Standards and Compliance - How to meet new U.S. food safety requirements

Tiêu chuẩn và Tuân thủ - Cách thức để đáp ứng các tiêu chuẩn an toàn thực phẩm mới của Hoa Kỳ
Introduction of the FSMA part PCHF - Preventive control for Human Food and part FSVP – Foreign Supplier Verification Program.

Date: 28/08/2017  
Presenter: Nguyễn Huy – Food Manager

Agenda

1. Brief introduction of Bureau Veritas

2. Introduction of the FSMA part PCHF - Preventive control for Human Food.

3. Introduction of the FSMA part FSVP – Foreign Supplier Verification Program.

BVC VIETNAM INFORMATION

- General Management System certification
  - Quality Management System (ISO 9001), Environmental management System (ISO 14001)
  - Occupational Health & Safety Assessment Series (OHSAS 18001)
  - Social Accountability (SA 8000, ISO 26000)

- Food Safety Certifications:
  - BRC Food, BRC IOP
  - IFS Food
  - ISO22000
  - FSSC 22000 Food, Packaging.
  - HACCP, GMP Food…

- Foods Laboratory – Cân Thơ Branch
  - Accredited ISO17025 – VILAS 392
  - Testing Chemical, Physical, Biology, Antibiotic, GMO… parameter on foods, Fish and Fishery contacts.

- Sustainable Aquaculture
  - ASC responsible aquaculture farm certification
  - ASC “Chain of Custody” Certification (“CoC”) Tracability
  - Global GAP Aqua, Crop base
  - BAP

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21 CFR Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food

Subpart A – General Provisions

Subpart B – Current Good Manufacturing Practice

Subpart C – Hazard Analysis and Risk-based Preventive Controls

Subpart D – Modified Requirements

Subpart E – Withdrawal of a Qualified Facility Exemption

Subpart F – Requirements Applying to Records That Must be Established and Maintained

Subpart G – Supply-chain Program

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Subpart C – Hazard Analysis and Risk-based Preventive Controls

§ 117.126 Food safety plan
§ 117.130 Hazard analysis
§ 117.135 Preventive controls
§ 117.139 Recall plan
§ 117.140 Preventive control management components
§ 117.150 Corrective actions and corrections
§ 117.155 Verification
§ 117.160 Validation
§ 117.170 Reanalysis
§ 117.180 Requirements applicable to a preventive controls qualified individual and qualified auditor
§ 117.190 Implementation records required for this subpart
Preventive Controls Qualified Individual Responsibilities
(§ 117.180(1))

- Must have **successfully completed training in the development and application of risk-based preventive controls**
  - At least equivalent to that received under a standardized curriculum recognized as adequate by FDA
- Or be **otherwise qualified** through job experience to develop and apply a food safety system.
- Can be an external consultant
- Training must be documented in records – date, type of training, person(s) trained

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Preventive Controls Qualified Individual Responsibilities
(§ 117.180(a))

- Oversees or performs
  - Preparation of the Food Safety Plan
  - Validation of the preventive controls
    - Justification for validation timeframe exceeding 90 days
    - Determination that validation is not required
  - Review of records
    - Justification for review of monitoring and corrective action records timeframe exceeding 7 working days
  - Reanalysis of the Food Safety Plan
    - Determining that the timeframe for reanalysis and additional preventive controls validation can exceed the first 90 days of production
Food Safety Plan Format is Flexible

Contents of a Food Safety Plan

Required
- Hazard analysis
- Preventive controls*
  - Process, food allergen, sanitation, supply-chain and other
  - Recall plan*
- Procedures for monitoring, corrective action and verification*

Useful
- Facility overview and Food Safety Team
- Product description
- Flow diagram
- Process description

* Required when a hazard requiring a preventive control is identified
Main Organizational Sections

1. Background information - optional
2. Hazard analysis
3. Preventive controls
4. Recall plan
5. Implementation procedures

What Is a Hazard?

- A hazard in human or animal food is, “any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.”
Biological Agents Cause Most Outbreaks

Reported Foodborne Illness Outbreaks 2009–2014

<table>
<thead>
<tr>
<th>Hazard Type</th>
<th>Outbreaks</th>
<th>Illnesses</th>
<th>Hospitalizations</th>
<th>Deaths</th>
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<tr>
<td>Biological</td>
<td>3,158</td>
<td>64,044</td>
<td>4,221</td>
<td>120</td>
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<tr>
<td>Chemical</td>
<td>215</td>
<td>834</td>
<td>93</td>
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<td>Physical</td>
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<tr>
<td>Unknown</td>
<td>1,391</td>
<td>15,072</td>
<td>292</td>
<td>3</td>
</tr>
</tbody>
</table>


Undeclared Food Allergens Are Common

- Undeclared allergens represent **more than 1/3** of Reportable Food Registry (RFR) reports.

Reportable Food Registry Reports 2009-2014

- Salmonella: 32%
- L. monocytogenes: 18%
- Undeclared allergens: 38%
- Other: 12%

Source: [www.fda.gov/ReportableFoodRegistry](http://www.fda.gov/ReportableFoodRegistry)
Food Allergy

- Major allergens - milk, egg, peanut, tree nut, fish, crustacean shellfish, wheat, and soy
- require specific labeling

Photo Sources: Microsoft Clip Art and KMJ Swanson (soybeans)

Food Allergy

- Food Allergy = adverse response by the body to foods containing allergenic proteins
- A miniscule amount of protein/allergen can trigger an allergic response
- Food allergy symptoms are unpredictable and vary from mild reactions to death
  - Mouth: swelling and tingling of lips, mouth or tongue
  - GI: cramping, vomiting, diarrhea
  - Skin: hives, eczema
  - Airway: wheezing, coughing, swelling of throat
  - Cardiovascular: loss of blood pressure
  - Anaphylaxis: most dangerous, life threatening
Hazard Analysis

- You must identify and evaluate known or reasonably foreseeable hazards to determine if they require a control, including:
  - Biological, chemical (including radiological), and physical hazards
  - Naturally occurring, unintentionally introduced, or intentionally introduced for economic gain

- The hazard analysis must include an evaluation of the identified hazards to assess:
  - The probability that the hazard will occur in the absence of controls, and
  - The severity of the illness or injury if the hazard were to occur.

- You may rely on another’s hazard analysis, but it must be reviewed by a qualified individual you employ or have retained.

Preventive and Other Controls May Include:

1. Process preventive controls
2. Food allergen preventive controls
   - Accurate labeling
   - Cross-contact prevention
3. Sanitation preventive controls
   - Environmental pathogens
   - Cross-contamination, cross-contact
4. Supply-chain preventive controls
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3. Introduction of the FSMA part FSVP – Foreign Supplier Verification Program.


Foreign Supplier Verification Programs Rule

► On November 27, 2015 FDA, also published the final FSVP rule:

   • Part 1 – Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

► The final FSVP rule was published in the Federal Register, along with its preamble explanations and responses to public comments.
FSMA Affects the Food Supply Chain

1. Foreign and domestic manufacturers or processors, packers, and holders of foods now must:
   - Assess hazards.
   - Implement preventive controls.

2. Foreign and domestic growers of fresh produce must:
   - Comply with produce safety requirements.

3. U.S. food importers must:
   - Ensure that their foreign food suppliers are sending foods to the U.S. that meet U.S. safety standards.

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Key Principles of FSVP Rule

- U.S. importers of foods play a vital role in ensuring that their foreign suppliers are:
  - Providing the first line of defense in preventing food hazards.

- Importers share responsibility with foreign suppliers to ensure safety of food imported into the U.S.

- FSVP requirements are risk-based (according to types of food, types of hazards, and supplier performance).

- Importers have flexibility in how they meet requirements.
Who is an “Importer” Under FSVP Rule?

Definition: “Importer means the U.S. owner or consignee of an article of food that is being offered for import into the United States…”

“…If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.”

- 21 CFR Part 1, Subpart L, 1.500 Definitions

Determining Who Will Be the FSVP Importer

- Often, more than one entity will meet the FDA definition of “importer” for FSVP purposes.

- Entities that meet the definition of FSVP “importer” will need to decide among themselves:
  - Who will agree to be identified as the FSVP importer for a particular food/foreign supplier, and
  - Thus, be responsible for carrying out FSVP obligations.
Importer of Record vs. FSVP Importer

- A key difference between the FSVP “importer” as defined by FDA in the FSVP rule and the “importer of record” (IOR) as defined by Customs and Border Protection (CBP) is that:
  - The FSVP “importer” must be someone in the U.S.
- If the IOR is located in the U.S., that importer can also be the FSVP importer (assuming that the IOR otherwise meets the FSVP Importer definition).
- Whoever is the FSVP importer, that person is who FDA will hold accountable if FSVP requirements are not met.

Who is a Qualified Individual?

- Food importers are required to do a number of things that can only be done by persons who meet the definition of “qualified individual.”
  - An FSVP Qualified Individual is “a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required” by the FSVP rule, “and can read and understand the language of any records that the person must review in performing this activity… .”
Required Tasks Must Be Done by a Qualified Individual

► The FSVP importer must be determined by persons involved in importing the food and must carry out the requirements contained in the FSVP rule.

► FSVP tasks must be carried out by qualified individuals.

► Different FSVP tasks may require different qualified individuals.

► Some qualified individuals may be qualified for more than one task, e.g. hazard analysis, determining verification activities.

► Qualified individuals may be, but aren’t required to be, employees of the importer.

► Qualified auditors are qualified individuals for conducting audits (audits are an example of a verification activity).

Does FSVP Apply to My Situation?

► FDA has provided a flowchart that helps you determine whether or not you are subject to the FSVP rule.

► We will be going through this flowchart at the end of this chapter as an exercise.

► The full version is available on FDA’s website at: http://www.fda.gov/downloads/food/guidance/regulation/fsma/ucm472461.pdf
The Question Is...

What foods are exempted?

Exempted Foods

- Foods under FDA Hazard Analysis Critical Control Points (HACCP) rules
- Alcoholic beverages (certain conditions)
- Foods not intended for sale or distribution in the U.S.
- Certain meat, poultry, and processed egg products (products subject to Federal Meat Inspection, Poultry Products Inspection, and Egg Products Inspection Acts)
- Food manufactured/processed, raised, or grown in U.S., then exported and returned without further manufacturing/processing in a foreign country
Certain Meat, Poultry, and Egg Products

- Those food products and species falling under USDA jurisdiction:
  - Federal Meat Inspection Act
  - Poultry Products Inspection Act
  - Egg Products Inspection Act

- USDA also is responsible for inspecting catfish (*Siluriformes* spp.)

Low-Acid Canned Foods

- An importer of low-acid canned foods (LACFs) must:
  - Verify and document that the food was produced in accord with LACF regulations (21 CFR Part 113), which pertain to microbiological hazards.
  - For all other hazards, the importer is required to have an FSVP.

- An importer who uses raw materials or other ingredients to manufacture/process an LACF in the U.S. is:
  - Required to be in compliance with Part 113, and
  - Must have an FSVP for all other hazards or comply with the PC rules.
KEY FSVP Requirements:

1. Conduct a hazard analysis of the food, including hazard identification and hazard risk evaluation.

2. Conduct an evaluation of the foreign supplier’s food safety performance and risk posed by the food.

3. Approve the foreign supplier (based on above evaluations) - establish written procedures.

4. Determine and apply appropriate verification activities and assess results.

5. Implement corrective action(s) and re-evaluate foreign supplier (at least every three years or when reason to).

6. Identify the FSVP importer at entry.

7. Keep required records and documentation.

IMPORTANT: Identify the FSVP importer at entry.

Question 1

► Are you an importer for FSVP purposes?

• That is, are you the U.S. owner or consignee of an article of food that is being offered for import into the U.S.? Or

• If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, are you the U.S. agent or representative of the foreign owner or consignee at the time of entry?

If your answer is:

► NO: FSVP does not apply to you.

► YES: Continue to the next slide.
**Question 2:**

Are you importing the following foods?

- Food imported for **personal consumption**
- Food that is **transshipped** through the U.S.
- Food that is **imported only to process and then export**
- U.S. food that had been **exported and returned** without further manufacturing/processing in a foreign country
- (Some more exemption options)

If your answer is:

- **YES:** FSVP does not apply to you.
- **NO:** **YOU ARE FSVP IMPORTER.**

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**Importance of Identifying FSVP Importer**

- Identifying the FSVP importer is a legal requirement for entering food into the U.S.
- Failure to provide such information will lead to a rejection of the entry filing.
- FDA will be building an inventory of FSVP importers off the Customs data.
You Must Have a Unique Facility Identifier

- The FSVP rule requires that each FSVP importer have a unique facility identifier (UFI) that is acceptable to FDA to be placed in the Customs entry filing.
  - The FSVP importer must, therefore, obtain an acceptable UFI.
  - The only UFI that FDA has recognized as acceptable at this time is a DUNS number that anyone can obtain at no cost from Dun and Bradstreet.
  - The DUNS number provided should be associated with the person listed as the FSVP importer.

Obtaining a Free DUNS Number

- You can go directly to the Dun & Bradstreet website “Get Started” web page

FREE D&B D-U-N-S® Number  https://www.dandb.com/free-duns-number/
Obtaining a Free DUNS Number (continued)

► Or, you can request a new DUNS number via Dun & Bradstreet's fedgov.dnb.com web page

Request for New D-U-N-S Number
https://fedgov.dnb.com/webform/newReq.do

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Some Importer Identification Issues

► Name on CBP entry = Person responsible for FSVP

- FDA will use the entry identification of the FSVP importer as the responsible party for follow-up to assure compliance with FSVP requirements.

- FDA does have the ability to determine if FSVP information is transmitted correctly.

- Make sure the person responsible for the Customs entry filing understands who is the appropriate FSVP importer.
Records Must Be Available to FDA

► All records required by the FSVP rule must be made available promptly:
  • To an authorized FDA representative, upon request,
  • For inspection and copying.

► If requested in writing by FDA, you must:
  • Send records to FDA electronically, or
  • Through another means that delivers the records promptly.

► An English translation of records must be provided within a reasonable amount of time.

Will FDA Inspect FSVP Importers?

► FDA has always conducted inspections of food-related operations falling within its jurisdiction to protect public health.

► To enforce FSVP, FDA will certainly inspect FSVP importers.

► FDA is expected to rely heavily on its authority to access the records that must be kept by FSVP importers to demonstrate compliance with FSVP requirements.
FDA Compliance Activity for FSVP

FDA may:
- Conduct an onsite inspection of records.
- Request electronic submission of your records.
  - FDA review of these records is the same as an onsite inspection.
- Request that records kept offsite be made available within 24 hours.
- Request that some records be translated into English within a reasonable time.

Form 482d and 483a

Request for FSVP Records (482d)

Form 482d available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493417.pdf

FSVP Observations (483a)

Form 483a available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493415.pdf
7. Illustration: FSVP Records

- If you are the FSVP importer subject to the standard requirements, all of the following records make up your FSVP:
  - Hazard analysis
  - Foreign supplier performance evaluation
  - Procedures for approving foreign suppliers
  - Foreign supplier approval
  - Procedures to assure use of only approved foreign suppliers
  - Determination of verification methods and frequency
  - Performance of verification activities
  - Any necessary corrective actions
  - Reevaluations of your FSVP either for cause or routinely every 3 years

Retaining Records

- You must retain records that relate to your processes and procedures for any required activities, including the results of evaluations and verifications you conduct:
  - For at least 2 years after their use is discontinued, e.g., after discontinuing use of a particular supplier.

- You must retain all other records:
  - For at least 2 years after you created or obtained the records.
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FSMA- PCQI / FSVP TRAINING COURSE INFORMATION

INFORMATION ABOUT FSMA-PCQI AND FSVP AT BUREAU VERITAS VIET NAM

- Tutor: course will be trained by the first tutor in Vietnam who had successful completed the FSPCA Lead Instructor course.

- Content and training program: program which has been standardized and accepted as adequate by FDA, Vietnamese subtitled .

- Training language: Vietnamese.

- Certificate: Official certificate from FSPCA – AFDO → Association of Food and Drug Officials
FSMA-PCQI/FSVP TRAINING COURSE INFORMATION

<table>
<thead>
<tr>
<th>Instructor</th>
<th>Company</th>
<th>Region</th>
</tr>
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<tr>
<td>Brigitte DHAINAUT</td>
<td>BUREAU VERITAS</td>
<td>Europe</td>
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<tr>
<td>Pascale GIRAUDET</td>
<td>BUREAU VERITAS</td>
<td>Europe</td>
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<tr>
<td>Christine SANCHIS</td>
<td>BUREAU VERITAS</td>
<td>France</td>
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<tr>
<td>Milind Apte</td>
<td>Bureau Veritas Certification</td>
<td>India</td>
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<tr>
<td>Nguyen Huynh</td>
<td>Bureau Veritas Certification Vietnam</td>
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<tr>
<td>Vinodh K P</td>
<td>Bureau Veritas International India LLC</td>
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</tbody>
</table>
CERTIFICATE OF TRAINING

is awarded to

Nguyen Huy

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

Lead Instructor Training for FSPCA Foreign Supplier Verification Programs
delivered by Lead Instructor

Gary Acuff
completed on
06/01/2017

FOR MORE INFORMATION, PLEASE CONTACT:

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  • Email: hai.nguyen@vn.bureauveritas.com

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➢ BV VIET NAM Food Business Development Manager
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How Food Industries can Ensure Safety and Compliance with US FSMA requirement

Food Safety Training Summit
ICMC Aug 28, 2017

Cargill at a glance
We operate within four key business segments:

<table>
<thead>
<tr>
<th>Food</th>
<th>Agriculture</th>
<th>Financial</th>
<th>Industrial</th>
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</thead>
<tbody>
<tr>
<td>We provide food and</td>
<td>We buy, process</td>
<td>We provide our</td>
<td>We serve industrial</td>
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<td>beverage manufacturers,</td>
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<td>users of energy, salt,</td>
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<td>and retailers with</td>
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<td>high-quality ingredients</td>
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<tr>
<td>and ingredient systems</td>
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</table>
Cargill in Vietnam

Cargill Vietnam Limited established in 1995

Operating nationwide with over 2,000* employees across 23 sites

11 animal nutrition plants

Business operations:
- Animal nutrition
- Food & beverage ingredients
- Agriculture supply chain
- Metal trading
- Unique aqua macro feed ingredients

2013 - 2016
No. 1
"Vietnam’s Best Place to Work" in Agriculture / Forestry / Feed sector**

* As of June 2017
** "Vietnam Best Place to Work" survey by Anphabe in collaboration with Nielsen

Food Safety Modernization Act (FSMA) Background

- Enacted in 2011
- Shift regulatory focus from responding contamination to preventing it
- The new requirements related to

  * Record Inspection
  * HACCP- Hazard Analysis and Risk-Based Preventive Controls
  * Intentional adulteration
  * Sanitary transportation of food
  * Import
Food Safety Modernization Act (FSMA)

Prevention

Enhanced Partnerships

Increased Inspections
Enhanced Response

Import Safety
Apply Domestic Standards to Imported Foods

The Seven Pillars of Prevention

✓ Preventive Controls for Human Food
✓ Preventive Controls for Animal Food
✓ Produce Safety
✓ Foreign Supplier Verification
✓ Third Party Accreditation
✓ Food Defense
✓ Sanitary Transport
Foreign Supplier Verification Programs (FSVP)

- FSMA Sec. 301 requires importers to have FSVPs
- Aligns with FSMA preventive controls (PC) supply-chain provisions

Purpose of the regulation -
- Foreign suppliers produce food using processes and procedures providing same level of public health protection as FSMA preventive controls
- Food is not adulterated or misbranded (as to allergen labeling)
More about FSVP

✓ FSVP applies to all “Importers” of “food” to the United States
✓ “Food” defined broadly to include raw materials, ingredients, finished food and food-contact substances
✓ Importer means - the U.S. owner or consignee of an article of food that is being offered for import into the United States.
✓ U.S. owner or consignee means - the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

Key Exemptions

✓ Food subject to seafood, juice, and LACF
✓ Food imported for R&D purposes or for personal use
✓ Alcoholic beverages imported from certain foreign suppliers
✓ Food transshipped or imported for processing and export
✓ Food returned to the U.S. without further processing in a foreign country
✓ Certain meat, poultry, and egg products under USDA jurisdiction
FSVP Core Requirements

- Conduct analysis of hazards
- Evaluate and approve foreign suppliers based on hazard analysis
- Conduct supplier verification activities
- Take corrective actions when appropriate
- Maintain records of FSVP activities
- Qualified Individual requirement

Hazard Analysis

- Evaluate known or reasonably foreseeable hazards to determine if they require a control
- To implement, importers must document and conduct a hazard analysis for all known or reasonably foreseeable hazards
Foreign Supplier Evaluation

- Food must be imported from foreign suppliers that have been evaluated and approved
- Evaluation must take into account:
  1. Hazard analysis
  2. Entities responsible for controlling hazards
  3. Foreign supplier’s food safety performance
  4. Foreign supplier’s compliance status under FDA or foreign regulations

- Importers must reevaluate their foreign suppliers at least once every three years

Other Requirements

- Corrective actions – must be written
- Importer identification at entry
- Recordkeeping – 2 years and provide to FDA upon request
FDA Inspection

Preparation for Inspection

- Prepare a room and team for the retrieval of documents
- Prepare another room for the investigator(s) to work
- Requested documents should be brought to the auditor(s) in their designated room
- Safety rules and access to the plant
- Make sure the office, all bathrooms/restrooms are clean, stocked with toilet paper, soap and hand towels
- Make sure spaces are clean and organized
  - Work zones
  - Warehouse(s)
  - Production areas
  - Lab spaces
- Personnel – prepared and courteous
Beginning of the Inspection

• The FDA should present a written Notice of Inspection (FDA 482); state purpose of the visit
• The FDA generally asks for a quick tour of the facility, first.
  • Move through the plant efficiently
  • Guard against too many people on this tour
  • Answer FDA’s questions as they come up during the tour, but table questions for later discussion if they require a longer explanation
  • Let the investigator know that he/she can come back to any area as necessary when the “local expert” is available
• The escort should be familiar with the site’s everyday operations and its inspection policies

During the Inspection

The investigator can:

- Ask for access to records
- Observe current operations
- Talk to the personnel about their activities and the procedures they use
Wrap-up Meeting

✓ At the end of each day, the investigator(s) meets to resume the findings of the day and plan the next day
✓ It is the best moment to discuss with the auditor or to give them any corrective actions
✓ All the observations are communicated during the final wrap-up meeting

Final Meeting Before FDA Leaves

☐ This meeting should be attended by someone in upper management, the escort(s), and those responsible for taking corrective actions.
☐ The investigator should discuss each of the objectionable conditions observed and provide the company with an opportunity to agree or disagree.
☐ Explain, for the record, any area where you disagree with the auditor. The investigator should be taking notes on what was said and who said it
☐ FDA uses a Form FDA-483 which is called a "List Of Observations" to provide a written statement of the observed objectionable matters.
Final Meeting Before FDA Leaves

- During the exit interview, you should understand all the observations listed in the FDA-483.
- Do not argue with the inspector about a particular observation
  - Do express disagreement, and the inspector should include the comment in the establishment inspection report (EIR)
- If the investigator makes oral observations, document these so it can be considered for corrective action after the investigator leaves
- Request a copy of the EIR
- The investigator should provide a “Receipt for Samples” (FDA-484) for all samples taken.
- Promise to respond to the 483 in writing, and ask the investigator for any other comments or suggestions