or "Not Applicable" responses will not be accepted.

1. For each product, identify the total number of direct customers your location typically has for that product.
2. Answer each question related to your location's Top Customer by volume for each product.
3. Indicate whether your location exports each product for any customer and provide the primary challenge your location faces with exporting that product. If other, write in comment box.

	Your Location's Products *(generated from Product Assortment responses)*	1. Total Customers: Total Number of Direct Customers Product is Sent to	2. Top Customer: Top Customer Name	Most Important Customer Criteria	Top Customer ZIP or Postal Code	Top Customer Country	Percentage of Annual Product Sales Attributable to Customer	Top Customer Use (if known)	Top Customer Product Description (if known)	3. Export Controls: Did your location export this product in 2022?	Primary Challenge Posed by Export Control Regime (If Subject to Export Controls)	ECCN (If Applicable)
A.								See Product list from Section 3		Yes No		
Comments:												

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Delivery Considerations
Financial Considerations
Number of Products/Services supported
Relationship Considerations
Technical Specifications
Other (write-in)

Application delays and Returned Without Action (RWA)
Burden of identifying end-users rather than third party intermediates
Controls on commercial use items, i.e. "specially designed" items
Difficult to obtain license exceptions
Excessive embargo restrictions
Frequent changes to requirements
License rejected during inter-agency review
Obsolete regulations
Uncertainty whether an item is controlled
Other (write-in)

Location
Corporate/Whole Organization

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11. Government Support

		Reporting Level	Location/Org Name (Auto-generated)
A.	Indicate the reporting level of the responses provided in this section. Location-based responses are preferred when possible. All responses in this section must be reported at the same level.		

Enter the number of government **(U.S. and non-U.S.)** agreements, awards, contracts, or grants received by your location for influenza vaccine-related products over the past **five years**. Estimates are acceptable if exact figures do not exist. If none, enter "0" in the adjacent cell and proceed to Part B.

B. Use the table to indicate your location's five largest U.S. Government government agreements, awards, contracts, or grants by dollar value in the past five years.

	Supporting U.S. Agency Name	Explain if "Other"	Support Type	Year Issued	Length of Support (Months)	Support Value ($)	Primary Product Provided
1.							
2.							
3.							
4.							
5.							

	Supporting Non-U.S. Agency Name	Country of Government Entity	Support Type	Year Issued	Length of Support (Months)	Support Value ($)	Primary Product Provided
1.							
2.							
3.							
4.							
5.							

Is your location dependent on selling to or funding from USG agencies or foreign governments for its continued viability? — Explain:

Has this location bid on a contract with the U.S. government in the past five years? If no, proceed to tab 12.

C.

1.	Indicate the number of priority rated orders (DO or DX) that your location received under the Defense Priorities and Allocations System (DPAS) regulation (15 CFR part 700) in the past five years. Definition: Priority Rated Orders		DO rated	DX rated
2.	If federal procurement contract lengths increased, would you be more likely to expand domestic manufacturing?	Yes /No	Explain:	
3.	Are there any contract clauses you would like to see added to future federal contracts?		Explain:	
4.	Are there any contract clauses you would like to see removed from future federal contracts?		Explain:	
5.	Do any of your federal procurement contracts include a guaranteed fair-price minimum requirement?		Explain:	
6.	Do you find the USG acquisition and contracts process challenging?		Explain:	
7.	Has your location ever had a USG contract proposal rejected?		What was the most common reason?	
8.	Has your location ever hired a third party federal acquisition expert to assist with contract proposals and/or negotiation?		What was the primary reason?	

Comments:

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2023
2022
2021
2020
2019
2018

Products previously listed by Respondent

Yes, USG Agencies
Yes, Foreign Governments
Yes, Both
No

Biomedical Advanced Research and Development Authority (BARDA)
Centers for Disease Control and Prevention (CDC)
Defense Advanced Research Projects Agency (DARPA)
Defense Health Agency
Defense Logistics Agency (DLA)
Defense Security Cooperation Agency (DCSA)
Defense Threat Reduction Agency (DTRA)
Department of Veterans Affairs
Federal Emergency Management Agency (FEMA)
Food and Drug Administration (FDA)
National Institutes of Health (NIH)
National Laboratories (DOE Labs)
Non-U.S. Government Entity
Office of the Assistant Secretary for Preparedness and Response (ASPR)
U.S. Air Force
U.S. Army
U.S. Coast Guard
U.S. Intelligence Community
U.S. Marine Corps
U.S. Navy
Other Agency (write-in)

Award
Contract - Cost-Plus
Contract - Firm-Fixed Price (FFP)
Contract - Indefinite-Quantity
Contract - Indefinite-Delivery
Contract - Labor-Hours
Contract - Requirements
Contract - Time and Materials
Cooperative Agreement
Grant
Other Transaction Agreement (OTA)
Other (write-in)

Does not align with agency mission
Financially infeasible
Lacks scientific detail
Low Technology Readiness Level
Other (write-in)

Because of limited capacity
Because of confusing regulations
To ensure federal compliance
Other (write-in)

12. Export Controls

A.	Indicate the reporting level of the responses provided in this section. Location-based responses are preferred when possible. All responses in this section must be reported at the same level.	Reporting Level: Location / Corporate/Whole Organization	Location/Org Name (Auto-generated)
B.	Has your location exported any influenza vaccine-related products in the previous 5 years? If no, proceed to the next tab.		Yes / No

C. Identify the influenza vaccine-related products that your location/organization exported in the past five years and the U.S. export control regime they are subject to if applicable.

Top Three Product Category Exported **by Revenue** in the Past Five Years (if applicable)	Product Category Exported 1	Product Category Exported 2	Product Category Exported 3
	Products generated Section 4		
Export Regime (Use Dropdown Menu)			

ITAR / EAR / Unknown / Both

Are your location's/organization's products subject to International Traffic in Arms Regulations (ITAR) or Export Administration Regulations (EAR)? If no, proceed to Part E. — Yes, EAR / Yes, ITAR / Yes, Both / No

Link: ***ITAR-Regulated Products*** Link: ***EAR-Regulated Products***

D. Identify the influenza vaccine-related products **most challenged by export controls** in in the past five years, including the primary challenge posed by the export control regime and the relevant Export Control Classification Number (ECCN), if applicable.

Definition of ***Influenza Vaccine-Related Products***

	Product Category Subject to Export Control	Export Regime	Primary Challenge Posed by Export Control Regime	Primary Mitigation Action	ECCN (ex: 9Y610)
1.	Products listed by respondent in Section 4	ITAR / EAR / Unknown / Both			
2.					
3.					
4.					
5.					

E. Answer the below questions regarding your location's/organization's export activities over **the past five years and the next five years.**

1.	Has your location/organization had any deemed exports in the past five years?	Yes / No	If yes, how many?	
2.	Indicate the country with the **greatest number of deemed exports** (including those with no license required) associated with your location/organziation between **2018-2022**.			
4.	Estimate the 2022 annual cost to abide by applicable export control regimes as a percentage of revenue.		Cost Estimate ($)/Revenue ($)	
4.	Estimate the 2027 annual cost to abide by applicable export control regimes as a percentage of revenue.			

Comments:	

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Application delays and Returned Without Action (RWA)
Burden of identifying end-users rather than third party intermediates
Controls on commercial use items, i.e. "specially designed" items
Difficult to obtain license exceptions
Excessive embargo restrictions
Frequent changes to requirements
License rejected during inter-agency review
Obsolete regulations
Uncertainty whether an item is controlled
Other (write-in)

Altered influenza vaccine product research and development expenditures
Conducted periodical audits of exports to ensure compliance with U.S. sanctions or export controls
Included contract obligation with intermediary or third-party sellers to ensure compliance with U.S. export controls
Established a compliance program to monitor exports
Changed scope of influenza vaccine product projects
Avoided the export of influenza vaccine products or services that are subject to EAR and/or ITAR-related controls
Abandoned or altered the composition of influenza vaccine product business lines
Outsourced influenza vaccine product production/R&D operations
Other, Write In

1A607 - Medical countermeasures equipment for use against chemical warfare agents
1C350 - Chemicals that may be used as precursors for toxic chemical agents
1C351 - Human and animal pathogens and "toxins"
1C353 - Genetic elements and genetically-modified organism
1C354 - Plant pathogens
1C395 - Mixtures and medical, analytical, diagnostic, and food testing kits
1C991 - Vaccines, immunotoxins, medical products, diagnostic and food testing kits
1E351 - Microbiological disposal technology
2B352 - Equipment capable of use in handling biological materials
Other (write-in)

Contract research organization
Non-profit research institute
Other private company
Other public company
University

Currently Use
In Development
Do Not Use
Plan to Use
Previously Used, but no Longer

Internal
External
Both

Location
Corporate/Whole Organization

Forecasting
Cyber Protection
Data Integrity
Error Detection
Lowered Cost
Process Efficiency
Other (write-in)

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13. Technology

A. Indicate the reporting level of the responses provided in this section. Location-based responses are preferred when possible. All responses in this section must be reported at the same level.

Reporting Source	Location/Org Name (Auto-generated)

B. Using the dropdown menu, select the types of emerging technology that your location uses or plans to use in the development, manufacturing, or distribution of influenza vaccine-related products.
Note: If used, indicate if you are sourcing the technology internally or externally, as well as the technology's application and benefit to the production of influenza vaccine-related products.

	Types of Technology	Use	Source of Technology	Primary Product Application	Primary Application Area	Greatest Challenge/Barrier to Implementation	Primary Benefit
1.							
2.							
3.							
4.							
5.							

Product list from Section 3

C. Answer the following questions related to the transfer of your location's influenza vaccine-related intellectual property.

Has your organization knowingly transferred intellectual property to another entity and/or been subject to an illicit technology transfer involving influenza vaccine-related intellectual property in the last five years? If no, proceed to section D. Yes / No

If yes, identify the five most recent recipients, the country of receipt, the primary method of transfer, and the type of IP.

	Recipient Entity Name	Country	Primary Method of Transfer	Type of IP	Explain
1.					
2.					
3.					
4.					
5.					

Forced Transfer
Information provided to potential investors
Joint ventures
Licensing IP
Non-Disclosure Agreements (NDAs)
Participation in scientific/ technical conferences
Research collaborations
Theft of IP
Other (write-in)

Design
Manufacture
Both

D. Indicate the number of U.S. and non-U.S. external entities with whom this location currently partners for any research and/or development efforts related to influenza vaccine-related products. Then, list your location's most important external research and/or development partners.

U.S.	Non-U.S.

	Partner Name	Partner Country	Partner Entity Type	Primary Product	Primary Benefit
1.					
2.					
3.					
4.					
5.					

Product list from Section 3

Access to new markets
Access to talent
Access to intellectual property
Decreased time to market
Innovative technology
Profit sharing
Risk sharing
Tax incentive
Other (write-in)

E. Does your location procure semiconductor **products or components to produce** its influenza vaccine-related products? If no, select "No" and proceed to the next tab. Yes / No

If yes, select each category of semiconductor products or components your location procures, identify recent and expected disruptions, associated products most likely to be impacted by a disruption, and expected changes in technology node (nm = nanometer) procurement from 2023 to 2027.

	Semiconductor Product Category	Disruption Experienced/Expected		Primary Product Impacted by Disruption/Potential Disruption (Generated from Section 2)	Anticipated Change in Procurement by Technology Node Range, **2023-2027**					
		2019-2022	2023-2027		<=10nm	12-26nm	28-55nm	65-130nm	150-500nm	>500nm
1.										
2.										
3.										
4.										
5.										

Product list from Section 3

Comments:

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More than 26 weeks
8-26 weeks
Less than 8 weeks
None

Advanced Manufacturing
Advanced Materials
Artificial Intelligence
Biomanufacturing and Bioprocessing
Bioprinting
Blockchain
Cloud Computing
Encryption Technologies
Genome and Protein Engineering
In Silico Testing
Internet of Things (IoT)
Quantum Computing
Robotics
Other (write-in)

Very Likely
Moderately Likely
Unlikely

Significant Increase (>50%)
Moderate Increase (10-50%)
Minimal Change (+/- 10%)
Moderate Decrease (10-50%)
Significant Decrease (>50%)

Basic Research
Clinical Research and Trials
Communication
Cybersecurity
Early Discovery
Manufacturing
Market Launch
New Product Development
Pre-Clinical Research and Trials
Process Efficiency
Product Design
Quality Control
Supply Chain Management

Analog Integrated Circuits (ICs)
Microcontroller and Microprocessor ICs
Logic ICs
Memory ICs
Application-Specific Integrated Circuits (ASICs)
Discretes
Optoelectronics
Sensors & Actuators

Asymmetric research constraints
Data privacy requirements
Inadequate IT infrastructure
Incompatible equipment
Lack of public trust
Lack of qualified talent
Lack of R&D investment
Licensing and permits
Product development costs
Product purchase costs
Regulatory approval process
Standards and regulations
Unfamiliarity with technology

Ability to deliver goods/services
Ability to receive necessary supplies/inputs
Health/safety and readiness of workforce
Property/facilities/equipment
Production capabilities

Immediate
Under 2 weeks
2 to 4 weeks
5 to 10 weeks
11 to 20 weeks
20 weeks
Not Possible

Location
Corporate/whole Organization

Lack of innovative solutions
Lack of organizational strategy
Pollution taxes
Solid waste disposal fees
Technical capabilities
Wastewater discharge fees
Water user fees
Other (specify here)

BSL-1
BSL-2
BSL-3
BSL-4

Yes
No
Will Apply in Future
Do Not Intend to Apply

Increase
Decrease
Stay Neutral

Electrical Safety Components
Emergency Planning
Fire Protection
General Environment Controls
General Machine Requirements
Hazardous Materials Handling
Hazardous Materials Disposal
Medical Services/First Aid
Personal Protective Equipment
Record keeping
Training
Other (specify here)

Capped allowance systems (cap-and-trade)
Emission reduction credits (ERC)
Energy use credits
Government grant programs
Government loan programs
Improved standards or policies
Investment tax credits
Tax subsidies
Other (specify here)

Directly
Indirectly
No Impact

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14. Health & Safety Practices

A. Indicate the reporting level of the responses provided in this section. Location-based responses are preferred when possible. All responses in this section must be reported at the same level.

Reporting Level	Location/Org Name (Auto-generated)

B. Indicate your location's emergency response capabilities.

1. How often is your location's business continuity plan updated? If your location does not have a plan, select "No Plan".
2. Does your business continuity plan include informing customers of any resulting disruptions/delays?
3. In the event of a large-scale emergency, what is the estimated average response time for your location to recover the following work inputs to normal levels?

	Work Input	Average Response Time	Primary Work Input Disrupted	Explain:
a.			See Input list from Section 6	Explain:
b.				Explain:
c.				Explain:

C. Answer the following questions about your location's health and safety policies.

1. Select each method your location employs to execute its hazards communication program.
   - Labels:
   - Training:
   - Material Data Sheets (MSDS):
   - Other: (Specify Here)

   Yes / No
2. Does this location include at least one laboratory in which biological agents are handled? Yes / No
   If yes, what is the highest Biosafety Lab Level applicable to your location's lab(s)? *Link: Biosafety Levels*
3. Estimate the annual cost for your location to comply with Occupational Safety and Health Administration (OSHA) regulations. *Link: OSHA*
   Identify the primary contributor to your location's annual cost of compliance with OSHA regulations.
4. Does this location use and/or store hazardous chemicals or materials on site?
   If so, is your location compliant with the Emergency Planning and Community Right-to-Know Act reporting requirements? *Link: EPCRA*

   Yes / No / Not Applicable
5. Does this location generate hazardous waste? Yes / No
   If yes, does this location have a hazardous waste storage location permit?

D. Answer the following questions regarding your location's energy and environmental policies.

1. Is your location ISO 50001 certified?
2. Does your location expect its energy consumption to increase, decrease, or stay neutral over the next five years? — Explain:
3. Does your location consider environmental impact assessments when choosing suppliers? Yes / No — Explain:
4. What are the top two challenges that your location faces in prioritizing environmentally sustainable policies?
   - Primary Challenge:
   - Secondary Challenge:
5. Which government incentive, if any, would most influence your location to prioritize environmental policies?
6. Does the adoption of environmentally-focused policies impact your location's ability to continue to produce influenza vaccine-related products?
   Explain:

Comments:

Location
Corporate/Whole Organization

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15. Employment

A. Indicate the reporting level of the responses provided in this section. Location-based responses are preferred when possible. All responses in this section must be reported at the same level.

Reporting Level	Location/Org Name (Auto-generated)

B. Record the total number of full-time equivalent (FTE) employees employed at this location for each year since 2019, including employees and contractors who work off-site but report to this location.

FTE Employees	2019	2020	2021	2022	2023 (Estimate)	Average Annual Turnover Rate
1. U.S. Citizen						
2. Non-U.S. Citizen						
2.1 China *(select primary visa type)*						
2.2 India *(select primary visa type)*						
2.3 Iran *(select primary visa type)*						
2.4 Pakistan *(select primary visa type)*						
2.5 Russia *(select primary visa type)*						

H1-B
F-1
L-1A
L-1B
O-1A
Other (write-in)

C. In descending order, identify your location's five most critical occupations necessary for the production of influenza vaccine-related products using the dropdown menu. Then, for each occupation category, identify your location's current number of FTE employees and contractors in 2022, the number of current vacancies, the top workforce issue, degree of difficulty in hiring qualified workers, job title most impacted, and primary method of recruitment.

	Occupation	Current Number of FTEs	Current Number of Vacancies	Top Hiring Challenge	Top Retainment Challenge	Degree of Difficulty in Hiring	Explain
1.							
2.							
3.							
4.							
5.							

Minor
Moderate
Great
Extreme
No Difficulty

Attracting workers to location
Employee turnover
Finding experienced workers
Finding qualified workers
Significant portion of workforce retiring
Unions/Collective bargaining
Workers unable/not allowed to access location
Other (write-in)

Comments:

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Costs from Response/ Recovery
Damage to Location Capabilities
Damage to IT Infrastructure
Exfiltration of Sensitive Data
Network Downtime
Loss of Sales/Business Interruption
Reputation Damage
Theft of Software and/or Source Code
Other (write-in)

Location
Corporate/Whole Organization

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16. Cybersecurity

reporting level of the responses provided in this section. Location-based responses are preferred when responses in this section must be reported at the same level.

Reporting Level	Location/Org Name (Auto-generated)

ch of the following security measures are in place at your location or organization.

B.

Account Monitoring and Control		Inventory of Authorized/Unauthorized Software	
Application Software Security		Limitation/Control of Network Ports and Services	
Boundary Defense		Maintenance, Monitoring, & Analysis of Audit Logs	
Continuous Vulnerability Assessment		Malware Defenses	
Controlled Access Based on Need to Know		Penetration Tests and Red Team Exercises	
Controlled Use of Administrative Privileges		Secure Configurations on Hardware	
Data Encryption - In Storage (at rest)		Secure Configurations of Network Devices	
Data Encryption - In Transit (internally or externally)		Secure Network Engineering	
Data Recovery Capability		Security Skills Assessments and Training	
Incident Response and Management		Wireless Access Control	
Inventory of Authorized/Unauthorized Devices		Other (Write-in)	

Yes
No
Not Applicable

C. Identify the five most significant impacts that this location or organization experienced as a result of malicious cyber activity in the past year.

	Significant Impacts from Malicious Cyber Activity	Reason for Significance	Length of Longest Impact	Typical Method of Attack	Typical Response	Most Impacted Product
1.						
2.						
3.						
4.						
5.						

Brute Force
Code/SQL Injection
Denial of Service (DoS/DDos)
Malware
Man in the Middle
Phishing
Ransomware
Supply Chain Attack
Zero-Day Exploit

Changed software/hardware vendors
Enhanced user training or policies
Exit from foreign markets or market segments
Incident ongoing/not resolved
Increased procurement standards
Legal action against responsible party
Major new investment in cyber security
Met attacker demands/Paid ransom
No response

List generated based on prior product declarations

0-3 days
3-7 days
1-2 weeks
2-4 weeks
1-6 months
7-12 months
Over a year

D. Answer the following questions using the dropdown menus, providing an explanation when applicable. Note: all responses must be reported at the same level.

1.	Does your location store any genetic data?	Yes / No	If yes, does your location have a genomic data sharing policy?		Yes / No
2.	In the event of a breach, does your cyber incident response protocol require notifying impacted parties and/or customers?				
3.	Does this location evaluate the cyber security practices of vendors before making a decision to buy from or subcontract to them?				
4.	Does this location impose requirements on the cyber security practices of vendors when buying from or subcontracting to them?				
5.	In the event that your location lost access to a significant portion of its data, how long do you estimate it would take to restore full functionality from system backups?				
6.	Does your location restrict or prohibit external data/cloud storage provider(s) from storing sensitive information outside of the U.S.?				
7.	How can the USG protect industry from malicious cyber activity?				
8.	Does your location depend on third-party software to produce influenza vaccine-related products?				
	If yes, does your location rely on software suppliers domiciled in the following countries? (Select all that apply)	China	Yes / No	Iran	Russia
		India		Pakistan	

Only Impacted Customers
All Customers
No
Not Applicable
No Plan

Immediate
1 to 7 Days
8 to 30 Days
Over 30 Days
No Backups Exist

Yes
No

E. Indicate if your location or organization has adopted, partially adopted, or plans to adopt the following cybersecurity standards and frameworks. Select the hyperlinked text to view additional information on each standard. Note: all responses must be reported at the same level.

NIST Cybersecurity Framework		
NIST Risk Management Framework		
ISO/IEC 27001:2022 - Information Security Management Systems		
ISO/IEC 27701:2019 - Privacy Information Management		
Other Cybersecurity Standard	(Specify Here)	

Comments:

The U.S. Government encourages the reporting of suspected or confirmed cybersecurity incidents to the Federal Bureau of Investigation (FBI) or the Cyber Security and Infrastructure Security Agency (CISA). Local FBI field offices can be identified at https://www.fbi.gov/contact-us/field-offices; the FBI's 24/7 Cyber Watch (CyWatch) can be contacted by phone at 855-292-3937, or by email at CyWatch@fbi.gov; and cybersecurity incidents and vulnerabilities can be reported to CISA at https://www.us-cert.gov/report. No-cost technical assistance can be requested from CISA, using the same website address.

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Improve information sharing of cyber threats
Invest in cyber workforce
Mandatory cyber incident reporting
S-BOM or H-BOM requirements
Strengthen industry cybersecurity system requirements
Subsidize cybersecurity infrastructure
Other (write-in)
None

Severity of Impact
Frequency of Occurrence
Significance of Impacted Assets
High Cost
Other (Specify Here)

Adopted / Certified
Partially Adopted
Plans to Adopt
Do Not Plan to Adopt
Not Applicable

Always
Sometimes
Never
Not applicable

Location
Corporate/Whole
Organization

Calendar Year
Fiscal Year

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17. Financials

A.	Indicate the reporting level and reporting schedule and then record the financial line items in parts B through D for 2019-2022.				
	Reporting Level:				
	Location/Organization Name (Auto-generated):				
	Reporting Schedule:				
B.	**Income Statement**				
		2019	2020	2021	2022
	Net Sales (and other revenue)				
	Influenza Vaccine-Related Product Sales Percentage				
	Cost of Sales / Cost of Goods Sold				
	Total Operating Income				
	Earnings Before Interest and Taxes (EBIT)				
	Net Income				
C.	**Balance Sheet**				
		2019	2020	2021	2022
	Cash and Cash Equivalents				
	Inventories				
	Current Assets				
	Total Assets				
	Current Liabilities				
	Total Liabilities				
	Total Owner's Equity				
D.	**Other**				
		2019	2020	2021	2022
	Research & Development (R&D) Expenditure				
	Capital Expenditures				
E.	On a scale of 1 to 10, estimate your organization's overall financial health (1 being imminent failure and 10 being highly profitable for the foreseeable future).				

Comment:	

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Data Confirmation
2022 Net Sales
None

Location
Corporate/Whole Organization

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18. Challenges

A.	Indicate the reporting level of the responses provided in this section. Location-based responses are preferred when possible. All responses in this section must be reported at the same level.	Reporting Level	Location/Org Name (Auto-generated)

Identify the issues that have impacted your location/organization from 2018 to 2022, and the issues that you anticipate will impact your location/organization between 2023 and 2027. Next, rank your location's/organization's top five issues for both time frames (1 being the most important issue; 2 being the next most important issue, etc.).

Explain the affirmative issues where examples and narrative will aid the U.S. Government's understanding of your concerns and provide any suggestions for ways the U.S. Government (USG) can help mitigate these issues. Note, explanations and suggested solutions are helpful but not required.

B.

Type of Issue	2018 to 2022		2023 to 2027		Explanation of Issue	Suggested USG Solution/Mitigation
	-Yes/No-	Rank	-Yes/No-	Rank		
Aging equipment, facilities, or infrastructure						
Aging workforce						
Competition - domestic						
Competition - foreign						
Counterfeit parts						
Cybersecurity						
Environmental regulations/remediation						
Export controls - EAR/ITAR						
Financing/credit availability						
Government acquisition process						
Government purchasing volatility						
Government regulatory burden						
Healthcare costs						
Industrial espionage - domestic						
Industrial espionage - foreign						
Input availability (e.g., materials)						
Input quality						
Intellectual property/patent infringement						
Labor availability/costs						
Lack of infrastructure						
Lack of public R&D partnerships (e.g., universities)						
Natural disasters (including disease/quarantine)						
Obsolescence						
Pension costs						
Proximity to customers						
Proximity to suppliers						
Qualifications/certifications						
R&D costs						
Reduction in USG demand						
Taxes						
Trade disputes						
Worker/skills retention						
Other (specify here)						
Other (specify here)						

C. Indicate whether your location/organization has been impacted by the war in Ukraine that began in Februrary 2022. Next, indicate the degree of impact, the influenza vaccine-related product most affected, and provide a brief explanation.

	-Yes/No-	Degree of Impact	Primary Product Impacted	Explanation of Issue
Has the war in Ukraine impacted your location/ organization's ability to produce or distribute influenza vaccine-related products?			Products listed in Section 4	

Comments	

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1 - Severe Impact
2 - Significant Impact
3 - Moderate Impact
4 - Slight Impact
5 - Little to No Impact

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19. Certification

The undersigned certifies that the information herein supplied in response to this questionnaire is complete and correct to the best of his/her knowledge. It is a criminal offense to willfully make a false statement or representation to any department or agency of the United States Government as to any matter within its jurisdiction (18 U.S.C. 1001).

Once this survey is complete, first save it to your computer, and then submit the document via the Census Bureau portal linked here:

REPLACE WITH LINK	
Location Name	
Organization Name	
Organization's Internet Address	
Name of Authorizing Official	
Title of Authorizing Official	
E-mail Address of Authorizing Official	
Phone Number and Extension of Authorizing Official	
Date Certified	

In the box, provide any additional comments or any other information you wish to include regarding this survey assessment.

How many hours did it take to complete this survey?	

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