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Lecture - 59 Good Manufacturing Practices (GMP)

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Hello friends. Let us study a very important aspect in food processing industry that is Good Manufacturing Practices, which is commonly known as or called as in short GMP. GMP is defined as the procedure which provides the basic environmental conditions and a management system structure for the production of safe foods.

Why GMP is needed, it is needed to assist the organization to implement and operate effective management practices to produce and process product as per the specifications and to reduce the risk of contamination. It is very important as far as the safety of the customers are concerned, it is required to maintain manufacturing consistency as well as it is needed or it is important for the image and reputation of the company.

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In this slide, just I have tried to (Refer Time: 01:35) you that what are the different pillars in GMP process that is overview that is there are four major that is one is the management, management responsibilities there for the GMP, then resources food processing resources, whatever they also should confirm to the GMP, then there should be measurement analysis and improvement to make sure that the GMP's force fully applied or implemented, and then another aspect is the product realization.

So, in the next slides in the next about 25 to 30 minutes, we will take up one by one these issues. So, first of all you know that in the any food processing industry that it is not only inside the factory, but it deals with that is the raw material that is how when the raw material is produced, there also that is the GMP means, it is the total overall whole holistic approach starting from the primary production of the raw materials, transportation, then storage, then food processing, finally retail etcetera. It involves that suppliers, raw materials, packaging material, processing aids, pesticides, fertilizers, cleaning chemicals etcetera.

So, good agronomical practices should be followed good, horticultural practices should be followed, good environmental practices must be ensured. So, as to get the good quality raw material, I had the processing plant.

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So, the role of organization as far as the implementation of the GMP is concerned, it has very very important role. Like it should set up a GMP team, then formation of the SOPs that is Standard Operating Procedures, and its documentation; a setting up of a quality assurance system for protection production as well as service, then communication both internal as well as external, proper hygiene and sanitation, proper training of the personnel, periodic evaluation and update and documentation.

So, all these comes under the role of the organizations that it is the organizations responsibility includes that is to plant, to document, to implement, to operate, to validate, to maintain, to improve, to upgrade that is a GMP system. So, as to ensure the quality products are produced which are safe for consumption, so that is the role as well as the responsibility of the organization is concerned.

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Regarding GMP and HACCP Hazard Analysis and Critical Control Point, it is a important aspect of GMP. It can be a part of the GMP and is a systematic program to assure food safety. HACCP is designed to be applied to every aspect of food industry as I told you from farm to table including growth, harvest, processing, distribution, and sales etcetera.

HACCP requires the use of SOPs maybe clearly written instructions, the generation of accurate, accountable records for all the process steps and measurements as well as the employment of the apart appropriately trained staff. So, this may be part of the HACCP system. A basic GMP program is a prerequisite of HACCP accreditation. HACCP is a vehicle to ensure safety for human consumers and eliminate as much risk as possible from a food processing or food manufacturing perspective.

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Before there are in the HACCP, there are seven steps, and these seven steps must be ensured their implementation in the chronological order. Like first is that depending upon the type of food that is being produced, whatever raw materials etcetera. In the process value chain steps find out that is conducted hazard analysis that is where are in the process line, where are the chances for the hazards or for the deterioration or the contamination with the health hazard micro organism etcetera.

So, conduct a hazard analysis first point, second is the determine the CCPs which is that is in the process line which is the critical control point, then establish the critical limit, establish a system to monitor control of the CCPs, and then establish the correct to action to be taken well monitoring indicate that a particular CCP is not in control, when established procedure for verification to confirm that the HACCP system is working efficiently or effectively, and finally established documentation concerning all procedures and records appropriate to these principles and their application. So, these are the seven.

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Then let us discuss about a standard operating procedures that is basically, it is a fixed methodology that is a production team should be provided with a SOPs, where it should be SOPs with a clear purpose and frequency. So, it is a need to maintain uniformity right that is just instruction that is or operating manual for the operating personals. It should have clear cut description of the procedures that it should be properly documented.

And it in fact documentation give the proof of work, and also that it helps in the correct to action that is whether if there is an SOPs, one can easily find that whether these SOP are standard protocols have been followed or not or if not what is the CAR that is the Corrective Action Request. So, in CAR for each deviation from the SOP that is the CAR.

So, whenever there is any CAR state the state the deviation, use objective evidence to estate the deviation, then action plan to prevent deviation reoccurrence that is to make sure that is in the future or in such deviations are not occurring, then set a deadline, verify that the action plan has been effective, and finally review and document. So, this is your corrective action to request.

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Documentation, obviously it is the proof of action taken. If it is not documented, it means that it did not happen. And good documentation practices, we are discussing good manufacturing practices. Similarly, good but documentation practices should be followed to maintain the document records should be readily available. Document must be legible, readily identifiable, retrievable, and they should be accurate and consistent with the SOPs etcetera.

And these documents; their control is important, they are reviewed and controlled prior to implementation. Updated and reapproved as and when necessary. Changes and the current revision states are the documents are identified. And obsolete documents are prevented from users that is the document which had become old, they should be appropriately removed from.

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Then very important GMP team. In fact, GMP team has to be separate from the manufacturing team. So, remember it is a basically a member of multidisciplinary knowledge and experience that it should have the people, who have knowledge of all aspects of the production product manufacturing, and its packaging and so on. So, it GMP team is responsible for the maintenance of the records of the process.

In fact, their team's knowledge and experience also should be properly recorded. The GMP team drafts the policies fulfilling the statutory and regulatory requirements. It maintains the integrity of the policy. It access team members efficiency. It conducts proper reviews, and submit reports to the top management that GMP is properly being implemented or it is SOPs, there is no deviation from the SOPs in the production life etcetera. And of course, the GMP team maintains proper communication, communication with the management, communication with the production, team communication with the other teams involved in the process.

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So, after that the next is the GMP regarding resources. Resources are very very essential for the implementation of GMP. And the resources include both the human resource as well as infrastructure that is they must strictly adopt hygienic and sanitary SOP's to attain GMP.

Human resource, for example personnel which are appointed in the factory, whether in the production team, whether in the market team or whether in the GMP team etcetera. They should have proper education. They should have adequate training, they should have proper skill and experience. Even personnel must be assessed periodically.

They should have that is awareness; they should have proper awareness among the personnel regarding food safety and food uses. They should know what is the food safety, how they put which is being produced, how it will be used, what are the different practices being followed during the storage, transportation, handling etcetera all those things. So, they must take care. And training programs should be routinely organized, it should be reviewed updated and documented. So, the human resources, they should be always update, they should have the current knowledge about the product about this process.

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Then next comes the GMP infrastructure that is the premises; the location of the premises. Food processing industry should be established away from polluted areas and industrial, general, non-food industrial activities. Areas subject to floods are prone to infestation by pests should not be used for establishment of food industry that is areas, where waste maybe solid waste or liquid waste cannot be removed effectively that is if it is not having a proper communication, road facility, and all those things that is area should not be so. The locations should be a good location easily communicated or directly linked and more importantly that is nearby surrounding, there should be contamination free environment, it must help in maintaining that.

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Then food industry building design both external as well as internal. The external about 45 centimeter width should surround the exterior of all production and storage buildings as you could see in this picture. The trees should be at least 10 meter away from the production and storage facility.

The facilities for disposal of sewage and wastewater should be provided in the building, the building materials or walls etcetera which are there should have proper protection from weather. Even outside building lighting should be made, so that it should be a yellow sodium lamps or such that they should not invite insects etcetera. So, they should be proper light arrangements.

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Then internal building design, as you can see here that is internal raw material storage, processing, and product storage. They should be separate even the movement of the material from in to out, they should be uni-directional that is you can see here in this picture. The material is coming from this side, then it is a moving alright that is raw material storage, raw material from raw material storage, it comes that is the even handling, and even if the washing, and primary processing etcetera.

And whatever rubbish is created, either in the raw material storage or in the primary processing, the rubbish or waste should to go out, and then the material comes to. Then maybe again that is in the primary processing, reacting, cleaning, grading, inserting etcetera. So, the waste generated should go out, and the material enters in the actual processing room, heating room, packaging room etcetera. So, from the processing, it comes to the packaging room.

And inside here near the packaging area that is the even tool area, this packaging materials is that should be a stored, and then finally from that material moves to comes to secondary packaging and loading. So, you can see here that is it enter from here, and it came follow this route, and the packaged material finally.

An outside there should be clear cut passage here as you can see, so that they went truck any truck comes. It unloads the material, even the same truck can move. It can go for the load the finished product, and go out. So, this way that is even inside interior, design surface of walls, doors, floors, they should be smooth, easy to clean, and they should be impervious.

Floors they should be should be free from cracks and open joints there should be advocate drainage for cleaning. Ceiling and overhead fixtures etcetera should be such that they should be clearly that easily cleaned cables and pipes should be fixed above ceiling are 40 millimeter away from the surface to enable their cleaning. Glass windows are should be protected against a breakage etcetera right.

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Then the food handling facilities. There is a water to be used, it should be portable water right WHO are guidelines right, both for manufacturing and well as hand washing etcetera portable water should be used. Even non-portable water can be used for control of pest control or even steam generation. However, the lines should be clearly marked that is a which is your portable water, which one is the non-portable water.

Personal hygienic facility hygiene facility, laboratories, and changing facilities should be provided with some hot water facility that is at least 40 degrees Celsius or more than that, so that they can hand wash and all those. They can do with little lukewarm water.

Then natural and mechanical ventilation, both facilities should be provided like even air handling units etcetera should be given, so that the past to present development, if needed in the processing facilities maintained to control or avoid contamination. Proper ventilation and temperature control mechanism should be provided in the processing facility, adequate natural as well as artificial lighting should be provided.

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Then next part is the equipment, GMP equipment that is the proper SOPs should be available for every equipment. They should be easy to dismount, they should be made from inert material that is the material of construction of equipment, should not react with the food component. This should be inclined, they should have round edges, which are easily accessible for cleaning etcetera.

As you can see here that is a these are the top, these are the good equipment from the GMP point of view whereas the bottom these two are the bad equipment, because even they are easy to clean, easy to remove the material removal etcetera.

So, they should be covered or protected to prevent contamination, this will be installed at a distance of 60 centimeter from walls and 30 centimeters from the floor. This should be cleaned and disinfested after every maintenance. All interior surfaces in contact with the product must be self impeding as you can see here the good equipment, which you have shown in the top of this picture. And final product handling this distance must be fitted with metal detectors of appropriate sensitivity.

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And pest control and prevention that is again very very important aspect that is all holes, drains, and places etcetera must be sealed. There should not be any chance of any pest contamination or pest growing etcetera. Food sources should be kept away from the walls and above the ground. Door should have self closing facility and curtains.

Should use of poisons etcetera are strictly prohibited in the raw material as well as in the production area. Insecticides and pesticides used should be of low toxicity and should be approved by the regulatory agencies for using a food factory, where plant infection and surveillance programs must be conducted and documented properly.

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Then GMP cleaning important, it is that is the removing gross debris from the surfaces. Applying a detergent solution to loosen soil and bacterial film and adding to the piping and to the container surfaces. Rinsing the equipment and all pipe is (Refer Time: 20:50) with water hot water and dry cleaning. Where necessary, disinfection maybe alcohol or such other disinfectant with subsequent rinsing should be done. And hygienic storage and handling of the clean portable equipment and utensils, so that is very important cleaning of the equipment, cleaning of the utensils, cleaning of the rooms, surfaces etcetera everything.

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Then other in general cleaning and sanitation that is procedure and frequency must be documented. Cleaning products which are used even the cleaning solutions acid solution, alkali solution, detergent etcetera. This should all be gross chemical or those which are recommended for the use in food industry. Labeled, if they all the cleaning solutions should be properly labeled and should be kept outside the production area, litter bins should be covered and fitted with plastic inserts.

A central rubbish collection point, preferably outside of the raw material and production building should be provided. Silos must be capable of totally emptied and cleaned. Adequate prevention and corrective maintenance to facilitate cleaning operations must be done, must be taken care of.

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Then personal hygiene both for staff as well as visitors that is people suffering from injuries and illness should not be allowed in the production or in the factory or they should not be allowed to visit. Hairs, moustache, beards etcetera must be properly covered. Uniform must be kept clean and must be replaced frequently, whenever necessary. Jewelleries, watches, pins, earrings etcetera are not allowed inside the production area or people should not be of these things except for the plain wedding rings and the stud earrings. Hand must be properly washed, handling a finished product must be minimized.

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Even smoking, chewing, sneezing over the unprotected food products are etcetera in the areas in the production area near by it should not be permitted, it should not be allowed. Visitors must adhere to the personal hygiene requirements. Smoking an eating areas must be segregated from the storage and production areas.

Proper training should be provided to the employees to be cautious on regarding the GMP, and they must be documented that what are the standard practices for the cleaning, for the personal hygiene etcetera. It should be properly documented, so that the and staff members should be time from time to time, they should be told about the proper educated about this for this should be properly reminded about this personal hygiene.

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Product realization	
 The organization shall plan and develop the processes needed to manufacture products. This involves 	
 Characteristics of raw materials Control of operation Characteristics of end product Quality management Storage Transportation 	 ✓ Labeling ✓ Lot identification & traceability ✓ Recall procedure ✓ Verification & validation

Then comes the product realization. So, the organization shall plan and develop the processes needed to manufacture the product. And this is again very important, this involves the characteristics of the raw material that is whether the raw material which is obtained in the factory, it is a good quality or not. Then the control of operations, process operations, storage operations, handling operations etcetera.

Characteristics of the end product required that is final processed product, what are the characteristics needed in that. Quality management, storage, transportation, labeling, lot identification and traceability, recall procedures, and verification and validation. All these should be properly maintained and should be taken care of by the organization.

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And like characteristics of the raw material as I told you that are raw material, even some process ingredients or whatever ingredients are to be used in the product manufacturing alright. Even the product contact material, packaging material, etcetera shall be described in the document in the SOPs as appropriate right.

The information include like biological, chemical and physical characteristics of the materials. Composition of formulated ingredients, including additives and processing aids. If any origin of the material for example, whether it is a animal food or plant food, method of production, packaging and delivery methods, storage conditions and shelf life, even preparation and or handling before use are processing, food safety and quality related acceptances attached. So, all these information regarding the raw material should be properly documented, and it should be provided on the level of the raw material.

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Even raw material should be inspected routinely, laboratory testing is done to evaluate the fitness, stocks are subjected to effective stock rotations, the descriptions are kept up to date, role of the authorities are defined, rejected materials are identified, and kept away from the accepted materials records are maintained properly.

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Then control of operations that is identify any point in the operation, which are critical to the safety. Maybe towards the end of this lecture, I will take up one example. And then I will tell you where GMPs to be and where HACCP is important. And then operation should be properly controlled, effect effective control of the procedures should be there, ensure that effectiveness of the procedure is maintained. Even it should be reviewed periodically temperature control systems should take into account, the nature of the food, extended shelf-life of the product, method of packaging and processing, even intended use and so on.

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Similarly, characteristics of the end product. So, although the information which are listed here similar to that of the raw material similarly that is the end product, what is the type of packaging labeling, how what is the method of distribution, how it should be stored, what are the different biological or chemical and other components is a type in the hazard specification and allergens etcetera are relevant for food safety. All should be properly provided, and the level of the food.

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Then product information are labeling, because adequate level information on the product enables the next person into the food chain to handle the product safely that is and of course this a labeling, what are the information should be provided on the food level. It is controlled by regulatory agencies in different countries.

But, general information like products, what is its composition, what is this serving size, it any is (Refer Time: 28:03) a one instructions or any that if it contains any permitted colour, flavor or additives etcetera. And all those things information's which are there are what is the best before date, batch number lot number that is every if the before consumption, if there is any instructions required, so that should be provided statuary provident. So, all this information should be provided on the label of the product.

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Then quality management that is an important, it is not only limited to laboratory operation, only but it include all it is included in all activities related to processing and product quality. Even independent of the production and has the right to reject the components that is even in fact in most of the factories almost all those factories food processing, factories which are making implementing GMP.

They should have a quality management team, quality checking team. And this quality management, and checking and analysis team had the right to change an approve process changes, sampling procedures, specifications for process control and reprocessing of the rejects etcetera. Even finished products should be analyzed raw material should be analyzed, so that is the there should be a laboratory proper laboratories, good laboratory, practices should be followed for the analysis and it is so that the quality.

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<section-header> **GMP - Storage**• Raw materials, process materials and products are stored separately at ideal conditions of temperature, RH and air velocity. • Chemicals, packaging, bagged raw materials and products are stores on sound pallets. • Storage area must be free from pests and other contaminants. • Materials and products stored must be inspected. • Raw materials and finished products must be rotated in First in-First out (FIFO) basis.

Similarly, GMP storage good manufacturing practices in the storage room that is the raw material, processing material, packaging material all those things. They should be stored separately, and of course ideally storage conditions of temperature, relative humidity, air velocity etcetera should be maintained, depending upon the type of the material. Then chemical, packaging, bagged raw material etcetera. They should be stored in and sound pallets. Storage area must be free from pests or any other contaminants. Materials and products should stored must be totally inspected.

And more important in both in the raw material as well as in the finished product First in-First out basis should be followed that is FIFO which is normally. So, accordingly the stalking etcetera of the raw material and produce good products should be done in such a way that the material which enters first inside the storage facility, it should go out first.

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Then GMP-recall that is recall information should include the information like amount of the product produced, and in inventory and distributed. Name, size, code or lot number of food recalled. Area of distribution, reason for the recall and final disposition of the product that is rework, discharge etcetera, how the recalled material was exposed.

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Then GMP transportation again that is good transportation practices should be followed design and construction of the vehicle, clean it should be clean and are disinfect. A separate is to facility in the vehicle should be there for food and non-food item, its proper

temperature should be maintained, verification of the temperature. And of course, the vehicle must ensure during transportation, it must be ensured that there is no damage to the product, there is no contamination to the product, and the quality of the product is maintained.

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It should be properly inspected. Even both loading, unloading restrain transportation of non-food item in the same vehicle that is and design and construction of the vehicles should be proper, so the as to it meets with the requirement. And materials used in the vehicle for food transportation should be to be there is permitted material for those, who can be in contact with the food.

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Then GMP verification, very important that is internal audits must be carried out at least every six months. Audits determined, so the GMP confirms to the plant arrangements and as per the required standards are not. Audits checks whether GMP effectively implemented and updated. All procedures for auditing like responsibilities, requirements, results, and records. They are all are defined in a documented process. And follow up action based on the results of the audit must be should be taken up, and it must be reviewed, and properly documented.

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And continual improvement that is very important management should ensure that the effectiveness of the GMP system is continually improved through communication, reviews, both internal as well external audit action, corrective action etcetera. And this should be done all evaluation and updating activities should be based on input from communication external as well as internal communication. Input from other information concerning the suitability, acceptability, and effectiveness of the GMP system. Output from the management review or activities all activities are recorded, documented, and reported as case may be.

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So, now I will just these were the some of the points which were shown. So, earlier in that maybe in those slides that is in any industry which is following GMP, they should take care of this. Now, I will take you that like GMP and HACCP what are the critical control point, I will with this example, I am taking example of production of fortified blended food by extrusion. And it is basically the raw material is the soya bean and maize that is the soya maize blended fortified food. And starting from the finish that is what are the different steps I will tell you that here CCP is to be adapted, and where GMP is to be.

So, the raw material intake and loading, the raw material comes like maize and this soya beans. So, there is one important factor is that. Here in fact, the CCP has to be maintained, because this maize alright even it is susceptible for a growth even in soya bean also that is the mycotoxins or the aspergillus molds etcetera. They can grow and produce mycotoxins.

So, and the moisture content of the grain is an important factor which can encourage the growth of the mould. So, it is important thing that is the raw materials that the both soya bean and maize, when it comes. It must be ensured that it does not have any already grown mold or already toxin that is maximum permissible level in this case is 20 ppb. And the moisture content for maize, maximum should be 13.5 and soya maximum 11.5. So, this is a critical control point because, if the maize moisture is more than 13.5 or soya is more than available, it will definitely encourage the growth of the mold and mycotoxins etcetera.

So, laboratory samples should be taken immediately laboratory should be performed. For aflatoxin determination, for moisture determination and so this is a critical controlled point. After that in other operations like raw material storage that cleaning, weighing even blending with soya in horizontal mix or whatever. So, all in all this is a good GMP should be followed alright that is even correct weighing procedure, correct blending, correct a storage procedure etcetera all this, GMP should be ensured.

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Then in grinding of maize and soya. Then finally there is after grinding, there is there is a even cooking process. After grinding sometime, because soya bean it contains some anti-

nutritional factor alright or it is a blended product, extruded products, so they maybe that is in extrusion cooking etcetera.

So, there whatever temperature is must be ensured, here it is a CCP critical control point that is the temperature in the extruder minimum that is at 145 degrees Celsius or minimum for that is 45 degrees Celsius maximum 160. So, it should be in that range of 135 to 160 are optimally at 145 degrees Celsius means, it must be ensured that the temperature inside the extruder is sufficient enough to remove those trips in incubator or biologically or two substances which are problematic. So, here it becomes a CCP critical control point alright, accordingly the samples should be taken should be measured.

And finally, after the extruder exclusion, the blend which is coming a material which is coming, it should be analyzed for its usage activity or such other test to make sure to ensure that the trips in inhibitors are completely inactivated, so that is a CCP. Then again after that this even cooling of the extruder etcetera, it becomes a GMP.

Then grinding of the extruder grinding that is the extruder, after extrusion it may comes in the different shape and sizes, sometime it is blended flour. So, it has to be grind and on converted into powder. So, this becomes again a CCP critical that is the grinding, when it is converted into powder, it must be ensure that during grinding the moisture, it should not absorb moisture alright, it should ensure the proper particle sizes etcetera. So, here the it is a CCP, the conditions should be properly controlled. Because otherwise it absorbs moisture, during grinding. Then from the environment and more systemic contaminated, they contaminate it will grow, so here it becomes CCP.

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Then finally, your weighing of the cooked maize's soya, sugars etcetera, this is GMP. Then blending cooked maize soya with vitamins and minerals, again here it is a critical control point. Because, if the even vitamins and minerals alright, there should not be maximum that is it homogeneous and coefficient of variation 10 percent or even better than that should be, because sometime this by incorrect weighing or by in proper formulation vitamins, minerals, premixes, etcetera.

If they are added in more, there may be some vitamins excessive consumption of vitamins or even excessive consumptions of certain minerals, maybe may provide some undesirable or toxic effects in the long run, so that should be it becomes a critical control point. Otherwise, then again bagging, weighing, stitching, product storage dispatch in all the cases, GMP should be followed. So, this gives similarly in any food processing starting from the raw material receiving to the end product, till it is product.

So, you find out that is in the process value chain which is the step, where there is a chance of the contamination. Contamination with a biological agent, contamination with a physical agent, which may ultimately lead to the safety hazard etcetera. So, all this that is the critical control point, and for that what is the control measures should be taken, so that that chance of contamination is not there.

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So, these are the next is there is obviously this is the record sheet. So, as a good documentation practices all these, whatever tests etcetera in all this is CCP, GMP as we all the steps. The proper at least the times whatever the testing done, how it what are the results are should be properly recorded.

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So, it again this step wise that is all the steps the proper recording whether it is GMP, whether it was CCP it should be properly recorded.

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So, I gave you an overview that how good manufacturing practices, good hygienic practices should be followed, and it becomes a very very important aspect in any food processing industries, all care needed should be taken to make sure that the product even starting from the material, during processing, during handling, during storage, till it reaches to the consumer on the table for the consumption at that point, it becomes responsibility that it should be safe.

So, all necessary points at the producer level, and whatever necessary guidelines are required by the consumers that should also be provided by the way under level etcetera, so that the food consume a process food or this food after eating, it does not produce any health hazard.

Thank you very much.