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Pharma/BioPharma cGMP - PSM Comparison

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

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In this discussion we will compare OSHA PSM elements with FDA cGMP requirements

- Catastrophic Events
- Employee Participation
- Process Safety Information
- Process Hazard Analysis
- Operating Procedures
- Training
- Contractors
- Pre-start up Safety Review
- Mechanical Integrity
- Hot Work Permit
- Management of Change
- Incident Investigations
- Emergency Planning and Response
- Compliance Audits

Both current Good Manufacturing Practices (cGMP) and Process Safety Management (PSM) are intended to lower the likelihood of a catastrophic event

	PSM	cGMP
Catastrophic Event	Loss of primary containment of a flammable or hazardous material	Drug/biological product contamination or incorrect formulation
Possible health consequences	Multiple worker or public injuries or fatalities	Multiple worker or public injuries or fatalities
Possible legal consequences	Multiple law suits OSHA fines	Multiple law suits FDA fines
Possible business consequences	Loss of business and damage to company reputation	Loss of business and damage to company reputation

Both regulations require employee participation in their implementation

PSM	cGMP
Requires a written plan of action regarding implementation of employee participation	Operating personnel is required to identify production and possible issues
Requires employee participation in development of process safety management elements such as: process hazard analysis, incident investigations and procedure updates	Quality, operations and maintenance personnel should be involved in the design of the process and production SOP's or batch records

Process descriptions, hazard information and equipment design have to be documented

PSM	cGMP
Information pertaining to hazards of the chemicals	Information on hazards of the process or materials used in the process
Process block flow diagram	Process flow diagram
Safe upper and lower control limits	Strategy for process control or a validated process with operating limits
Design information on the equipment used in the process	Design information on equipment used in the process
Equipment design needs to follow Recognized and Generally Accepted Good Engineering Practice (RAGAGEP)	Design of facilities, ventilations, lighting plumbing and sanitation system have to meet specific requirements and follow cGMP design guidelines

Risk analysis has to be conducted to determine controls and safeguards required

PSM	cGMP
Initial process hazard analysis is required on a new or modified process	Risk analysis to screen potential variables and to determine the type and extent of process controls in the initial design
Process hazard analysis has to be revalidated at least every 5 years to assure that it is consistent with the current process	Use risk analysis to enhance and improve process as experience is gained or if the process is changed

Operating procedures are essential to proper conduct of operations

PSM	cGMP
Implement written operating procedures	Implement written production and process control procedures (Batch Records)
Operating procedures shall be reviewed to reflect current operating practices including all changes made	Procedures reviewed and approved by quality control unit
Develop and implement safe work practices for the control of hazards	Develop and implement safe work practices for control of the process including equipment cleaning procedures, sample handling, operating limits

Proper training of personnel is necessary to minimize human error

PSM	cGMP
Personnel shall be trained on overview of the process and operating procedures before being involved in the process	Personnel shall be trained in the process, operating conditions and cGMP before being involved in the process
Refresher training will be conducted at least every 3 years	Training will be completed on a continuing basis with sufficient frequency to assure employees remain familiar with the procedures
Training has to be documented	Training has to be documented

Proper contractor management is required to minimize risk

PSM	cGMP
Contractor evaluation must include their safety performance	Consultant/Contractor qualifications have to be documented
Contractor employee have proper training for the tasks they re performing	Consultants/Contractors shall have proper training and experience

Approval for start-up of a process is required under FDA and OSHA

PSM	cGMP
Pre-start up review is required for new or modified facilities	Process qualification for new processes is required
Pre-start up team verifies that: • Equipment is properly designed and installed • Operating procedures are in place • Training was completed	Process qualification verify that: • Equipment and facilities are properly designed • Process performs correctly per operating procedures and requirements

Equipment failure is addressed by proper equipment maintenance

PSM	cGMP
Equipment inspection and proper testing required including Instrumentation calibration and functionality checks	Automatic, mechanical or electronic equipment shall be routinely calibrated, inspected, or checked
Written procedures are required	Written procedures are required
Deficiencies have to be addressed	Deficiencies have to be addressed
Training for maintenance personnel	Training for maintenance personnel
Quality assurance for installation and spare parts	Written procedure for control of components, process equipment, drug product/substance containers and closure

Specific procedures are required to mitigate most credible cause of catastrophic events

PSM	cGMP
Hot work permit shall be issues for hot work operations conducted on or near a covered process	Equipment cleaning procedures shall be developed to minimize possibility of contamination
Permit will include area testing for flammables and area inspection	Batch Records and other processing procedures will including any testing required by quality control
Permit will be issues by a party independent of the personnel performing the work	Inspection of equipment for cleanliness immediately before use

Control of changes to the equipment, process and procedures require approval of an independent party

PSM	cGMP
Written procedure to manage changes	Procedures for changes in master production and control records
Impact of changes on safety and heath	Impact of changes on process performance
Authorization requirements for proposed change	Changes have to be approved by multiple groups including quality control
Process information has to be updated	Process information has to be updated
Affected employees have to be informed	Affected employees have to be informed

Investigation have to be completed for near misses and incidents

PSM	cGMP
Investigate incident which resulted in or could reasonably have resulted in a catastrophic release of hazardous material	Production records reviews will identify near misses and/or deviations that need to be investigated. Customer complaints are investigated as incidents
Investigation has to be documented	Investigation has to be documented
Promptly address and resolve incident investigation findings and recommendations	Promptly address and resolve findings

Crisis management system has to be establish to handle catastrophic events

PSM	cGMP
Emergency action plan shall be developed to handle possible loss of primary containment events	Recall procedures shall be developed to handle possible contamination or formulation issues
Training on the action plan for all employees	Training on recall procedures should be conducted
Drills should be conducted	Recall procedures testing should be conducted

Audits are required to evaluate effectiveness of the management system

PSM	cGMP
Conduct internal audit at least every 3 years	Continued Process Verification/Validation- information and operating data about product quality and manufacturing experience are reviewed to determine whether changes to the validated process are warranted.
Promptly resolve findings and correct deficiencies	Promptly resolve any findings
OSHA audits can be for cause or programmed	FDA audits can be for cause or routine

You can leverage most of the existing cGMP management systems for PSM implementation

- Process information system
- Operating procedures
- Training system
- Consultant/contractor management system
- Process qualifications
- Equipment inspections
- Management of Change

You can leverage most of the existing cGMP management systems for PSM implementation

- Incident investigations
- Corrective actions tracking and resolution system

It is easy to update the existing cGMP procedures for these systems to include specific PSM requirements instead of creating dual systems to handle these similar regulatory processes.

About ioMosaic Corporation

Through innovation and dedication to continual improvement, ioMosaic has become a leading provider of integrated process safety and risk management solutions. ioMosaic has expertise in a wide variety of areas, including pressure relief systems design, process safety management, expert litigation support, laboratory services, training, and software development.

ioMosaic offers integrated process safety and risk management services to help you manage and reduce episodic risk. Because when safety, efficiency, and compliance are improved, you can sleep better at night. Our extensive expertise allows us the flexibility, resources, and capabilities to determine what you need to reduce and manage episodic risk, maintain compliance, and prevent injuries and catastrophic incidents.

Our mission is to help you protect your people, plant, stakeholder value, and our planet.

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