Text of online GMP Pharma Survey

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Start of Section: Front Matter

Purpose of this survey

The primary purpose of this survey is to obtain current, industry-wide data on how facilities that **process** drug products ensure the quality of their operations, including current risk management approaches and practices for ensuring the quality and suitability of drug components, containers, and closures used by drug **processors**.

How your company's information will be treated

Please note that your responses and your company's participation in this survey are **PRIVATE**. An FDA contractor, Eastern Research Group, Inc. (ERG), is administering this survey. ERG will report aggregated data to FDA; individual responses to questions will not be shared with FDA. ERG will not identify any individual or company to FDA, nor will they provide information that enables the identification of a respondent company. No individual person or individual company will be identified in any public or internal report issued by the contractor. Your information will be kept secure to the extent permitted by law. The survey is unrelated to any enforcement activity.

How FDA will use the results of this survey

FDA intends to use this information to inform its understanding of human and animal drug production and **processing** practices and provide objective information for use in policy evaluations and possible future policy-making. Your survey responses will be aggregated with those of other companies to improve FDA's understanding of the range of industry practices. More specifically, FDA wishes to learn how processors of drug products approach managing risks, to better understand the supply chains linking producers of raw materials and product manufacturers, and to better understand general quality management practices.

IMPORTANT: MANY OF THE QUESTIONS ASK ABOUT ACTIVITIES AT "YOUR FACILITY." IF YOUR FACILITY COMPRISES ONLY ADMINISTRATIVE OFFICES, PLEASE REFER TO YOUR COMPANY'S PRIMARY DRUG PROCESSING FACILITY WHEN RESPONDING TO QUESTIONS ABOUT "YOUR FACILITY."

If you DON'T KNOW the correct response to a question, please ask for input from someone else knowledgeable about your facility's operations.
If you are NOT SURE how to interpret a question or what information is being requested, please (1) Call the survey helpline at 1-800-XXX-XXXX or (2) send an email to MyGMPsurvey@erg.com**.**

Start of Section: YOUR FACILITY Q1-Q7

Place your cursor over a **blue phrase** to see a popup definition.

For this survey the term **process** or **processing** means any one of, or any combination of, MANUFACTURING, PACKING or RE-PACKING, LABELING or RE-LABELING, TESTING, and/or STERILIZING any form prescription or OTC drug for use by humans or animals.

☐ **CHECK HERE IF YOUR FACILITY COMPRISES ONLY ADMINISTRATIVE OFFICES. PLEASE REFER TO YOUR COMPANY'S PRIMARY DRUG PROCESSING FACILITY WHEN RESPONDING TO QUESTIONS BELOW ABOUT "YOUR FACILITY."**

1. For each of the types of drug products in the left-hand column below, check the appropriate box if your facility manufactures, packs/re-packs, labels/re-labels, tests, or sterilizes that type of product at your facility at {…}.

Please check (✔) all that apply.

	Processing activity at your facility				
	Manufacturing	Packing or Re-packing	Labeling or Re-labeling	Testing	Sterilizing
Rx Drugs for Humans	☐	☐	☐	☐	☐
OTC Drugs for Humans	☐	☐	☐	☐	☐
Rx Drugs for Animals	☐	☐	☐	☐	☐
OTC Drugs for Animals	☐	☐	☐	☐	☐
Other, please specify:	_____				

☐ **Check (✔) here if you do not do any of the above activities.**

[IF CHECKED, ASK Q2 THROUGH 7, THEN SKIP TO END]

2. Is your facility in the United States?

○ YES ○ NO

3. Are any of the drug products that your facility processes marketed …

3.1. … In the United States?

○ YES ○ NO ○ DON'T KNOW

3.2. …Outside of the United States?

○ YES ○ NO ○ DON'T KNOW

[IF NO TO Q3.1, SKIP TO END AFTER Q7.]

4. What is your facility's main business activity? _____

5. Approximately how many employees work at your facility?

○ 1-19 employees
○ 20-99 employees
○ 100-499 employees
○ 500 or more employees

By **parent company**, we mean the company that controls the management and operations of your facility; the company of which your facility or company is a subsidiary.

By **gross revenue**, we mean the total earnings of a company through sales, services, and any other income generating activity, before expenses such as labor and material costs, taxes, interest, etc. are deducted.

6. Does your parent company (including all manufacturing, packaging, labeling, testing, sterilization, and administration facilities) have more than 1,250 employees?

○ YES, the company as a whole has more than 1,250 employees.
○ NO, the company as a whole has less than 1,250 employees.

7. Please indicate your parent company's approximate gross revenue in your last fiscal year.

○ Less than $1 million
○ > $1 million to $10 million
○ > $10 million to $50 million
○ > $50 million to $250 million
○ > $250 million to $1 billion
○ > $1 billion to $10 billion
○ Over $10 billion

End of Section: YOUR FACILITY Q1-Q7

By management with executive responsibility, we mean any employee who has the authority to provide resources, to establish or make changes to organizational structure, buildings, facilities, equipment, or the manufacture, processing, packing, or holding of a drug product.

8. Do you have management with executive responsibility assure drug quality or the quality of your processes?

O YES O NO O DON'T KNOW

9. How does management with executive responsibility assure drug quality or the quality of your processes?
Please check (✔) all that apply.

At our facility, management personnel with executive responsibility…
O …Participate in routine batch record review and batch release decision-making.
O …Participate in developing a corrective action response plan or in reviewing such plans.
O …Review data to determine the need for preventive actions (e.g., maintenance, facility improvements, **process** optimization, utility upgrades, organization, staffing levels) to maintain high product or **process** quality.
O …Evaluate new policies issued by regulatory agencies that impact drug quality-related operations to ensure ongoing compliance.
O …Bear primary responsibility for routinely evaluating trends in quality-related data to determine the need for corrective or preventive actions.
O …Other *(please describe)* _____

By **joint review meetings**, we mean meetings scheduled between members of facility executive management, departmental managers, and shop floor personnel meant to discuss, anticipate, and inform everyone about current and potential issues.

10. At your facility, are there periodic joint review meetings between management with executive responsibility and the manufacturing or other processing divisions or departments at the facility?

O YES O NO O DON'T KNOW

11. Who usually attends these joint review meetings, aside from management with executive responsibility?
Please (✔) check all that apply.
O Managers of divisions or departments at the facility, including managers from:
- O Production
- O Lab
- O Packaging/labeling
- O Product testing
- O Product sterilizing

- ○ Materials/component purchasing
- ○ Quality control
- ○ Quality assurance
- ○ Warehousing
- ○ Operations
- ○ Workplace health and safety personnel

○ Floor employees from divisions or departments

Other (*please describe*) _____

12. Do you have written procedures that address the scope and scheduling of these periodic joint review meetings between management with executive responsibility and the respective divisions or departments within the establishment?

○ YES ○ NO ○ DON'T KNOW

13.1. Are these written procedures easily available to facility personnel?

○ YES ○ NO ○ DON'T KNOW

13.2. Are these written procedures reviewed periodically for potential revisions?

○ YES ○ NO ○ DON'T KNOW

14. Is management with executive responsibility routinely made aware of any data or trends that might negatively impact quality?

○ YES ○ NO ○ DON'T KNOW

15. Do you have written procedures prescribing how negative quality-related data or trends are reported to management with executive responsibility?

○ YES ○ NO ○ DON'T KNOW

End of Section: 211.20: Mgmt Resp (Q8-Q15)

Start of Section: 211.22: Resp Quality Unit (Q16-Q23)

REMINDER: **In the following questions, "Processing" includes manufacturing, packing/re-packing, labeling/re-labeling, testing, and/or sterilizing of drug products.**

16. Is there a Quality Unit at your processing facility that has the authority to make final determinations, independent of other departments?

○ YES ○ NO ○ DON'T KNOW

By **drug product component**, we mean each active pharmaceutical ingredient and inactive agent (including fillers and coloring agents) that are combined to form a drug product.

By **drug product containers and closures**, we mean the packaging that contains and protects the drug product as it is marketed and delivered to end-user health care providers.

17. For each of the following items, does your Quality Unit have the responsibility and authority to segregate and dispose of any products that deviate from or do not conform to specified requirements or in-process test requirements?
Please (✔) check YES or NO for each of the items listed below.

	YES	NO	DOES NOT APPLY
Drug product component	○	○	○
Drug product container and closure	○	○	○
Labeling	○	○	○
Drug products	○	○	○

If you checked DOES NOT APPLY, please explain: _____

18. For each of the following items, if a quality or compliance deviation is discovered, what does your facility consider a reasonable time for segregating affected items from the production area?

	Within 1 hour	Within 24 hours	Does not apply	Don't know
Drug product component	○	○	○	○
Drug product container and closure	○	○	○	○
Labeling	○	○	○	○
Drug products	○	○	○	○

19. Does your Quality Unit have the responsibility and authority to verify that an <u>appropriate and timely investigation</u> is performed if …

	YES	NO	N/A	DON'T KNOW
…***a drug product component*** fails to conform to specified requirements or any other test?	○	○	○	○
… ***a drug product container and closure*** fails to conform to specified requirements or any other test?	○	○	○	○
… ***labeling*** fails to conform to specified requirements, including accuracy and legibility?	○	○	○	○
… ***a drug product*** fails to conform to specified requirements, including any in-**process** test?	○	○	○	○

20. For each of the following items, how does your processing facility define "timely manner" for initiating an appropriate investigation into quality problems with:

	Within a day	Within a week	Within a month	Does not apply	Don't know
Drug product component	○	○	○	○	○
Drug product container and closure	○	○	○	○	○
Labeling	○	○	○	○	○
Drug products	○	○	○	○	○

21. Does your facility process drug products on a contractual basis for other companies?

○ YES ○ NO ○ DON'T KNOW

22. For your contract processing, are the roles and responsibilities defined in writing?

○ YES ○ NO ○ DON'T KNOW

23. For drug products that your facility processes under contract with another company, does the product owner's Quality Unit approve or reject those drug products?

○ YES ○ YES, FOR SOME, BUT NOT ALL ○ NO ○ DON'T KNOW

End of Section: 211.22: Resp Quality Unit (Q16-Q23)

Start of Section: 211.25: Personnel Quals (Q24-Q26)

24. Does your facility or parent company train all employees that supervise or perform manufacturing, packing/re-packing, labeling/re-labeling, testing, or sterilizing of drug products?
Please (✓) check all that apply.

- ○ YES, EMPLOYEES ARE TRAINED BY PARENT COMPANY
- ○ YES, EMPLOYEES ARE TRAINED BY FACILITY
- ○ NO
- ○ DON'T KNOW

OTHER (PLEASE EXPLAIN) _____

25. Does your facility maintain written documentation of this training?

○ YES ○ NO ○ DON'T KNOW

26. Does this written documentation include any of the following elements for each employee trained?

Date(s) of training	○ YES	○ NO
Type of training	○ YES	○ NO
Completion criteria	○ YES	○ NO
Test results (if applicable)	○ YES	○ NO
Other (please describe):	○ YES	○ NO

End of Section: 211.25: Personnel Quals (Q24-Q26)

Start of Section: 211.48: Plumbing (Q27-Q33)

In the following questions, **potable water** means water supplied to the facility that is safe for humans and animals to drink without risk of harm.

27. Does the potable water supplied to your facility meet EPA 40 CFR 141 or an equivalent drinking water quality standard?

○ YES ○ NO ○ DON'T KNOW

28. If you use a standard other than EPA 40 CFR 141, what standard do you use?

_____

29. Does your facility have risk-based procedures for monitoring the quality of potable water used in your facility?

○ YES ○ NO ○ DON'T KNOW

30. Are the procedures for monitoring the quality of potable water written?

O YES O NO O DON'T KNOW

31. Do you identify and control for potential hazards to the quality of potable water used in your facility in addition to the minimum standard for potable water?

O YES O NO O DON'T KNOW

32. Is appropriate testing in place to monitor for potential hazards to potable water used in your facility?

O YES O NO O DON'T KNOW

33. Does your facility maintain the records of your monitoring of potable water?

O YES O NO O DON'T KNOW

End of Section: 211.48: Plumbing (Q27-Q33)

Start of Section: 211.80: Water as a DPC (Q34-Q41)

SCREENER: DOES YOUR FACILITY USE WATER IN *ANY* OF YOUR PROCESSES OR AS A FINAL RINSE AFTER CLEANING DRUG PROCESSING EQUIPMENT?

O YES O NO O DON'T KNOW

[IF NO TO SCREENER, SKIP TO 42A]

34. Does your facility process drinking water (potable water) into any specific type of water to be used for other purposes?

O YES O NO O DON'T KNOW

35. For each of the specialized types of water in the left-hand column below, do you make that type of water at your facility?
Please check (✓) YES or NO for each item below.

	YES	NO	DON'T KNOW
a. Purified water	O	O	O
b. Water for injection	O	O	O
c. Water for use as a **drug product component**	O	O	O
d. Water to be used for final rinsing of equipment after cleaning	O	O	O
e. Other *(please describe)*: _____			

36. Does the purified water that you use at your facility meet the USP monograph for purified water?

O YES O NO O DON'T KNOW/NOT SURE

O DOES NOT APPLY (Please explain): _____

37. What are your requirements for ${Q35/ChoiceTextEntryValue/6}? Please specify.

_____

38. For each of the specialized types of water in the left hand column below, does your drug product processing facility maintain written manufacturing procedures and quality standards for that type of water?
Please check (✓) N/A (NOT APPLICABLE) if your facility does not use that type of water. Please check (✓) DK (DON'T KNOW) if appropriate.

	YES	NO	N/A	DON'T KNOW
a. Purified water	O	O	O	O
b. Water for injection	O	O	O	O
c. Water for use as a drug product component	O	O	O	O
d. Water to be used for final rinsing of equipment after cleaning	O	O	O	O
e. Other (please describe): _____				

39. For the types of water that you produce at your facility, have you validated the water purification/treatment procedure to ensure that the water as used meets pre-established specifications?

O YES O NO O DON'T KNOW/NOT SURE

40. Is the quality of the water at your facility routinely monitored?

	YES	NO	This type of water is not used at this facility.	DON'T KNOW
a. Potable (drinking) water	○	○	○	○
b. Purified water	○	○	○	○
c. Water for injection	○	○	○	○
d. Water for use as a **drug product component**	○	○	○	○
e. Water to be used for final rinsing of equipment after cleaning	○	○	○	○

f. Other *(please describe)*: _____

41. Is the approach you take to monitoring the water used in your drug product processing facility a part of your overall risk assessment?
The approach you take to monitoring would include things like location of monitoring, frequency of monitoring, and types of tests performed.

○ YES ○ NO ○ DON'T KNOW/NOT SURE

End of Section: 211.80: Water as a DPC (Q34-Q41)
Start of Section: Combined DPC and DPCC Quality and Safety (Q42-Q73)

42a. DOES YOUR FACILITY RECEIVE ANY SHIPMENTS OF ANY DRUG PRODUCT COMPONENTS FOR USE IN YOUR OPERATIONS? By **drug product component**, we mean each active pharmaceutical ingredient and inactive agent (including fillers and coloring agents) that are combined to form a drug product.

○ YES ○ NO

42b. DOES YOUR FACILITY RECEIVE ANY SHIPMENTS OF ANY DRUG PRODUCT CONTAINERS AND CLOSURES FOR USE IN YOUR OPERATIONS? By **drug product containers and closures**, we mean the packaging that contains and protects the drug product as it is marketed and delivered to end-user health care providers.

○ YES ○ NO

[IF NO TO BOTH 42A AND 42B]: Based on your previous responses, you are being skipped past some questions that do not apply to your facility.]

An effective **supplier qualification program** includes determining expectations and requirements, identifying potential suppliers, evaluating them, selecting a supplier, and re-evaluating the selected suppliers, and, if issues arise, communicating with the supplier and managing corrective action. The major purposes are: (1) to determine who is good enough to start doing business with; and (2) who the company should continue to do business with.

43. At your facility, do you have a supplier qualification program for your suppliers of...

...drug product components? ○ YES ○ NO

...drug product containers/closures? ○ YES ○ NO

44. Regarding the quality and safety of the drug product components and/or **drug product containers and closures** used in the processes at your facility, *please check YES or NO for each statement below*.

	Drug product components		**Drug product containers/closures**	
	YES	NO	YES	NO
*Our **supplier qualification program** allows for:* **44a. Reduced testing of new drug product components and/or new containers/closures shipped to us by qualified suppliers.**	○	○	○	○
*Our **supplier qualification program** allows for:* **44b. Reduced testing of repeat shipments of drug product components and/or containers/closures from suppliers after they are qualified.**	○	○	○	○
44c. We perform complete testing of every shipment of all drug product components and/or containers/closures before using them in manufacturing or packing.	○	○	○	○

45. Who qualifies the suppliers of your...

	Please check (✔) all that apply.			If other, Please describe:
	Facility personnel	Parent company personnel	Other	
...drug product components?				
...drug product containers and closures?				

46. Are you or other facility personnel knowledgeable about your parent company's procedures when qualifying the suppliers of …

...drug product components? O YES O NO O DON'T KNOW

...drug product containers/closures? O YES O NO O DON'T KNOW

47. What steps does your facility (or your parent company) take when initially qualifying a **new supplier** of a **drug product component** and/or **container/closure**?
Please check (✓) a response for each statement below.

	Drug product components				**Drug product containers/closures**			
	YES, by parent company	YES, by facility	YES, by parent company AND/OR facility	NO	YES, by parent company	YES, by facility	YES, by parent company AND/OR facility	NO
When first qualifying a new supplier: **47a. Our facility (or parent company) samples and tests the new supplier's components and/or containers/closures.**	○	○	○	○	○	○	○	○
When first qualifying a new supplier: **47b. Our facility (or parent company) evaluates the new supplier's supply chain.**	○	○	○	○	○	○	○	○
When first qualifying a new supplier: **47c. Our facility (or parent company) evaluates the outcomes and conclusions of any audits of the new supplier.**	○	○	○	○	○	○	○	○
When first qualifying a new supplier: **47d. Our facility (or parent company) enters into a written agreement with the new supplier.**	○	○	○	○	○	○	○	○

47e. Other *(please explain)*: _____
_

48. Our written agreements with new suppliers of drug product components and/or drug product containers and closures specify:

	Drug product components		Drug product containers/closures	
	YES	NO	YES	NO
Our written agreements with new suppliers specify: **48a. each party's responsibilities.**	O	O	O	O
Our written agreements with new suppliers specifiy: **48b. a communication procedure for quality-related activities.**	O	O	O	O

49. Are ongoing or periodic audits performed of your **established suppliers** of...

...drug product components? O YES O NO

...drug product containers/closures? O YES O NO

50. Are the procedures <u>written</u> for the audits of your suppliers of **drug product components** and/or **drug product containers and closures**?

	Drug product components			Drug product containers/closures		
	YES	NO	DON'T KNOW	YES	NO	DON'T KNOW
50a. *Procedures are <u>written</u> for the audits of our* **New suppliers**	O	O	O	O	O	O
50b. *Procedures are <u>written</u> for the audits of our* **Established suppliers**	O	O	O	O	O	O

51. Who usually performs the audits of your suppliers of drug product components and/or drug product containers and closures?
Please check (✓) a response for each statement below.

	Drug product components			Drug product containers/closures		
	YES	NO	DON'T KNOW	YES	NO	DON'T KNOW
51a. Audits are performed by facility personnel.	○	○	○	○	○	○
51b. Audits are performed by parent company personnel from outside facility.	○	○	○	○	○	○
51c. Audits are performed by third party auditors.	○	○	○	○	○	○
51d. Other *(please explain)*:	_____					

52. Do you use GMP standards as the basis for your audits of suppliers of...

	YES	YES, FOR SOME BUT NOT ALL	NO	DON'T KNOW / NOT SURE
...drug product components?	○	○	○	○
...drug product containers and closures?	○	○	○	○

53. What standard(s) do you use as the basis for your initial and ongoing supplier audits of ...

...drug product components? _____

...drug product containers and closures? _____

54. Do the audits of your suppliers assess and determine any of the following for suppliers of drug product components and/or drug product containers and closures?
Please check (✓) a response for each statement below.

	Drug product components			Drug product containers/closures		
	YES	YES FOR SOME BUT NOT ALL	NO	YES	YES FOR SOME BUT NOT ALL	NO

	Drug product components			Drug product containers/closures		
The audits of our suppliers assess... **54a. the adequacy of the supplier's operations.**	○	○	○	○	○	○
The audits of our suppliers assess... **54b. Whether the supplier's quality unit has the responsibility and authority to assess all operations related to manufacturing.**	○	○	○	○	○	○
The audits of our suppliers assess... **54c. The adequacy of the conditions of transportation and storage throughout the supply chain.**	○	○	○	○	○	○

55. Does your re-evaluation procedure for ongoing suppliers of drug product components and/or drug product containers and closures include any of the following elements?
Please check (✓) a response for each statement below.

	Drug product components				Drug product containers/closures			
	YES	YES FOR SOME BUT NOT ALL	NO	NOT SURE	YES	YES FOR SOME BUT NOT ALL	NO	NOT SURE
55a. *When re-evaluating an ongoing supplier, our facility (or our parent company):* **Reviews any information from monitoring the quality of the final drug product.**	○	○	○	○	○	○	○	○
55b. *When re-evaluating an ongoing supplier, our facility (or our parent company):* **Checks for any relevant drug product component or container/closure Alert Reports submitted to FDA.**	○	○	○	○	○	○	○	○
55c. *When re-evaluating an ongoing supplier, our facility (or our parent company):* **Reviews communication from the supplier or elsewhere about any changes in manufacturing or distribution that may impact safety, identity, quality, strength, or purity.**	○	○	○	○	○	○	○	○
55d. *When re-evaluating an ongoing supplier, our facility (or our parent company):* **Conducts periodic re-evaluations of the quality agreements made with suppliers.**	○	○	○	○	○	○	○	○
55e. *When re-evaluating an ongoing supplier, our facility (or our parent company):* **Conducts periodic testing of the data on the supplier's certificate of analysis.**	○	○	○	○	○	○	○	○
55f. *When re-evaluating an ongoing supplier, our facility (or our parent company):* **Reviews any changes in the supply chain.**	○	○	○	○	○	○	○	○
55g. *When re-evaluating an ongoing supplier, our facility (or our parent company):* **Conducts periodic audits at least every 5 years.**	○	○	○	○	○	○	○	○
55h. *When re-evaluating an ongoing supplier, our facility (or our parent company):* **Conducts a risk assessment to determine whether an audit is needed more frequently.**	○	○	○	○	○	○	○	○

56. What aspects of the risk assessment determine that an audit of an ongoing supplier should be performed more often than every 5 years?

_____

_____

57. Does your facility maintain records of your supplier audits?
Please check (✔) a response for each statement below.

	Drug product components			Drug product containers/closures		
	YES	NO	DON'T KNOW	YES	NO	DON'T KNOW
57a. Our facility maintains records of *initial audits of new suppliers*.	O	O	O	O	O	O
57b. Our facility maintains records of *audits of established suppliers*.	O	O	O	O	O	O
57c. Once an audit is completed, the records are archived off site or disposed of.	O	O	O	O	O	O
57d. Other *(please explain)*: _____						

58. Does the risk management program at your facility require the evaluation of existing and new knowledge relating to your suppliers of ...

...drug product components? O YES O NO O DON'T KNOW/NOT SURE

...drug product containers/closures? O YES O NO O DON'T KNOW/NOT SURE

In Q59e below: All drugs can have side effects, but by "serious adverse event" we mean an unintended effect that is life-threatening or damages the user's life and health.

59. Does your risk management program address any of the following elements?
Please check (✓) a response for each statement below.

	Drug product components			Drug product containers/closures		
	YES	NO	DON'T KNOW	YES	NO	DON'T KNOW
59a. *Does your risk management program address:* **Risks associated with the characteristics and use of your components and/or containers/closures?**	○	○	○	○	○	○
60a. IF YES, do you document the process when you assess this risk?	○	○	○	○	○	○
59b. *Does your risk management program address***: Risks associated with the initial and ongoing qualification of your suppliers of components and/or containers/closures?**	○	○	○	○	○	○
60b. IF YES, do you document the process when you assess this risk?	○	○	○	○	○	○
59c. *Does your risk management program address***: Risks associated with whether the component and/or container/closure is the subject of an existing FDA advisory action or alert?**	○	○	○	○	○	○
60c. IF YES, do you document the process when you assess this risk?	○	○	○	○	○	○
59d. *Does your risk management program address***: Risks associated with whether the component and/or container/closure is known to be at risk for substitution by inferior material?**	○	○	○	○	○	○
60d. IF YES, do you document the process when you assess this risk?	○	○	○	○	○	○
59e. *Does your risk management program address:* **Risks associated with whether the component and/or container/closure has been found to cause serious adverse events?**	○	○	○	○	○	○
60e. IF YES, do you document the process when you assess this risk?	○	○	○	○	○	○

61. Does your drug product processing facility perform a systematic visual examination of each received shipment of each lot of ...

...drug product components? ○ YES ○ NO ○ DON'T KNOW/NOT SURE

...drug product containers/closures? ○ YES ○ NO ○ DON'T KNOW/NOT SURE

62. What are the elements of this systematic visual examination? That is, what are you looking for when examining an incoming shipment of...

...drug product components? _____

...drug product containers and closures? _____

63. Once you've accepted a shipment into your warehouse, but before releasing its contents for use in processing, does your facility have a list of things to verify about received shipments of...

...drug product components? ○ YES ○ NO ○ DON'T KNOW/NOT SURE

...drug product containers/closures? ○ YES ○ NO ○ DON'T KNOW/NOT SURE

64. What are the things you check for or verify before releasing for use in processing each shipment of...

...drug product components? _____

...drug product containers and closures? _____

65. When a shipment fails any of the examinations you listed in Q58 above, does your facility do any of the actions below for failed shipments of drug product components and/or drug product containers and closures?
Please check (✓) a response for each factor listed below.

	Drug product components				Drug product containers/closures			
	YES	YES FOR SOME BUT NOT ALL	NO	DK	YES	YES FOR SOME BUT NOT ALL	NO	DK
When a shipment fails any of the examinations you listed, do you… **65a. Record the details of the shipment examination failure?**	○	○	○	○	○	○	○	○
When a shipment fails any of the examinations you listed, do you… **65b. Reject the shipment for use?**	○	○	○	○	○	○	○	○
When a shipment fails any of the examinations you listed, do you… **65c. Quarantine and segregate the shipment?**	○	○	○	○	○	○	○	○
When a shipment fails any of the examinations you listed, do you… **65d. Document all actions taken?**	○	○	○	○	○	○	○	○

65e. Other *(please describe)*: _____

66. Have you established the reliability of the supplier's certificate of analysis (COA) via a comprehensive risk assessment program for incoming shipments of...

	YES	YES, FOR SOME BUT NOT ALL	NO	DON'T KNOW/ NOT APPLICABLE
...drug product components?	○	○	○	○
...drug product containers/closures?	○	○	○	○

67. Do you approve <u>any</u> shipments based *only* on the previously established reliability of the supplier's COA for ...

...drug product components? ○ YES ○ NO ○ DON'T KNOW

...drug product containers/closures? ○ YES ○ NO ○ DON'T KNOW

68. What percentage of your shipments are accepted based ***only* on the previously established reliability of the supplier of...?**

...drug product components?_____

...drug product containers and closures? _____

69. Does your facility apply a statistically justified sampling plan for testing shipments of…

...drug product components? ○ YES ○ NO ○ DON'T KNOW

...drug product containers/closures? ○ YES ○ NO ○ DON'T KNOW

70.1. What statistical tool(s) do you use for <u>sampling</u> your incoming shipments of...

...drug product components?_____

...drug product containers and closures? _____

70.2. What statistical tool(s) do you use for <u>approving</u> your incoming shipments of...

...drug product components? _____

...drug product containers and closures? _____

71. Does your drug product processing facility apply different sampling and testing strategies depending on the levels of risk associated with ...

...drug product components? ○ YES ○ NO ○ DON'T KNOW

...drug product containers/closures? ○ YES ○ NO ○ DON'T KNOW

72. Is your drug product processing facility flexible about sampling and testing shipments from a supplier that has consistently delivered quality... ...drug product components? ○ YES ○ NO ○ DON'T KNOW

...drug product containers/closures? ○ YES ○ NO ○ DON'T KNOW

73. Does your drug product processing facility maintain the certificate of analysis from the supplier for <u>each shipment of each lot</u> of ...

...drug product components? O YES O NO O DON'T KNOW

...drug product containers/closures? O YES O NO O DON'T KNOW

End of Section: Combined DPC and DPCC Quality and Safety (Q42-Q73)

Start of Section: 211.89: Rejected DPC/DPCC Deficiencies (Q74-Q75)

74. Does your drug product processing facility submit a report to FDA when deficiencies are found with a…

...drug product component? O YES O NO O DON'T KNOW

...drug product containers/closure? O YES O NO O DON'T KNOW

74a. How long does it usually take to submit the report to FDA after the deficiency is discovered?

For drug product components? _____
For drug product containers and closures? _____

74b. What information do you usually include in such a report?

For drug product components? _____
For drug product containers and closures? _____

74c. How do you submit the report to FDA? (email, hard copy by mail, fax, etc.)

For drug product components? _____
For drug product containers and closures? _____

75. Over the past 10 years, what was the average annual number of deficient shipments associated with …

...drug product components? _____

...drug product containers and closures? _____

End of Section: 211.89: Rejected DPC/DPCC Deficiencies (Q74-Q75)

Start of Section: 211.137: Expiration Dating (Q76-Q77)

76. Does your facility process OR apply expiration dating to ANY OTC DRUGS?

O YES O NO O DON'T KNOW

77. Can you estimate the annual cost to your facility of applying expiration dates to the labels of OTC products that are currently exempt from expiration dating? Such exempt products include: OTC drugs that are stable for 3 years or longer; OTC drugs without dosage limits on their labeling; homeopathic drug products; allergenic extracts labeled "No U.S. Standard of Potency."

Estimated annual cost to your facility of applying expiration dates to currently exempt OTC products:

$_____.00 per year

End of Section: 211.137: Expiration Dating (Q76-Q77)

Start of Section: 211.180: Records and Reports – Gen Req (Q78-Q81)

78. Does your drug product processing facility evaluate records related to the quality standards applicable to all batches of all drug products to determine whether any changes are needed in drug product specifications, manufacturing, or control procedures?

O YES O NO O DON'T KNOW/ NOT SURE

79. Do you have a written procedure for evaluating these records?

O YES O NO O DON'T KNOW

80. Does your drug product processing facility use data analysis methods to monitor quality data and information, and to identify, resolve, anticipate, and prevent potential problems?

O YES O NO O DON'T KNOW

81. When your facility identifies potential problems by data analysis methods, do you conduct follow-up investigations?

O YES O NO O DON'T KNOW

End of Section: 211.180: Records and Reports – Gen Req (Q78-Q81)

Start of Section: 211.181: Change Control (Q82-Q84)

82. Does your drug product processing facility maintain written procedures for managing the implementation of changes to your processes?

O YES O NO O DON'T KNOW

83. Does the Quality Unit of your drug product processing facility have control and final approval of these written change-management procedures?

O YES O NO O DON'T KNOW

84. Does the Quality Unit assess and document the potential effects of any process changes on product quality and elevated risk associated with a particular process change?

O YES O NO O DON'T KNOW

End of Section: 211.181: Change Control (Q82-Q84)

Start of Section: 211.183 Internal Audits (Q85-91)

85. Does your drug product processing facility have written procedures for performing scheduled internal audits related to your facility's CGMP compliance?

O YES O NO O DON'T KNOW

86. Who performs these CGMP internal audits?

_____
_____
_____
_____

87. How frequently are these scheduled CGMP internal audits performed?

- O About every 3 months, or 4 times a year
- O At least once a year
- O Every 2 years
- O Every 5 years

88. Are formal audit reports maintained that include details such as: dates of inspections, persons performing inspections, and other details?

O YES O NO O DON'T KNOW

89. If formal audit reports are maintained, are they reviewed by management?

O YES O NO O DON'T KNOW O DOES NOT APPLY

90. Does your drug product processing facility maintain the reports of both the initial and ongoing risk assessments of your suppliers, including the conclusions of those assessments?

O YES O NO O DON'T KNOW

91. Does your drug product processing facility maintain the supplier qualification reports and audit reports for all your suppliers?

O YES O NO O DON'T KNOW

End of Section: 211.183 Internal Audits (Q85-Q91)

Start of Section: 211.192: Production record review (Q92-Q94)

92. Does your drug product processing facility investigate any specification discrepancies or potential problems that are identified in the drug products you **process**?

O YES O NO O DON'T KNOW

93. Who is notified if there is a discrepancy?
Please check (✓) all that apply.

- O Entities responsible for the discrepancies
- O Your **drug product processing facility**'s management
- O Facility Quality Unit
- O Other _____

94. Are there written procedures and requirements for investigation of drug product or **process** discrepancies?

O YES O NO O DON'T KNOW

End of Section: 211.192: Production record review (Q92-Q94)

Start of Section: 211.240: Special Controls Cross-Contam (Q95-Q102)

95. Does your drug product processing facility use dedicated facilities when processing drug products that pose serious cross-contamination risks (such as any drug that becomes highly allergenic, toxic, or infectious to the recipient of the drug when a cross-contamination occurs)?

O YES O NO O DON'T KNOW

96. Does your drug product processing facility use controls that can decontaminate processing areas and equipment when producing drugs that pose serious cross-contamination risks (such as any drug that becomes highly allergenic, toxic, or infectious to the recipient of the drug when a cross-contamination occurs)?

O YES O NO O DON'T KNOW

97. Does your facility maintain written documentation of every time your decontamination controls are activated?

O YES O NO O DON'T KNOW

98. Does your facility periodically review or update your decontamination controls to ensure their effectiveness?

O YES O NO O DON'T KNOW

99. Does your facility process—meaning manufacture, pack/re-pack, test, label/re-label, or sterilize—any sensitizing beta-lactams?

O YES O NO O DON'T KNOW

100. Do you have separate facilities using separate air handling systems for processing sensitizing beta-lactams?

O YES O NO O DON'T KNOW

101. Does your drug product processing facility have written procedures for testing products when there is a reasonable possibility of cross-contamination?

O YES O NO O DON'T KNOW

102. Does your drug product processing facility have written procedures for conducting followup investigations of any potential cross-contaminations?

O YES O NO O DON'T KNOW

End of Section: 211.240: Special Controls Cross-Contam (Q95-Q102)

Start of Section: Length of Survey

103. Overall, it took approximately _____ minutes to complete this survey. Please do not include any time that may have elapsed while you were waiting for information from other knowledgeable people.