This checklist has been developed to accompany the IADSA global Guide to Good Manufacturing Practice for Supplements.

Each series of questions is specifically related to a chapter of the IADSA Guide.

By completing the questionnaire, companies will be able to assess their GMP status and identify possible gaps in their operations, through a ‘No’ response to a question.
1. COMPANY INFORMATION

1.1. Name of Company

1.2. Address of Company

1.3. Telephone No

1.4. Contact Name

1.5. Email

1.6. Position within Company

1.7. Type of Business
   - Manufacturing / Packaging
   - Packaging only
   - Contract manufacturer / Packer
   - Marketing

1.8. Does your company manufacture and / or pack supplements
   - On site
   - At another site within group
   - Contract out manufacturing
   - Contract out packing

1.9. No. of full-time employees

1.10. No. of part-time / seasonal employees

1.11. Size of facility
   - Manufacturing
   - Storage
   - Laboratories
   - Overall
2. QUALITY MANAGEMENT

2.1. Is your company registered / registering for an accredited quality system, e.g. ISO?
   - If Yes, which?

2.2. Does the company have personnel specifically responsible for quality (e.g. Quality Control / Quality Assurance Manager)?
   - If Yes, are the authority and responsibilities of these personnel clearly defined?

2.3. Do these personnel have the authority to make independent decisions on product quality?

2.4. Is there documented evidence for all lots (batches) of product that demonstrates the following?
   - all steps during manufacture are being carried out as per the defined procedures
   - quantity and quality produced are as expected
   - finished batches are enclosed in the proper container and bear the correct label
   - finished products are stored, distributed, and recommendations given for subsequent handling

2.5. Is there documented evidence for all lots (batches) of product that demonstrates the following?
   - Starting materials?
   - Finished products in the final pack?

2.6. Are there procedures in place to define the process of pulling above samples?

2.7. Are there procedures in place to ensure the traceability of all raw material, intermediate and finished product?

2.8. Do the traceability records allow for rapid identification of:
   - the suppliers of the raw materials
   - the complete manufacturing history of a lot of finished product
   - the businesses to which finished products have been supplied?
## 2. QUALITY MANAGEMENT

2.9. Is the information on traceability in a form that can be made available to the authorities on demand?  
- Yes  
- No

2.10. Is there a Supplier Quality Assurance procedure in place, laying down the criteria for selection, approval, review and ongoing approval, to ensure that the supplied products and services meet the expected requirements?  
- Yes  
- No

2.11. Are the Quality Assurance procedures of suppliers of raw and packaging materials monitored?  
- Yes  
- No

2.12. Is there a program in place to determine environmental quality?  
- Yes  
- No

2.13. Is there a system in place allowing rapid feedback to the purchasing department if concerns are raised on the quality of purchased materials?  
- Yes  
- No

2.14. Is there a system in place allowing rapid feedback to the manufacturing department regarding modifications or corrective actions to be taken, if required?  
- Yes  
- No

2.15. Are summaries of quality performance data and advice (where relevant) regularly given to manufacturing personnel?  
- Yes  
- No

2.17. Are results of inspection and testing of material reviewed against established specifications?  
- Yes  
- No

2.18. Does product assessment include the review of relevant manufacturing and packaging documentation?  
- Yes  
- No

2.19. Is product dispositioned by Quality?  
- Yes  
- No
## 3. PREMISES AND EQUIPMENT

### PREMISES

3.1. Is there a Maintenance Plan that ensures the condition of buildings (both internal and external)?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

3.2. Equipment is regularly reviewed and action taken when necessary

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

3.3. Are the floor, wall, ceilings, windows, and doors easily cleanable?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

3.4. Are the manufacturing areas separate and distinct from other functional areas such maintenance and laboratories?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

### VENTILATION AND LIGHTING

3.5. Are manufacturing and packaging areas ventilated with a constant supply of appropriately filtered air to ensure contaminants are not introduced into products?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

3.6. Where required, is there a system in place to monitor temperature, and humidity?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

3.7. Are there shatterproof covers on lights in the following areas:

- raw material storage area?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

- manufacturing areas?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

- finished products storage area?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

3.8. Is there a formal glass, ceramic, or hard plastic breakage control procedure?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

3.9. Are the floors in the manufacturing areas made of an impervious and non-absorbent material?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
3. PREMISES AND EQUIPMENT

**FLOORS, WALLS, AND CEILINGS**

3.9. Are the floors in the manufacturing areas made of an impervious and non-absorbent material? [ ] Yes [ ] No

3.10. Are the floors free from cracks and joints in areas where product is exposed? [ ] Yes [ ] No

3.11. Do drains have trapped gullies and proper ventilation? [ ] Yes [ ] No

3.12. Are all open drainage channels shallow and easy to clean? [ ] Yes [ ] No

3.13. Are walls intact, free of faults, and finished with a smooth, impervious, and easily cleaned material? [ ] Yes [ ] No

3.14. Are windows made of toughened glass or plastic? [ ] Yes [ ] No

3.15. Are there screens on windows that open? [ ] Yes [ ] No

3.16. Do window ledges slope away from the glass at an angle to prevent items being placed on them? [ ] Yes [ ] No

3.17. Do doors have smooth, non-absorbent, easy to clean and disinfect surfaces? [ ] Yes [ ] No

3.18. Does the ceiling construction in manufacturing areas prevent the accumulation of dirt/growth of mold/shedding of particles? [ ] Yes [ ] No

**CLEANING AND WASTE**

3.19. Is there a Site Hygiene Plan or Master Sanitation Schedule? [ ] Yes [ ] No

- If Yes, is the plan regularly reviewed? [ ] Yes [ ] No

3.20. Is there a process in place to control the disposal of printed packaging materials or raw materials and rejected products? [ ] Yes [ ] No

3.21. Is production waste collected in clearly identifiable receptacles for removal to specific collection points outside the buildings? [ ] Yes [ ] No

3.22. Is production waste removed from the manufacturing areas throughout the day? [ ] Yes [ ] No

3.23. How often is waste removed from the site? [ ] Yes [ ] No

3.24. Are cleaning products approved for their intended use? [ ] Yes [ ] No

3.25. Are cleaning products stored in a location that is separate from the processing areas? [ ] Yes [ ] No
3. PREMISES AND EQUIPMENT

RECEIVING AND DISPATCH AREAS

3.26. Do the receiving and dispatch areas provide protection from the weather for materials or product in transit?  
- Yes  - No

3.27. Where appropriate, is there a defined deboxing/debagging area for those materials which arrive in external packaging?  
- Yes  - No

PERSONNEL HYGIENE FACILITIES

3.28. Are the following provided:
   - Changing rooms or facilities segregated from production area?  
     - Yes  - No
   - Toilet and hand washing facilities segregated from manufacturing areas?  
     - Yes  - No
   - Separate accommodation for clothing and footwear not being worn during working hours?  
     - Yes  - No
   - First Aid facilities and an accident book?  
     - Yes  - No
   - A rest and refreshment room segregated from production area?  
     - Yes  - No

PEST CONTROL

3.29. Is there a Pest Control program in place?  
- Yes  - No

3.30. Is pest control contracted out?
   - Yes  - No
   - If No, are personnel trained to oversee pest control and are there appropriate procedures in place for in-house pest management?  
     - Yes  - No

3.31. What steps are taken to protect against the entrance and harboring of vermin, birds, pests and pets in all buildings on site?
3. PREMISES AND EQUIPMENT

EQUIPMENT

3.32. Are all surfaces and materials in contact with raw materials and finished product:
- Inert to the raw materials / product? Yes  No
- Microbiologically cleanable, smooth and non-porous? Yes  No
- Visible for inspection (or equipment is easily dismantled for inspection)? Yes  No
- Easily dismantled and readily accessible for cleaning? Yes  No

3.33. Do you have cleaning procedures for all equipment and areas? Yes  No

3.34. Do you have documented results to show that your cleaning procedure is sufficient for manual and clean-in-place techniques? Yes  No

3.35. Is all equipment cleaned and serviced immediately after use? Yes  No

3.36. Are fumes from power driven equipment, heaters etc. ventilated away from the manufacturing areas? Yes  No

3.37. Are there maintenance procedures in place for all equipment? Yes  No

3.38. Is all equipment regularly serviced and calibrated?
- If Yes, are appropriate records maintained? Yes  No
- Are these regularly checked to ensure calibration is up to date and equipment is working accurately? Yes  No

3.39. Are there procedures in place outlining the action to be taken in the event of a recognized malfunction of the inspection and testing equipment? Yes  No

WATER

3.40. Is the water supply monitored and controlled? Yes  No

3.41. Is potable water the minimum standard used for all manufacturing purposes? Yes  No

3.42. Is the water that is used for all manufacturing purposes periodically analyzed? Yes  No
4. PERSONNEL AND TRAINING

<table>
<thead>
<tr>
<th>Training Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1. Is training given to all new employees?</td>
<td></td>
<td></td>
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<tr>
<td>- If Yes, does this training include personal hygiene?</td>
<td></td>
<td></td>
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<tr>
<td>4.2. Is additional appropriate regular training offered to personnel?</td>
<td></td>
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<tr>
<td>4.3. Is required training specific to an individual’s assigned function?</td>
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<tr>
<td>4.4. For full time personnel, is their training subjected to formal review and assessment?</td>
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<tr>
<td>4.5. Are individual training records kept and maintained?</td>
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<tr>
<td>4.6. Do office, maintenance and cleaning staff and any contractors who enter the production or storage areas receive hygiene instructions?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.7. Are employees trained on principles of product safety, including the potential for microbiological, chemical, and foreign body hazards?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. PERSONNEL AND TRAINING

HYGIENE

4.8. Is appropriate protective clothing, including safety footwear and suitable overclothing provided to employees?  
4.9. Is there a requirement for protective outerwear to be removed when leaving the manufacturing areas?  
4.10. Are pre-employment medical checks carried out?  
4.11. Are all visitors made aware of the Company’s hygiene policy?  
4.12. Is there a reporting procedure for staff suffering from, or who are in close contact with people suffering from, specific medical conditions?  
4.13. Is there a personal medication procedure in place?  
4.14. Is there a Return to Work procedure in place following illness or holidays abroad?  
4.15. Are there clear written policies in place:  
- on the wearing of wristwatches and jewelry in the manufacturing areas?  
- on items of clothing or jewelry that may be allowed in the manufacturing areas for medical, ethnic or religious reasons?  
- on the carrying of loose items (pens, mobile phones etc.) in the same areas?  
- on the removal of protective clothing before break periods and on leaving the production area?  
4.16. Are procedures in place for hand washing?  
- Do the procedures address the maintenance of fingernails clean, short, and unvarnished?  
4.17. Is antibacterial cream, foam or gel available for applying after hand washing for personnel working in areas of high microbiological sensitivity?  
4.18. Is there a procedure in place to control glove issue?
5. PRODUCT AND PROCESS DEVELOPMENT

5.1. Are checks carried out on all new products to establish whether the ingredients and formulation are suitable, safe and legal for all intended markets?

- Yes □  No □

5.2. Are the same checks as above carried out when any significant change is proposed e.g. change of raw material or equipment?

- Yes □  No □

5.3. Are potential allergen sources identified during the development process?

- Yes □  No □

5.4. Has stability been checked (either through actual stability tests or the use of previously confirmed data) and the shelf life correctly determined for:

- All products?

- Yes □  No □

- Risk products?

- Yes □  No □

5.5. Is shelf life testing a requirement of the product development program?

- Yes □  No □

5.6. Are proposed labels checked to ensure they conform to all relevant labelling legislation?

- Yes □  No □

5.7. Are all proposed claims checked to ensure they comply with current legislation?

- Yes □  No □

5.8. For all new or revised products, is the appropriateness and legality of the packaging checked to ensure compliance?

- Yes □  No □

5.9. Are all new and revised products checked to ensure that the planned methods and procedures are suitable and that consistent quality products can be produced?

- Yes □  No □
6. MANUFACTURE

6.1. **Does each product have:**

- A defined and authorized Master Formula?  
  - Yes  
  - No

- Defined and authorized Master Manufacturing Instructions?  
  - Yes  
  - No

- Related Standard Operating Procedures?  
  - Yes  
  - No

6.2. **Are all instructions and operating procedures clear and unambiguous and written in the official working language of the manufacturing facility?**  
  - Yes  
  - No

6.3. **Have appropriate trials been undertaken for each product to confirm that the formulation, methods and procedures specified in the Master Manufacturing Instructions:**

- are suitable for factory production?  
  - Yes  
  - No

- are capable of consistently yielding products within the Finished Product Specification?  
  - Yes  
  - No

6.4. **Are periodic checks undertaken to ensure the Master Manufacturing Instructions are being followed and that they are still applicable and relevant?**  
  - Yes  
  - No

6.5. **Have the following been developed and brought to the attention of all relevant personnel:**

- Written operating procedures for each piece of equipment / instrument?  
  - Yes  
  - No

- Written instructions detailing the action to be taken in the event of stoppages, breakdowns or other unexpected events?  
  - Yes  
  - No

- Formal procedures setting out the action to be taken in the event of foreign body contamination at any stage during the manufacturing process?  
  - Yes  
  - No

**PRODUCTION**

6.6. **Have procedures been established for ensuring that the work area and equipment are clean and free from any starting material, packaging material, products, product-residues or documents before production begins?**  
  - Yes  
  - No

6.7. **During production, are all materials, bulk containers and major items of equipment labeled to indicate the stage of manufacture and status, where applicable?**  
  - Yes  
  - No

6.8. **Is the final yield, and any significant intermediate yield, of each production lot recorded and checked against the expected yield within defined limits?**  
  - Yes  
  - No
6. MANUFACTURE

RAW MATERIALS

6.9. Are detailed specifications established for all raw materials?

- Yes
- No

6.10. Are internal lot (batch) numbers allocated to all raw materials?

- Yes
- No

6.11. Are the contents of all containers identified?

- Yes
- No

6.12. Are raw materials entering the premises quarantined until they appropriately checked and a decision made on their status i.e. whether approved or rejected?

- Yes
- No

6.13. Are all raw material lots (batches) tested and laboratory records maintained?

- Yes
- No

- If No, specify what portion are tested

6.14. Are Certificates of Analysis (CoA) for raw materials checked to confirm compliance with the specifications?

- Yes
- No

- If Yes, are periodic checks undertaken to verify the quality of the supplier’s CoAs

6.15. Are the temperature and humidity for storing raw materials controlled and recorded?

- Yes
- No

- If Yes, what are the tolerances?

6.16. Are there procedures in place for issuing raw materials from storage?

- Yes
- No

6.17. Is correct stock rotation followed when issuing raw materials from storage?

- Yes
- No

6.18. Is there a procedure in place for the reconciliation of the quantities of raw materials issued against the quantity of product manufactured?

- Yes
- No

6.19. When lot quantities are dispensed manually into containers in advance, is this process done in a segregated area?

- Yes
- No

6.20. Are all weighings checked by a second operator or by use of a validated computerized weighing control system?

- Yes
- No
6. MANUFACTURE

PACKAGING AND LABELLING MATERIALS

6.21. Are packaging materials certified for food contact use (i.e. in conformance with current legislation on materials and articles in contact with food)?

- Yes
- No

6.22. Is there a procedure in place to ensure that changes in product formulation are reflected in the label copy?

- Yes
- No

6.23. Are internal reference codes allocated to each delivery or lot/batch of packaging material?

- Yes
- No

6.24. Is packaging material entering the premises quarantined until it is appropriately checked and a decision made on its status i.e. whether approved or rejected?

- Yes
- No

6.25. Are stocks of packaging materials in storage inspected regularly to check their condition?

- Yes
- No

6.26. Is stock rotation followed when issuing packaging materials from storage?

- Yes
- No

6.27. Are all packaging materials inspected immediately before use?

- Yes
- No

6.28. Are procedures in place for:

- the issue of packaging materials from storage?

- Yes
- No

- the return of part-used lots of packaging to storage?

- Yes
- No

- the re-sealing of part-used boxes of packaging, to prevent foreign contamination?

- Yes
- No

- the reconciliation of all printed packaging component stock from quantity issued, quantity used, wastage and that returned to store?

- Yes
- No

- the removal and destruction of superseded packaging or labels?

- Yes
- No

- All plant and equipment is clean and ready for use?

- Yes
- No
6. MANUFACTURE

PROCESSING AND PACKAGING

6.29. Are multiple packaging lines (where present) segregated to avoid the risk of cross-contamination?

6.30. Are the following checks always carried out before the start of any process:
- The name and appropriate reference to the product being processed is clearly displayed on each production line?
- The production area is clean and free from any items not relevant to the process to be undertaken?
- The correct materials and documents have been issued?
- The correct machine settings have been made?
- All plant and equipment is clean and ready for use?

6.31. Are in-process conditions monitored (e.g. by sensory, instrumental and/or laboratory testing, correct packaging and date-marking)?

6.32. Are samples analyzed:
- After production?
- If Yes, are these samples tested:
  - In-house
  - Contract Laboratory
- Are the samples during production tested according to pre-set specifications?

6.33. Are intermediate products and packed finished products quarantined until checked and approved by Quality Control?

6.34. Are there procedures in place for the management of non-conforming products?

INTERMEDIATE AND FINISHED PRODUCTS

6.35. Are products quarantined until it is appropriately checked and a decision made on its status i.e. whether approved or rejected?

6.36. Does Quality Control release all products for sale once the appropriate checks are completed and acceptable?

6.37. Are all results that fail to meet the specification investigated?
6. MANUFACTURE

DISPOSAL OF WASTE AND EFFLUENT

6.38. Is the disposal of printed packaging materials, raw materials and reject product appropriately controlled?  
- Yes  
- No

6.39. Is a reconciliation carried out on quantities of materials or product used and/or produced against those being disposed of?  
- Yes  
- No

6.40. Are all waste materials and effluent disposed of by a route appropriate to the class of material?  
- Yes  
- No
### 7. Recovery or Re-working of Materials

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7.1.</strong></td>
<td>Are there procedures in place to control recovered, reworked, or reprocessed material?</td>
<td>![Yes]</td>
<td>![No]</td>
</tr>
<tr>
<td><strong>7.2.</strong></td>
<td>Is the recovery, re-working or re-processing of materials or products clearly documented and these records kept for a previously decided period?</td>
<td>![Yes]</td>
<td>![No]</td>
</tr>
<tr>
<td><strong>7.3.</strong></td>
<td>Is recovered, reworked, or reprocessed material quarantined until checked by Quality Control and a disposition decision is made?</td>
<td>![Yes]</td>
<td>![No]</td>
</tr>
<tr>
<td><strong>7.4.</strong></td>
<td>Is there a system in place to ensure that when there is doubt regarding the quality of materials or product, they should not be recovered, reworked, or re-processed but are destroyed?</td>
<td>![Yes]</td>
<td>![No]</td>
</tr>
<tr>
<td><strong>7.5.</strong></td>
<td>Are authorized and validated methods used for re-processing?</td>
<td>![Yes]</td>
<td>![No]</td>
</tr>
<tr>
<td><strong>7.6.</strong></td>
<td>Are finished products that have been returned from the market assessed and released by Quality Control before consideration is given for re-sale?</td>
<td>![Yes]</td>
<td>![No]</td>
</tr>
</tbody>
</table>
8. STORAGE

ACCESS TO STORAGE AREAS

8.1. Is access to material and product storage areas restricted to those working in these areas and to other authorized persons?

8.2. Is there a suitable curtain at all entrances and exits of the storage area?

8.3. If the storage area connects to the manufacturing area, is a buffer area/pass box provided between the two areas?

TEMPERATURE AND LIGHTING

8.4. Is temperature mapping and recording carried out in the storage area(s)?

PRODUCT STORAGE

8.6. Is a stock rotation system followed?

8.7. Are all aisles in the storage area(s) kept clear?

8.8. Is pest control in place in the storage area(s)?

8.9. Are pallets regularly checked for structural integrity?

8.10. Are packed products stored in conditions necessary for safe storage, appropriate to their specifications?

8.11. Are stored materials and product clearly identifiable, even when stacked?

8.12. Is there a specific quarantine area for material deliveries/product batches awaiting results of testing?

DAMAGED GOODS

8.13. Is there a specific holding area for damaged goods, awaiting Quality Control inspection?
8. STORAGE

CLEANING OF STORAGE AREAS

8.14. Are the storage facilities periodically inspected:
   - For cleanliness? [Yes] [No]
   - For pest infestation? [Yes] [No]
   - To identify materials and product exceeding its shelf life? [Yes] [No]

8.15. Are such inspections documented and any corrective actions noted? [Yes] [No]

8.16. Are there procedures in place for cleaning of the storage premises and equipment? [Yes] [No]
9. TRANSPORT AND DISTRIBUTION

9.1. **Are vehicle / container interiors inspected:**
- before loading materials / products?  
  ![Yes](yes_icon) ![No](no_icon)
- on unloading materials / products  
  ![Yes](yes_icon) ![No](no_icon)

9.2. **Are contaminated and damaged containers kept apart from those that are clean and in good condition?**
  ![Yes](yes_icon) ![No](no_icon)

9.3. **Are security measures in place that:**
- Help deter tampering with goods in storage and distribution?  
  ![Yes](yes_icon) ![No](no_icon)
- Show whether any tampering has occurred?  
  ![Yes](yes_icon) ![No](no_icon)

9.4. **Is there a written procedure to deal with damages occurring to goods during storage and distribution?**
  ![Yes](yes_icon) ![No](no_icon)

9.5. **Are audits carried out on contracted-out transport facilities and procedures, where relevant**
  ![Yes](yes_icon) ![No](no_icon)

9.6. **Are the relevant personnel informed when care is needed to reduce large temperature fluctuations during transport and delivery?**
  ![Yes](yes_icon) ![No](no_icon)
### 10. DOCUMENTATION

10.1. **Is there a written procedure covering the complete documentation system**  
- Yes  - No

10.2. **- If Yes, does this include procedures for the:**  
- Maintaining the history of each lot of product?  
  - Yes  - No  
- Issue of documents?  
  - Yes  - No  
- Authorization of documents?  
  - Yes  - No  
- Distribution of documents?  
  - Yes  - No  
- Periodic review of documents?  
  - Yes  - No  
- Revision of documents?  
  - Yes  - No

10.3. **For electronic documentation, are there safeguards in place to ensure that:**  
- Data is entered correctly?  
  - Yes  - No  
- Sufficient back-ups are made and retained?  
  - Yes  - No  
- Unauthorized access is prevented?  
  - Yes  - No

10.4. **Are relevant personnel given appropriate training on how to complete the documents?**  
- If Yes, is this training regularly reviewed? Unauthorized access is prevented?  
  - Yes  - No

10.5. **Are there safeguards in place to restrict the entering of data to authorized persons only?**  
- Yes  - No

10.6. **Are any amendments to documentation clearly corrected and authorized?**  
- Yes  - No

10.7. **Are superseded documents removed from active use and a copy retained, clearly marked as superseded?**  
- Yes  - No

10.8. **Has a manual been prepared that describes the overall Quality Assurance system, the procedures employed and the documents used?**  
- Yes  - No

10.9. **Are there procedures in place outlining the action to be taken in the event of system failure or breakdown?**  
- Yes  - No
## 10. DOCUMENTATION

10.10. Do you periodically review and revise your documentation system?  
Yes [ ]  No [ ]

10.11. Are documents in place that describe product manufacturing and requirements (i.e. manufacturing formula, process instructions, packaging instructions, specifications, cleaning, testing, and equipment operation)?  
Yes [ ]  No [ ]

10.12. In general, for how long are records retained?  
[ ]

10.13. Has it been confirmed that this complies with any legal requirements?  
Yes [ ]  No [ ]

10.14. Are lot (batch) records retained for the shelf life of the product, plus one year?  
Yes [ ]  No [ ]

10.15. Is personnel data retained in accordance with national laws on such data?  
Yes [ ]  No [ ]

10.16. Is a Controlled Records List utilized?  
Yes [ ]  No [ ]

10.17. Are there safeguards in place to protect all documentation (both electronic and paper copy) in the event of a fire?  
Yes [ ]  No [ ]
11. COMPLAINTS PROCEDURE, PRODUCT RECALL AND EMERGENCY PROCEDURE

COMPLAINTS

11.1. Are there procedures in place for handling product related complaints?

11.2. Are personnel appropriately trained to ensure that all complaints are recognized, communicated and recorded?

11.3. Is the Quality Control Manager kept fully informed and closely consulted on all complaints?

11.4. Is there a procedure in place for handling complaints specifically related to adverse events?
   - If Yes, is there a designated person who is responsible for implementing and monitoring this procedure?

11.5. Is complaint analysis carried out at periodic intervals?

11.6. Are summaries of complaints and / or trends sent to key senior personnel?

PRODUCT WITHDRAWAL AND RECALL

11.7. Are there procedures in place for:
   - Product withdrawal?
   - Product recall?

11.8. Is there a nominated, responsible person and nominated deputies to co-ordinate recall activities?

11.9. Has a crisis management team been established?

11.10. Has the withdrawal/recall system been tested?

11.11. Are there procedures in place regarding the proper treatment of withdrawn or recalled material or product?

EMERGENCY PROCEDURE

11.12. Are there procedures in place for responding to emergencies?
12. SELF-INSPECTION

12.1. Is there a prearranged program for self-inspections to monitor the implementation and compliance with GMP principles and to propose necessary corrective measures?

- If Yes, are they conducted at least once a year?

12.2. Are records made of all observations, corrective measures, and the subsequent action taken?

12.3. Are the self-inspections periodically reviewed by senior management?
13. SUB-CONTRACTING OPERATIONS

13.1. Is your company a Contract Giver?
- If Yes, please go to question 13.3

13.2. Is your company a Contract Acceptor?
- If Yes, please go to question 13.3

13.3. Contract Giver:

a. Is there a program for auditing the key suppliers i.e. those who supply ‘risk’ materials?
- Yes
- No

b. Are all suppliers assessed by means of:
- A site audit?
- A self-assessment form?
- Yes
- No

- Yes
- No

- Yes
- No

- Yes
- No

c. Are detailed product specifications agreed with every supplier?
- Yes
- No

d. Are any special quality control / GMP requirements agreed with every supplier?
- Yes
- No

e. Is there a Technical Agreement in place with every supplier?
- Yes
- No

13.3. Contract Giver:

a. Are detailed product specifications agreed with every customer?
- Yes
- No

b. Are any special quality control / GMP requirements agreed with every customer?
- Yes
- No

c. Is there a Technical Agreement in place with every customer?
- Yes
- No
14. LABORATORY TESTING

14.1. **Is there an in-house company laboratory?**
- If No, please go to question 14.5.
- If Yes, is the laboratory accredited?
  - If Yes, please specify

14.2. **Is all laboratory equipment and instrumentation regularly serviced and calibrated?**

14.3. **Are there written procedures for:**
- each piece of equipment / instrument?
- reagent and standard preparation?
- sampling?

14.4. **Are samples analyzed according to written procedures, using internationally accepted test methods or other methods that have been scientifically validated?**

14.5. **Does the laboratory use analytical methods that include a control step to verify the instrument is functioning accurately, when necessary**

14.6. **Is there adequate storage space for storage of samples at the appropriate temperature**

14.7. **Does your company use a contract laboratory?**
- If Yes, is the laboratory accredited?

14.8. **Is the performance of the laboratory monitored and audited?**