MLC SERVICES · 11

Quality Plant Setup and Upgradation

Plant setup and upgrade support across planning, engineering, qualification and quality systems.

PLANT SETUP

- Conceptualization
- Facility Plan and Design or Layout
- Total Engineering Support
- Procurement Support
- Installation- IQ, OQ, PQ Support
- Commissioning and Qualification
- Computer System development and Validation

- URS, FRS, SAT and FAT support
- Vendor Identification and Management

PLANT UPGRADATION

If you already have the API or Formulation Plant which is approved by the local regulatory authority and if you want to expand your reach to regulated territories like USFDA, EMEA, WHO, MHRA, PIC/S etc. then you may opt for Plant Upgradation Service.

Plant Upgradation Includes the Following:

- Establishment of Proper scope for which regulatory is being targeted.
- GAP Audit of Existing Plant (API/Formulation)
- Preparation of GAP Audit Report
- Preparation of CAPA Plan
- Identification of GAPS and making time bound milestones for upgradation
- Validation
- Changes in Layout and design in required.
- SOP and Procedures upgradation
- Policies redesign
- Training
- QMS system establishment/ restructuring as per requirement
- Internal Audit System development

FAQ

Q. What does MLC's plant setup service cover?

Conceptualisation, facility planning and layout, engineering and procurement support, IQ/OQ/PQ installation and qualification, commissioning, computer system validation, URS/FRS/SAT/FAT support and vendor management.

Q. Who is plant upgradation for?

API or formulation plants approved by local regulators that want to reach regulated markets such as USFDA, EMEA, WHO, MHRA or PIC/S.

Q. What does an upgradation project involve?

Defining the regulatory scope, a gap audit and report, a CAPA plan with time-bound milestones, validation, layout changes where needed, upgraded SOPs and policies, training, and QMS and internal audit systems.

Useful details to share when you enquire

- New-plant or upgrade objectives
- Existing layouts and facility information
- Qualification needs and proposed timeline

TALK TO MLC

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