CACCP

Confinement Analysis and Critical Control Points Approach to PMP Production
Confinement Analysis and Critical Control Points (CACCP)

- An approach to confinement of PMP material modeled on the Hazard Analysis and Critical Control Points (HACCP) approach used in the food and pharma industries
- Some common elements with other risk assessment/management methodologies such as Zurich hazard analysis
7 Principles

– Conduct loss of confinement analysis
– Determine critical control points
– Establish critical limits
– Establish monitoring procedures
– Establish corrective actions
– Establish verification procedures
– Establish record keeping and documentation
Overview of CACCP process

• Assemble CACCP team
  – Multidisciplinary group with specific knowledge and expertise relevant to product/process
• Describe product, distribution, intended use
• Develop Process flow map and verify
• The CACCP team analyses each of 20 high level operation steps of the process flow map from the perspective of the 7 principles
Process Map

Selection of trial site → Seed Transport to Field facility → Seed Storage at Field facility → Pre-Plant planning

Site Preparation → Seed Transport to trial site

Planting
Confinement analysis

• Identify loss of confinement scenarios/control measures for each step of process map
• Scenario evaluation-severity /likelihood
• Identification of process modifications/improvements
• Provides basis for identification of critical control points
Determine critical control points

• A step at which control can be applied and is essential to prevent or reduce loss of confinement
• Identified using decision tree
• Example: flowering step and possible loss of containment via cross-pollination
Critical process parameters

• Critical process parameter is a process parameter that must be maintained within proscribed limits (critical limits) to achieve the desired quality outcome
• There may be more than one CPP for a process step
• Examples:
  – isolation distance
  – Bee netting
Critical Limits

• Critical limits are upper and/or lower boundaries within which the CPP must be maintained

• Example: 200m minimum isolation distance
Monitoring procedures

• Critical control points must be monitored to ensure that process parameters are within the appropriate range.
Corrective action

• Predetermined response to deviation of Critical Process Parameter outside the acceptable range or lack of adequate control at a Critical Control Point
Verification

- Initial validation of plan to determine that it is scientifically and technically sound
- Periodic auditing to ensure plan is being followed
- Review of plan, CCP monitoring records and corrective action records
Record Keeping and Documentation

• Documentation should include:
  – Summary of the CACCP analysis
  – The CACCP plan
  – All records generated during operation
    • Monitoring record, corrective actions etc
  – place holder
Factors for success

• Commitment from management to the CACCP process
• Pre-requisite programs/ practices, examples
  – cGMP or other QA systems
  – Facilities standards
  – Supplier control
  – Cleaning and sanitation practices
• Education and training
Useful references

• “Hazard Analysis and critical control points principles and applications guidelines”, National Advisory committee on microbiological criteria for foods (http://www.cfsan.fda.gov/~comm/nacmcfp.html)