

PDA Research

IMPLEMENTATION OF THE NEW EU GMP
ANNEX 1 AND IMPLEMENTATION OF BARRIER
SYSTEMS Survey Results

August 2023



Connecting People, Science and Regulation®

PDA SURVEY:
Implementation of the
New EU GMP Annex 1 and
Implementation of Barrier
Systems Survey

August 2023

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Introduction

This survey was conducted to gather information on the implementation of the new EU GMP Annex 1 and implementation of barrier systems.

This was a blinded survey. The Survey opened on 19 July 2023 and closed on 11 Aug 2023. In cases where a respondent only completed the first 3 questions on general demographic information and no other information, the data was not included in the analysis.

General Demographic Information

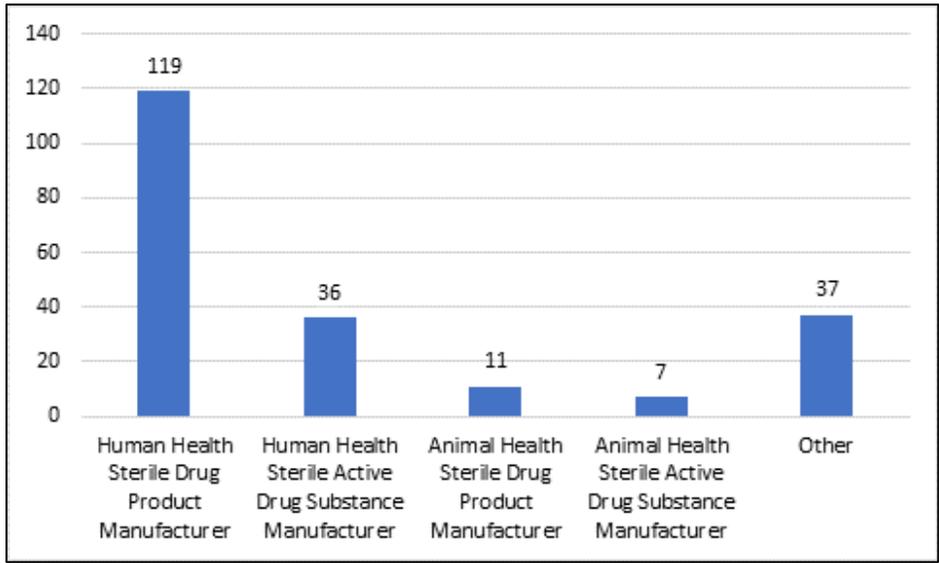
Question Q1

Q1. Which of the choices below best describes your company (select all that apply)?

<input type="checkbox"/> Human Health Sterile Drug Product Manufacturer	<input type="checkbox"/> Animal Health Sterile Drug Product Manufacturer	<input type="checkbox"/> Other <input type="text"/>
<input type="checkbox"/> Human Health Sterile Active Drug Substance Manufacturer	<input type="checkbox"/> Animal Health Sterile Active Drug Substance Manufacturer	

Results:

Respondents 169, with 20% of respondents choosing more than one response.



Other: Distributor for Sterile Drug Products; CDMO; Human Health Cell Therapy Manufacturer; Human Cell Therapy DS and DP; Equipment manufacturer; Pharma Equipment Manufacturer; Life Science Supplier; Reg agency; Reg, ATMP manufacturer; Cleanroom Consultant; Consulting to all of above; Safety Testing Service Provider of Human Drug products; Consultant; Gene Therapy, consulting; Non sterile API for sterile DP; Consultant; packaging for sterile products; Processing Equipment Supplier; Consulting service provider; Medical device; Virtual Combination Product Manufacturer; OEM for sterile fill/finish; Life Science Manufacturer/Supplier; Human Health low bioburden API Manufacturer; Contract Laboratory; CRO and drug discovery; Medical device; Contract Laboratory; consultancy for HH sterile DP manufacturer

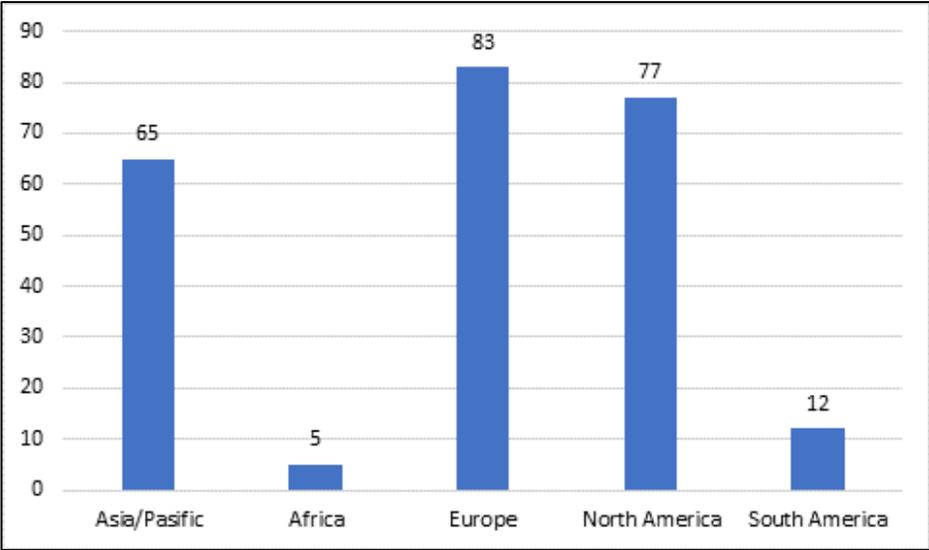
Question Q2

Q2. In what geographic region is your company's manufacturing facility or facilities located, that are included in this survey? (Select all that apply)

- Asia/Pacific
- Europe
- South America
- Africa
- North America

Results:

Respondents 169, with 22% of respondents choosing more than one response.



Question Q3

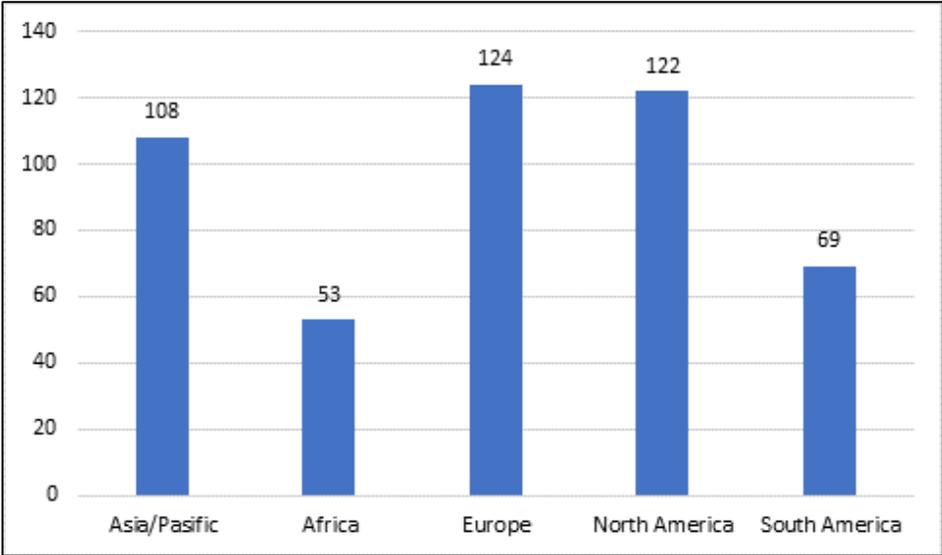
Q3. What geographic region(s) does your company's facility or facilities, included in this survey, provide product to?
(Select all that Apply)

Asia/Pacific Europe South America

Africa North America

Results:

Respondents 169, with 67% of respondents choosing more than one response.



Implementation of EU Annex 1 "Manufacture of Sterile Medicinal Products"

Question Q4

Q4. Will your company's facility(s), included in this survey, be in full compliance to the revised EU Annex 1 requirements that come into force on 25 August 2023?

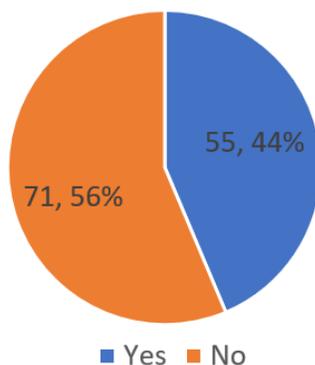
Yes

No

Do Not Know

Results:

Respondents 126 (no respondents selecting "Do Not Know")



Question Q4.a.

Respondents answering "No" to question Q4 above were presented with this question

Q4.a. Has your company had the opportunity to discuss any of the areas of non-compliance with the local regulatory authorities?

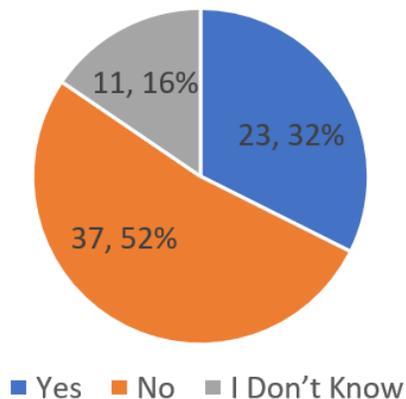
Yes

No

Do Not Know

Results:

Respondents 71



Question Q4.b.

Respondents answering "No" to Q4 were presented with this question

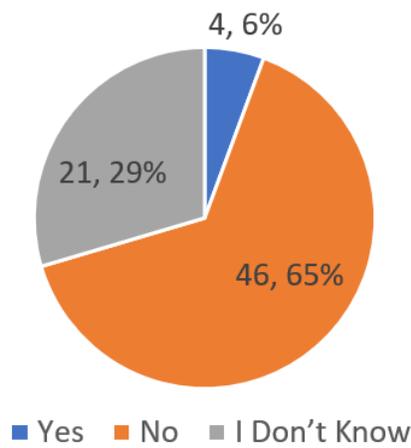
Respondents 71

Q4.b. Will there be any impact on the ability of the Qualified Person (or other Individual Authorized to Perform Product Release) to release product as a result of the non-compliance?

Yes No Do Not Know

Results:

Respondents 71



Question Q4.c.

Respondents answering "Yes" to Q4.b above were presented with this question

Q4.c. Will this impact on product release have a potential to impact product availability?

Yes No Do Not Know

Results:

Respondents 4

Yes - 2 respondents
No - 1 respondent
Do Not Know - 1 respondent

Implementation of Barrier Systems

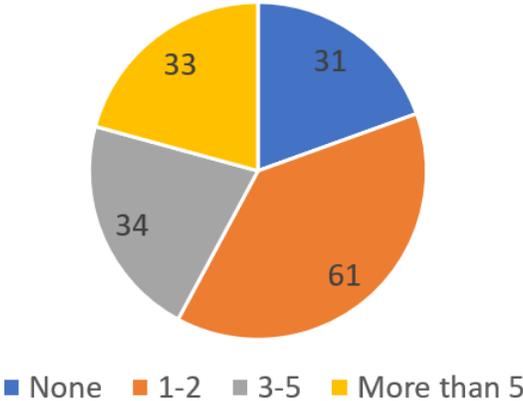
Question Q5

Q5. How many facilities does your company have that perform drug product aseptic filling operations?

None	1-2	3-5	More than 5
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Results:

Respondents 159



Question Q5.a.

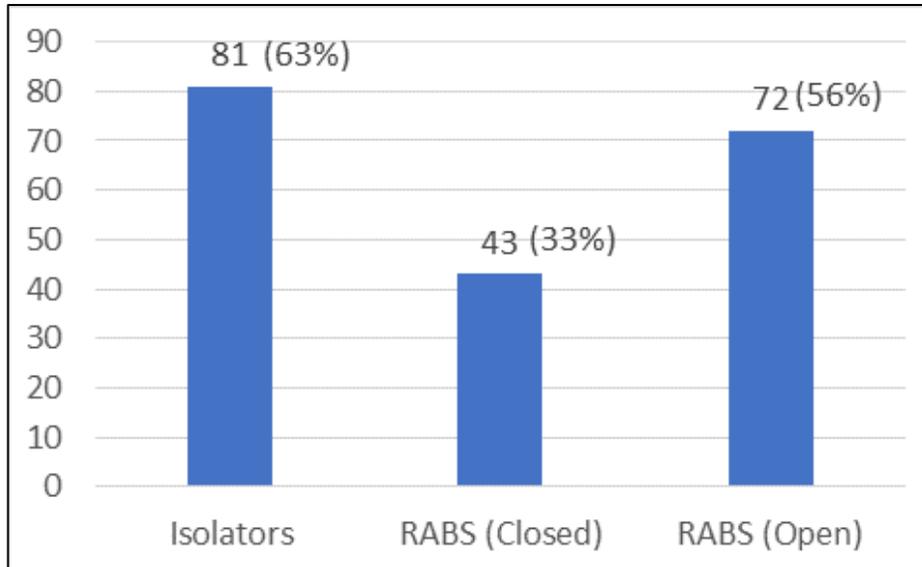
Respondents answering "1-2", "3-5", or "More than 5" to Q5.a above were presented with this question

Q5.a. If your company uses sterile product filling lines with barrier systems, which ones are in use (Select all the apply)?

- Isolators RABS (open) RABS (closed)

Results:

Respondents 129



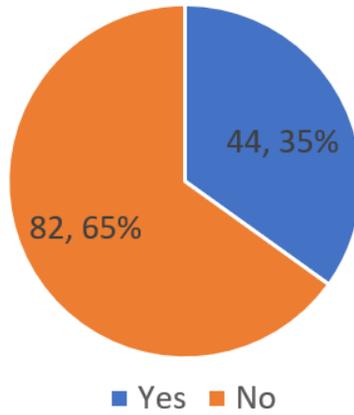
Question Q5.b.

Respondents answering "1-2", "3-5", or "More than 5" to Q5.a above were presented with this question

Q5.b. Does your company currently use any traditional sterile product filling lines that do not employ the used of an Isolator or RABS system?	
Yes <input type="radio"/>	No <input type="radio"/>

Results:

Respondents 126



Question Q5.c.

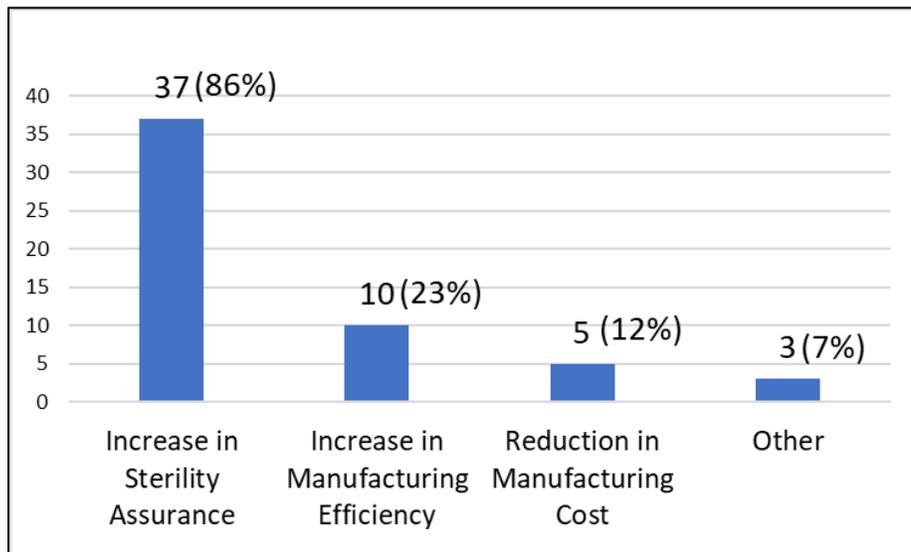
Respondents answering “Yes” to Q5.b above were presented with this question. Respondents were allowed to pick more than one answer.

Q5.c. If you were to evaluate moving to the use of more barrier systems (Isolators or RABS) which of the following would describe the main reason for the move:

- Increase in Sterility Assurance
- Increase in Manufacturing Efficiency
- Reduction in Manufacturing Cost
- Other

Results:

Respondents 43



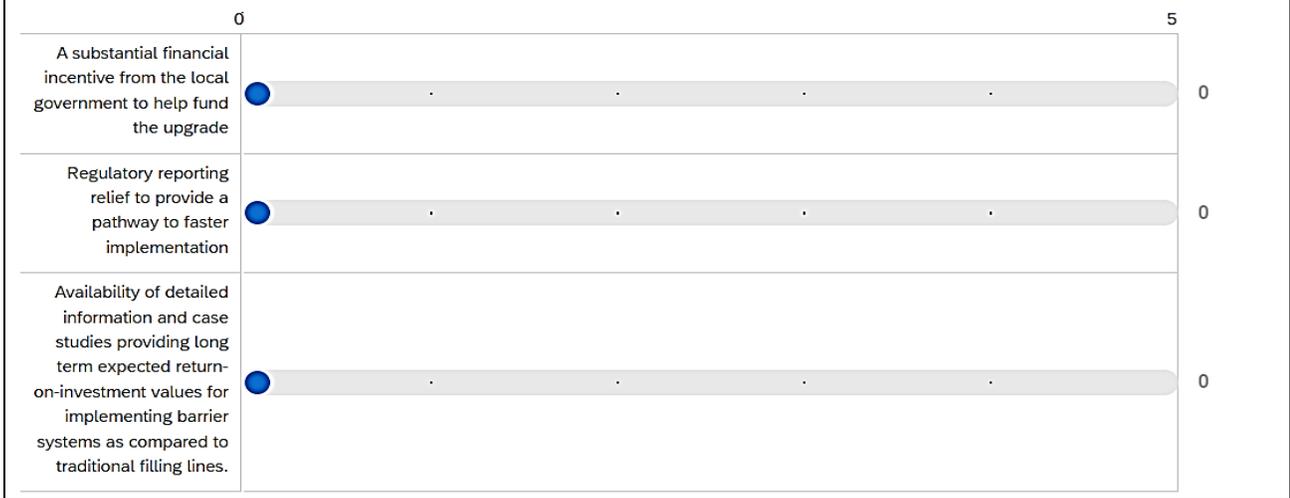
Other: Reason would be strictly because of these onerous regulations; Regulations; Annex 1

Question Q5.d.

Respondents answering “Yes” in Q5.b were presented with this question. For this question the default starting value was set to zero for each slider.

Q5.d. If you were to evaluate upgrading your traditional sterile product filling lines to filling lines with barrier systems (Isolators and RABS) would any of the factors below, if available, increase the likelihood that your company would implement these systems?

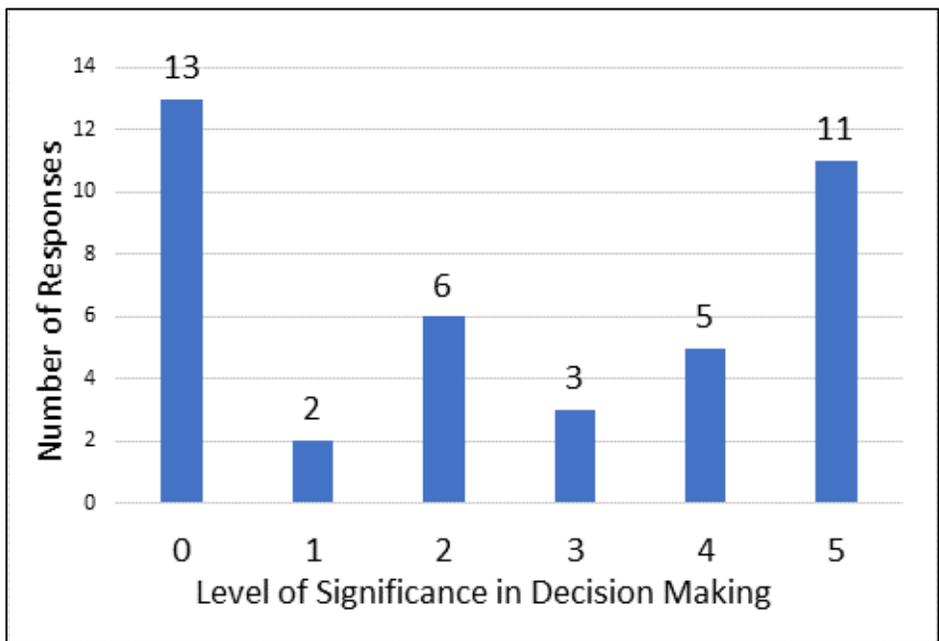
(Where: 0 = No Role in the Decision and 5 = Significant Role in the Decision)



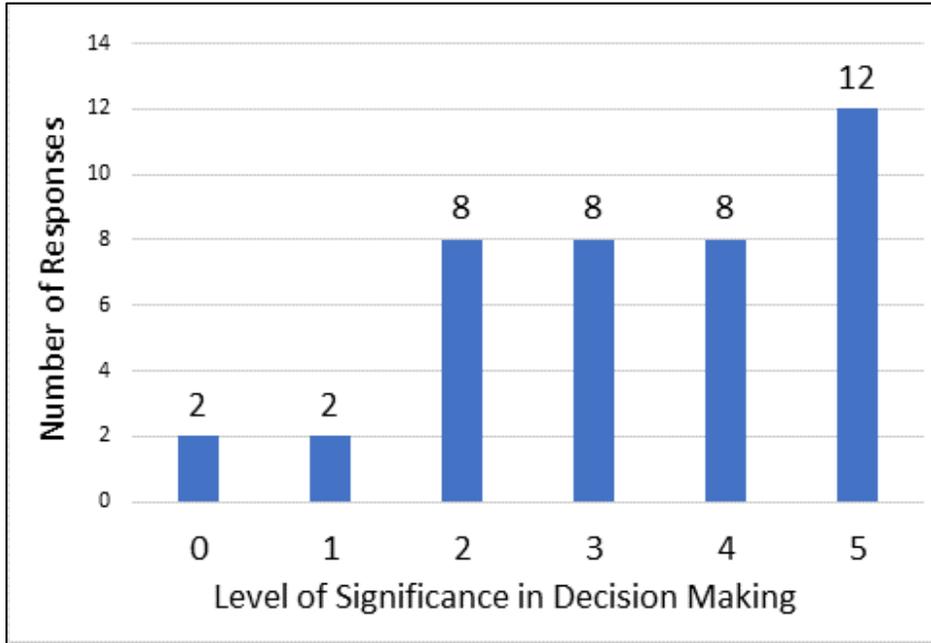
Results:

Respondents 40

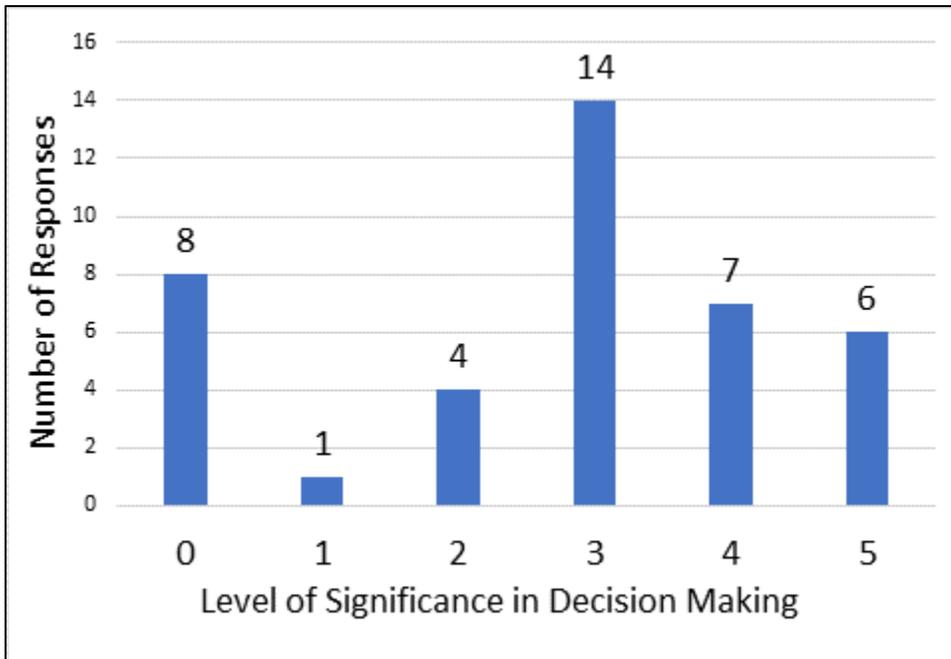
- Substantial financial incentive from the local government to help fund the upgrade



- Regulatory reporting relief to provide a pathway to faster implementation



- Availability of detailed information and case studies providing long term expected return-on-investment values for implementing barrier systems as compared to traditional filling lines





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