

GUIDELINES FOR IMPLEMENTING GMP IN FOOD PROCESSING

6. Quality Assurance

6.1 *Comprehensive QA system*

6.1.1 The company must have a comprehensive system of quality assurance and monitoring, to ensure the consistent production of safe, legal product in compliance with the agreed specification.

6.1.2 The company must have sufficient properly trained personnel to maintain agreed quality standards, with clearly defined responsibilities covering all aspects of the operation.

6.1.3 The Quality Assurance department should be operational at all times when production is in progress, even if only a skeleton staff is required.

6.1.4 The Quality Assurance department should be independent from the production and purchasing functions, although they must liaise with each other to achieve the required product specification.

6.1.5 Adequate resources and facilities must be made available for the Quality Assurance department to fulfil its tasks. This may necessitate the use of offices, laboratories and other designated areas within the factory.

6.1.6 Where chemical, physical, microbiological and sensory analysis of raw materials and finished product is required, appropriate facilities must be provided for this, which are physically separated from each other and the production area. Additionally, sample storage areas must be allocated for chilled, frozen and ambient products.

6.1.7 The company should have a Quality Assurance Manual, detailing the type and frequency of checks carried out and the documentation records to be filed.

6.1.8 The results of the checks, together with any corrective actions taken in response to adverse results must be legibly documented and held for a minimum period of one year or longer dependent on the product's shelf life or where required by legislation.

6.1.9 All Quality Assurance Systems must take consideration of HACCP, all relevant legislation and good manufacturing practice.

6.2 *Authority of QA department to stop production*

6.2.1 The Quality Assurance department must have the authority to accept or reject raw materials, packaging materials, work in progress and finished product against an agreed specification.

6.2.2 Where good manufacturing practice is not being exercised, and product is at risk or non-conforming, the Quality Assurance department must have the authority to stop production.

6.2.3 In the event of a line stoppage by the Quality Assurance department, the reasons for it must be explained to production and the appropriate corrective action agreed and implemented prior to the line re-starting.

6.3 *Finished product specifications accurate and up to date*

6.3.1 All products manufactured on site must conform to a written specification, which has been agreed between the manufacturer and the customer, signed and dated.

6.3.2 Details within a product specification must not be altered without prior consent from the customer. All amendments must be signed and dated.

6.3.3 All products must be manufactured according to the specification. Suspect or non-conforming raw material, part processed or finished products must be clearly identified as such, and dealt with accordingly. e.g non-conforming raw materials are returned to supplier

6.4 ***Microbiological testing as appropriate***

6.4.1 The microbiological testing regime and resource required, will ultimately depend on the nature of the product to be tested (e.g. degree of risk, shelf life and composition).

6.4.2 Where microbiological laboratory facilities are provided on site, they must be physically separated from production, and good laboratory practice must be evident.

6.4 ***Microbiological testing as appropriate (Continued)***

6.4.3 Adequate measures must be taken to ensure that the risk of cross contamination from laboratory areas to production is eliminated:-

- i. Access must be restricted to "authorised" personnel only.
- ii. Protective clothing worn in microbiological laboratories must not be worn in production areas.
- iii. Provision should be made for the safe storage and disposal of laboratory waste (both microbiological and chemical) in accordance with existing legislation .
- iv. Although not recommended where microbiological testing of pathogens is undertaken, this must be segregated within the laboratory and strict precautions taken by staff to eliminate any possible threat to product.
- v. Stringent precautions must be exercised when sampling to avoid any contamination risks which would result in an inaccurate test e.g use of contaminated glass, chemicals

6.4.4 Laboratory personnel must be competently trained to undertake the analysis, interpret the results and flag up problems when they arise.

Reference standards for microbial limits should be defined e.g absence of Salmonella in 25g, E. coli <10 in 25g, Coliforms <100/g, TPC <100,000 CFU/g

6.4.5 There must be daily communication between the microbiological laboratory and Quality Assurance department, through designated staff, to ensure that corrective action is taken in response to out of specification results.

6.4.6 It is recommended that In accordance with the appropriate hazards regulations, all laboratory methods adopted should be written up, including an assessment of the hazard of each chemical used and relevant instructions to contain any hazard.

6.4.7 All laboratory equipment and instrumentation used should be clean, well maintained, serviced and calibrated at regular intervals, to ensure its accuracy, and this information kept on record.

6.4.8 Where outside laboratories are used, whether for all or part of the microbiological testing regime (e.g. pathogens) the premises should be vetted prior to commencement of the contract, to ensure that they too comply with points 6.4.1 to 6.4.7 above.

Contract laboratories should therefore be assessed using 6.4.1- 6.4.7 -

6.5 Vehicle temperature checks and condition

6.5.1 For chilled products, a designated person should check the internal temperature of the product by placing temperature recording device in gills, for all vehicles. Despatched frozen or chilled product must be maintained at correct temperature and monitored at the airport prior to release. The QA team should be aware of these checks. It is recommended that external digital temperature recorders are on trucks delivering to the port of exit e.g airports, seaports.

6.5.2 The internal condition of delivery vehicles must be inspected prior to unloading deliveries or loading finished product, to ensure that vehicles are clean, well maintained and free of foreign bodies, pests and odours.

6.5.3 Where, for whatever reason the use of a vehicle is rejected by the Quality Assurance department, the reasons for rejection must be recorded, dated, signed and appropriate corrective action taken. Where contract distribution companies are used, this will mean talking to them directly.

6.6 Products returned to chill store at breaks

6.6.1 Depending on the product being manufactured and the ingredients involved, there may be a definite need to return all pre-weighed raw materials, work in progress materials and finished products to the appropriate chill store at break times.

6.6.2 Products which do need to be kept chilled should be suitably racked or contained and covered to prevent product contamination from external sources.

6.7 Manual temperature checks carried out and recorded

6.6.1 Where temperature control is a critical factor in the process, from a safety or manufacturing point of view, it should be manually checked at an agreed frequency e.g every 2 hrs and records maintained. Temperature control charts or written records must be evident.

6.6.2 Where manual temperature checking is carried out against a standard, the recording document must have the target value and tolerances indicated e.g finished product < 2 C plus or minus 1 centigrade .

6.6.3 Where manual temperature checking is carried out to cross reference an automated system or independent dial reading, any discrepancies must be investigated and rectified.

6.8 Adverse temperature reaction procedure

6.8.1 Whenever temperature is checked, and it is found to be totally out of the tolerance range, swift action must be taken, which will result in minimum risk to the product and its safety. The action taken must be recorded.

6.8.2 Where the adverse temperature has already caused problems to the product, or where the duration of the adverse temperature is unknown, then the product should be quarantined, investigated and relevant action taken dependent on the results. e.g low temperature will result in product discolouration.

6.8.3 If the adverse temperature is the result of an equipment fault, then the maintenance department should be informed immediately, the fault and date recorded and a time for the repair agreed.

6.9 ***Proper calibration of all measuring equipment***

6.9.1 All measuring equipment which has a direct effect on the production process, safety and quality of the product being manufactured, should be regularly calibrated against a given standard.

6.9.2 Results of the calibration should be formally documented and signed and the next due calibration date given, to ensure accuracy of all measuring equipment.

6.9.3 Where measuring equipment is taken off site for calibration, provision must be made for "reserve" equipment which is also accurate, well maintained and calibrated to be available.

6.10 ***Proper product recall procedures***

6.10.1 The company must have a formalised, written complaints procedure, detailing the person responsible through whom all product complaints must be channelled.

6.10.2 If a person other than the Quality Assurance Manager has been allocated this task, then they must have sufficient product knowledge, experience and authority to implement the appropriate corrective action.

6.10.3 All quality complaints should be recorded when received (either through verbal or written communication), investigated within a given time scale according to their urgency and a report prepared as the basis for corrective action and for company records.

6.10.4 Corrective action should include responding to the complainant and local enforcement authority if involved. Copies of these letters must be kept on file. Procedures should be implemented to remove the cause of the complaint and therefore prevent its recurrence.

6.10.5 Complaints reports should be used to "monitor" trends and should therefore be regularly reviewed. They may indicate a potential product recall or a specific problem. Review findings, including comparative data should be regularly distributed to Directors and Senior Management.

6.10.6 It is recommended that the company should have a formalised, written product recall procedure, which should be capable of being put into operation at anytime of the day or night.

6.10.7 A nominated person, with appropriate authority, should co-ordinate the activities of the named recall "team", under complete confidentiality. That person should be the point of contact with the competent authority. If the media becomes involved, the company must have a designated spokesperson.

6.10.8 The recall procedure should be workable and effective within a reasonable time scale, but must be regularly reviewed in the event of changing circumstances.

6.10.9 The recall procedure should give the precise method of notifying all distribution networks and retailers involved, including contact names and telephone numbers. The procedure must be able to halt the transit of products at any stage in the distribution chain.

6.10.10 Notification of recall should give full product details, batch code identification, the nature of the defect, the action required and the degree of risk involved.

6.10.11 All recalled material at whatever stage of the distribution chain, must be quarantined, clearly labelled as such and held whilst a decision is made as to its destiny.