Risk management must be a part of this process.

The local QA unit must be involved in reviewing and approving all changes proposed.

The implementation procedure for all changes must ensure that regulatory and GMP compliance is maintained.

The operation of the system shall ensure adequate control and monitoring of change projects.

The system shall be designed to ensure the complete and accurate recording of the decisions to approve or reject a change and the history of the change from inception to implementation.

The system shall ensure that relevant documentation is updated accordingly.

All sites shall appoint a Site Change Manager with clearly defined roles and responsibilities.
All site should appoint a lead team which is responsible for the contractors are ensuring that appropriate links are established and maintained between the contractor and coordinated MCM process.

5.2 Changes with International or regulatory impact

The changes that have an impact on the registered data and/or on international supply must be handled in the global change management process. This process is supported by the MCM data system. This global process and system facilitates the tracking, review and approval/rejection of changes that may impact on the registered data and on the international supply of products.

Decisions for Products affected by a manufacturing change require a QAJD and a RPS, if requested. The risk assessment may be done during different stages of a change in accordance with the IRM framework.

> For example, at the high level planning phase (in MCM), when a change has to be implemented on a tight schedule according to the regulatory submission strategy or from a supply point of view.
>
> During regulatory approval from the markets or from a supply point of view.

The RPS document describes the regulatory implications of a change (i.e. parts of the dossier affected and type of regulatory procedures to be used in the different regions), the regulatory strategy (i.e. for the different regions, planned submission timelines and expected approval times) and a regulatory risk assessment. The RPS document should also include or refer to a list of markets where the change has already been approved or where submission is not needed.

The regulatory position statement must include as a minimum:

