

## **1 Purpose**

To define the principles for management of change within Operations.

## **2 Scope and Applicability**

This document may apply to the Change Management, MCM process, to Regulatory Affairs CMC and to all cGMP activities performed by an Operation sites. It applies to all facilities, processes, systems and procedures used during manufacture, testing and distribution that may directly or indirectly affect the quality of pharmaceuticals products.

The principles contained in this document apply to contractors. The teams/sites managing contractors has the responsibility to serve as the link between the contractor local change system and the company's Change Control system.

## **3 Definitions**

### **3.1 Change Control**

A formal process by which qualified representatives of appropriate disciplines review (including technical and operational impact assessment), authorize, approve and close proposed or actual changes to facilities, systems, equipment and processes to ensure that they are maintained in a controlled manner.

### **3.2 MCM (Manufacturing Change Management)**

Manufacturing Change Management. This is the process that facilitates the tracking, review and approval/rejection of changes that may impact on the registered data and on the international supply of products.

### **3.3 CMT (Change Management Team)**

Teams with members from Operations and Regulatory CMC (Chemistry Manufacturing & Control) for monitoring and follow-up of manufacturing/control changes administered in the MCM system. (Manufacturing Change Management). There are several teams per therapy area.

### **3.4 RA (Regulatory Affairs)**

An organizational function responsible for company regulatory activities.

### **3.5 CMC (Chemistry, Manufacturing and Controls)**

FDA term to describe the section of the NDA which details the pharmaceutical development and the stability as well as the **manufacturing** processes and the analytical **controls** used in the production of a drug substance and a drug product.

accountable for setting up and running the CMT. The responsibility of running the CMT can be delegated.

The CMT shall have participants from at least the following functions:

Supply Chain  
RA- CMC  
Operations

The CMT is the forum to discuss all changes, the implications of the changes and the implementation plans.

#### **4.3 Site Change Manager (SCM) or responsible person at site**

For Operations which consist of multiple sites, the SCM is responsible for the management of the change control procedure that is operated locally, for interaction with the other site or process and the MCM system.

The SCM is accountable for highlighting the need for a Regulatory Position Statement when required from an Operations point of view and communicating this to the RA Regulatory CMC.

#### **4.4 QP (or QA manager at non EU site)**

Is responsible for batch release for products affected by a change and where all regulatory approvals have not yet been obtained. The justification for such decision shall be documented using a QA Justification Document according to this procedure.

#### **4.5 Regulatory Affairs (RA) - CMC**

Is responsible for providing a Regulatory Position Statement (RPS), which may include consultation with company's RA group and MCs and as appropriate. The need for a RPS may also be identified in the regulatory strategy for the change.

The RA CMC Manager is also responsible for archiving the document and for making it available in the MCM system (preferably at the high level plan stage or regulatory submit & approve stage).

### **5 Procedure**

#### **5.1 Local Change Control**

All manufacturing sites shall establish a formal, documented system that evaluates the effectiveness of all changes proposed.

The impact of the change on the validation and registration status must be assessed.

affected QA department.

Some changes are initiated by regulatory initiatives such as scheduled updates of the registered documentation, other drivers are external initiatives e.g. pharmacopoeia changes that might impact the registered data. Also these types of shall be handled in MCM.

### **5.3 Pharmacopoeia changes**

A Pharmacopoeial Committee should handle changes in the different pharmacopoeias, some of these changes might affect the submitted documentation. If that is the case the implementation of the change is a subject of the MCM process and the secretary of Pharmacopoeial Committee is responsible for raising a MCM errand.