IADSA

International Alliance of Dietary/
Food Supplement Associations

IADSA SELF-ASSESSMENT TOOL ON GOOD MANUFACTURING PRACTICE FOR SUPPLEMENTS

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?** Yes No

- If Yes, which?

2.2. **Does the company have personnel specifically responsible for quality (e.g. Quality Control / Quality Assurance Manager)?** Yes No

- If Yes, are the authority and responsibilities of these personnel clearly defined? Yes No

2.3. **Do these personnel have the authority to make independent decisions on product quality?** Yes No

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 Yes No
- quantity and quality produced are as expected Yes No
- finished batches are enclosed in the proper container and bear the correct label Yes No
- finished products are stored, distributed, and recommendations given for subsequent handling Yes No

2.5. **Is there documented evidence for all lots (batches) of product that demonstrates the following?**

- Starting materials? Yes No
- Finished products in the final pack? Yes No

2.6. **Are there procedures in place to define the process of pulling above samples?** Yes No

2.7. **Are there procedures in place to ensure the traceability of all raw material, intermediate and finished product?** Yes No

2.8. **Do the traceability records allow for rapid identification of:**

- the suppliers of the raw materials Yes No
- the complete manufacturing history of a lot of finished product Yes No
- the businesses to which finished products have been supplied? Yes No

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)?** Yes No

3.2. **Equipment is regularly reviewed and action taken when necessary** Yes No

3.3. **Are the floor, wall, ceilings, windows, and doors easily cleanable?** Yes No

3.4. **Are the manufacturing areas separate and distinct from other functional areas such maintenance and laboratories?** Yes No

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?** Yes No

3.6. **Where required, is there a system in place to monitor temperature, and humidity?** Yes No

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

- raw material storage area? Yes No
- manufacturing areas? Yes No
- finished products storage area? Yes No

3.8. **Is there a formal glass, ceramic, or hard plastic breakage control procedure?** Yes No

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

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? ○ Yes ○ No

- 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

TRAINING

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

4. PERSONNEL AND TRAINING

HYGIENE

4.8.	**Is appropriate protective clothing, including safety footwear and suitable overclothing provided to employees?**	Yes	No
4.9.	**Is there a requirement for protective outerwear to be removed when leaving the manufacturing areas?**	Yes	No
4.10.	**Are pre-employment medical checks carried out?**	Yes	No
4.11.	**Are all visitors made aware of the Company's hygiene policy?**	Yes	No
4.12.	**Is there a reporting procedure for staff suffering from, or who are in close contact with people suffering from, specific medical conditions?**	Yes	No
4.13.	**Is there a personal medication procedure in place?**	Yes	No
4.14.	**Is there a Return to Work procedure in place following illness or holidays abroad?**	Yes	No
4.15.	**Are there clear written policies in place:**		
	- on the wearing of wristwatches and jewelry in the manufacturing areas?	Yes	No
	- on items of clothing or jewelry that may be allowed in the manufacturing areas for medical, ethnic or religious reasons?	Yes	No
	- on the carrying of loose items (pens, mobile phones etc.) in the same areas?	Yes	No
	- on the removal of protective clothing before break periods and on leaving the production area?	Yes	No
4.16.	**Are procedures in place for hand washing?**	Yes	No
	- Do the procedures address the maintenance of fingernails clean, short, and unvarnished?	Yes	No
4.17.	**Is antibacterial cream, foam or gel available for applying after hand washing for personnel working in areas of high microbiological sensitivity?**	Yes	No
4.18.	**Is there a procedure in place to control glove issue?**	Yes	No

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	Yes	No
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? Yes No

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? Yes No
- The production area is clean and free from any items not relevant to the process to be undertaken? Yes No
- The correct materials and documents have been issued? Yes No
- The correct machine settings have been made? Yes No
- All plant and equipment is clean and ready for use? Yes No

6.31. Are in-process conditions monitored (e.g. by sensory, instrumental and / or laboratory testing, correct packaging and date-marking)? Yes No

6.32. Are samples analyzed:

- After production? Yes No
  - If Yes, are these samples tested:

    In-house Contract Laboratory
- Are the samples during production tested according to pre-set specifications? Yes No

6.33. Are intermediate products and packed finished products quarantined until checked and approved by Quality Control? Yes No

6.34. Are there procedures in place for the management of non-conforming products? Yes No

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? Yes No

6.36. Does Quality Control release all products for sale once the appropriate checks are completed and acceptable? Yes No

6.37. Are all results that fail to meet the specification investigated? Yes No

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

7.1.	Are there procedures in place to control recovered, reworked, or reprocessed material?	Yes	No
7.2.	Is the recovery, re-working or re-processing of materials or products clearly documented and these records kept for a previously decided period?	Yes	No
7.3.	Is recovered, reworked, or reprocessed material quarantined until checked by Quality Control and a disposition decision is made?	Yes	No
7.4.	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?	Yes	No
7.5.	Are authorized and validated methods used for re-processing?	Yes	No
7.6.	Are finished products that have been returned from the market assessed and released by Quality Control before consideration is given for re-sale?	Yes	No

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?	Yes	No
8.2.	Is there a suitable curtain at all entrances and exits of the storage area?	Yes	No
8.3.	If the storage area connects to the manufacturing area, is a buffer area/pass box provided between the two areas?	Yes	No

TEMPERATURE AND LIGHTING

8.4.	Is temperature mapping and recording carried out in the storage area(s)?	Yes	No

PRODUCT STORAGE

8.6.	Is a stock rotation system followed?	Yes	No
8.7.	Are all aisles in the storage area(s) kept clear?	Yes	No
8.8.	Is pest control in place in the storage area(s)?	Yes	No
8.9.	Are pallets regularly checked for structural integrity?	Yes	No
8.10.	Are packed products stored in conditions necessary for safe storage, appropriate to their specifications?	Yes	No
8.11.	Are stored materials and product clearly identifiable, even when stacked?	Yes	No
8.12.	Is there a specific quarantine area for material deliveries/product batches awaiting results of testing?	Yes	No

DAMAGED GOODS

8.13.	Is there a specific holding area for damaged goods, awaiting Quality Control inspection	Yes	No

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 ○ No

- on unloading materials / products ○ Yes ○ No

9.2. Are contaminated and damaged containers kept apart from those that are clean and in good condition? ○ Yes ○ No

9.3. Are security measures in place that:

- Help deter tampering with goods in storage and distribution? ○ Yes ○ No

- Show whether any tampering has occurred? ○ Yes ○ No

9.4. Is there a written procedure to deal with damages occurring to goods during storage and distribution? ○ Yes ○ No

9.5. Are audits carried out on contracted-out transport facilities and procedures, where relevant ○ Yes ○ No

9.6. Are the relevant personnel informed when care is needed to reduce large temperature fluctuations during transport and delivery? ○ Yes ○ No

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?**	Yes	No
	- 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?** Yes No

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?** Yes No

11.4. **Is there a procedure in place for handling complaints specifically related to adverse events?** Yes No

- If Yes, is there a designated person who is responsible for implementing and monitoring this procedure? Yes No

11.5. **Is complaint analysis carried out at periodic intervals?** Yes No

11.6. **Are summaries of complaints and / or trends sent to key senior personnel?** Yes No

PRODUCT WITHDRAWAL AND RECALL

11.7. **Are there procedures in place for:** Yes No

- Product withdrawal? Yes No

- Product recall? Yes No

11.8. **Is there a nominated, responsible person and nominated deputies to co-ordinate recall activities?** Yes No

11.9. **Has a crisis management team been established?** Yes No

11.10. **Has the withdrawal/recall system been tested?** Yes No

11.11. **Are there procedures in place regarding the proper treatment of withdrawn or recalled material or product?** Yes No

EMERGENCY PROCEDURE

11.12. **Are there procedures in place for responding to emergencies?** Yes No

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?**	Yes	No
	- If Yes, are they conducted at least once a year?	Yes	No
12.2.	**Are records made of all observations, corrective measures, and the subsequent action taken?**	Yes	No
12.3.	**Are the self-inspections periodically reviewed by senior management?**	Yes	No

13. SUB-CONTRACTING OPERATIONS

13.1. Is your company a Contract Giver? Yes No

- If Yes, please go to question 13.3

13.2. Is your company a Contract Acceptor? Yes No

- 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? Yes No

- A self-assessment form? 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? Yes No

- If No, please go to question 14.5.

- If Yes, is the laboratory accredited? Yes No

  - If Yes, please specify

14.2. Is all laboratory equipment and instrumentation regularly serviced and calibrated? Yes No

14.3. Are there written procedures for:

- each piece of equipment / instrument? Yes No

- reagent and standard preparation? Yes No

- sampling? Yes No

14.4. Are samples analyzed according to written procedures, using internationally accepted test methods or other methods that have been scientifically validated? Yes No

14.5. Does the laboratory use analytical methods that include a control step to verify the instrument is functioning accurately, when necessary Yes No

14.6. Is there adequate storage space for storage of samples at the appropriate temperature Yes No

14.7. Does your company use a contract laboratory? Yes No

- If Yes, is the laboratory accredited? Yes No

14.8. Is the performance of the laboratory monitored and audited? Yes No