PDA Research

PDA Coronavirus Pandemic Industry Survey Results

April/May 2020



PDA Survey PDA Coronavirus Pandemic Industry Survey Results

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PDA Coronavirus Pandemic Industry Survey Results — PDA Task Force Members

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Introduction

PDA conducts informal surveys to assess and provide information on the state of the industries we serve. We explore such topics as the current challenges in regulatory science, quality, analytical testing and manufacturing. In April of 2020, PDA conducted a general nonscientific industry survey as part of its efforts to better understand the challenges being faced by the industry due to the Coronavirus pandemic. This was a blinded survey open to all PDA members as well as nonmembers. As such, it is possible that more than one individual from a given company responded. The intent of the study, and its design, were intended to collect general information on the topic. The survey was open for responses from April 6 through April 23, and 620 responses were received. We want to thank those industry members who took the time to complete the survey.

There is no way to ascertain the level of knowledge of the respondents regarding their organization's actual status. As such, this was a voluntary, non-scientific survey, and the results should be interpreted accordlingly. It is useful to see the trend of the perspectives of the respondents.

As the survey covered a number of different topic areas, not all respondents were expected to answer every question. Respondents who only answered the initial demographical questions and no others were excluded from the analysis; based on this exclusion, a total of 487 responses were included.

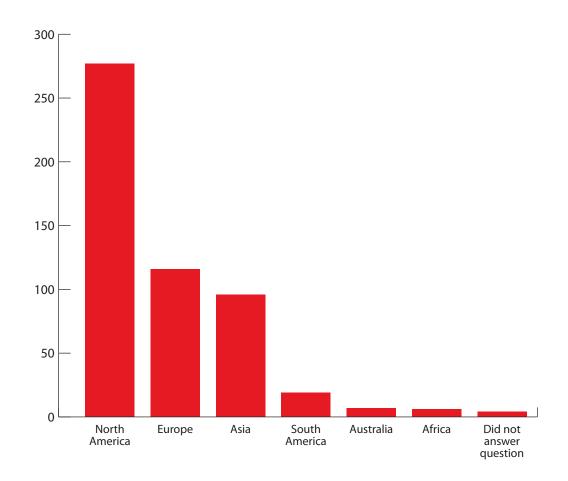
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Survey Results

Survey results from the 11 questions asked are provided below. The respondent values (%) presented are based on the 487 respondents.

1. Where are you located?

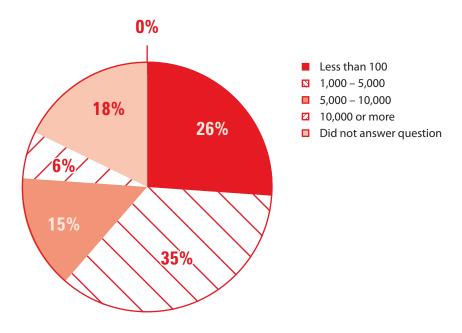
Answer	Count	%
North America	277	57%
Europe	116	24%
Asia	96	20%
South America	19	4%
Australia	7	1%
Africa	6	1%
Did not answer question	4	1%



2. What is the size of your company (number of employees)?

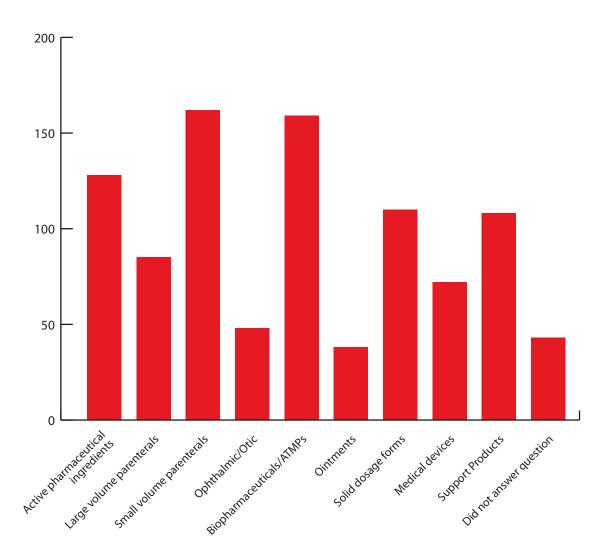
*single answer question

Answer	Count	%
Less than 100	128	26%
100 – 1,000	171	35%
1,000 – 5,000	72	15%
5,000 – 10,000	30	6%
10,000 or more	86	18%
Did not answer question	0	0%



3. What types of products do you manufacture?

Answer	Count	%
Active pharmaceutical ingredients	128	26%
Large volume parenterals	85	17%
Small volume parenterals	162	33%
Ophthalmic/Otic	48	10%
Biopharmaceuticals/ATMPs	159	33%
Ointments	38	8%
Solid dosage forms	110	23%
Medical devices	72	15%
Support products (media, filters, cleaning materials, primary packaging, etc.)	108	22%
Did not answer question	43	9%



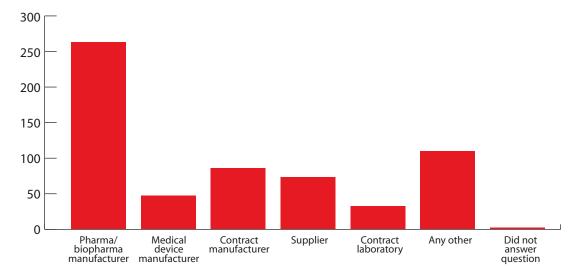
4. What is the type of organization?

Answer	Count	%
Pharma/biopharma manufacturer	263	54%
Medical device manufacturer	48	10%
Contract manufacturer	86	18%
Supplier	74	15%
Contract test laboratory	33	7%
Any other, please specify *	110	23%
Did not answer question	3	1%

- * Other:
- Consult/Consulting (x39)
- Blank (x5)
- Contract Research Organization (x4)
- · Virtual Organization (x4)
- Engineering Consulting (x2)
- Hospital Pharmacy (x2)
- Machine Manufacturer (x2)
- NPO (x2)
- · A Validation (x2)
- &E EPCM CQV
- A/E, CQV Consultants
- Animal Health
- Bioinformatic Solutions
- Biotech Startup
- Biotechnological Manufacturer
- Calibration Services
- Cleaners and DisinfectantsCold Chain Packaging Mfg.
- Combination Product
- Compounding Pharmacy
- Consultant for Package Engineering

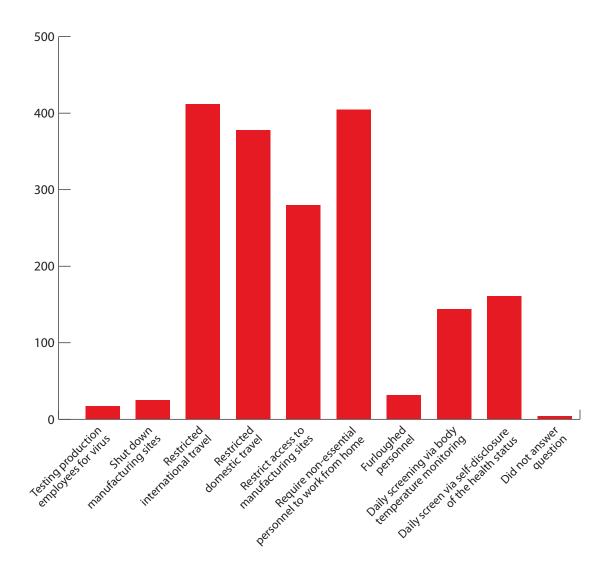
- Consulting Biopharma/ Engineering
- Consumer Goods
- Contamination Control Equipment
- Contamination Control Technology Consultant
- Contract Researcher
- Contract Services
- Contract Support for CMC, QA, Clinical Ops, etc.
- Custom Automated Manufacturing Machinery
- Distribution Excipient
- Distributor
- Engineering
- Equipment Manufacturers for Medical Devices
- Gene Therapy INDs
- Government
- HVAC Validation Provider
- IT Support
- NGO

- NRA
- Other
- Packaging Producer, Secondary Packaging
- Pharma Consultant Pharma/ Biopharma Sponsor
- Pharmaceutical
- Pharmacy
- Primary Packaging
- Process Equipment Manufacturer
- Procurement
- Professional Services Publisher
- QA and CMC Consulting
- Quality and Technical Consulting
- Radiopharma
- Research
- Research and Development
- Service Provider Sterilization
- Transportation and Warehousing
- University
- Clinical Phase II



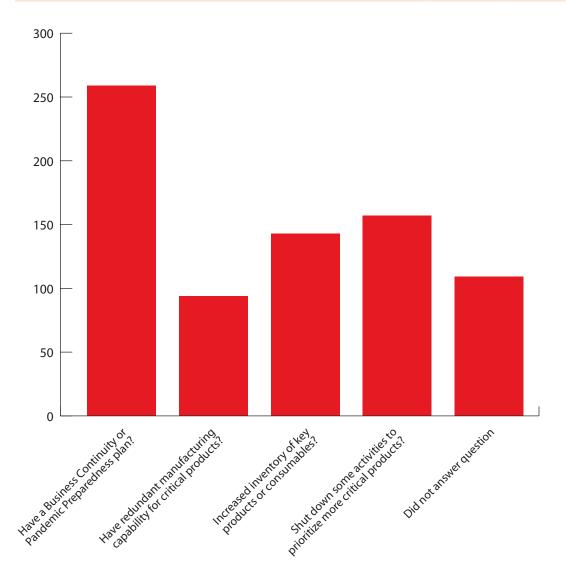
5. What steps have you taken regarding workforce, in response to the pandemic?

Answer	Count	%
Testing production employees for Novel Coronavirus	17	3%
Shut down manufacturing sites	25	5%
Restricted international travel	412	85%
Restricted domestic travel	378	78%
Restrict access to manufacturing sites	280	57%
Require non-essential personnel to work from home	405	83%
Furloughed personnel	32	7%
Daily screening via body temperature monitoring of Personnel entering site	144	30%
Daily screen via self-disclosure of the health status of Personnel entering site	161	33%
Did not answer question	4	1%



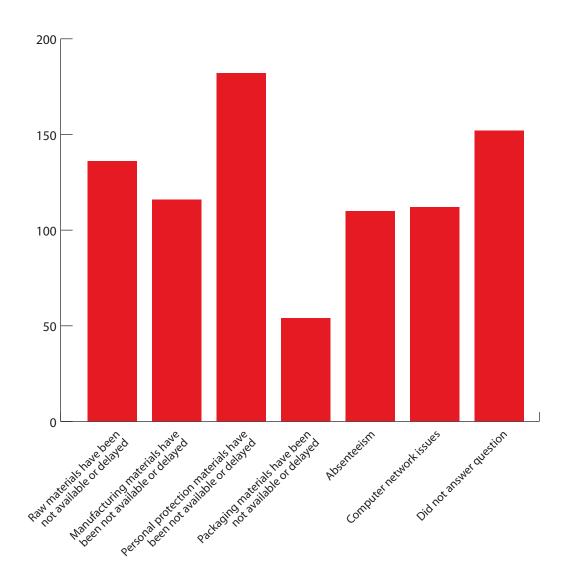
6. Regarding manufacturing, do you:

Answer	Count	%
Have a Business Continuity or Pandemic Preparedness plan?	259	53%
Have redundant manufacturing capability for critical products?	94	19%
Increased inventory of key products or consumables?	143	29%
Shut down some activities to prioritize more critical products?	157	32%
Did not answer question	109	22%



7. Have you experienced any shortages that impact manufacturing? *mark all answers that apply to question

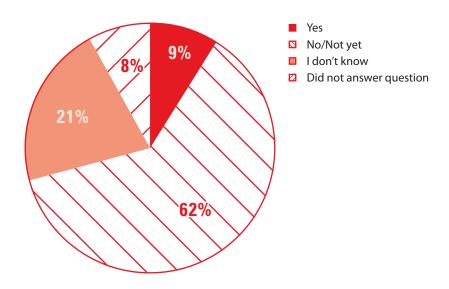
Answer	Count	%
Raw materials have been not available or delayed	136	28%
Manufacturing materials have been not available or delayed	116	24%
Personal protection materials have been not available or delayed	182	37%
Packaging materials have been not available or delayed	54	11%
Absenteeism	110	23%
Computer network issues	112	23%
Did not answer question	152	31%



8. Have you had any direct employees who have tested positive for the novel coronavirus?

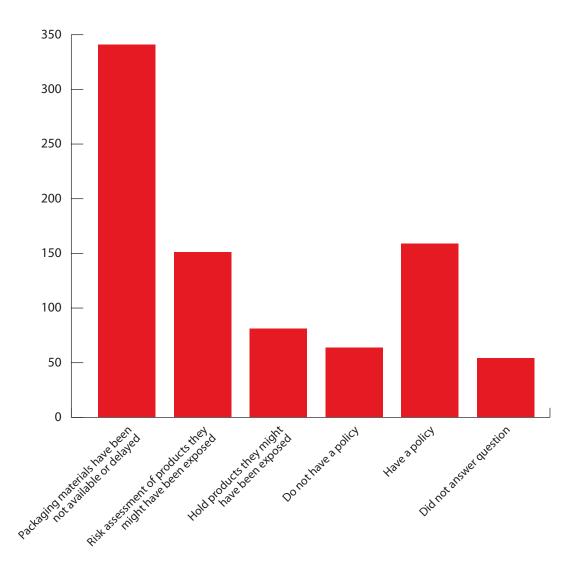
*single answer question

Answer	Count	%
Yes	45	9%
No/Not yet	302	62%
I don't know	103	21%
Did not answer question	37	8%



9. What is your policy regarding your workforce if they are confirmed to have the novel coronavirus?

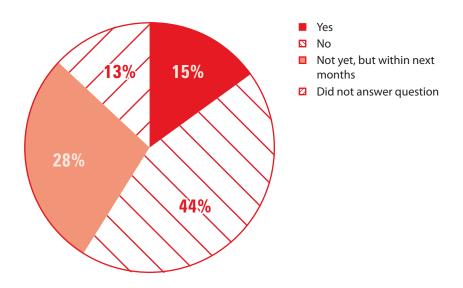
Answer	Count	%
They are excluded from the workforce and work from home if possible	341	70%
Risk assessment of products they might have been exposed	151	31%
Hold products they might have been exposed	81	17%
Do not have a policy	64	13%
Have a policy	159	33%
Did not answer question	54	12%



10. Do you anticipate any shortages of products you manufacture due to the novel coronavirus pandemic?

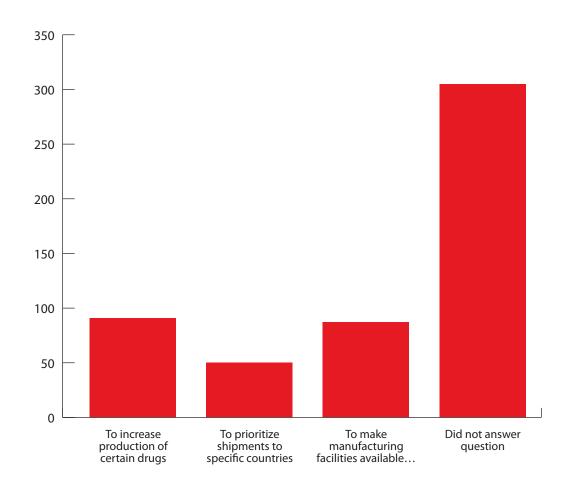
*single answer question

Answer	Count	%
Yes	72	15%
No	216	44%
Not yet, but within next months	134	28%
Did not answer question	65	13%



11. Health authority request:

Answer	Count	%
To increase production of certain drugs	91	19%
To prioritize shipments to specific countries	50	10%
To make manufacturing facilities available for production of new or products currently not approved at a facility	87	18%
Did not answer question	305	63%



Discussion

From the survey data, the respondents represented a wide cross section of the industry (location, company size and type of products manufactured). The data provided insight into the challenges being faced due to the pandemic. Several points are highlighted below from the review of the results.

At the time of the survey steps were already being taking to perform daily monitoring of employees for the illness.

From the survey data (question #5), 47% indicated that their company was performing daily monitoring of employees.

(This was a "mark all that apply" question. The overall percentage was determined by considering the number of respondents marking any of the three choices — "Testing production employees for Novel Coronavirus", "Daily screening via body temperature monitoring of personnel entering site", and/or "Daily screen via self-disclosure of the health status of personnel entering site" (a respondent marking multiple of these choices was counted only once) — over the total number of respondents to the survey.)

Work was already ongoing to increase inventory levels or key products and consumables.

From the survey data (question #6), 29% of respondents indicated that their company had increased the inventory of key products and consumables.

(This was a "mark all that apply" question. The percentage for each answer was determined by considering the number of respondents selecting the specific choices over the total number of respondents to the survey.)

Prioritization of operations were occurring to support more critical products.

From the survey data (question #6), approximately 32% (almost one-third) of total respondents indicated that their company shut down some activities to prioritize more critical products.

(This was a "mark all that apply" question. The percentage for each answer was determined by considering the number of respondents selecting the specific choices over the total number of respondents to the survey.)

The supply chain for materials needed for manufacturing operations was becoming more constrained.

From the survey data (question #7), a significant number of total respondents indicated that Raw Materials, Manufacturing Materials and Personal Protective Equipment have not been available or have been delayed (28% Raw material, 24% Manufacturing materials, 37% Personal protective equipment, Packaging materials, 11%).

(This was a "mark all that apply" question. The percentage for each answer was determined by considering the number of respondents selecting the specific choices over the total number of respondents to the survey.)

Respondents indicated that drug product supply has and will continue to be impacted in the future.

From the survey data (question #10), 15% of respondents indicated they were expecting to have a product drug shortage due to the Novel Coronavirus, while 28% of respondents indicated they were expecting to experience a drug shortage situation in the next few months.

(This was a "mark only one" question. The percentage for each answer was determined by considering the number of respondents selecting the specific choice over the total number of respondents to the survey.)

Respondents indicated that health authorities are reaching out to partner with industry to ensure product supply.

From the survey data (question #11), 37% of respondents overall indicated that Health Authorities have been reaching out to them requesting increased production (19% of respondents), prioritized shipments (10% respondents), and/or making manufacturing facilities available for new products or products not approved at the facility (18% respondents).

(This was a "mark all that apply" question. The overall percentage of 37% was determined by considering the number of respondents marking any of the three choices (a respondent marking multiple choices was counted only once) over the total number of respondents to the survey. The percentages for each answer was determined by considering the number of respondents selecting the specific choices over the total number of respondents to the survey.)

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About PDA Surveys

PDA conducts benchmarking surveys to assess the state of the industries we serve. We explore such topics as the current challenges in regulatory science, quality, analytical and manufacturing site operations, and processes of pharmaceuticals and biotechnology products. These surveys are research tools used to gain information, usually from a targeted audience within PDA's areas of interest. The results, which are published or presented at meetings, represent the perspective of PDA survey respondents. Findings are used to focus PDA support activities or to contribute to the development of technical documents, courses, and meetings, fulfilling the professional needs and bringing additional value to PDA members.

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