

## Directive Agenda Process Equipment

### Scope:

This document discusses the process equipment used in the manufacture and testing of medical devices, pharmaceuticals, and other biotechnology products.

### Objective:

To present the concepts of the design, selection, specification, installation, qualification, operation and maintenance of process equipment by transforming general concepts into concrete directions and steps that a company can take to continuously improve its effectiveness and performance in this area.

### Disclaimer:

This is presented by Atzari Consulting, L.L.C. to its existing and prospective customers as a way to review and assess their current state and use this as a tool to guide their efforts in this area. It is not intended to replace existing guidance for regulatory compliance in this area.

### Philosophy and Discussion:

When used in a regulated industry, manufacturing process equipment must be designed and specified with ISO, OSHA, EPA, quality systems and cGMP/QSR requirements in mind as well as other international standards. This should be incorporated in a Master Validation Plan where Installation Qualification (IQ) and applicable parts of the Operational Qualification (OQ) are planned from the earliest stages of acquiring the equipment. All measurement devices and controls should be such that these can be calibrated and maintained. Equipment drawings, spare parts lists, service instructions, installation requirements, preventive maintenance requirements should be specified. A key requirement of any manufacturing plant is the ability to provide uninterrupted service. As such, the most critical pieces of manufacturing equipment should be redundant. While it is not feasible to order duplicates in all cases, those pieces of equipment that are not easily replaced and/or repaired, are built to order or have a long lead time should fall under this category. Another option is to maintain critical spare parts in stock and readily available. It is also important that the equipment be designed with standard, easily available components that can easily be



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### Philosophy and Discussion (continued):

serviced and replaced. For purposes of record-keeping, each piece of equipment should be assigned a unique identification number. This will help later in tracking and diagnosing trends and problems.

One of the key aspects of equipment design, selection, specification, installation, qualification, and operation is the equipment be fully capable of providing what the process requires of it, especially in the ability to control critical parameters with both accuracy and precision. While sometimes overlooked, design controls do apply to designing a new process, hence by extension these apply to new process equipment. Part of this is the ability to produce small lot sizes, making quick changeover (QCO) a strong requirement.

In anticipation of the possibility of computer integrated manufacturing, instruments should be specified such that these can be integrated into a central computer control and operated or monitored from a remote location. Also, since equipment output is closely related to process output and SPC, the data recordings from its process should be easily downloaded or at least printed as a permanent process record.

For purposes of set-up, operation, and service, the location and installation of the equipment should allow for easy service access. In a new installation, having utility drops from the ceiling will allow easy cleaning and access. Also, locating the equipment away from walls and off the floor, where possible, will allow for easy cleaning of the area. This is especially important in clean rooms and controlled environments.

When equipment is to be located in clean rooms and controlled environments, equipment that can produce hydrocarbons, oil mists, or other similar sources of contamination, should be located outside the clean room and in a location where it cannot possibly contaminate the clean room. In anticipation that a company may grow into an international operation and that an offshore duplicate facility may be built in the future, manufacturing process equipment should meet international standards, especially providing measurements and readings in SI units. This will avoid the costly future expenses of converting procedures, standards and requirements to another country's system.



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Stages of Development—Hierarchy of Needs:

**Startup—Vital Level:**

- (1) Have you selected the correct equipment for your process ?
- (2) Has this equipment been acquired, received, and properly installed?
- (3) Do you have sufficient equipment with capability of producing the right throughput?
- (4) Does your facility have adequate utilities to supply this equipment?

**Operation—Functional Level:**

- (1) Does the equipment perform as designed?
- (2) Is the equipment able to reach and control at and beyond the desired settings?
- (3) Is the equipment reliable and repeatable?

**Systems Integration—Interactive Level:**

- (1) Is the equipment a constraint?
- (2) Does it need to supply various production lines?
- (3) How well does the equipment facilitate the flow of product in the production line?
- (4) How quickly can tooling be changed over in this equipment?

**Future Growth—Developmental Level:**

- (1) Do future product introductions account for new or existing process equipment?



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Strengths, Weaknesses, Opportunities, and Threats (SWOT):

**Strengths / Weaknesses (Internal):**

- (1) Process equipment is fairly new and robust
- (2) Plant has a history of compliance with existing design control standards for process equipment.
- (3) Plant has a strong preventive maintenance program
- (4) Equipment changeover time can be accomplished quickly

**Opportunities / Threats (External Opportunities or Challenges):**

- (1) Your company is building a plant in another location, and needs to duplicate this equipment.
- (2) Additional products will be manufactured on this process equipment



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Proposed Direction for Improving Process Equipment at Your Company:

(Examples)

- (1) Create a master list of all process equipment.
- (2) Establish a robust program of preventive maintenance.
- (3) Establish quick changeover goals for critical pieces of equipment.
- (4) \_\_\_\_\_
- (5) \_\_\_\_\_
- (6) \_\_\_\_\_
- (7) \_\_\_\_\_
- (8) \_\_\_\_\_
- (9) \_\_\_\_\_



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