

# Role of the Preventive Control Qualified Individual



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- **Describe the roles of individuals as described within the Preventive controls human food rule**
  - **Qualified individual**
  - **Qualified auditor**
  - **Preventive Control Qualified Individual (PCQI)**
- **Review the criteria for each role**
- **Define the responsibilities for the PCQI**

- **117.4 – management must ensure that all individuals are qualified to perform their assigned duties**
  - **Qualified individual – have education, training or experience necessary to perform assigned tasks**
  - **Receive training in the principles of food hygiene and food safety – Records maintained**
- **117.180 – Preventative controls qualified individual**
  - **Attend preventive control training course (FDA recognized) OR**
  - **Qualified through job experience**

# Preventive Controls Qualified Individual Definition

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- A qualified individual who has 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 is otherwise qualified through job experience to develop and apply a food safety system.
  - 21 CFR 117.3 Definitions

# Preventive Controls Qualified Individual Qualification

- **Standardized curriculum recognized as adequate by the FDA** 
- **Food Safety Preventive Control Alliance (FSPCA) 2.5 day human food course**
- **Qualified through job experience to develop a food safety system** 
- **No defined criteria on what is acceptable in regards to training and experience, competency determined by state of food safety plan?**

- **Process PC** → • **HACCP**
- **Sanitation PC** → • **Sanitation SOPs**
- **Allergen PC** → • **Allergen mgt program**
- **Supplier PC** → • **Approved supplier programs**
- **Recall PC** → • **Recall program**

**A preventive controls qualified individual\* must do or oversee the following activities:**

- 1. Preparation of the food safety plan**
- 2. Validation of the process preventive controls (CCPs)**
- 3. Determine if validation is not required**
- 4. Review of records within 7 days of creation**
- 5. Reanalysis of food safety plan (at least every 3 years)**

**\*Individual does not need to be an employee of the facility**

# Verification Record Review



- All monitoring and corrective action records must be reviewed within seven (7) working days from the time they were created.
  - Preferably, prior to release of product
- Verification records, including calibration, product testing, environmental monitoring and supplier program records
  - Reviewed in a reasonable time
- Performed or overseen by a preventive controls qualified individual

*When issues are identified during the review, corrective action is required*

- A food safety system changes with time
- Periodic reanalysis must be done to verify that the whole system works
- When
  - At least every three (3) years
  - Significant change in product or process
  - New information becomes available about potential hazards associated with the food
  - Unanticipated problem
  - Preventive control ineffective

# Qualified Auditor

- **Person who is a preventive controls qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing functions**
- **Must have technical expertise by a combination of training and experience appropriate to perform the auditing function**



- **Does not need to be the preventive control qualified individual**
- **Training can be through education, training and/or experience**
- **Examples of qualified auditor include government employee including a foreign government employee and an audit agent of a certification body that is accredited in accordance with regulation**
- **Must conduct an onsite audits**
  - **As a verification step for supplier preventive control**
  - **Part of compliance to Foreign Supplier Verification Program (FSVP)**

- **Each FDA registered facility which needs to meet the FSMA final rules should have a designated Preventive Controls Qualified Individual**
- **Everyone has a role in the development, implementation and compliance with the rule**
- **The PCQI has an important role to play to lead each facility through the transition to FSMA compliance**

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