



Flexibility by Design: GMP Manufacturing for the Diverse Product Portfolio

3rd Annual DME Facility Focus Program

04/18/2018, 10:30 AM to 11:30AM

Technical Conference Stage 1, Booth 1076, Exhibit Hall



INTERPHEX



About DME Facility Focus

- An INTERPHEX 2018 Technical Education Program.
- **Surveys**
 - Invited engineers, manufacturers, and other life sciences professionals like you to express views on the latest trends and technologies affecting our industry.
 - Two Surveys, executed Q4 2017.
 - Flexible Facilities
 - RABS Retrofits
- **Presentations** with Distinguished Industry Panels.
 - Flexibility by Design: *GMP Manufacturing for the Diverse Product Portfolio*
 - Restricted Access Barriers: *Best Industry Practices for Retrofitting Legacy Filling Lines with a RABS Barrier*
 - Central Utilities for GMP Manufacturing: *A Practical Dialog on Cost and Reliability*





Speakers

David M. Marks, P.E.
Speaker/Moderator

- President
- DME

Sean Illig
Discussion Panel

- Director, Process Technology
- Sanofi Pasteur

Leo Krieg
Discussion Panel

- Leader
- AstraZeneca Biologics

Daniel Rudolf, Ph.D.
Discussion Panel

- Principal Engineer, S & T
- Emergent BioSolutions



2017-18 Survey Results



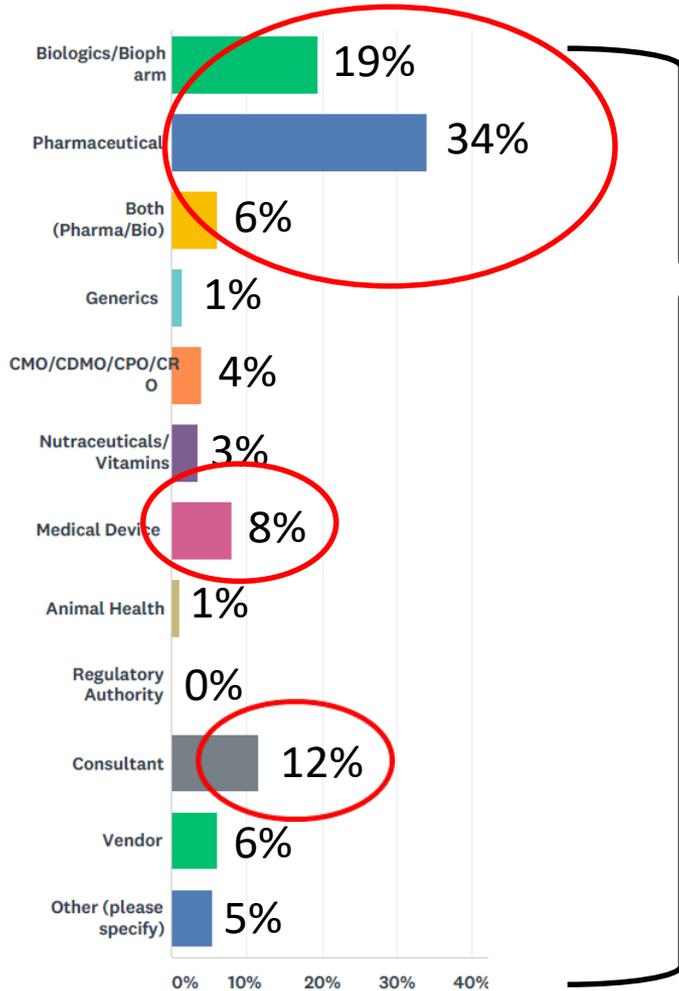
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Survey Participant Affiliation

Q1 What is your primary affiliation?

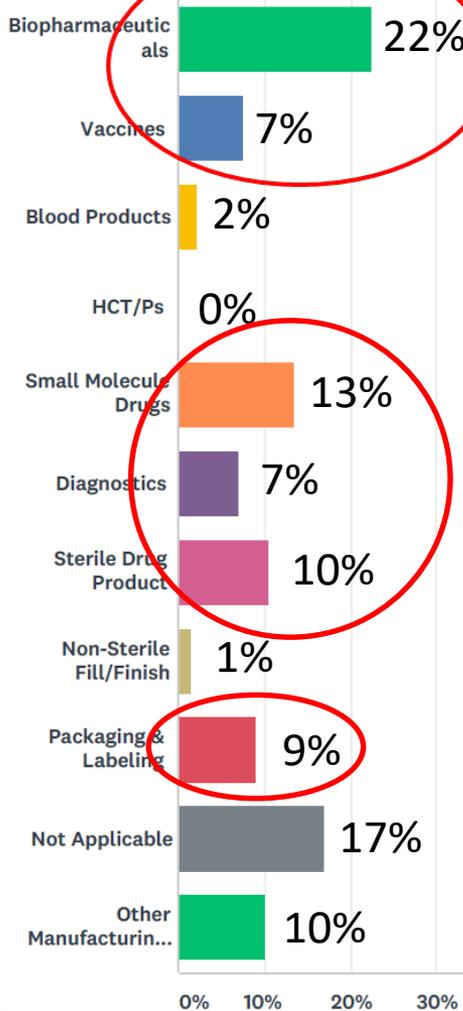


Biologics/BioPharm	19%
Pharmaceutical	34%
Both Pharma/Bio	6%
Medical Devices	8%
<u>Consultant</u>	<u>12%</u>
SUBTOTAL	79%
THE REST	21%



Facility Type

Q2 Which best describes your facility's primary area of cGMP manufacturing?

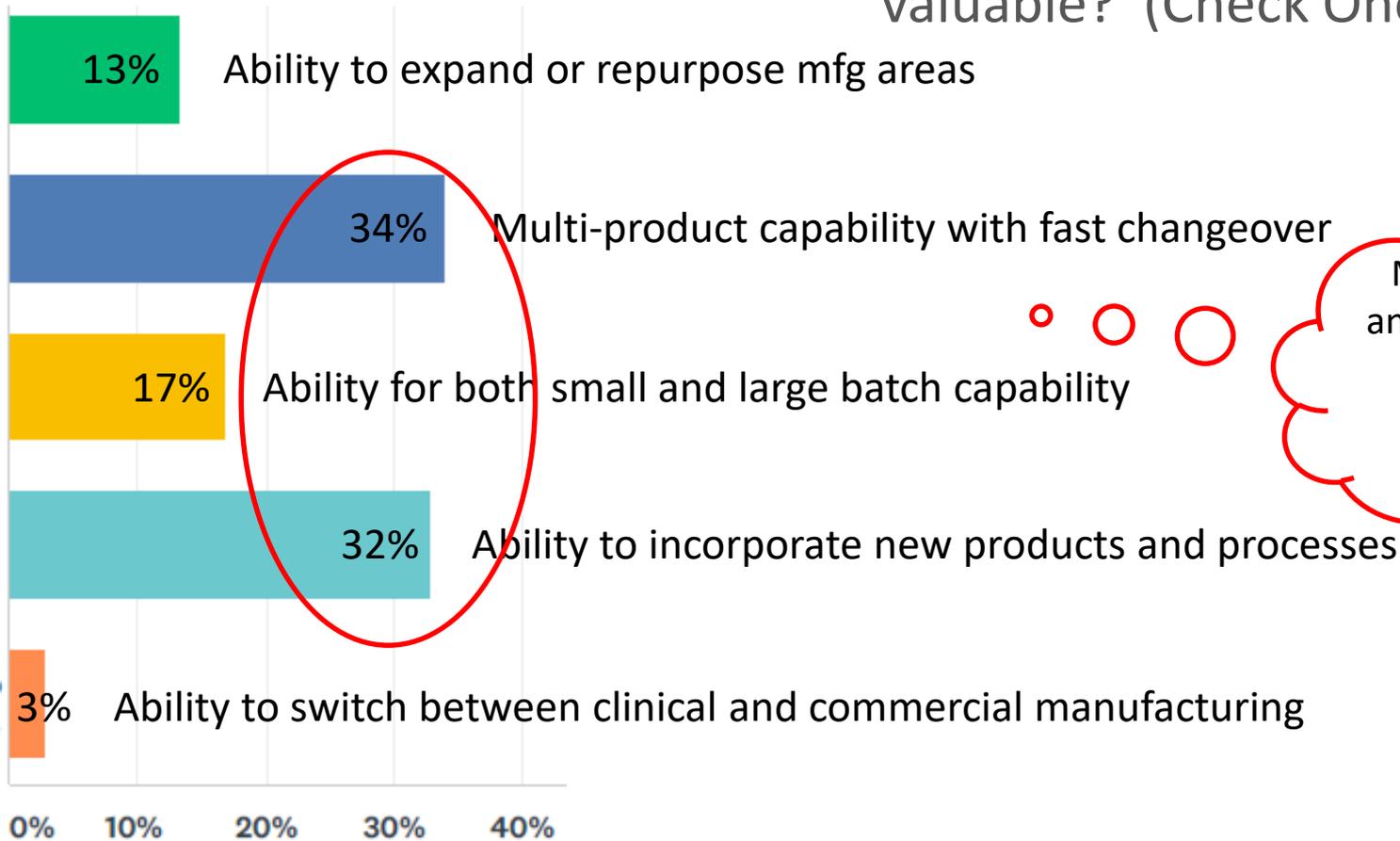


BioPharm	22%
Vaccines	7%
Small molecule	13%
Diagnostics	7%
Sterile drugs	10%
<u>Packaging & labeling</u>	<u>9%</u>
SUBTOTAL	69%
THE REST	31%



Value

Q3 What aspect of GMP facility flexibility do you consider the most valuable? (Check One)

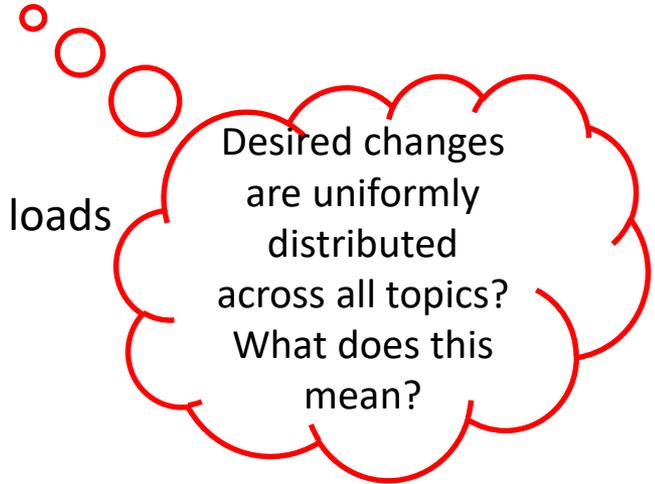
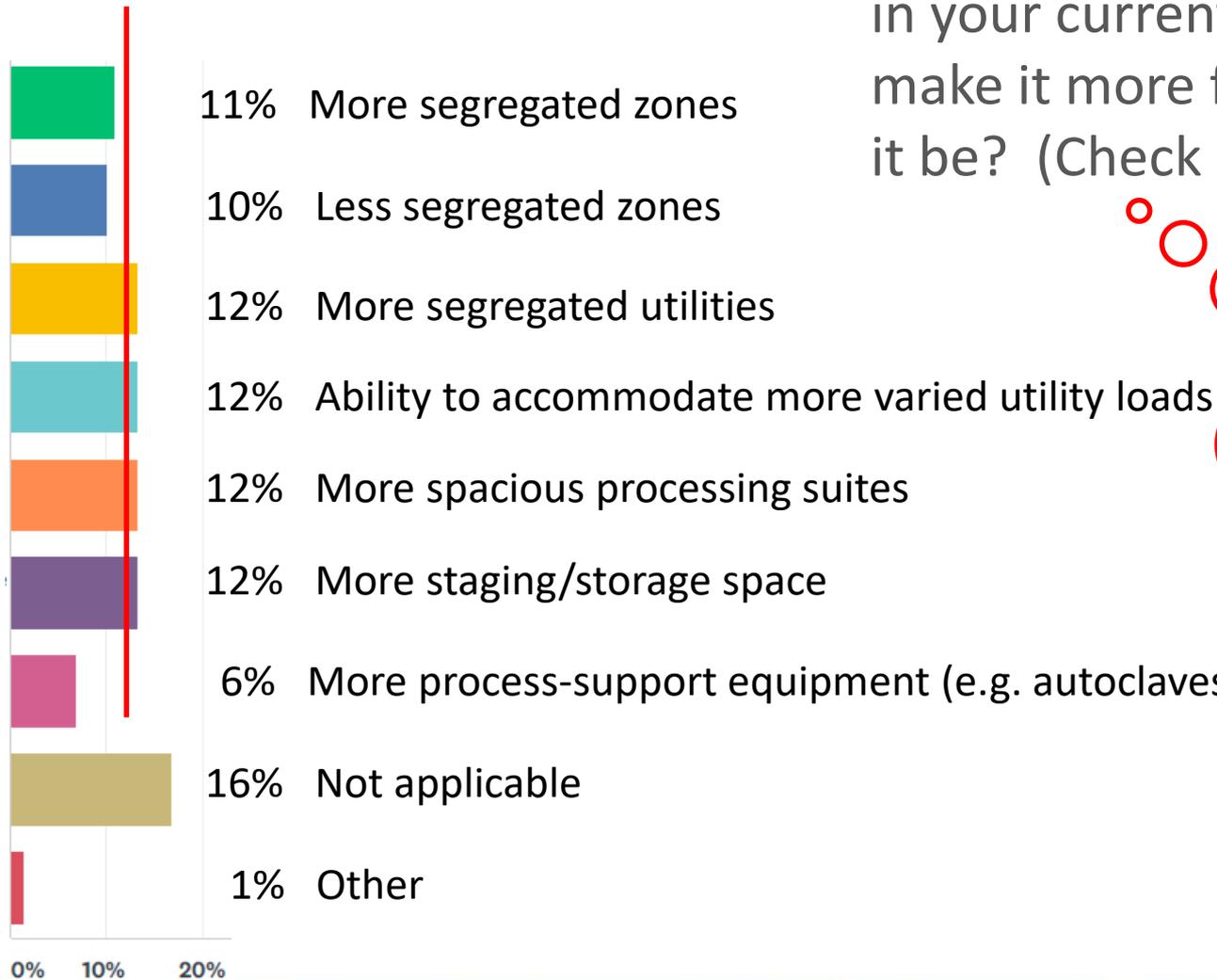


Multi-product and new product capabilities appear most valuable?



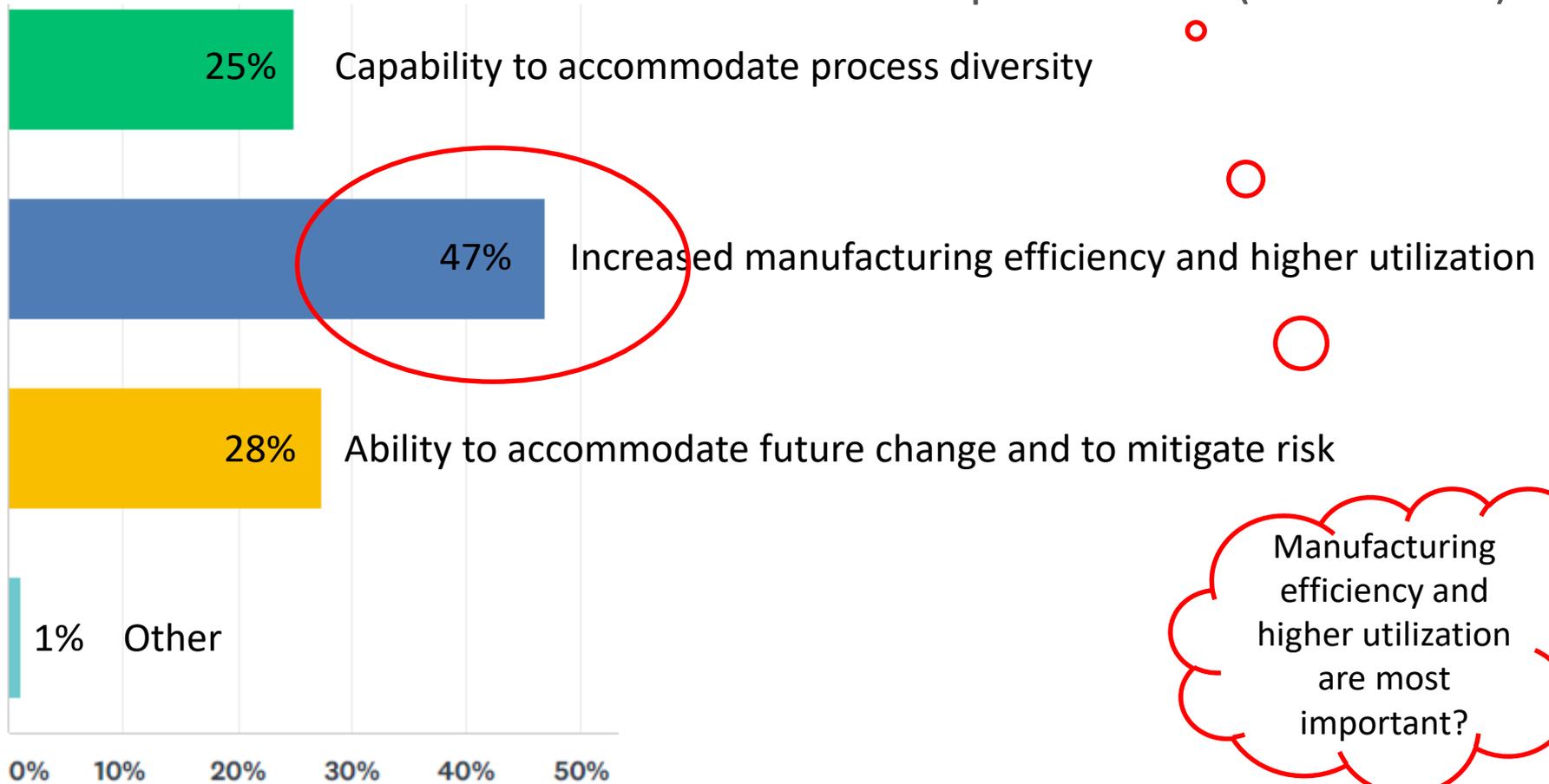
Changes

Q4 If you could change one thing in your current GMP facility to make it more flexible, what would it be? (Check One)



Benefits

Q5 What is the most important benefit of facility flexibility for GMP operations? (Check One)

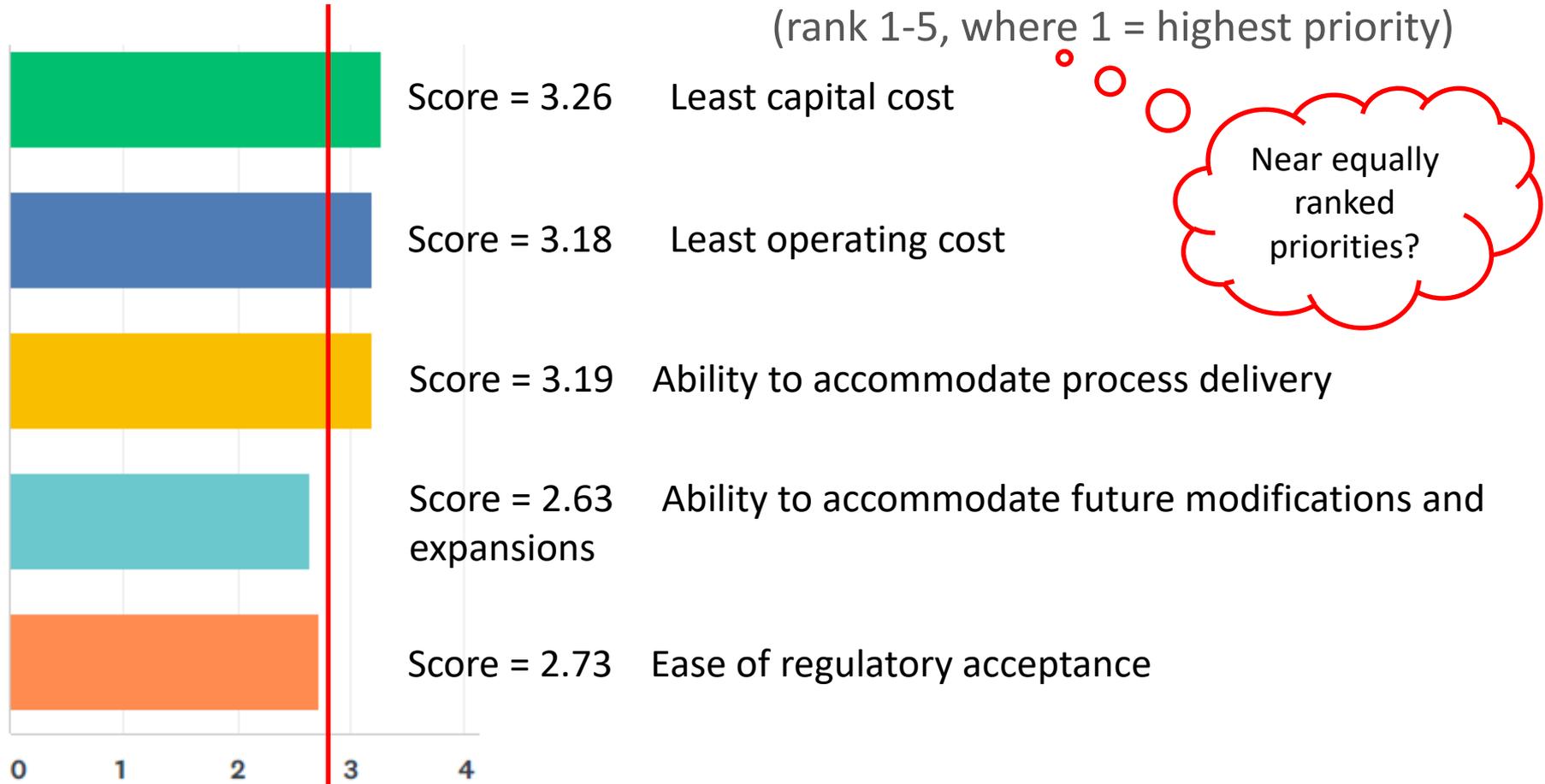


Manufacturing efficiency and higher utilization are most important?



Priorities

Q6 In your organization, please rank the typical project priorities associated with GMP facility renovations or expansions? (rank 1-5, where 1 = highest priority)

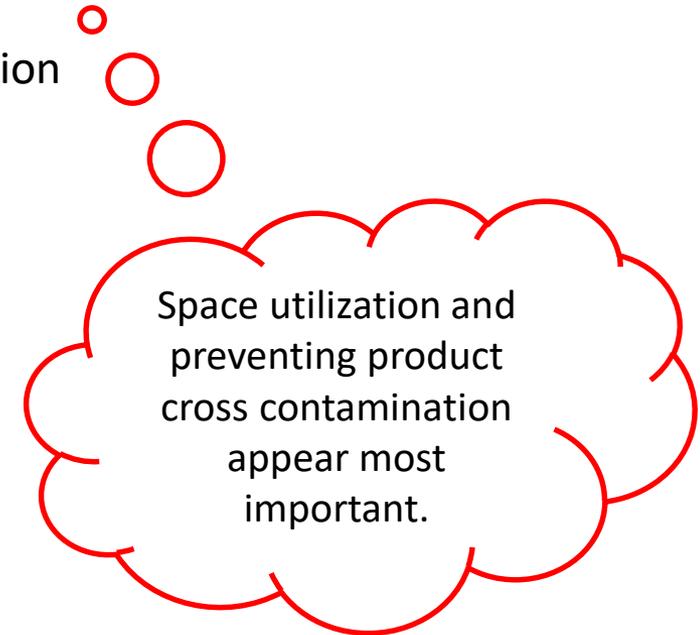
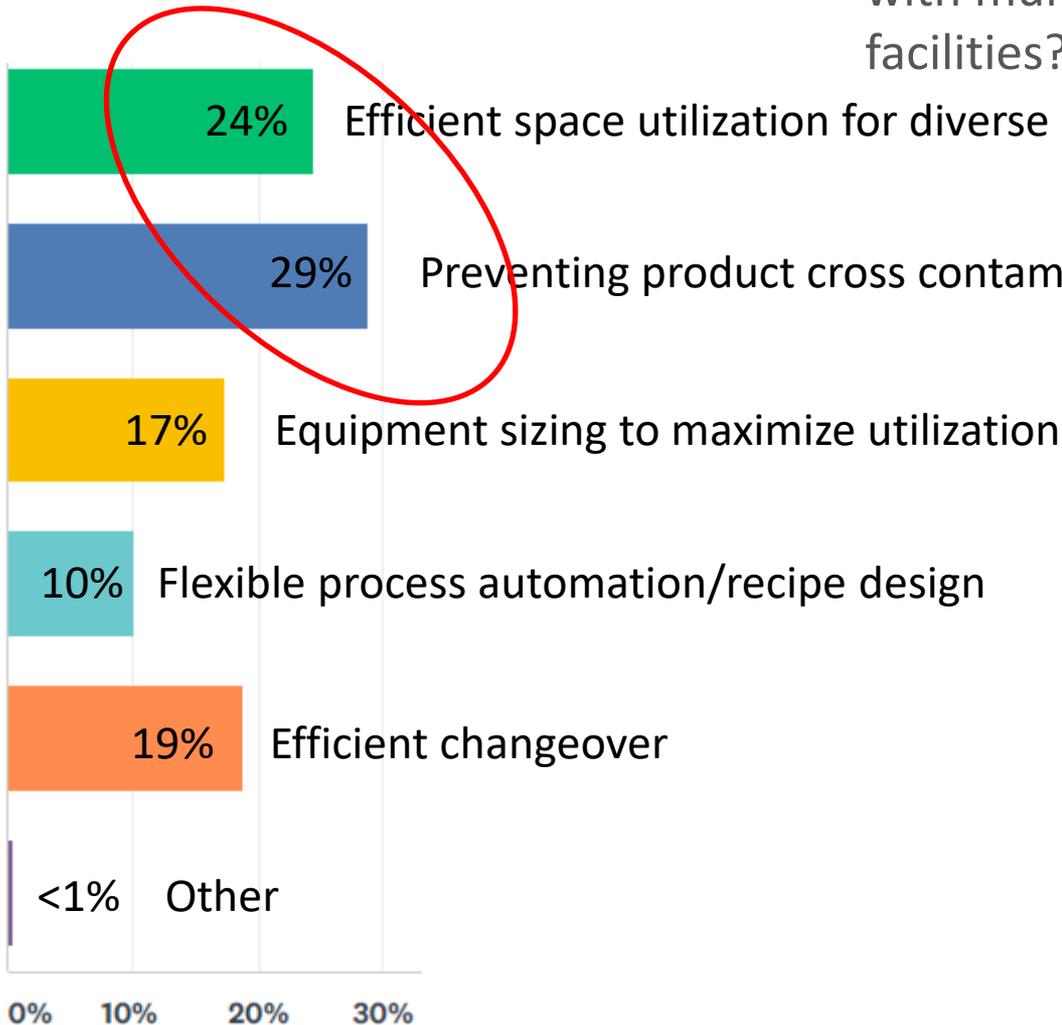


Near equally ranked priorities?



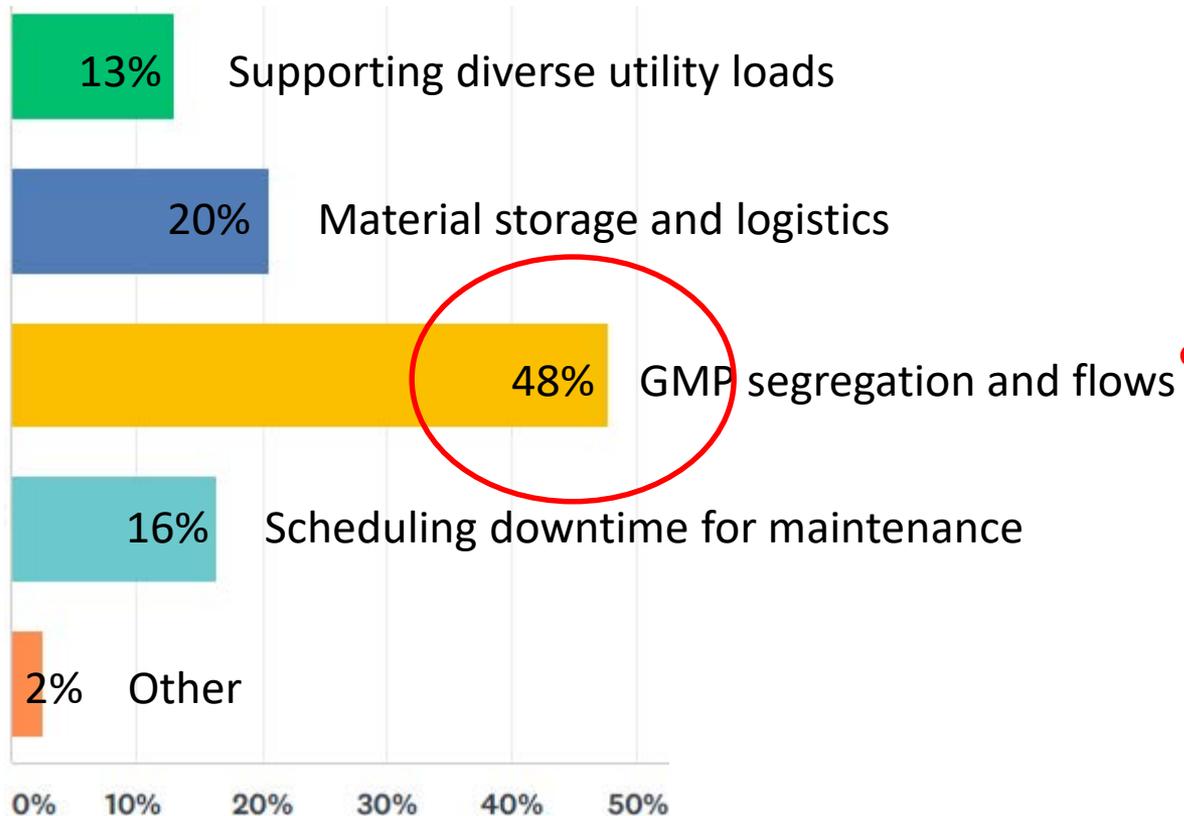
Priorities

Q7 What is the biggest challenge associated with multiproduct manufacturing in GMP facilities? (check one)



Difficulty

Q8 In terms of the demands on a facility, what is the most difficult aspect of multiproduct manufacturing? (check one)

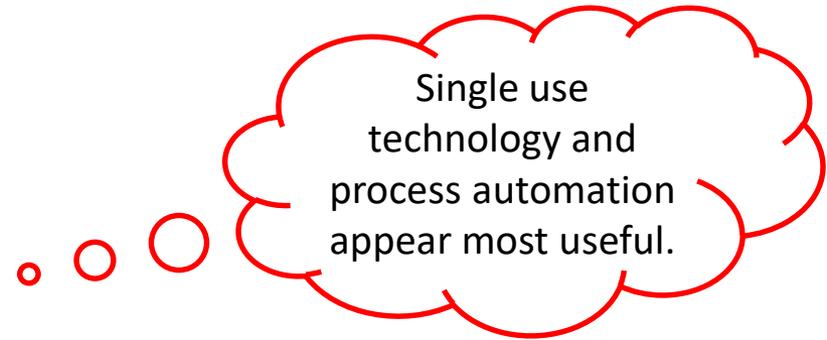
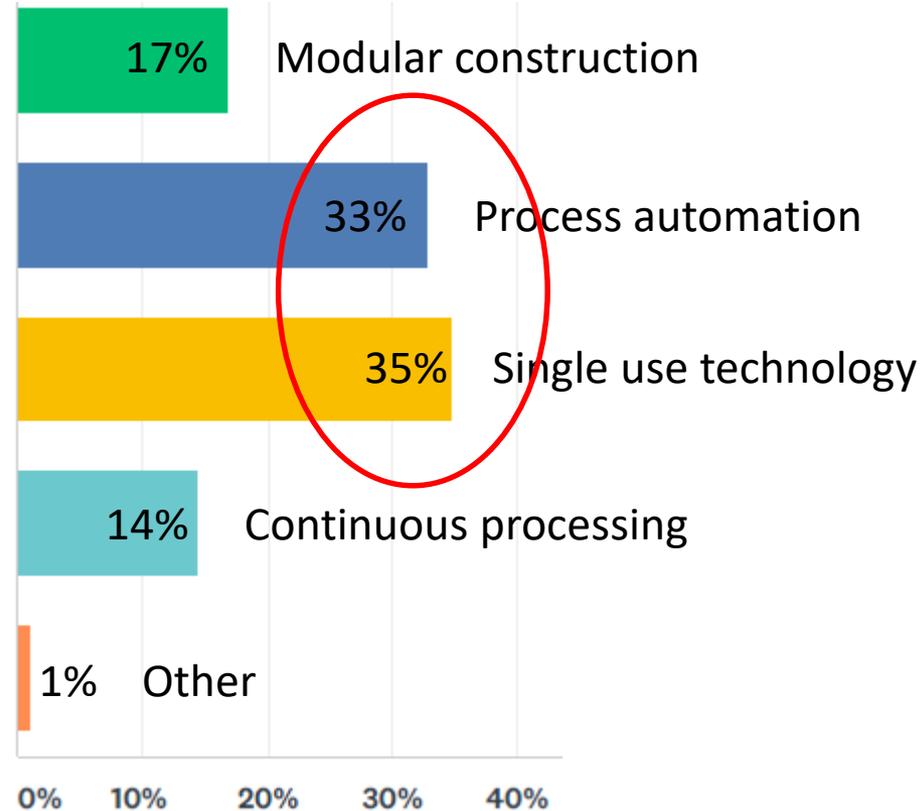


Maintaining GMP segregation and flows is most difficult

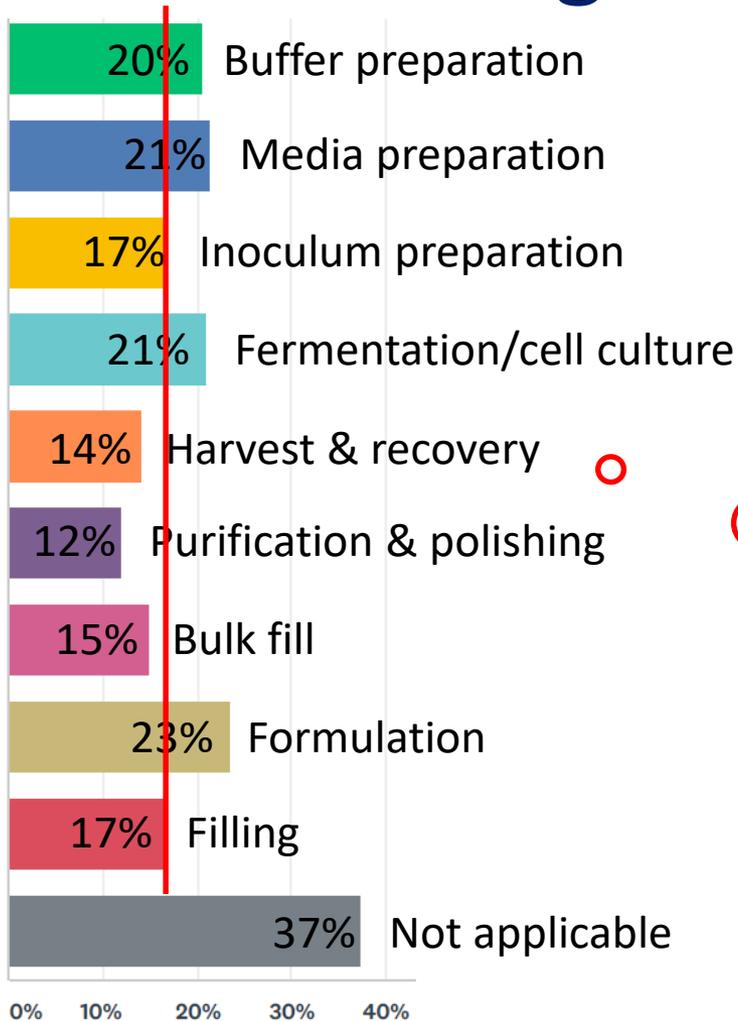


Technology

Q9 What do you consider the most useful technology to improve facility flexibility? (check one)



Single Use



Q10 In what areas of your cGMP process are you currently using single use technology exclusively (i.e., disposables in all product-contact applications)? (check all that apply)

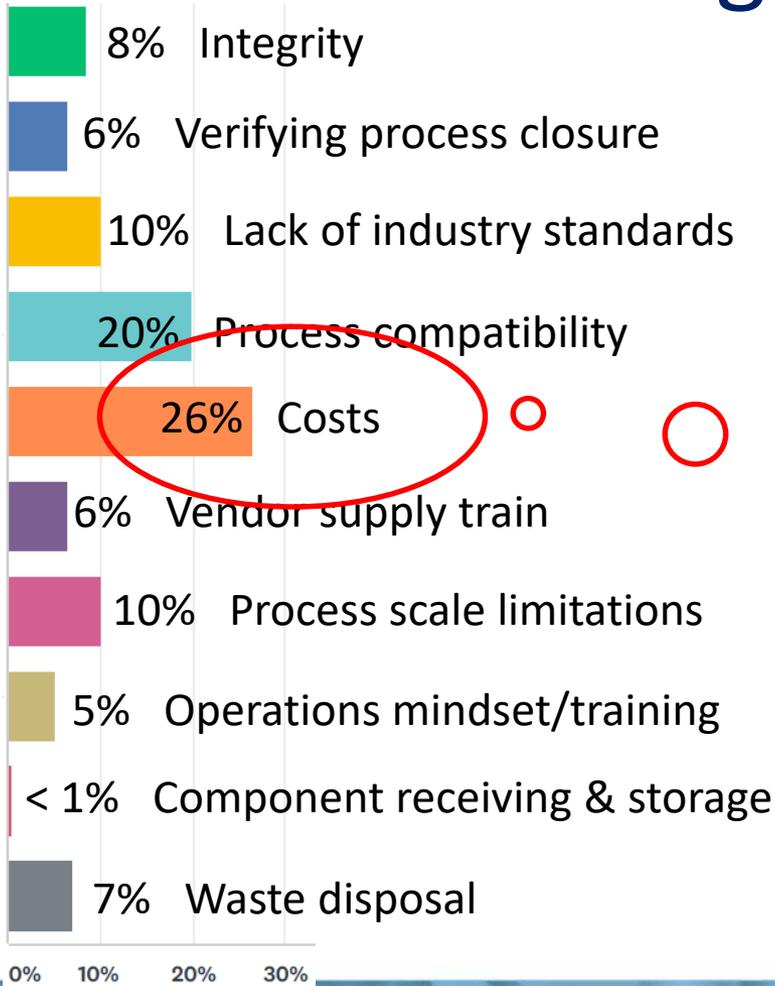


Single use technology is being used widely across all process steps.



SUD Challenges

Q11 What has been your most significant challenge associated with single use technology?

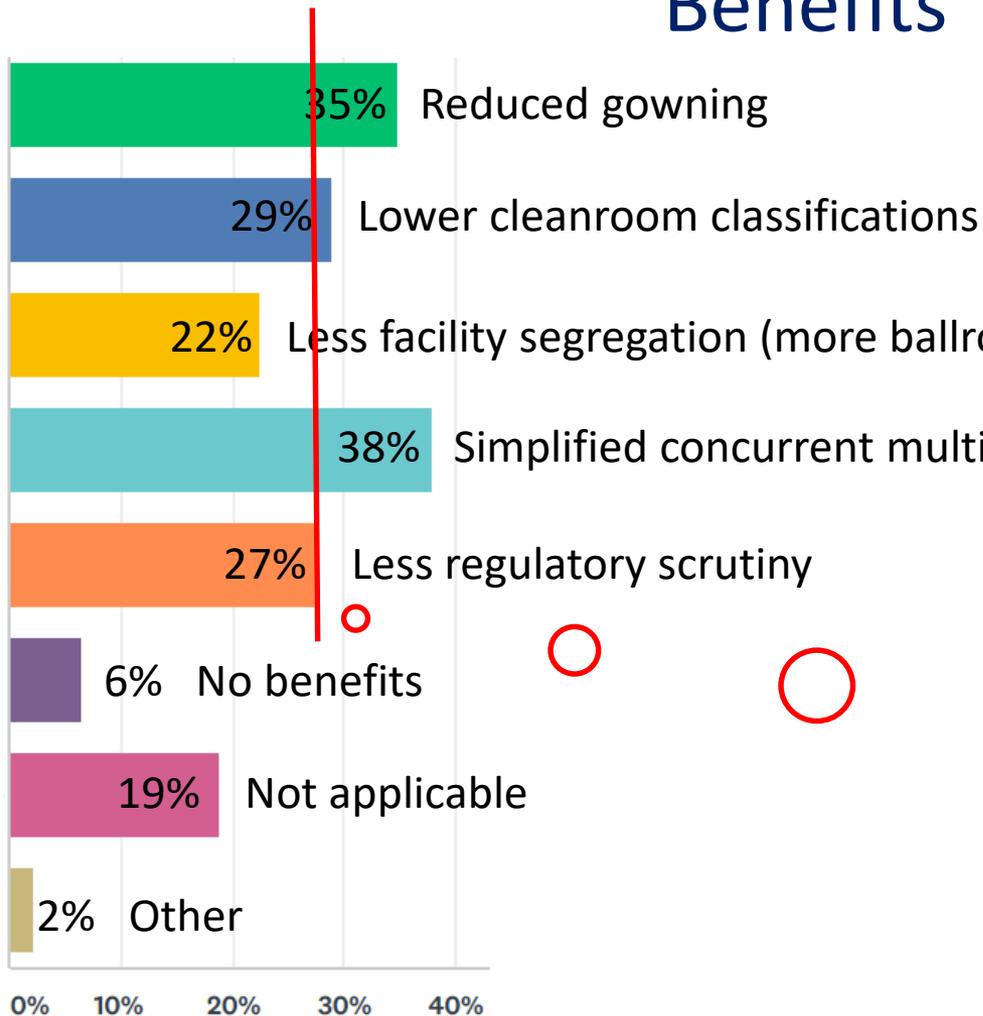


Not surprisingly ...
cost is the primary
challenge?

Is there anything else
notable about these
data?

Closed System Benefits

Q12 How would your company benefit if you converted all of your open GMP operations to closed processing (i.e., manufacturing under conditions where the product is never exposed to the surrounding environment)? (check all that apply)



It appears that closed processing offers benefits across the board.

Audience Input

- Was anything surprising?
- Any worries or concerns?
- What was useful?
- Did you change your mind about anything?
- What will you take back to your company?
- What did this survey miss?
- If the FDA were here, then what would you like them to hear from this survey?



Survey Overview



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Wrapup

- 66% indicated flexibility hinged mainly upon multi-product capability, fast changeovers and ease of new production introductions
- 47% indicated the biggest benefits of flexibility were manufacturing efficiency and higher utilization of assets
- Capital project priorities (CAPEX, OPEX, schedule, expandability and regulatory acceptance) were nearly equally ranked
- 53% indicated that the biggest challenges to multi-product facilities were efficient space utilization and prevention of cross contamination
- 48% indicated the most demanding aspect of operating a multiproduct facility is managing GMP segregation and flows
- 68% indicated the most useful technologies to improve flexibility were process automation and single use technology, over modular construction and continuous processing
- High costs were identified as the single biggest challenge for single use technology
- Closed system processing was polled to enhance nearly every step of sterile manufacturing



For More Information

- Learn more about DME Facility Focus
 - Available at www.dmeforallife.com/about-us/facility-focus
- Attend our next DME Facility Focus session!
 - *Session 2: RABS Retrofitting: Industry Best Practices*
 - Wednesday, April 18, 1:00-2:00pm, Stage 1, Booth 1076
- Contact Information
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