

Meeting Summary  
 PQRI Aseptic Processing Working Group  
 February 27<sup>th</sup> and 28<sup>th</sup>, 2003

**February 27<sup>th</sup> Summary:**

Working Group Members Present:

	James P. Agalloco Agalloco & Associates	X	Carol M. Lampe Baxter Healthcare Corporation
	James E. Akers, Ph.D. Akers Kennedy & Associates	X	John Lindsay Aseptic Solutions Inc.
	Barbara Bassler Bridge Associates International		Russell E. Madsen PDA
X	Martyn Becker Merck & Co.		Andy Minor Eli Lilly & Co.
X	Susan Bruederle FDA	X	Leonard Mestrandrea Pfizer Inc.
	Don Burstyn Alkermes	X	Kenneth Muhvich, Ph.D. Micro-Reliance.
	Roger Dabbah USP	X	Terry Munson KMI/PAREXEL, Inc.
X	Roger Deschenes Astra Zeneca		Rainer F. Newman Johnson & Johnson
	Joseph Famulare FDA		Jean I. Olsen GlaxoSmithKline
X	William R. Friebe, Ph.D. Pharmacia Corporation		Carolyn Renshaw FDA
X	Rick Friedman FDA	X	Robert Sausville FDA
X	John G. Grazal AstraZeneca Pharmaceuticals	X	Neal Sweeney FDA
X	Klaus Haberer Compliance Advice & Services	X	Ian D. Symonds GlaxoSmithKline
	Nigel Halls, Ph.D. GlaxoSmith Kline (ret.)		Laura Thoma, Ph.D. University of Tennessee
	Karl L. Hofmann Bristol-Myers Squibb Co.	X	Debbie Trout FDA
X	David Hussong FDA		Martin Van Trieste Abbott Laboratories
X	Richard M. Johnson Abbott Laboratories		Brenda Uratani FDA
	Kunio Kawamura Otsuka Pharma. Co., Ltd.		Richard T. Wood, Ph.D. Pfizer, Inc.
	Lee Kirsch, Ph.D. University of Iowa	X	Glenn E. Wright Eli Lilly & Co.
	Joe Lasich Alcon Laboratories, Inc.		Jeff Yuen Jeff Yuen and Associates

- The meeting began at 1:00 PM. Members had the option of calling in for the meeting or attending in person. This teleconferencing option was provided for the entire length of the meeting.
- The group began with a final review of Recommendation drafts which had been prepared previous. The discussions were active and centered around providing more specific information in the recommendations.
- The group stopped this review at recommendation # 4 at approximately 3:30 PM and began the discussion on Recommendation # 3.

The discussion was led by Richard Johnson. The group actively discussed the topic and as indicated in the agenda, ask Richard to compile a draft recommendation based on the groups discussion for day 2.

- The group adjourned at 5:00PM

**February 28<sup>th</sup> Summary:**

Working Group Members Present:

	James P. Agalloco Agalloco & Associates	X	Carol M. Lampe Baxter Healthcare Corporation
	James E. Akers, Ph.D. Akers Kennedy & Associates	X	John Lindsay Aseptic Solutions Inc.
	Barbara Bassler Bridge Associates International		Russell E. Madsen PDA
X	Martyn Becker Merck & Co.		Andy Minor Eli Lilly & Co.
X	Susan Bruederle FDA	X	Leonard Mestrandrea Pfizer Inc.
	Don Burstyn Alkermes	X	Kenneth Muhvich, Ph.D. Micro-Reliance.
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X	Rick Friedman FDA	X	Robert Sausville FDA
X	John G. Grazal AstraZeneca Pharmaceuticals	X	Neal Sweeney FDA
X	Klaus Haberer Compliance Advice & Services	X	Ian D. Symonds GlaxoSmithKline
	Nigel Halls, Ph.D. GlaxoSmith Kline (ret.)		Laura Thoma, Ph.D. University of Tennessee
	Karl L. Hofmann Bristol-Myers Squibb Co.	X	Debbie Trout FDA
X	David Hussong FDA		Martin Van Trieste Abbott Laboratories
X	Richard M. Johnson Abbott Laboratories		Brenda Uratani FDA
	Kunio Kawamura Otsuka Pharma. Co., Ltd.		Richard T. Wood, Ph.D. Pfizer, Inc.
	Lee Kirsch, Ph.D. University of Iowa	X	Glenn E. Wright Eli Lilly & Co.
	Joe Lasich Alcon Laboratories, Inc.		Jeff Yuen Jeff Yuen and Associates

- The meeting began at 9:00 PM. Members again had the option of calling in for the meeting or attending in person. This teleconferencing option was provided for the entire length of the meeting.
- The group began with a review and discussion on Recommendation #3 led by Richard Johnson. See Attachment for Recommendation #1.

- The group then completed the review and discussion of the remaining recommendations that had been previously drafted.
- Two assignments were made as a result of the reviews.
  - Rick Friedman and John Grazal would complete the rationale for #1.
  - Martyn Becker would complete the rationale for #3.
- A timeline for completion of the recommendations was developed.
  - The completed recommendations will be sent out to the group by Monday (March 3rd) for an editorial review.
  - The proposed rationale sections for #1 and #3 will be sent out for comment on Monday (March 3<sup>rd</sup>) with a 24 hour turn around..
  - By Tuesday afternoon (March 5<sup>th</sup>) finalized rationale will be incorporation into draft recommendations as well as any editorial comments on the recommendation and the final draft will be sent out to the group.
  - On Wednesday afternoon (March 6<sup>th</sup>) the finalized document will be sent to the PQRI steering committee for approval.
- The group completed all reviews and adjourned at 1:30 PM.  
(See attachment for reviewed recommendations 1-10)

**-ATTACHMENT-**

**RECOMMENDATION #1**

*Concept Paper Line Number Reference: 661*

Question: What is an appropriate number of units to be filled during process simulation (media fill)?

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**Recommendation:**

- The number of units to be filled should be sufficient to accurately simulate activities that are representative of the manufacturing process. Such activities include but not limited to:
  - Aseptic manipulations during setup
    - Interventions – type and number
    - Typical/Routine
  - Atypical/Non-Routine
  - Staffing Levels
  - Shift Changes
  - Gown Changes
  - Multiple day fills
- A generally acceptable starting point is between 5,000 to 10,000. For batch sizes under 5,000 the number of media filled units should equal the batch size.
- Where the technology is such that the possibility of contamination is higher (manually intensive filling lines), a larger number of units, generally at or approaching the full batch size, should be considered.

**Rationale:**

- For instance, an isolator can have a very low risk of contamination because of the lack of human intervention, while a manual filling operation for clinical trial materials has a high risk of contamination. In these instances the isolator would fill the minimum number of units to meet the acceptance criteria, while the manual operation would fill the maximum number of units (approaching the maximum batch size).

**Survey Data Summary:**

- What is the number of units filled during the process simulation compared to production batch sizes?

Mfg. Lot Size 5,000 units and under	≥Lot size	92%
	<Lot size	8%
Mfg. Lot Size 5,001 – 10,000	>75% of lot size	33%
	50% to 75% of lot size	63%
	<50% of lot size	4%
Mfg. Lot Size 10,001 – 20,000	>75% of lot size	28%
	50% to 75%	25%
	<50%	47%
Mfg. Lot Size 20,001 – 40,000	>75% of lot size	1%
	51% to 75%	3%
	25% to 50%	49%
	<25%	47%

Mfg. Lot Size 40,001 – 80,000	>75% of lot size	6%
	51% to 75%	2%
	25% to 50%	18%
	<25%	74%
Mfg. Lot Size >80,000	>75% of lot size	0%
	51% to 75%	0%
	25% to 50%	9%
	<25%	90%

- From the survey data what is the distribution for the total number of media units filled?

Media Fill Lot Size $\leq 5,000$	23%
Media Fill Lot Size $\leq 10,000$	38%
Media Fill Lot Size $\leq 20,000$	28%
Media Fill Lot Size $> 20,000$	11%

## RECOMMENDATION #2

*Concept Paper Line Number Reference: 730*

Question: What is an acceptable temperature range for the incubation of media fill units using TSB and FTM? If alternative practices are used what type of justification is required?

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### Recommendation:

- Incubation temperatures should be suitable for recovery of bioburden and environmental isolates.
- Incubation conditions should be not less than 14 days at either a temperature or temperatures between 20-35°C. If two temperatures are used for incubation the media fill samples then these filled containers should be incubated for at least 7 days at each temperature.
- The incubation temperature should be maintained within 2.5°C of the target temperature. The temperature should at no time be below 20°C or above 35°C.

### Rationale:

- The temperature range provided is suitable for the recovery of wide range of mesophilic bacteria (the largest portion of bacteria are classified as mesophilic). The temperature range is similarly suitable for a wide range of yeast and molds.
- The recommendation is consistent with current USP, PDA, JP and PIC/S guidance.
- Regarding the second part of the rationale question. No specific temperature was selected as a set temperature to allow flexibility for the individual firms to select the temperature range(s) appropriate for their operation. The justification for all temperatures is specified in bullet one.
- The survey data indicates that industry currently uses various incubation conditions that can recover a wide range of mesophilic flora. The recommendation provides for the use of these different approaches.

### References:

- PDA Technical Report No. 22, "Process Simulation Testing for Aseptically Filled Products" 1996.
- PIC/S, "Recommendation on The Validation Of Aseptic Processes," April 2000.

### Survey Data Summary:

- What is temperature range does your firm currently use for the incubation of media fill units?  
*Number of respondents =49*

A	20-25 ° C	1	2%
B	25-30 ° C	1	2%
C	30-35 ° C	3	6%
D	20-25 then 30-35 ° C	24	49%
E	30-35 then 20-25 ° C	7	14%
F	other (specify) _____	13	27%

2 30-32C  
5 A + C  
1 28C  
1 28-32C  
1 A + D  
1 C + E  
1 C + D  
1 NA (small batch)

### RECOMMENDATION #3

*Concept Paper Line Number Reference: 787*

Question: What is an appropriate limit for the contamination rate in a process simulation (media fill)? What is an appropriate target for contaminated units in a process simulation (media fill)?

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#### **Recommendation:**

- The target is zero contaminated units.
- Any contaminated unit indicates a potential sterility assurance problem, regardless of run size. All contaminated units should result in a thorough, documented investigation.
- Clear acceptance criteria should be established for media fills.
- The following criteria are generally acceptable:
  - When filling less than 5000 units no contaminated units should be detected.
  - When filling from 5,000 to 10,000 units
    - 1 contaminated unit requires an investigation and a determination if any further action is needed such as a repeat of the media fill.
    - 2 contaminated units are considered cause for revalidation following investigation.
  - When filling more than 10,000 units
    - 1 contaminated unit requires an investigation
    - 2 contaminated units are considered cause for revalidation following investigation.
- Recurring incidents of contaminated units from media fills for an individual line, regardless of the set acceptance criteria, should be a signal that action should be taken.

Rationale:

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References:

Survey Data Summary:

## Recommendation #4

Concept Paper Line Number Reference: 981

Question: When should critical surfaces be monitored? What are appropriate expectations in regards to results obtained?

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### Recommendation:

- The selection of sample sites should be strategic in an environmental monitoring program. This should include consideration as to when, or if a critical site should be monitored.
- Each manufacturer should review each type of process and the points of risk for product contamination. Consideration should be given to the level of contamination risk based on factors such as: difficulty of set-up; length or processing time; impact of interventions, etc.
- It is well understood that the sampling and incubation methods used in surface monitoring are manual operations that, due to personnel involvement, results in a low rate of false positives. For this reason, the detection of microorganisms on a critical site should not necessarily result in batch rejection, but should be investigated. The other EM data and procedures, that support the operation, should be reviewed to determine if the positive result is supported. If this review does not support the positive result and there is no negative trend for the critical surface site there is a strong case for not rejecting the lot due to the positive result.
- PQRI strongly supports the concept discussed on line 993 of the concept paper; that, when performed, "Critical surface sampling should be performed at the conclusion of the aseptic processing operation to avoid direct contact with sterile surfaces during processing."

### Rationale:

- The strategic monitoring of critical surfaces can provide useful data on the state of environmental control within the aseptic processing area. It can allow adverse trends to be detected, investigated and corrected promptly.
- Environmental monitoring is performed in an environment that does not afford the same controls as that present in sterility testing. For this reason the testing cannot be used to determine the sterility of the product. Occasional positive results are expected due to the involvement of EM monitoring personnel during sampling and as a result of sample handling and incubation within the laboratories.
- The sampling process requires contact with the critical surface (i.e. Rodac sample). To reduce the possible negative impact this activity has on the critical areas, it should be performed at the conclusion of the processing operation.

### Survey Data Summary:

- When does your firm perform environmental monitoring on critical surfaces (product contact surfaces)?  
*Number of respondents = 49*

A	at beginning of operations	0	0%
B	during operations	7	14%
C	conclusion of operations	26	53%
D	not monitored	4	8%
E	other (add specific comment)	12	24%

1 B + C

4 A + B + C

- 1 C + D
  - 2 end of media fill
  - 1 C (UK), D (US)
  - 1 do not test product contact surface, sample surface nearby not monitored routinely, only in case of failure investigation
- How does your firm respond when positive results are obtained from critical surface monitoring? (If your firm does not monitor these surfaces go to next question) *[Number of respondents =49]*

A	automatic rejection	0	0%
B	investigation	40	81%
C	no follow-up necessary	0	0%
D	other (add specific comment)	9	18%

    - 1 not monitored (BFS)
    - 2 less than alert, no action; > alert, investigation
    - 5 NA
    - 1 media fill monitoring of critical surface, if exceed, investigation

## RECOMMENDATION #5

*Concept Paper Line Number Reference: 1014*

Question: What data should be considered when initially establishing monitoring limits? What is an appropriate frequency for re-evaluating monitoring limits?

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### Recommendation:

- Initially, published data and/or historical data from similar operations should be used to set action and alert levels
- Historical data may be derived from areas of similar aseptic operations or represent a homogenization of a company's monitoring levels, by room class, across lines and facilities.
- For aseptic areas where the allowable levels are less than 1 cfu, consideration should be given to the use of count incidence rates as an indicator of an unfavorable trend.
- Alert and action levels are generally re-evaluated (and re-set if deemed necessary) on an annual basis using primarily the previous years data for setting monitoring levels for the upcoming year. Published data should be considered when re-evaluating the action level.

### Rationale:

- There are no US regulations stipulating environmental action levels. However, published data should be considered when setting action levels to assure that historical data-based action levels do not slowly creep beyond generally accepted levels.
- Remedial action to exceeding alert or actions levels in all room classes should be taken based on unfavorable trends as opposed to individual data point excursions. This is particularly true (and difficult to accurately measure) for ISO Class 5 aseptic areas where the action level is 1cfu/m<sup>3</sup>.
- The frequency at which monitoring levels are re-evaluated is somewhat dependant on the frequency at which the line is used. It may take additional time to gather sufficient data to re-evaluate lines that are seldom used.

### Survey Data Summary:

- What data does your firm consider when initially establishing monitoring limits for a new area?

	<u># Respondents</u>	<u>Yes</u>	<u>No</u>
A. Historical databases	49	39 (80%)	10 (20%)
B. Cleanroom qualification	45	35 (78%)	10 (22%)
C. Sanitization studies	46	15 (33%)	31 (67%)
D. Publications	49	45(92%)	4 (8%)
E. Media fills	47	16 (34%)	31 (66%)
F. Relationship of monitoring location to overall operation	46	33 (72%)	13 (28%)
G. Other (add specific comment)	0		

- What data does your firm consider when reevaluating monitoring limits for an existing area?

	<u># Respondents</u>	<u>Yes</u>	<u>No</u>
A. Historical databases	47	45 (96%)	2 (4%)
B. Cleanroom qualification	45	21 (47%)	24 (53%)
C. Sanitization studies	45	15 (33%)	30 (67%)
D. Publications	44	35 (80%)	9 (20%)
E. Media fills	44	19 (43%)	25 (57%)
F. Relationship of monitoring location to overall operation	45	26 (58%)	19 (42%)
G. Other (add specific comment)	0		

- What frequency does your firm use for re-evaluating environmental monitoring limits? Answer in *number of months* between reevaluations, e.g., 6, 12, 18, 24, etc.

*Number of respondents = 47*

	<u>Frequency</u>
6 mo.	1 (2%)
12 mo.	33 (70%)
18 mo.	0 (0%)
24 mo.	5 (11%)
Other:	8 (17%)

2	5 yr.
1	12-18 mo.
1	6 and 12 mo.
1	12 and 24 mo.
3	no SOP

## Recommendation #6

Concept Paper Line Number Reference: 82

Question: What is the maximum number of viable organisms allowed in air samples for the various classifications?

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### Recommendation:

- The document should be standardized to the ISO designations.
- The air classification table should only use metric units for the microbial action levels.
- Replace the term “limits” in the table with “Action Levels”.
- Add Microbial Settling Plates to Harmonize with EU Annex 1

**TABLE 1- Air Classifications<sup>a</sup>**

Clean Area Classification	ISO Designation	$\geq 0.5$ um particles/m <sup>3</sup>	Microbiological Action Levels <sup>b</sup> cfu/m <sup>3</sup>	Microbiological Settling Plates <sup>b,c</sup> (diam. 90mm) cfu/4 hours
100	5	3,520	1 <sup>d</sup>	1 <sup>d</sup>
1000	6	35,200	7	3
10,000	7	352,000	10	5
100,000	8	3,520,000	100	50

- a- All classifications based on data measured in the vicinity of exposed articles during periods of activity.
- b- Alternate microbiological standards may be established where justified by the nature of the operation.
- c- The use of settling plates are optional and if used please reference Section A.4.c in the Environmental Monitoring section.
- d- Samples from class 100 environments should normally yield no microbiological contaminants.

- Remedial action when exceeding actions levels in all room classes should be taken based on unfavorable trends as opposed to individual data point excursions.

### Rationale:

- The recommend modifications to the table harmonize it with international standards and reflect the most current published standards.
- The incorporation of the term “action levels” clearly convey that the numbers provided are not product related specifications but levels that when exceeded must be investigated.
- Note: ISO class 5 is approximately equal to EU Grade A.

### References:

- <1116> Microbiological Evaluation of Clean Rooms and Other Controlled Environments, USP 24, United States Pharmacopeial Convention, Inc., Rockville, MD, 1999.
- PDA Technical Report No. 13 (Revised), “Fundamentals of an Environmental Monitoring Program” Sept/Oct 2001.
- ISO 13408-1, “Aseptic Processing of Health Care Products- Part 1: General Requirements,” August 1, 1998.

- ISO 14644-1 “Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness”, 1999.
- EU Annex 1

**Survey Data Summary:**

- What air microbial action level does your firm use for your Class 1,000 area? Answer in number of CFU per cubic meter.

*Number of respondents =47*

facility has a class 1000 area	10	21%
no class1000 area	37	79%

What action level is used (CFU/m<sup>3</sup>) for class 1000 area:

(<0.0042, 1, 3, 4, 6, 7, 10, 15, 18)

## RECOMMENDATION #7

*Concept Paper Line Number Reference: 1369*

Question: What type of airflow is required in a closed isolator?

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### Recommendation:

- The section needs to recognize, up front, that there are two major ‘types’ of isolators; open and closed.
- The term “Unidirectional” in 1369 should be split out for open isolators.
- Within a closed isolator turbulent flow is normally acceptable.
- The terms open isolator and closed isolators should be better defined. Recommend that the definitions be based on those contained in PDA Technical Report No. 34.

### Rationale:

- It is important that open and closed isolators be differentiated between in the document since they have different operational expectations. Open isolators are characterized by an interface between the external and internal environments (i.e., to allow ingress of sterile vials and/or egress of filled vials), and therefore, uses elements of conventional clean room technology (i.e., pressure differentials and unidirectional flow air) to provide assurance of environmental quality. Closed isolators have no such openings and therefore generally do not require unidirectional airflow.

### Survey Data Summary:

- What type of airflow is required at your firm for closed isolators?  
*Number of respondents =14*  

A	unidirectional	8 (57%)
B	turbulent	6 (43%)

NOTE: Some question was raised, in regards to the survey results, if those reporting unidirectional airflow in close isolators truly had unidirectional flow.

## RECOMMENDATION #8

Concept Paper Line Number Reference: 1372

Question: What is the appropriate recommendation for air handling systems in isolators?

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### Recommendation:

- Redundant HEPA (or ULPA) filters, in series, are not necessary.
- The document should not specify the type of filter to be used to reduce the microbial load of the air entering isolator.
- Suggest the following wording... **“The air handling system should be capable of maintaining the requisite environmental conditions within the isolator”**

### Rationale:

- Redundant filters HEPA (or ULPA) are also not required for traditional aseptic processing areas; therefore, there should be no *a priori* requirement to use them to maintain the environment of an isolator.
- Multiple types of filters and potentially new technologies can be used for this purpose. The purpose of these filters is to insure air entering the isolator meets environmental requirements.
- The important point is that we control ingress and egress of everything entering and exiting the isolator (air, components, etc.) to insure maintenance of a suitable environment for assurance of sterility of the products of aseptic processing. How we do it is less important.

### Survey Data Summary:

- Does your firm use ULPA and HEPA filters installed in series on its isolator system?  
*Number of respondents =14*  

Yes	6 (43%)
No	8 (57%)
- If you answered "no" to the last question, do you have multiple pre-filters, including one that is at least 95% ASHREA-rated, preceding the single terminal HEPA or ULPA?  
*Number of respondents =12*  

Yes	9 (75%)
No	3 (25%)

## RECOMMENDATION #9

*Concept Paper Line Number Reference: 1448*

Question: What are appropriate methods for use in the development of decontamination cycles?

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### Recommendation:

- Isolators should be decontaminated with a sporicidal agent. The decontamination cycle needs to be qualified.
- Normally, a 4 – 6 log reduction can be justified depending on the application. The specific BI spore titer used and the selection of BI placement sites should be justified.
- All product contact surfaces, within the isolator should be sterilized, i.e., demonstration of 6 log reduction of suitable BIs.
- Chemical indicators and fraction negative studies can be used to help develop a decontamination cycle. However, demonstration of suitable kill of BIs is the ultimate standard.
- It is important to ensure uniform distribution of the decontaminating agent during cycle development.
- Recommend that no change is made in the statement regarding fraction negative studies.
- Clarify various materials statement to reflect texture and porosity rather than composition.

### Rationale:

- The environment within an isolator is not purported to be sterilized. Sterilization, in this instance, would be an imprecise technical term. The internal environment is decontaminated to ensure a suitable environment for aseptic processing.
- Requirements for isolators should not be greater than for conventional areas used for the same function. Just as with conventional filling areas the use dictates the acceptable decontamination requirements and environmental expectations.

### Survey Data Summary:

- What method/s does your firm use in the development of decontamination cycles?

total kill analysis	<i>Number of respondents =21</i>	Yes 16 (76%)	No 5 (24%)
half-cycle	<i>Number of respondents =18</i>	Yes 10 (55%)	No 8 (45%)
fraction negative	<i>Number of respondents =17</i>	Yes 7 (41%)	No 10 (59%)

## Recommendation #10

Concept Paper Line Number Reference: 57

**Question:** With respect to terminal sterilization and adjunct processing what flowcharts represent the most risk-based and scientifically developed approach?

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### Recommendation:

- No detail should be added to the current text present in the concept paper.
- The comment beginning on line #56 regarding adjunct processing should be reworded to clearly indicate that adjunct processing is not an expectation at this point.
- The group strongly recommends to PQRI that a group be formed within PQRI or another organization to further discuss and develop this topic.

### Rationale:

- This topic involves adjunct processing being used in conjunction with aseptic processing as a general concept to increase sterility assurance. As indicated by the survey the topic of adjunct processing has value and should be explored. However, it will need to be further developed before it can be included, on a scientific basis, in a guidance document. Added scientific discussion, research, and the establishment of new standard methods will be needed to understand how it might be used and what expectations from a regulatory perspective should be considered.
- Since terminal sterilization is far better understood, a firm should not default automatically to aseptic processing but should explore terminal sterilization during product development.

### Survey Data Summary:

- What of the following flowcharts represent the most risk-based and scientific development approach? [Pick only one.]

*Number of respondents = 44*

A	terminal sterilization (explore heat methods only) -> aseptic processing	12	27%
B	terminal sterilization (explore heat and irradiation methods) -> aseptic Processing	7	16%
C	terminal sterilization (explore heat methods only) -> consider adjunct process -> aseptic processing	5	11%
D	terminal sterilization (explore heat and irradiation methods) -> consider adjunct process-> aseptic processing	14	32%
E	automatically default to aseptic process without any studies	6	14%

- What percentage of sterile products at your firm are aseptically filled and could be terminally sterilized (capable of withstanding  $F_0 > 8$  minutes without change in current packaging and formulation)? [Enter a number as a percentage.]

*Number of respondents = 49*

0%	36
2%	2
5%	2
10%	4
20%	1
30%	2
don't know	2