

BIOPHARMA

TRENDS



2019–2020

TRENDS IN BIOPHARMA MANUFACTURING SURVEY REPORT

Sponsored by NIBRT and The Medicine Maker (Texere Publishing)
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EXECUTIVE SUMMARY

This report summarizes the results of an online survey conducted by the National Institute for Bioprocessing Research and Training (NIBRT) and The Medicine Maker (a Texere Publication) to learn more about current manufacturing practices and trends in the biopharma industry. The survey was fielded from 18 December 2019 to 3 February 2020. During the time that this survey was open, 104 qualified surveys were collected which served as the basis for this report.

DEMOGRAPHICS

Forty-six percent (46%) of the survey respondents were located in Europe; 35% were in North America; and 17% were in Asia, Australia, Pacific Rim. The remaining 2% were located in South America.

Sixty-one percent (61%) of the respondents worked for biopharma manufacturers and 13% worked for contract service providers. Nine percent (9%) were affiliated with academic institutions, and 4% worked for suppliers/vendors. Thirteen percent (13%) selected “Other,” with fill-in responses including various consultants, industrial manufacturers, and training organization.

Just over one-half (52%) of the industry survey respondents worked in large companies, 28% worked in small companies or start-ups, and 17% worked in medium-size companies.

The most common focus for respondents’ organizations was monoclonal antibodies (mAbs) (59%), followed cell therapies (37%). Gene therapies (26%), antibody-drug conjugates (24%) vaccines (24%) and Non-mAb recombinant proteins (22%) were cited less often. RNA-based therapies were a focus for 17% of these organizations.

Nearly two thirds (65%) of the survey respondents had 10 or more years of work experience. Twenty-two percent (22%) had 3 to 9 years of work experience, and 11% had 1 to 2 years of work experience. The remaining 2% of the respondents were still students.

KEY FINDINGS

THE PRODUCT PIPELINE

Respondents believe that the most commercially important biopharma therapeutic product currently available is mAbs (64%), closely followed by vaccines (60%). The remaining products were cited less often: antibody drug conjugates (33%), gene therapies (27%), cell therapies (22%), non-mAb recombinant proteins (21%), and RNA-based therapies (9%).

Regarding the biopharma therapeutic products that were likely to be the most important in the next 5 to 10 years, survey respondents most often cited gene therapies (61%), mAbs (54%), and cell therapies (46%). Vaccines (36%), RNA-based therapies (30%), Antibody drug conjugates (25%), and non-mAb recombinant proteins (12%) were cited less often.

Gene therapies, cell therapies, and RNA-based therapies are all expected to be more important in 5 to 10 years than they are today. mAbs and antibody drug conjugates will be less important in the next 5 to 10 years. Vaccines will be a lot less important in 5 to 10 years.

The issues that respondents felt were the most challenging with regard to bringing new biopharma therapies to market were the scientific complexities in discovering effective therapies for unmet medical needs (75%) and the duration and cost of the drug discovery process (75%). Cost-effective manufacturing and supply chain methods (65%), pricing models for new products (52%) and gaining regulatory approval (48%) were considered less challenging.

Survey respondents felt that the main barriers to more widespread adoption of cell and gene therapies were the scientific complexity/immature nature of the field (67%), inefficient manufacturing processes/lack of turnkey solutions (63%), regulatory uncertainty (54%), and issues with pricing and reimbursement (48%). Supply chain/logistical challenges (38%) and a lack of infrastructure (35%) were cited less often.

Sixty-one percent (61%) of respondents cited cell and gene therapies as the most exciting therapeutic innovation of recent times (CAR-T cell therapy and CRISPR-Cas9 were mentioned specifically).

MANUFACTURING

Survey respondents felt that the highest priority areas of biopharma manufacturing for further innovation were bioanalytical capabilities (60%, high rating) and cell line development and optimization (56%), and aseptic manufacturing and fill-finish technologies (54%). Downstream (50%), upstream processing (40%), and supply chain logistics (19%) were cited less often.

Data analytics and digitalization (63%, high rating), automation of manufacturing processes (58%), continuous manufacturing (48%), and Industry 4.0 technologies (46%) were expected to have the greatest impact on biopharma manufacturing in the next five years. New expression platforms (31%) and single-use technologies (29%) were expected to have less impact.

The technologies that were considered to be the most relevant with regard to successful implementation of Industry 4.0 were data analytics/cloud computing (63%, major relevance),

KEY FINDINGS

smart sensors (56%), and artificial intelligence applications (43%). Computer simulation/modeling (52%), cybersecurity (52%), robotics, co-robotics/intelligent automation (50%) and machine learning (38%) were cited less often. Additive manufacturing (29%) and augmented/virtual reality (21%) were cited least often.

The biggest challenges cited with regard to biopharma manufacturing were product characterization (58%, major challenge), product yield optimization (54%), and process reproducibility (52%). Process robustness (42%) was considered to be somewhat less challenging. Aggregation issues (33%) and supply chain management (23%) were considered to be the least challenging issues.

STAFF DEVELOPMENT

A majority (96%) of the survey respondents had difficulty filling one or more positions. Respondents had the most difficulty hiring bioprocess engineers (51%), followed by automation engineers (45%), manufacturing science and technology staff (43%), CQ&V engineers (28%), and QA staff (27%).

The most important skill set for new hires was identified as scientific, engineering, and technical skills (87%). Around two thirds of respondents considered the following skills to be important: business skills, such as communication, team work (68%), emotional intelligence competencies (64%), and prior experience in a GMP environment (57%)

An overwhelming number of respondents felt that on-the-job training (96%) and practical training in a lab and/or pilot plant environment (91%) were the most effective types of training. An accredited post-graduate education program from a higher-level education institute was considered less effective (55%). Classroom training (38%), a 1- or 2-day course from a third-party provider on a particular topic (34%), and online training (30%) were considered to be the least effective types of training.

OPPORTUNITIES AND CHALLENGES

The biggest challenge for the growth of the biopharma industry concerned costs/product pricing (33%), regulations (20%), staff, technical skills (20%). Several other types of responses were cited less often: R&D/new products (13%), quality (8%), manufacturing (8%).

The biggest opportunities for the growth of the biopharma industry concerned R&D, new products (21%), cell and gene therapy (18%), and new technologies (15%). Other types of responses were cited somewhat less often: staff, training (9%), and patent expiries/biosimilars (9%).

A majority (81%) of the survey respondents were very optimistic (55%) or moderately optimistic (26%) about the future growth of the biopharma industry. Five percent (9%) were neutral and 11% were highly pessimistic.

HIGHLIGHTS OF FOUR-YEAR TRENDS

DEMOGRAPHICS

The location of survey respondents was not tracked in the 2016 survey. In the 2017 survey there were fewer respondents from Europe and more respondents from North America and Asia, Australia, Pacific Rim. In the 2017 survey, 45% were from Europe, 35% were from North America, and 16% were from Asia, Australia, Pacific Rim). In 2018, 78% of the survey respondents were located in Europe; 10% were in Asia, Australia, Pacific Rim; and 8% were in North America. The remaining 4% were located in South Africa.

In 2019, the number of respondents working for biopharma manufacturers (61%) was larger than any previous year (38% in 2016, 57% in 2017, 46% in 2018).

Respondents in the 2017, 2018, and 2019 surveys were similarly experienced – and more so than those in the 2016 survey: 45% had 10 or more years of work experience in 2016, 65% had 10 or more years of experience in 2017, 60% had 10 or more years of experience in 2018, and 65% had 10 or more years of experience in 2019.

MOST COMMERCIALY IMPORTANT BIOPHARMA THERAPEUTICS THAT ARE CURRENTLY AVAILABLE

In general, the ranking for these responses has been similar over the four years. Notably, mAbs have dropped from 80% (2018) to 64% (2019), while vaccines rose in importance (51% to 60%). Another noticeable difference is that gene therapies appear to have risen in importance in the list (from sixth to fourth) and non-mAb recombinant proteins have slipped (from third to sixth; it should be noted that fewer respondents cited non-mAb recombinant proteins as the primary focus of their organization, which likely accounts for the shift).

MOST COMMERCIALY IMPORTANT BIOPHARMA THERAPEUTICS IN THE NEXT 5 TO 10 YEARS

The ranking for these responses changed significantly from 2016 to 2018, but the 2018 trends are repeated in 2019. The following table depicts the ranking and percent response for the top three responses by year.

Most commercially important biopharma therapeutics in the next 5 to 10 years: top three responses

Rank	2016*	2017	2018	2019
First	Vaccines (78%)	mAbs (56%)	Gene therapies (66%)	Gene therapies (61%)
Second	mAbs (68%)	Cell therapies (43%)	mAbs (58%)	mAbs (54%)
Third	Antibody drug conjugates (68%)	Gene therapies (42%)	Cell therapies (52%)	Cell therapies (46%)

* The rating scale for this question was changed in the 2017 survey so the 2016 figures are not directly comparable to those from the 2017, 2018 and 2019 surveys.

HIGHLIGHTS OF FOUR-YEAR TRENDS

Monoclonal Abs has been in the top 3 responses in all years. Gene therapies and cell therapies have been in the top 3 responses for the last three years. While vaccines was cited most often in the 2016 survey, it ranked much lower in the 2017 and 2018 surveys (ranked 5th in 2017 and 2018), but moved back up to 4th in 2019.

PRIORITIES FOR FURTHER INNOVATION IN BIOPHARMA MANUFACTURING

Cell line development and bioanalytical capabilities have remained among the top three responses over the four years. Bioanalytical capabilities looked to be trending downwards in importance (61% high importance in 2016, 57% in 2017, and 47% in 2018), but 2019 appears to break that trend (60%).

IMPACT OF TECHNOLOGIES ON BIOPHARMA MANUFACTURING IN THE NEXT FIVE YEARS

Data analytics and digitalization saw a jump from 54% (2018) to 63% (2019). Single-use technologies saw a significant drop from 56% (2018) to 29% (2019). Automation of the manufacturing process is trending upwards in the level of impact on biopharma manufacturing expected in the next five years (47% high level of impact in 2016, 49% in 2017, and 57% in 2018, 58% in 2019).

Industry 4.0 technologies have risen through the ranks from the 2018 survey, from 6th (34%) to 4th (46%).

CHALLENGES WITH CONTINUOUS MANUFACTURING

Challenges in the process development of continuous manufacturing processes has been the most often cited major challenge in all four surveys. In contrast, regulatory uncertainties and a lack of real-time monitoring technologies appear to be trending downward in terms of being major challenges. Three-fifths (60%) considered regulatory uncertainties a major challenge in 2016, 49% did so in 2017, 45% did so in 2018, and 44% did so in 2019. Fifty-six percent (56%) considered a lack of real-time monitoring technologies a major challenge in 2016, 52% did so in 2017, 44% did so in 2018, and 40% did so in 2019.

INDUSTRY 4.0 ADOPTION – 2018 VERSUS 2019

Technologies that are relevant to successful implementation of industry 4.0 In biopharma: top three responses

Rank	2018	2019
First	Smart sensors (71%)	Data analytics, cloud computing (63%)
Second	Data analytics, cloud computing, computer simulation, modeling (67%)	Smart sensors (56%)
Third	Robotics, co-robotics/ intelligent automation (64%)	Artificial intelligence applications (54%)

This topic was first introduced in the 2018 survey; notably, “data analytics and cloud computing” was grouped with “computer simulation and modeling.” In 2019, these technologies were split into two separate options to refine the survey.

HIGHLIGHTS OF FOUR-YEAR TRENDS

STAFF DEVELOPMENT

The importance of various skill sets has remained relatively constant over the three years. One exception concerns the importance of business skills, such as communication or team work: 39% considered it to be quite important in 2016, 63% did so in 2017, 61% did so in 2018, and 68% did so in 2019.

In 2019, all skill sets were deemed to be more important than in previous years.

CHALLENGES AND OPPORTUNITIES

Unlike in 2017 and 2018, when the biggest challenge for the growth of the biopharma industry concerned staff, technical skills (29% and 46%, respectively), in 2019, the biggest challenge for growth in 2019 is costs, pricing, which was cited by 33% of survey respondents (Staff, technical skills were still a concern for 19% of respondents in 2019). Costs, pricing was considered less of a challenge in 2018 compared to 2017 (29% cited this as a major challenge in 2017 while only 10% did so in 2018).

New technologies, R&D/new products, and cell and gene therapy were the top three responses for the 2017, 2018 and 2019 surveys – though with shifting positions. New technologies were cited by 16% of the respondents in 2017 and by 27% of the respondents in 2018 (1st position), dropping back down to 15% (3rd position) in 2019.

METHODS

The Medicine Maker, a Texere Publication, conducted a web-based survey to learn more about current manufacturing practices and trends in the industry in partnership with the National Institute for Bioprocessing Research and Training (NIBRT).

This survey has been conducted in the fall or winter of 2016, 2017, 2018, and 2019. This report covers the findings from the 2019 survey as well as significant changes or trends over these four years. In general, the survey questions have remained the same; the responses for some questions have been changed or simplified where possible over this time. In particular, some questions where several attributes were rated have been changed to multiple choice questions and some open-ended or fill-in response questions have been changed to multiple choice questions.

Some of the questions for the 2018 and 2019 surveys were changed from open-ended or fill-in responses to “select all that apply” responses based on the verbatim responses provided in the 2016 and 2017 surveys, to simplify taking the survey and to reduce the time required to complete the survey.

This survey was fielded from 18 December 2019 through 3 February 2020. During this time, several email blasts were sent to registrants from both NIBRT’s and Texere’s databases; other promotional efforts included e-newsletters and social media. A prize draw for one of two 100 euro Amazon Gift Cards was offered as an incentive to participate.

During the seven weeks that this survey was fielded, 104 surveys were collected from individuals who were involved in biopharmaceutical manufacturing; some of these surveys were only partially completed. These 104 qualified surveys served as the basis for this report.

RESULTS AND CONCLUSIONS

Each question is presented along with the results and comments. Comparisons are made where there were significant differences in the responses from this year's (2019) survey versus the 2018, 2017, and 2016 surveys.

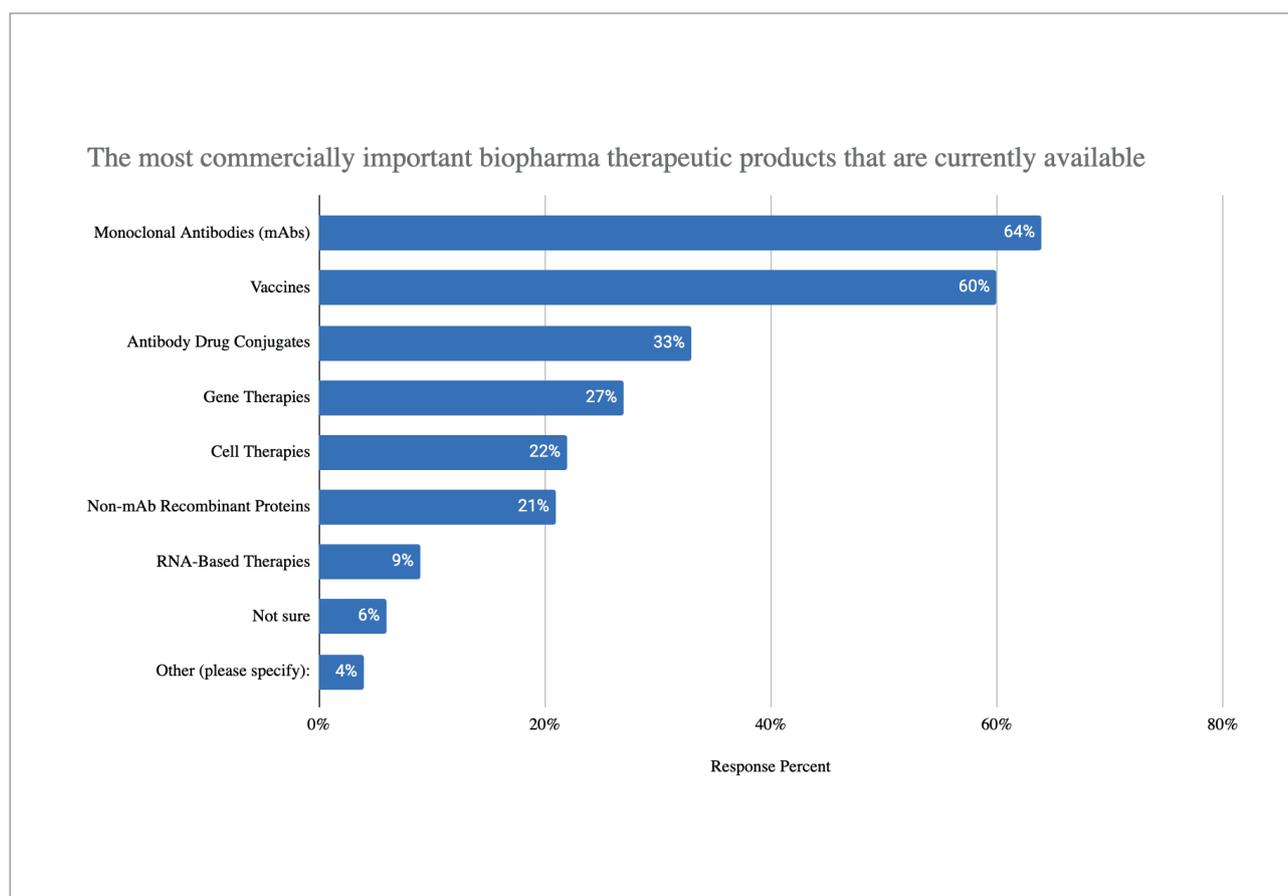
1. *Are you currently involved in biopharmaceutical manufacturing? **

All (100%) of the 104 survey respondents were involved in biopharmaceutical manufacturing.

There were 101 respondents for the 2016, 210 respondents for the 2017, and 151 respondents to the 2018 surveys.

THE PRODUCT PIPELINE

2. *Please select the most commercially important biopharma therapeutic products that are currently available. (Select up to three)*



Survey respondents were allowed to choose more than one response to this question; therefore the responses total more than 100%. .

RESULTS AND CONCLUSIONS

The most commercially important biopharma therapeutic product that was currently available was monoclonal antibodies (mAbs) (64%), followed by vaccines (60%) and antibody drug conjugates (33%).

The remaining products were cited less often: gene therapies (27%), cell therapies (12%), non-mAb recombinant proteins (21%) and RNA-based therapies (9%).

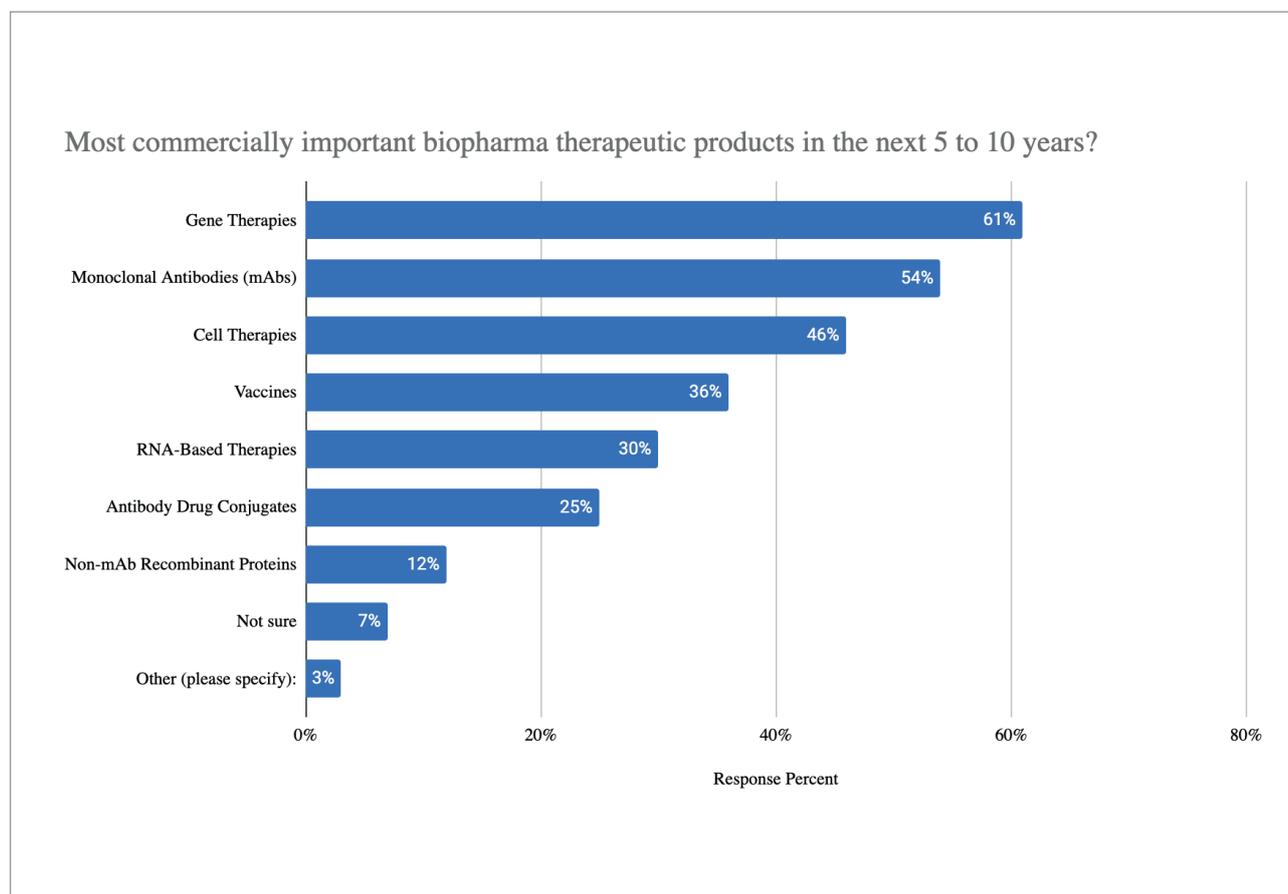
Other fill-in responses (4%) included 3D bioprinted therapies, live biotherapeutic products, and anti-infectives.

In general, the ranking for these responses has been similar over the four years. Notably, mAbs have dropped from 80% (2018) to 64% (2019), while vaccines rose in importance (51% to 60%). Another noticeable difference is that gene therapies appear to have risen in importance in the list (from sixth to fourth) and non-mAb recombinant proteins have slipped* (from third to sixth).

*It should be noted that fewer respondents cited non-mAb recombinant proteins as the primary focus of their organization, which likely accounts for the shift.

RESULTS AND CONCLUSIONS

3. Which of the following are likely to be the most commercially important biopharma therapeutic products in the next 5 to 10 years? (Select up to three)



Survey respondents were allowed to choose more than one response to this question; therefore the responses total more than 100%.

Regarding the biopharma therapeutic products that were likely to be the most important in the next 5 to 10 years, survey respondents most often cited gene therapies (61%), mAbs (54%), and cell therapies (46%).

Vaccines (36%), RNA-based therapies (30%), and antibody drug conjugates (25%), and non-mAb recombinant proteins (12%) were cited less often.

The ranking for these responses changed significantly from 2016 to 2018 surveys, but the 2018 trends are repeated in 2019. The following table depicts the ranking and percent response for the top three responses by year.

RESULTS AND CONCLUSIONS

Most commercially important biopharma therapeutics in the next 5 to 10 years: top three responses

<i>Rank</i>	<i>2016*</i>	<i>2017</i>	<i>2018</i>	<i>2019</i>
First	Vaccines (78%)	mAbs (56%)	Gene therapies (66%)	Gene therapies (61%)
Second	mAbs (68%)	Cell therapies (43%)	mAbs (58%)	mAbs (54%)
Third	Antibody drug conjugates (68%)	Gene therapies (42%)	Cell therapies (52%)	Cell therapies (46%)

** The rating scale for this question was changed in the 2017 survey so the 2016 figures are not directly comparable to those from the 2017, 2018 and 2019 surveys.*

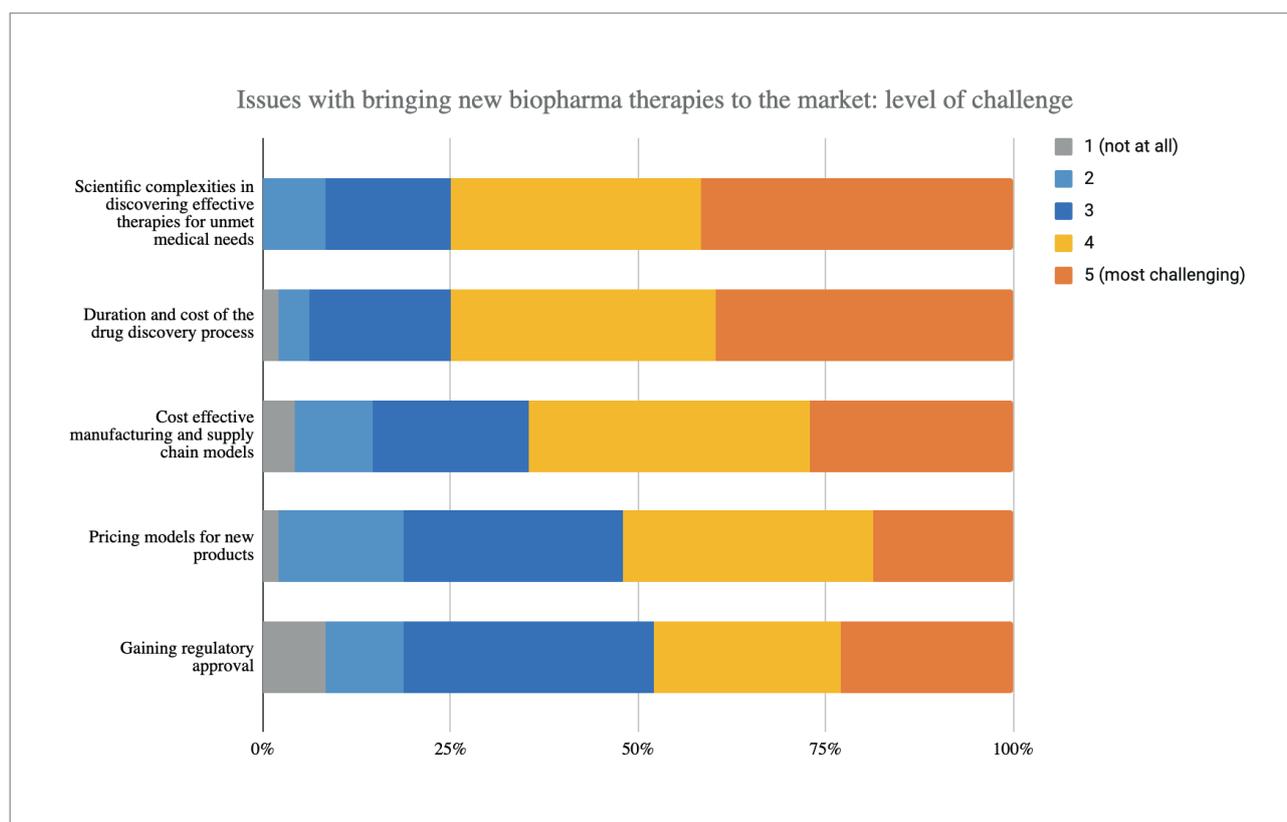
Monoclonal antibodies have been in the top 3 responses in all years. Gene therapies and cell therapies have been in the top 3 responses for the last three years. While vaccines was cited most often in the 2016 survey, it ranked much lower in the 2017 and 2018 surveys (ranked 5th in 2017 and 2018), but moved back up to 4th in 2019.

MOST COMMERCIALY IMPORTANT BIOPHARMA THERAPEUTIC PRODUCTS: NOW VERSUS THE NEXT 5 TO 10 YEARS

Gene therapies, cell therapies, and RNA-based therapies are all expected to be more important in 5 to 10 years than they are today. mAbs and antibody drug conjugates will be less important in the next 5 to 10 years. Vaccines will be a lot less important in 5 to 10 years.

RESULTS AND CONCLUSIONS

4. Please rate the following issues as to how challenging each is with regard to bringing new biopharma therapies to the market. (Please use a scale from 1 to 5, with 1 being not at all challenging and 5 being the most challenging.)



The attributes in this graph are listed in descending percentage of a rating of 4 plus 5, with 5 being “most challenging”. The values in each horizontal bar total 100%.

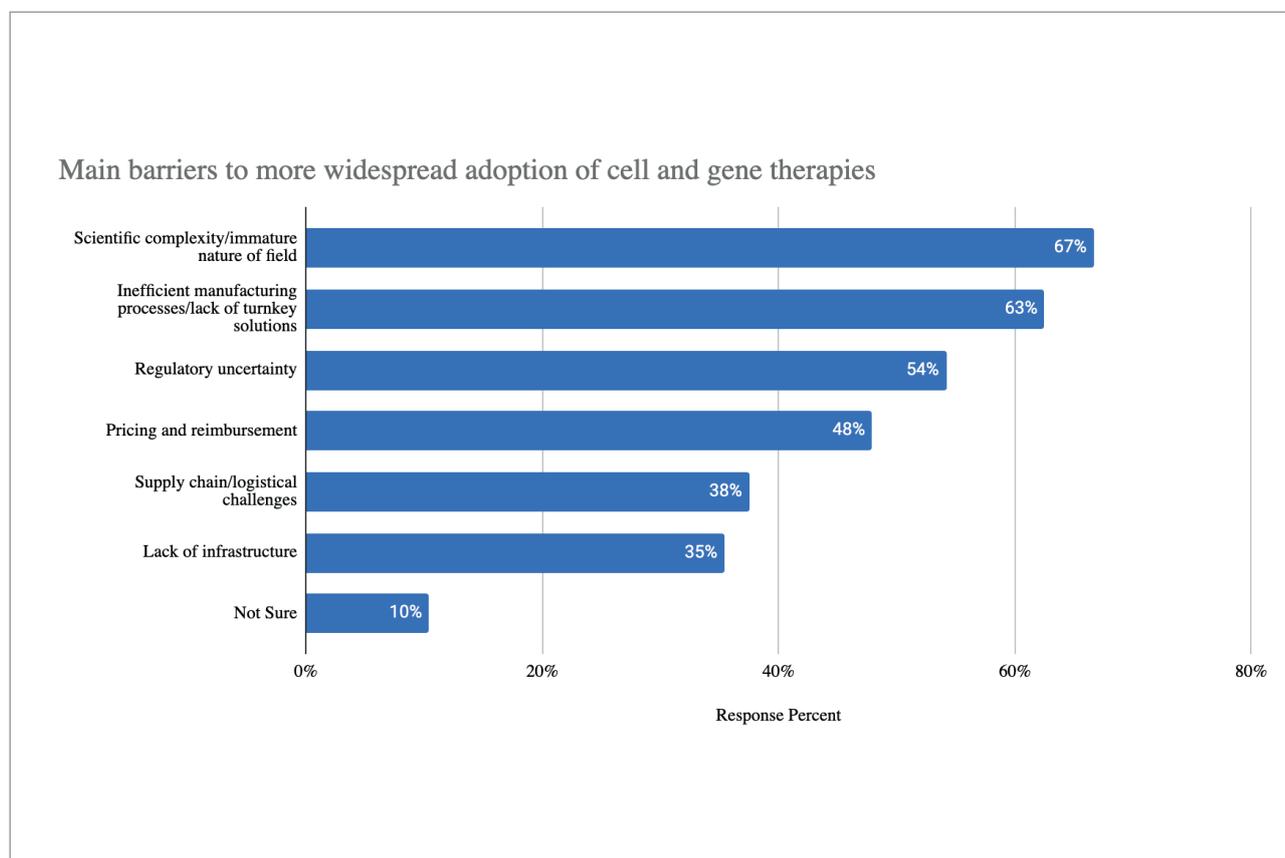
The issues that survey respondents felt were the most challenging with regard to bringing new biopharma therapies to market were the scientific complexities in discovering effective therapies for unmet medical needs (75% rating of 4 plus 5, with 5 being most challenging) and the duration and cost of the drug discovery process (75%).

Cost-effective manufacturing and supply chain methods (65%), pricing models for new products (52%) and gaining regulatory approval (48%) were considered less challenging.

A notable change is the increase in the number of respondents who consider cost-effective manufacturing and supply chain methods to be challenging – from 46% in 2018 to 65% in 2019. An opposite trend is seen in gaining regulatory approval, which appears to be less challenging for the 2019 respondents (48%) compared with the 2018 respondents (61%).

RESULTS AND CONCLUSIONS

5. Regarding cell and gene therapies, what are the main barriers to more widespread adoption?
(Select all that apply)



Survey respondents were allowed to select more than one response to this question; therefore the responses total more than 100%.

Survey respondents felt that the main barriers to more widespread adoption of cell and gene therapies were the scientific complexity/immature nature of the field (67%), inefficient manufacturing processes/lack of turnkey solutions (63%), regulatory uncertainty (54%), and issues with pricing and reimbursement (48%).

Supply chain/logistical challenges (38%) and a lack of infrastructure (35%) were cited less often.

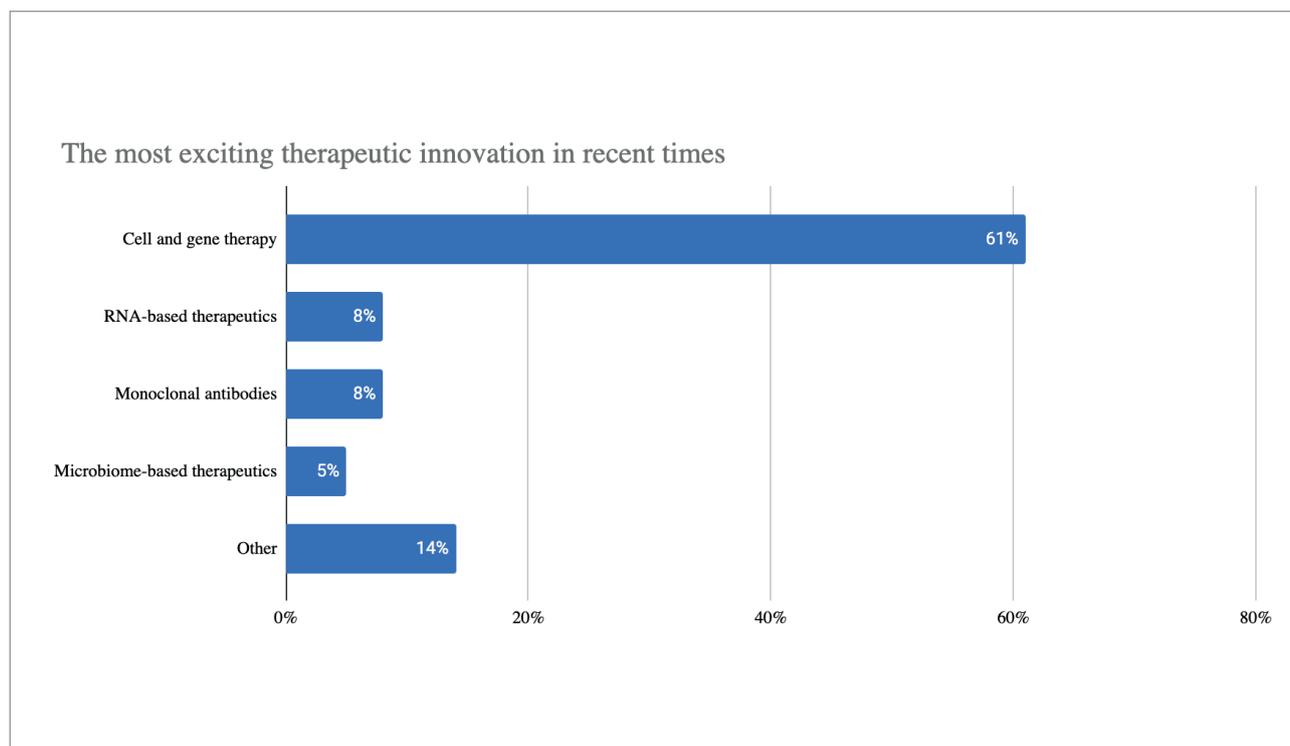
Comparing 2019 with 2018, there has been an increase in the percentage of respondents who consider inefficient manufacturing processes/lack of turnkey solutions to be a main barrier (from 44% in 2018 to 63% in 2019). Supply chain/logistical challenges and lack of infrastructure also jumped from 21% and 19%, respectively, in 2018 to 38% and 35%, respectively, in 2019. Other responses remained similar.

This question was not asked in 2016 and 2017.

RESULTS AND CONCLUSIONS

6. What has been the most exciting therapeutic innovation in recent times?

The verbatim responses for this question were categorized to produce the following graph.



Survey respondents were allowed to provide more than one response to this question; therefore the responses total more than 100%.

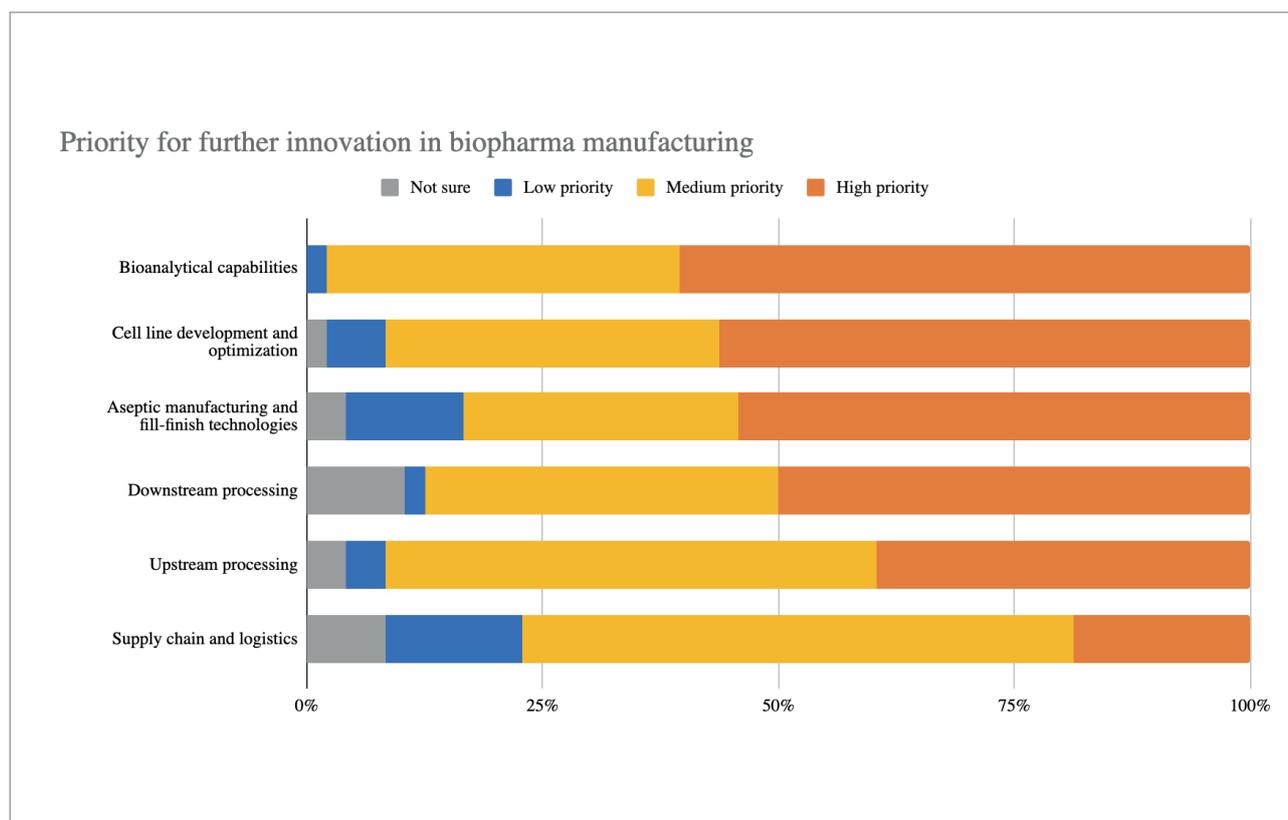
As in 2018, by far the most often cited recent therapeutic innovation was cell and gene therapy, being cited by 61% of the survey respondents; CAR T-cell therapy and CRISPR-Cas9 gene editing were mentioned specifically.

Eight percent (8%) felt that RNA-based therapeutics were the most exciting innovation – and increase from 2018 (3%).

RESULTS AND CONCLUSIONS

MANUFACTURING

7. Please rate the priority for further innovation in each of the following areas of biopharma manufacturing.



The attributes in this graph are listed in descending percentage of a “high” rating. The values in each horizontal bar total 100%.

Survey respondents felt that the highest priority areas of biopharma manufacturing for further innovation were bioanalytical capabilities (60%, high rating) and cell line development and optimization (56%), and aseptic manufacturing and fill-finish technologies (54%).

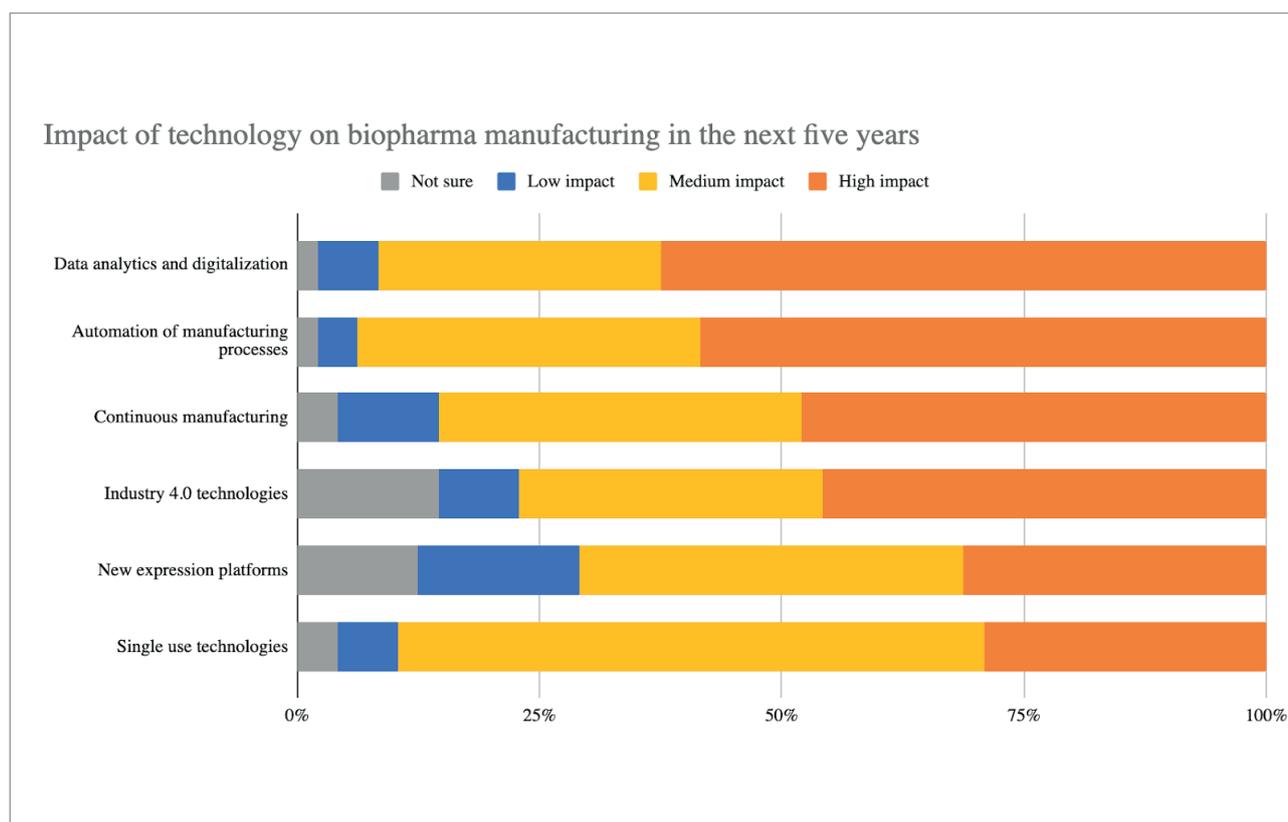
Downstream (50%), upstream processing (40%), and supply chain logistics (19%) were cited less often.

Cell line development and bioanalytical capabilities have remained among the top three responses over the four years. Bioanalytical capabilities looked to be trending downwards in importance (61% high importance in 2016, 57% in 2017, and 47% in 2018), but 2019 appears to break that trend (60%).

Aseptic manufacturing and fill-finish technologies saw a significant increase from 2018 (36%) to 2019 (54%).

RESULTS AND CONCLUSIONS

8. Please rate each of the following with regard to their impact on biopharma manufacturing in the next five years.



The attributes in this graph are listed in descending percentage of a “high” rating. The values in each horizontal bar total 100%.

Data analytics and digitalization (63%, high rating), automation of manufacturing processes (58%), continuous manufacturing (48%), and Industry 4.0 technologies (46%) were expected to have the greatest impact on biopharma manufacturing in the next five years.

New expression platforms (31%) and single-use technologies (29%) were expected to have less impact.

Data analytics and digitalization saw a jump from 54% (2018) to 63% (2019).

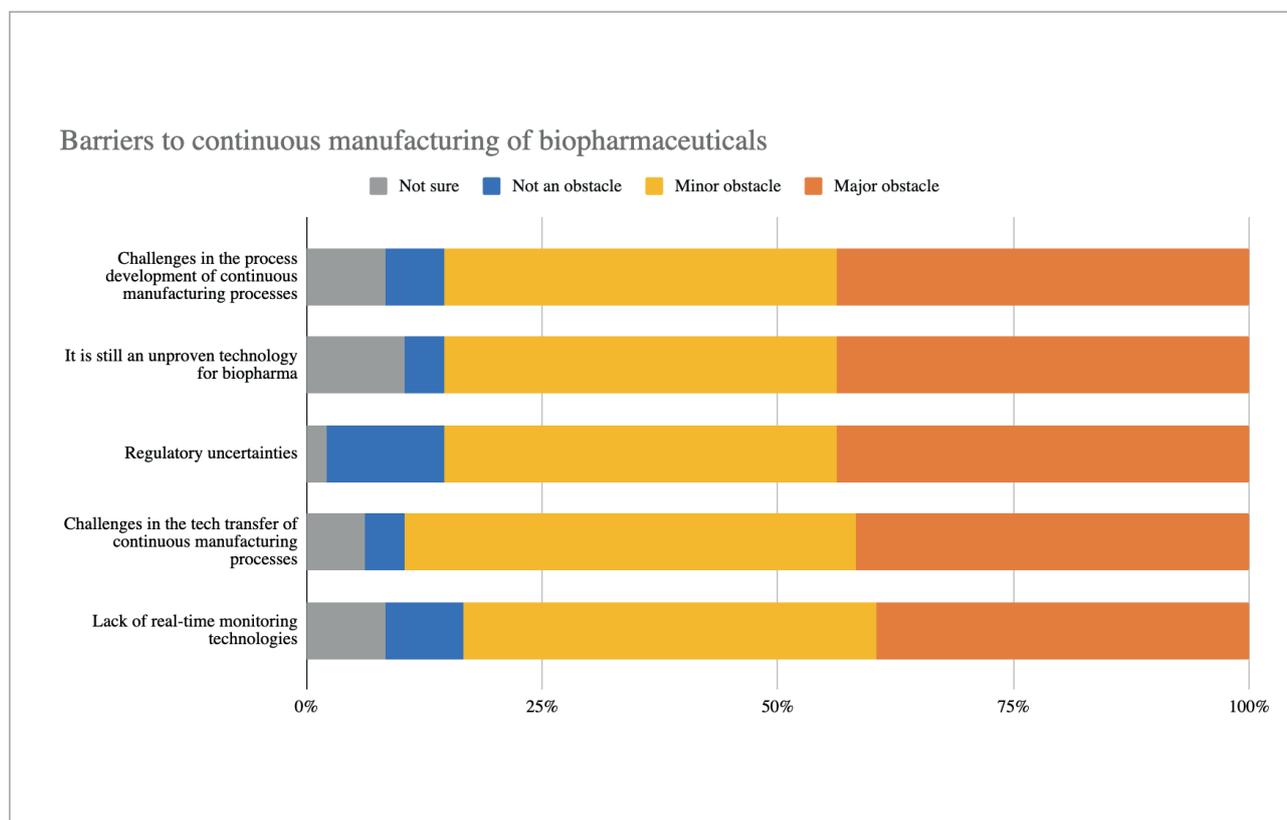
Single-use technologies saw a significant drop from 56% (2018) to 29% (2019).

Automation of the manufacturing process is trending upwards in the level of impact on biopharma manufacturing expected in the next five years (47% high level of impact in 2016, 49% in 2017, and 57% in 2018, 58% in 2019).

Industry 4.0 technologies have risen through the ranks from the 2018 survey, from 6th (34%) to 4th (46%).

RESULTS AND CONCLUSIONS

9. Interest in the continuous manufacturing of biopharmaceuticals is on the rise. How much of an obstacle is each of the following issues?



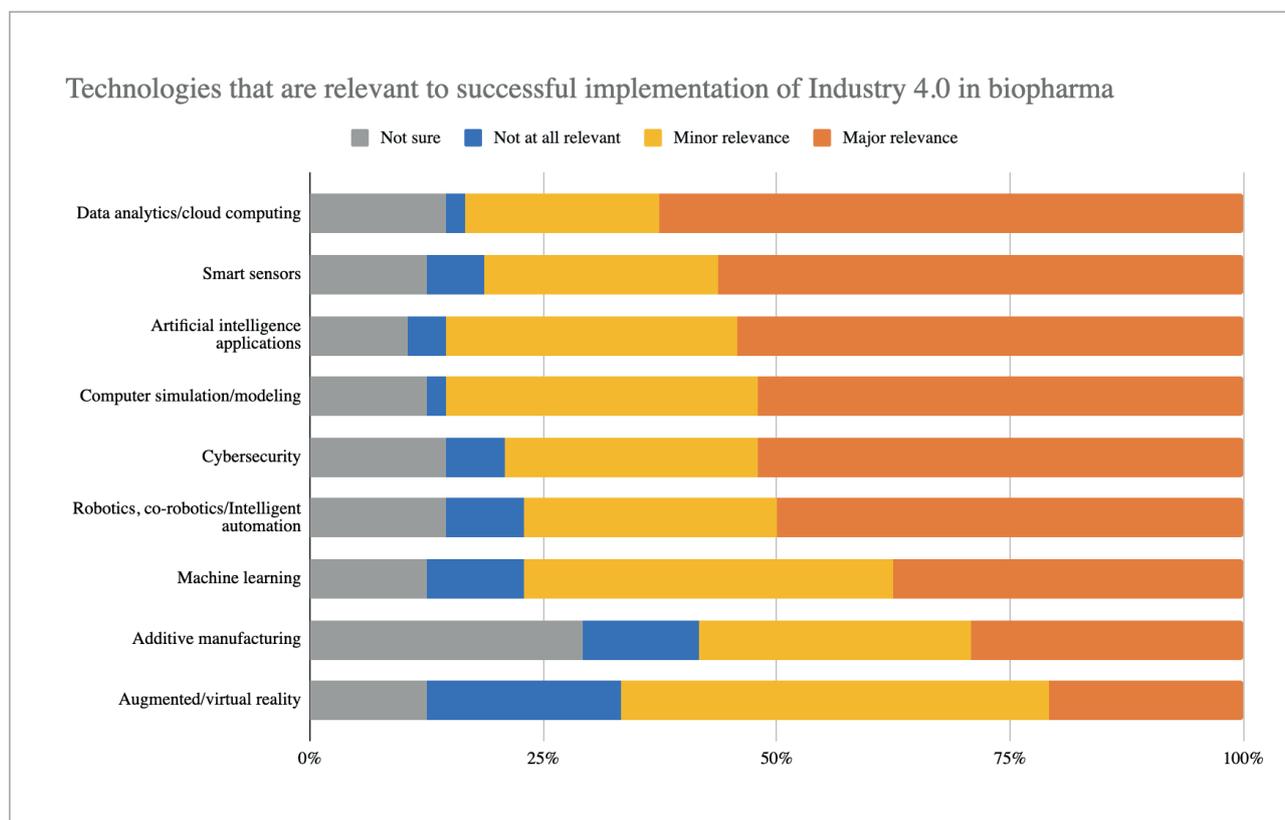
The attributes in this graph are listed in descending percentage of a “major obstacle” rating. The values in each horizontal bar total 100%.

Survey respondents considered most of these challenges to be substantial obstacles in the continuous manufacturing of biopharmaceuticals: challenges in the process development of continuous manufacturing processes (44%), still being an unproven technology for biopharma (44%), regulatory uncertainties (44%), challenges in the tech transfer of continuous manufacturing processes (42%), and a lack of real-time monitoring technologies (40%).

Challenges in the process development of continuous manufacturing processes has been the most often cited major challenge in all four surveys. In contrast, regulatory uncertainties and a lack of real-time monitoring technologies appear to be trending downward in terms of being major challenges. Three-fifths (60%) considered regulatory uncertainties a major challenge in 2016, 49% did so in 2017, 45% did so in 2018, and 44% did so in 2019. Fifty-six percent (56%) considered a lack of real-time monitoring technologies a major challenge in 2016, 52% did so in 2017, 44% did so in 2018, and 40% did so in 2019.

RESULTS AND CONCLUSIONS

10. How relevant are the following technologies with regard to the successful implementation of Industry 4.0 in biopharma?



The attributes in this graph are listed in descending percentage of a “major relevance” rating. The values in each horizontal bar total 100%.

The technologies that were considered to be the most relevant with regard to implementation of Industry 4.0 were data analytics, cloud computing (63%), smart sensors (56%), and artificial intelligence applications (54%).

Computer simulation, modeling (52%), cybersecurity (52%), robotics,co-robotics/intelligent automation (50%), and machine learning (38%) were cited less often.

Additive manufacturing (29%) and augmented and virtual reality (21%) and were cited least often.

This question was first asked in the 2018 survey, but “data analytics and cloud computing” was grouped with “computer simulation and modeling.” In 2019, these technologies were split into two separate options to refine the survey.

RESULTS AND CONCLUSIONS

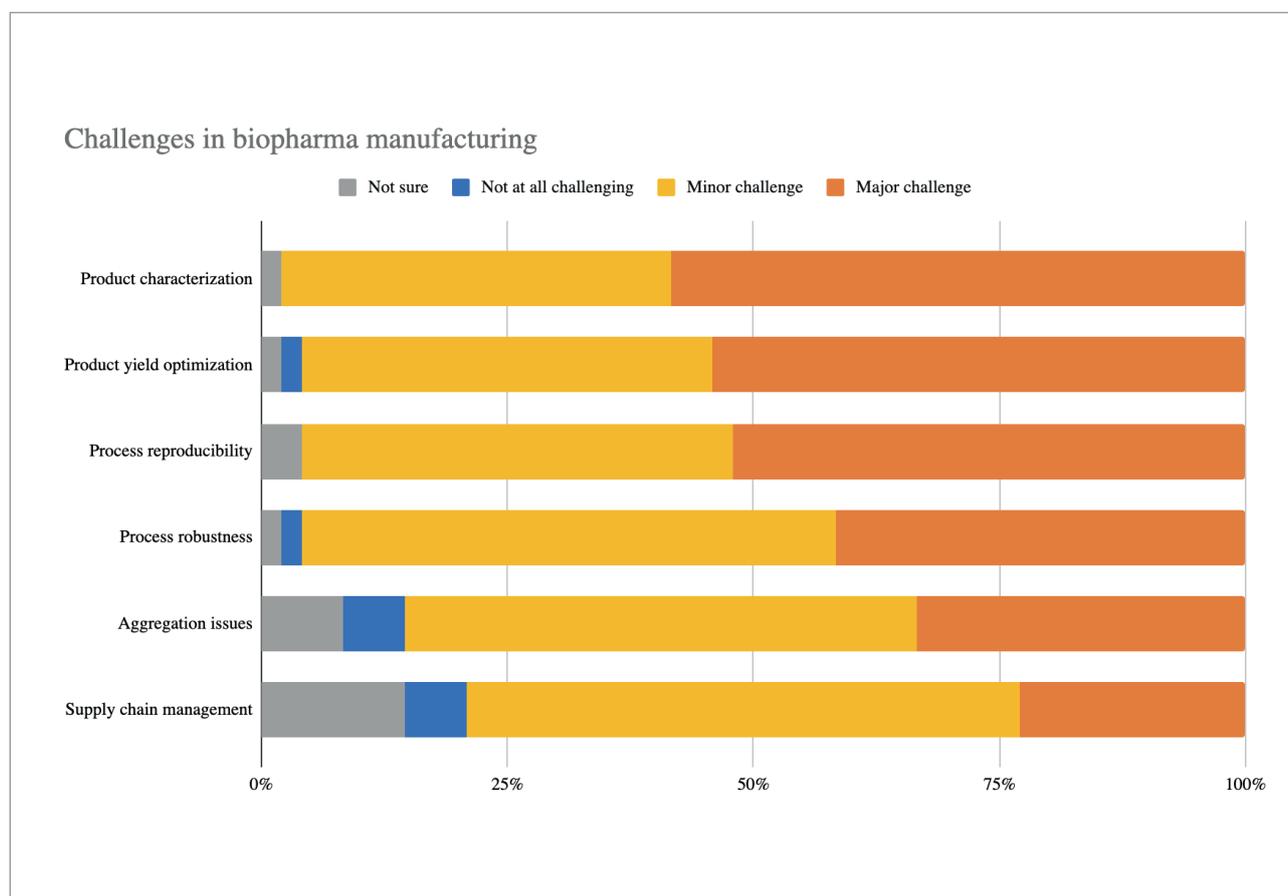
Technologies that are relevant to successful implementation of industry 4.0 In biopharma: top three responses

Rank	2018	2019
First	Smart sensors (71%)	Data analytics, cloud computing (63%)
Second	Data analytics, cloud computing, computer simulation, modeling (67%)	Smart sensors (56%)
Third	Robotics, co-robotics/ intelligent automation (64%)	Artificial intelligence applications (54%)

In the 2016 and 2017 surveys this question concerned Process Analytical Technologies (PAT).

RESULTS AND CONCLUSIONS

11. How challenging is each of the following issues regarding biopharma manufacturing?



The attributes in this graph are listed in descending percentage of a “major challenge” rating. The values in each horizontal bar total 100%.

The biggest challenges cited with regard to biopharma manufacturing were product characterization (58% considered this a major challenge), product yield optimization (54%), and process reproducibility (52%).

Process robustness (42%) was considered to be somewhat less challenging. Aggregation issues (33%) and supply chain management (23%) were considered to be the least challenging issues.

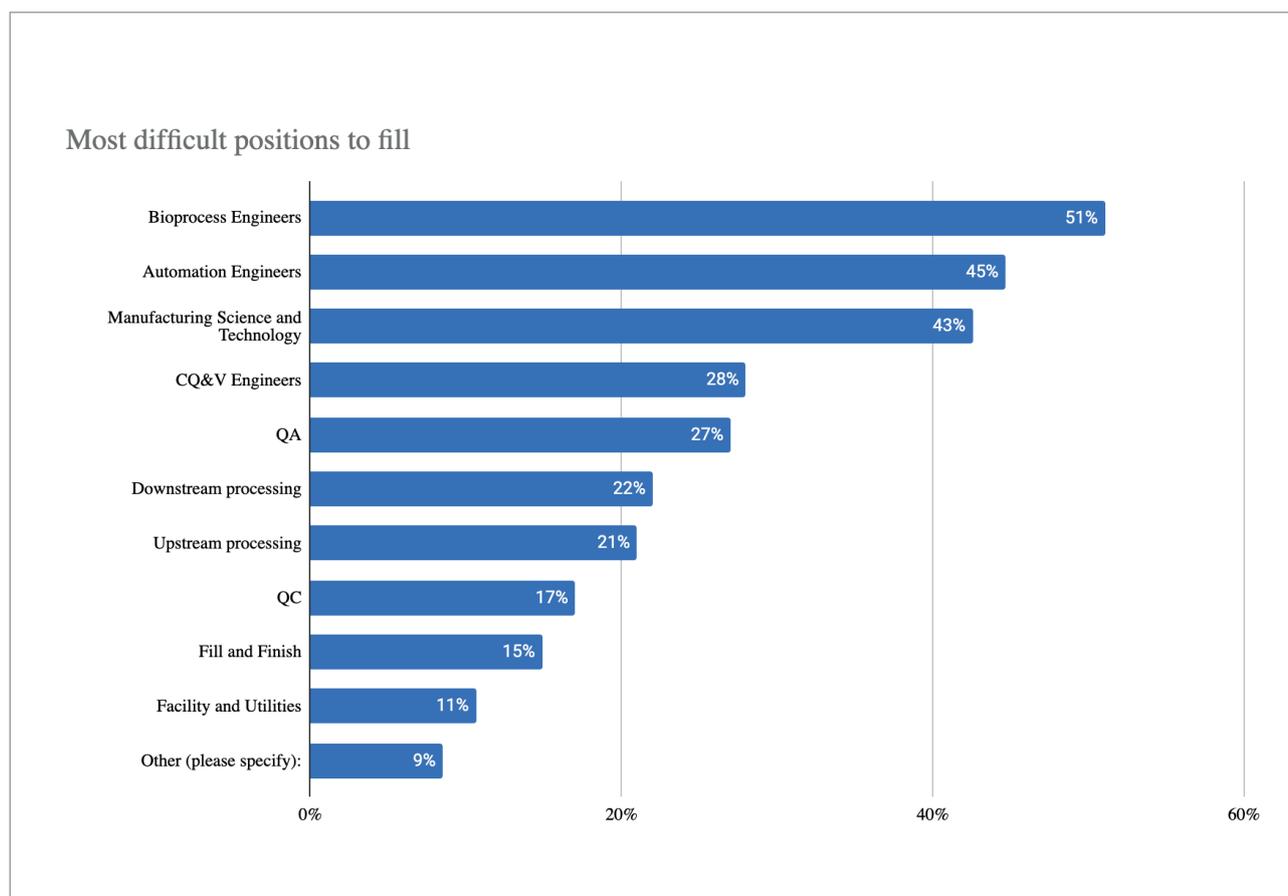
The key challenges faced with regard to biopharma manufacturing were similar over the 2016, 2017, and 2018 surveys. However, product characterization jumped from 4th (42% in 2018) to 1st position as the biggest challenge in 2019.

Over the four years, there is a slight downward trend in the level of challenge for supply chain management: in 2016 34% considered it a major challenge, 28% did so in 2017, 25% did so in 2018, and 23% did so in 2019.

RESULTS AND CONCLUSIONS

STAFF DEVELOPMENT

12. Which of the following types of staff are you having the most difficulty hiring? (Select up to five)



Survey respondents were allowed to choose more than one response to this question; therefore the responses total more than 100%.

A majority (96%) of the survey respondents had difficulty filling one or more positions. Only 4% had either no issues with hiring staff or had issues with retention rather than hiring.

Survey respondents had the most difficulty hiring bioprocess engineers (51%), followed by automation engineers (45%), manufacturing science and technology staff (43%), CQ&V engineers (28%), and QA staff (27%).

The remaining types of positions were cited less often: downstream processing (22%), upstream processing (21%), QC (17%), fill and finish (15%), and facility and utilities (11%).

RESULTS AND CONCLUSIONS

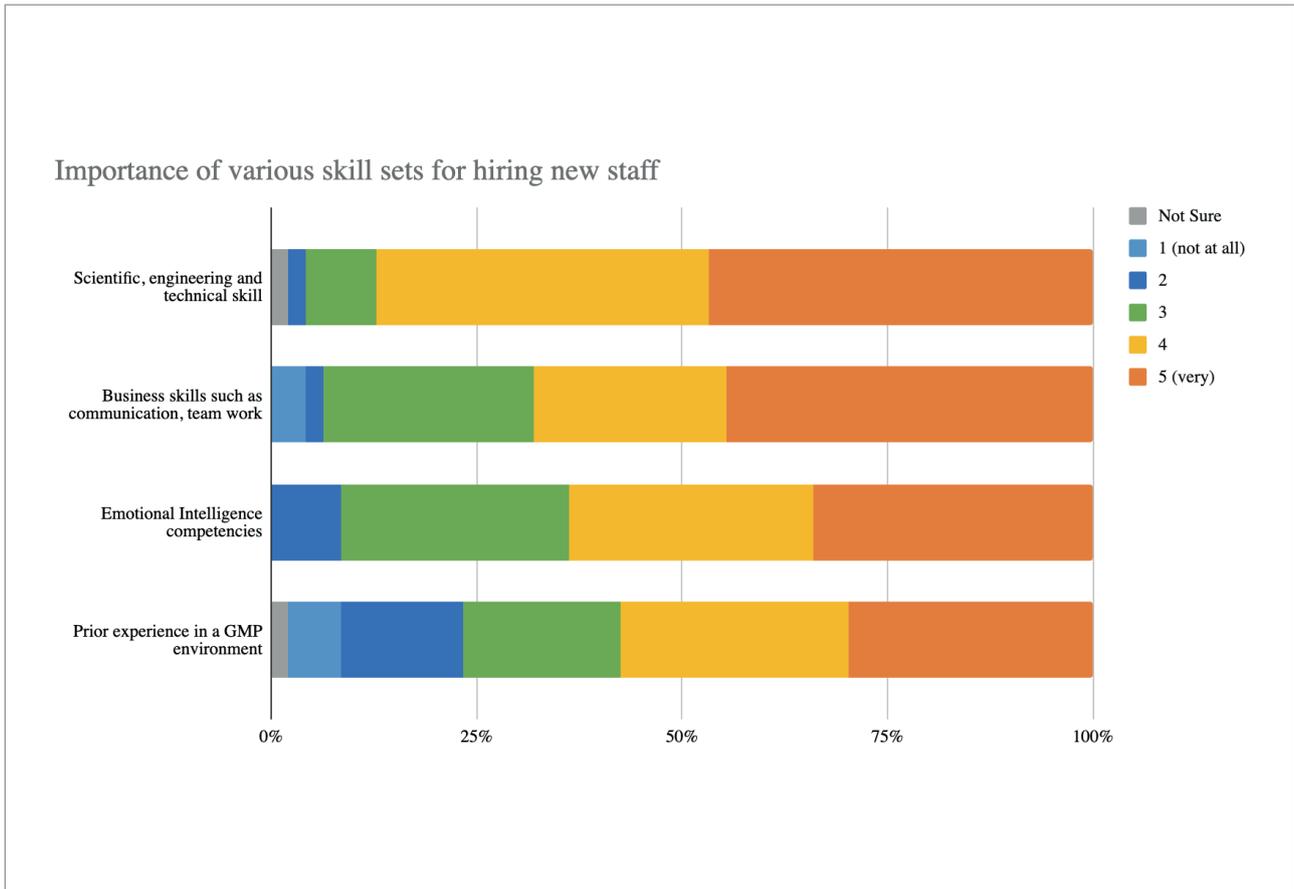
Technologies that are relevant to successful implementation of industry 4.0 In biopharma: top three responses

Rank	2018	2019
First	Bioprocess engineers (45%)	Bioprocess engineers (51%)
Second	Automation engineers (33%)	Automation engineers (45%)
Third	Manufacturing science and technology (29%)	Manufacturing science and technology (43%)
Fourth	Downstream processing (28%)	CQ&V Engineers (28%)
Fifth	CQ&V Engineers (27%)	QA (27%)

This question was changed in 2017 from one where each position was rated in terms of difficulty in hiring to a multiple-choice question (selecting up to five positions). The difficulty in hiring specialized staff in biopharma manufacturing was similar in 2017 and 2018.

RESULTS AND CONCLUSIONS

13. With regard to hiring new staff, how important is each of the following skill sets? (Please use a scale from 1 to 5, with 1 being not at all important and 5 being very important.)



The attributes in this graph are listed in descending percentage of a rating of 4 plus 5, with 5 being “very important”. The values in each horizontal bar total 100%.

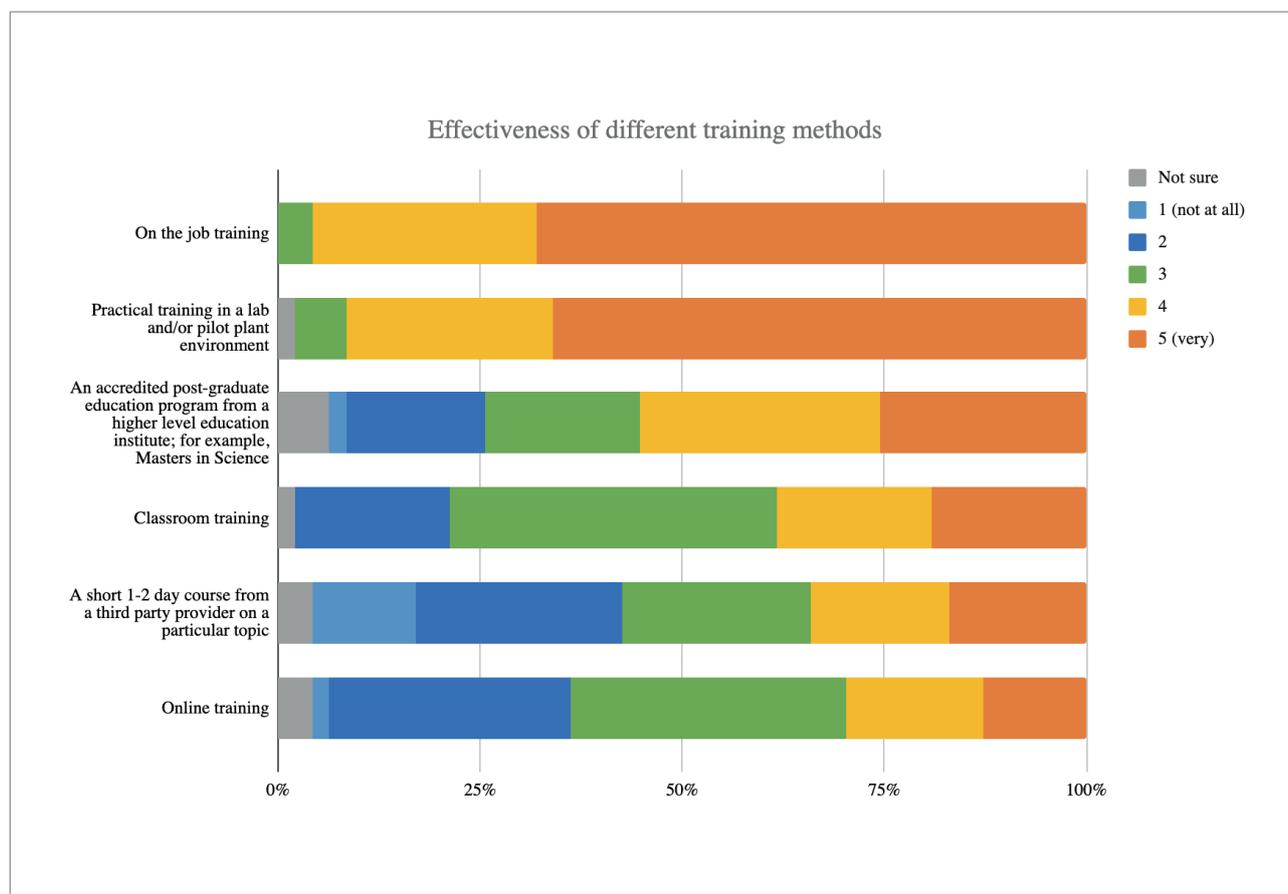
When the top two categories are considered, the most important skill set for new hires was scientific, engineering, and technical skills (rated as 4 or 5 by 87% of the survey respondents). The remaining skill sets were each considered quite important: business skills, such as communication or team work (68%), emotional intelligence competencies (64%), and prior experience in a GMP environment (57%).

The importance of various skill sets has remained relatively constant over the four years. One exception concerns the importance of business skills, such as communication or team work: 39% considered it to be quite important in 2016, 63% did so in 2017, 61% did so in 2018, and 68% did so in 2019.

In 2019, all skill sets were deemed to be more important than in previous years.

RESULTS AND CONCLUSIONS

14. How effective is each of the following types of training? (Please use a scale from 1 to 5, with 1 being not at all effective and 5 being very effective.)



The attributes in this graph are listed in descending percentage of a rating of 4 plus 5, with 5 being “very effective”. The values in each horizontal bar total 100%.

When the top two categories are considered, by far the most effective types of training were on-the-job training (rated as 4 or 5 by 96% of the respondents) and practical training in a lab and/or pilot plant environment (91%). An accredited post-graduate education program from a higher-level education institute; for example, Master’s in Science program was considered less effective (55%).

Classroom training (38%), a 1- or 2-day course from a third-party provider on a particular topic (34%), and online training (30%) were considered to be the least effective types of training.

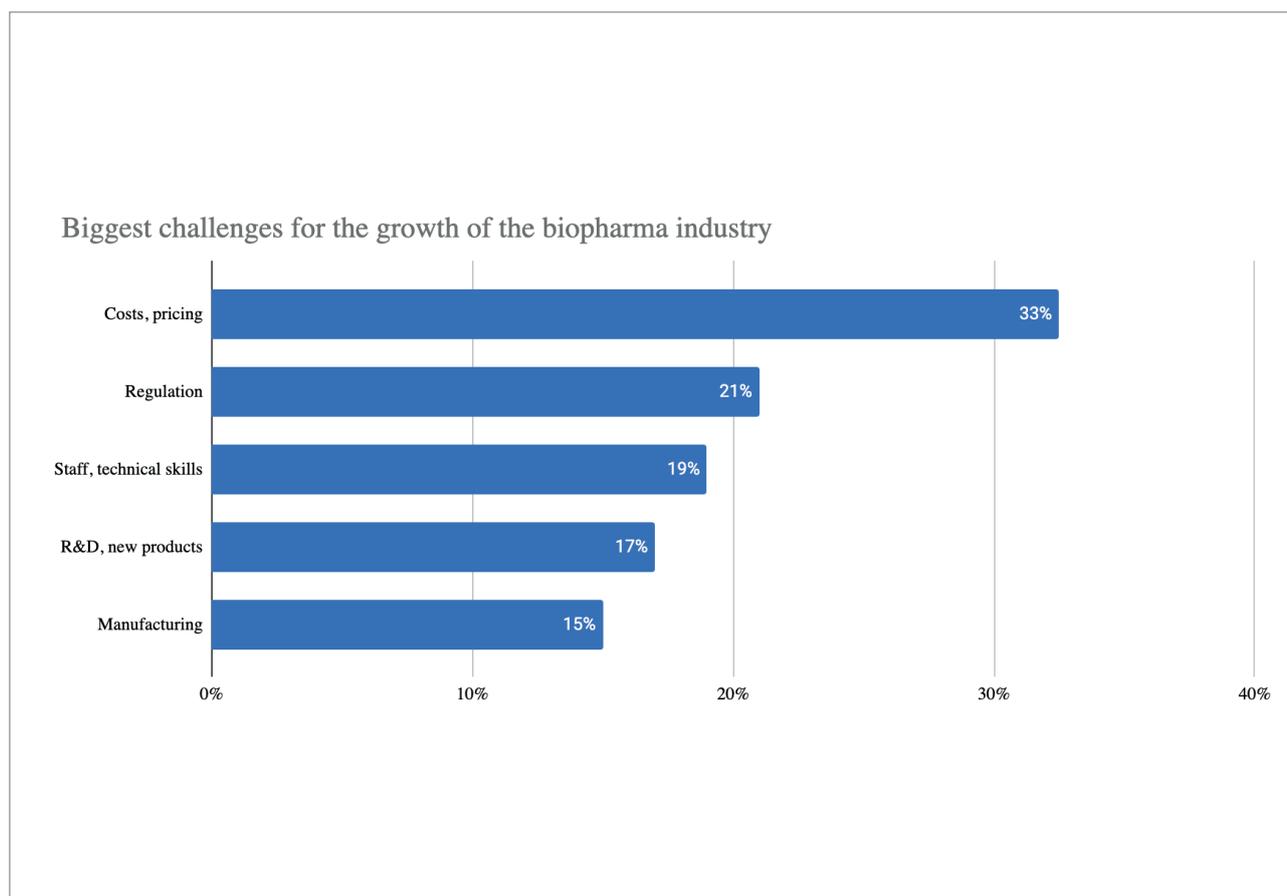
The effectiveness of the various types of training has been similar over the four years.

RESULTS AND CONCLUSIONS

OPPORTUNITIES AND CHALLENGES

15. What are the biggest challenges for the growth of the biopharma industry?

The verbatim responses for this question were categorized to produce the following graph which depicts the top responses.



Survey respondents were allowed to provide more than one response to this question; therefore the responses total more than 100%.

Unlike in 2018 – when the biggest challenge for the growth of the biopharma industry concerned staff, technical skills (46%) – in 2019, biggest challenge for growth is costs, pricing, which was cited by 33% of survey respondents.

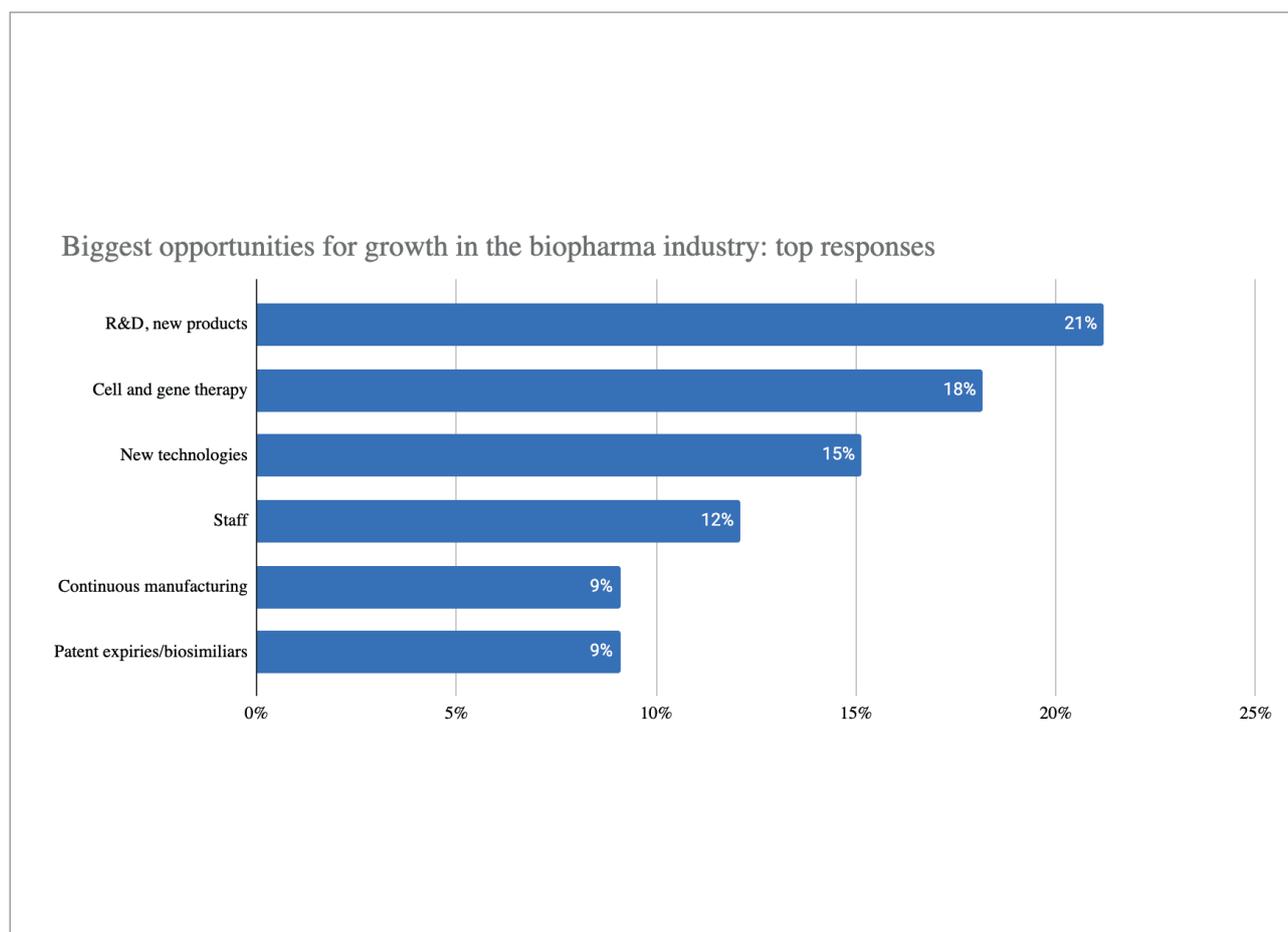
Staff, technical skills were still a concern for 19% of respondents.

Other types of responses were cited less often: R&D/new products (17%), manufacturing (15%).

RESULTS AND CONCLUSIONS

16. What are the biggest opportunities for the growth of the biopharma industry?

The verbatim responses for this question were categorized to produce the following graph which depicts the top responses..



Survey respondents were allowed to provide more than one response to this question.

The biggest opportunities for the growth of the biopharma industry concerned general R&D or new products (21%) – but cell & gene therapies were specifically cited by 18% of respondents. New technologies were cited by 15% of respondents.

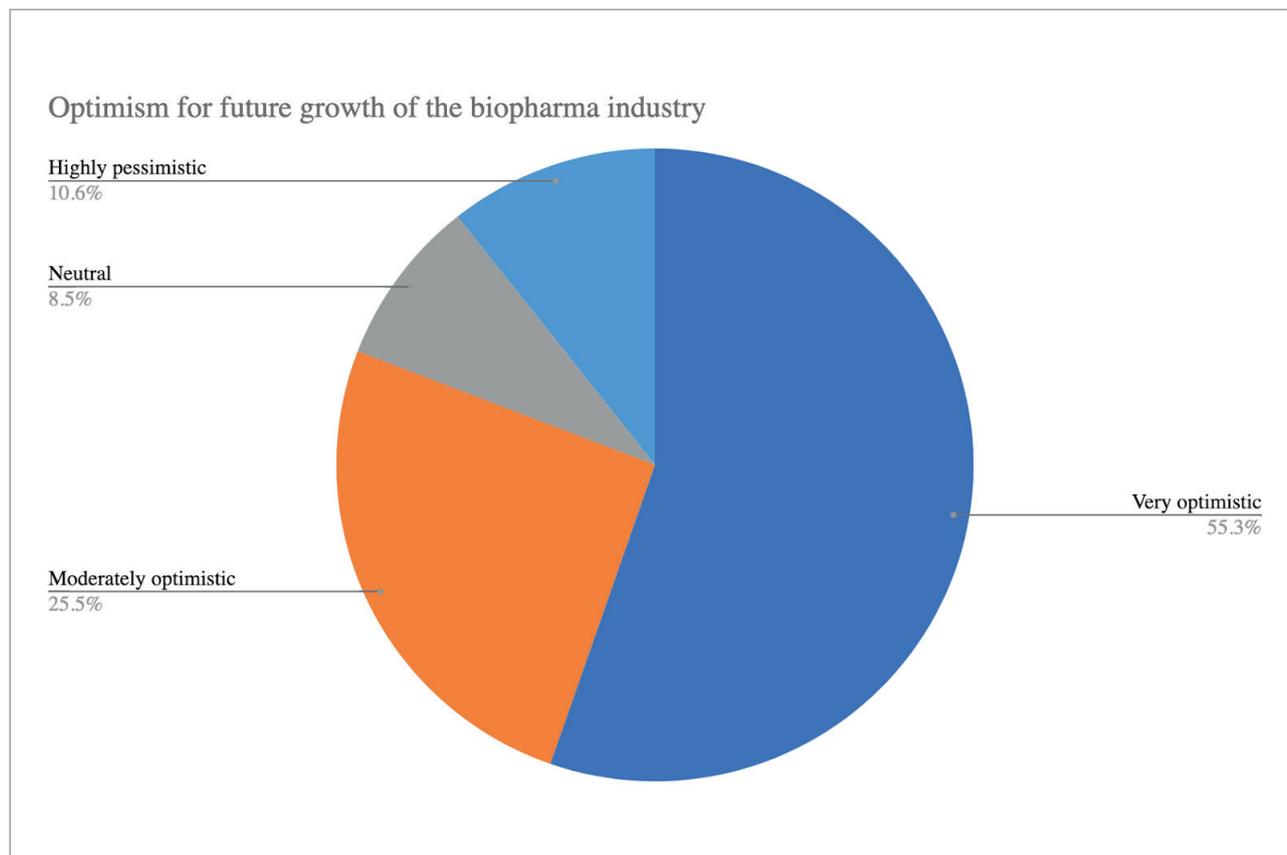
Other types of responses were cited somewhat less often: staff (12%), continuous manufacturing (9%), and patent expiries/biosimilars (9%).

New technologies, R&D/new products, and cell and gene therapy were the top three responses for the 2017, 2018 and 2019 surveys – though with shifting positions.

New technologies were cited by 16% of the respondents in 2017 and by 27% of the respondents in 2018 (1st position), dropping back down to 15% (3rd position) in 2019.

RESULTS AND CONCLUSIONS

17. Overall, how optimistic are you for the future growth of the biopharma industry?



A majority (81%) of the survey respondents were very optimistic (55%) or moderately optimistic (26%) for the future growth of the biopharma industry. Nine percent (9%) were neutral and 11% were highly pessimistic.

The level of optimism for the future growth of the biopharma industry has not changed dramatically over the four surveys; however, respondents in 2019 are less optimistic about the future growth of the biopharma industry – see comparison table below for the shift towards pessimism. Note that, in 2019, no respondents selected “somewhat pessimistic.”

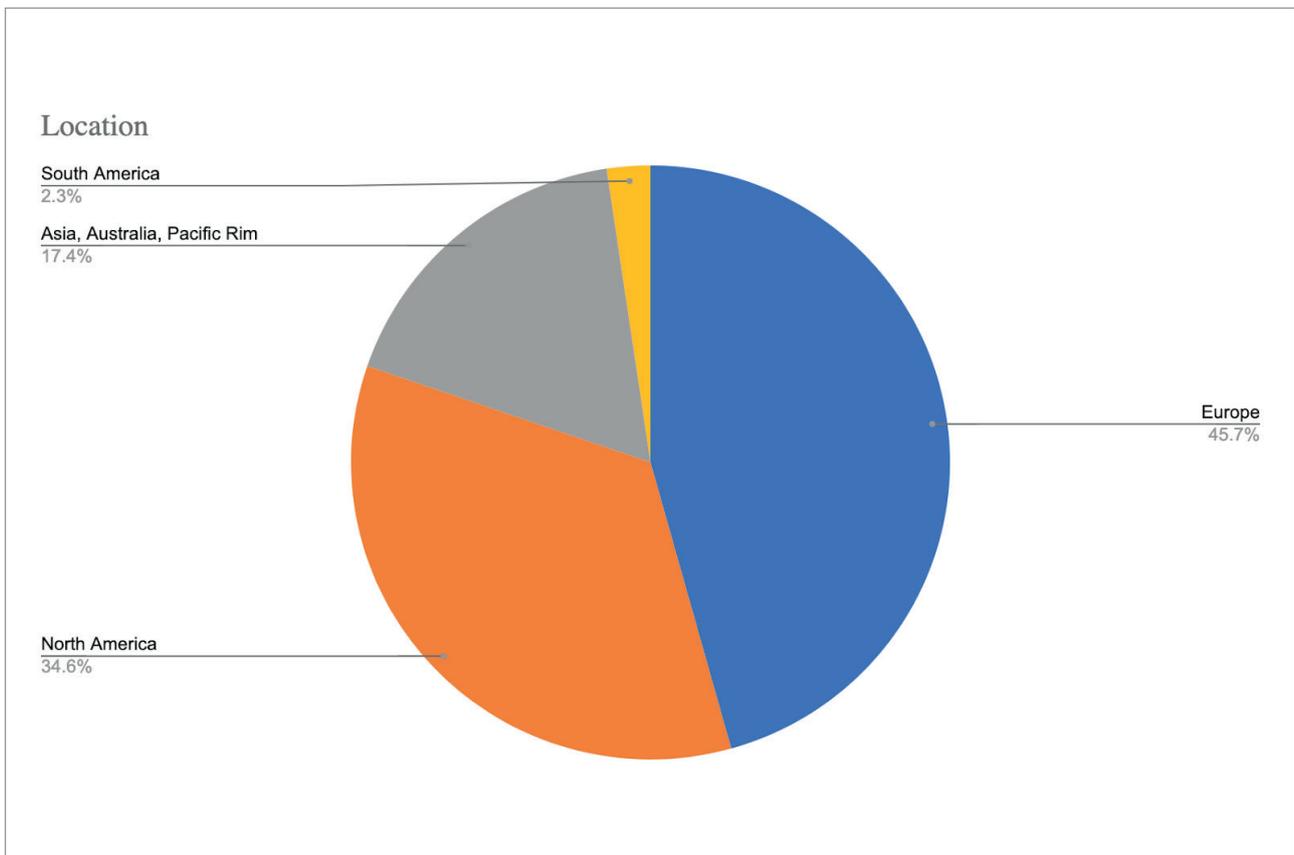
Optimism in the future growth of the biopharm industry 2018 versus 2019 comparison

Level	2018	2019
Very optimistic	61%	55%
Moderately optimistic	24%	26%
Neutral	5%	9%
Somewhat pessimistic	4%	0%
Highly pessimistic	4%	11%
Not sure	2%	0%

RESULTS AND CONCLUSIONS

OPPORTUNITIES AND CHALLENGES

18. Where are you located?

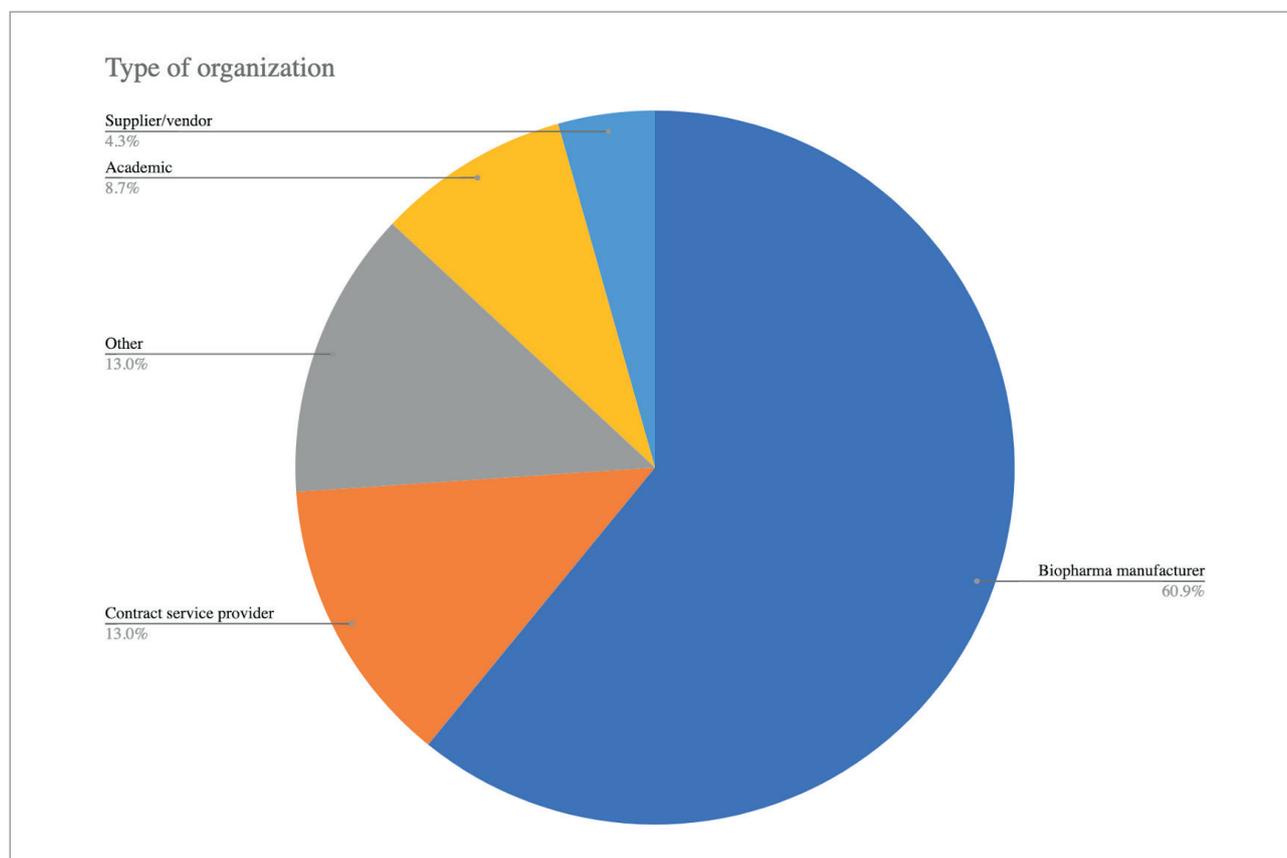


Forty-six percent (46%) of survey respondents were located in Europe; 35% were North America; 17% were in Asia, Australia, Pacific Rim. The remaining 2% were located in South America.

The location of survey respondents was not tracked in the 2016 survey. In the 2017 survey there were fewer respondents from Europe and more respondents from North America and Asia, Australia, Pacific Rim. In the 2017 survey, 45% were from Europe, 35% were from North America, and 16% were from Asia, Australia, Pacific Rim). In 2018, 78% of the survey respondents were located in Europe; 10% were in Asia, Australia, Pacific Rim; and 8% were in North America. The remaining 4% were located in South Africa.

RESULTS AND CONCLUSIONS

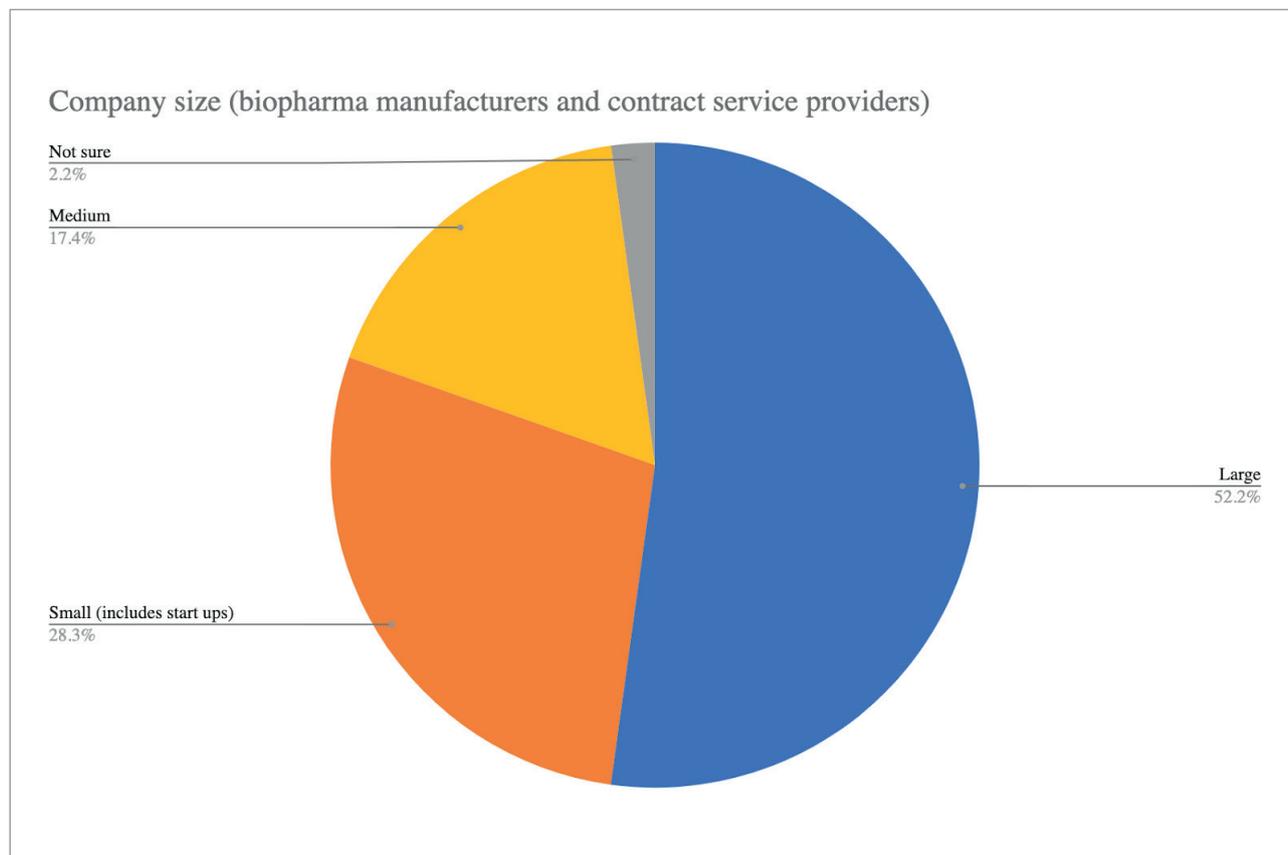
19. In which of the following types of organization do you work or study?
(If more than one applies, please select the one where you spend the most time.)



Sixty-one percent (61%) of the survey respondents worked for biopharma manufacturers, 13% worked for contract service providers, 9%, were affiliated with academic institutions, 4% worked for suppliers/vendors. Thirteen percent (13%) selected “Other,” with fill-in responses including various consultants, industrial manufacturers, and training organization.

RESULTS AND CONCLUSIONS

20. Which best describes your company?



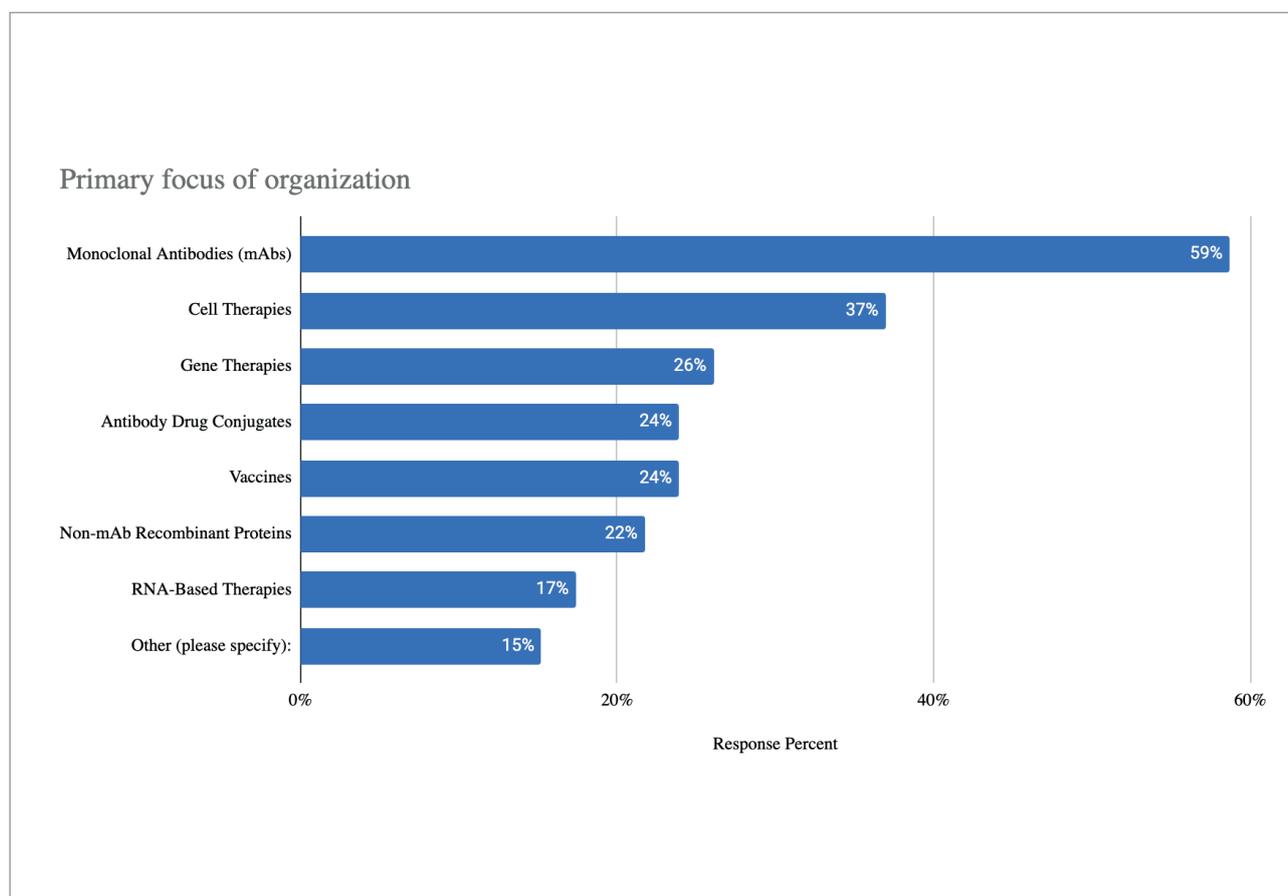
This question was presented to those survey respondents who worked for biopharma manufacturers or contract service providers.

One-half (52%) of these industry survey respondents worked in large companies. Twenty-eight percent (28%) worked in small companies (including start ups). And 17% worked in medium companies. The remaining 2% were not sure.

In 2019, there were more respondents from small companies (28%) and fewer from medium companies compared with 2018 (18% small, 28% medium). The responses from 2017 and 2018 were similar (the question was not asked in 2016).

RESULTS AND CONCLUSIONS

21. *What therapies are the primary focus of your organization? * (Select all that apply)*



Survey respondents were allowed to provide more than one response to this question; therefore the responses total more than 100%.

On average, each survey respondent cited two areas of primary focus for their organization.

The most common focus for organizations was mAbs (59%), followed by cell therapies (37%), and gene therapies (26%).

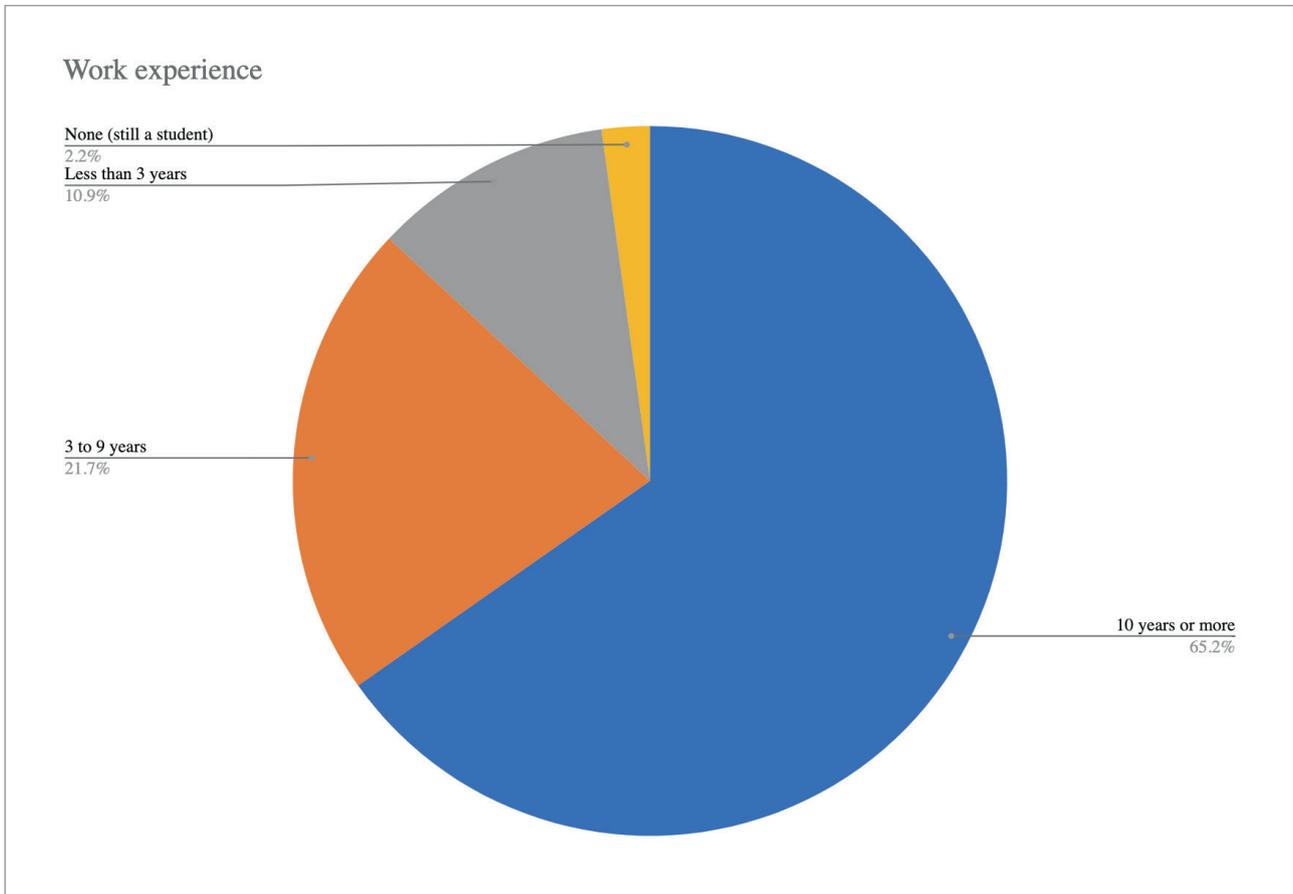
Antibody drug conjugates (24%), vaccines (24%), and non-mAb recombinant proteins (22%) were cited less often. RNA-based therapies were a focus for 17% of organizations.

Other fill-in responses (8%) included small molecules, living biotherapeutic products, generics, and peptides.

This question was first asked in the 2018 survey, and there are some stark differences between 2018 and 2019, which may account for shifts in responses to questions 2 & 3. In particular, there were far fewer represented organizations working on non-mAb recombinant proteins – 22% in 2019 versus 40% in 2018 – and many more organizations working on cell therapies – 37% in 2019 versus 24% in 2018. Other responses were similar between 2018 and 2019.

RESULTS AND CONCLUSIONS

22. How many years of work experience do you have?



Three-fifths (60%) of the survey respondents had 10 or more years of work experience. Twenty-seven percent (27%) had 3 to 9 years of work experience and 12% had 1 to 2 years of work experience. The remaining 1% of the respondents had no work experience.

Respondents in the 2016 survey were less experienced: 45% had 10 or more years of work experience in 2016, 65% had 10 or more years of experience in 2017, 60% had 10 or more years of experience in 2018, and 65% had 10 or more years of experience in 2019.

Years of work experience were similar for the 2017, 2018 and 2019 surveys

BIOPHARMA

TRENDS