Mechanical Demand Specification

(Reference SOP: _____)

Project:	**Project No:**
Equipment Description:	
Location:	
Equipment No.:	**Protocol No.:**

PROGRAM INDEX

Maintenance and replaceable elements are to be easily accessible for replacement, inspection or maintenance. This shall include mechanical and electrical components.

All mechanical adjustments are to be designed with the ability to carry out fine adjustment with out the need to strip down or remove other equipment to carry out the desired function.

Where intricate adjustment is required consideration shall be given to complete removal of an assembly so that adjustment can be carried out off line prior to assembly or inclusion in the machine.

1.4.1. Special tools

Special tools for maintenance shall be furnished with the equipment.

1.4.2. Clearances Under Equipment

Equipment shall be free standing above the floor with at least 150mm clear space beneath items for cleaning. Where equipment is lower than 150mm from the floor the space beneath this item shall be closed and sealed to the floor with a secure coving strip. Suitable coving shall be for permanent fixtures, an epoxy material or semipermanent items, a silicon coving strip or similar.

The operation side of equipment shall allow for operators to have clearance to clear away fallen items from the floor.

1.5. Component Materials Selection

Equipment will be used to manufacture pharmaceuticals. The cleanliness of the machine operating environment will be specified for specific applications. As a minimum the equipment shall not generate particles or breakdown surface finishes due to exposure to salt solutions or abrasion.

1.5.1. Product Components.

Where Product, solutions or powders without primary packaging are in contact with the equipment. The materials shall be selected with consideration of the intended use of equipment. There shall be no chance of cross contamination, possibility of residual product being retained or transfer of component materials into the product. Product seals and gaskets selected should be verified for use. The use of triclover style gaskets for connection of pipes is acceptable. For example, use the yellow & white dot Vitron material as a standard on all connections where steam will be present.

A list of the materials in contact with solutions or powders shall be prepared with the design for approval by the project co-ordinator before implementation.

The use of either vacuum or grippers is acceptable on most products. In the event of vacuum cups it may be necessary to consider the effect of picking up on printed surfaces as ink could build up and cause brittlement on suction cups.

Mechanism weights, acceleration and inertia effects are to be calculated and a Factor of safety (FOS = 2) in design employed so that long life can be achieved, over 24 months continuous duty would be acceptable. The designer may be asked to prove the design by way of presenting the calculations used.

In the event that linear cylinders are used refer to the pneumatics section of this document for details.

1.15. Conveyor systems

Use a standard extrusion frame conveyor for product transfers where a standard width fabric belt is to be installed. This conveyor is suitable for most product transfers that do not require high accuracy of positioning. Details of this frame section and full drawings of the mechanical system will be provided on request. Dimensions and tolerances shall be adhered to for spares etc.

All belt lengths and details must be recorded as spares.

Drives are to be wire reinforced timing belts, not chains. The standard pitch used will be specified on the conveyor system drawings along with the drive and motor size.

1.16. Pneumatic devices

Guided rodless cylinders shall use heavy duty ball race guides not bushes. The design shall be as a minimum to have a Factor of Safety (FOS=2). Load application calculations may be requested before acceptance agreed.

In the event that the line emergency switch is activated all pneumatic devices shall be able to release stored energy and become safe.

Where the design of releasing stored energy after activating an emergency switch is not desirable, alternate designs should be considered.

1.17. Spare parts

Stock spare parts are to be defined.

1.18. Documentation

1.18.1. Manuals

Enclosed with the machine there must be a minimum of three copies of the following items in English:-

- list of components :