

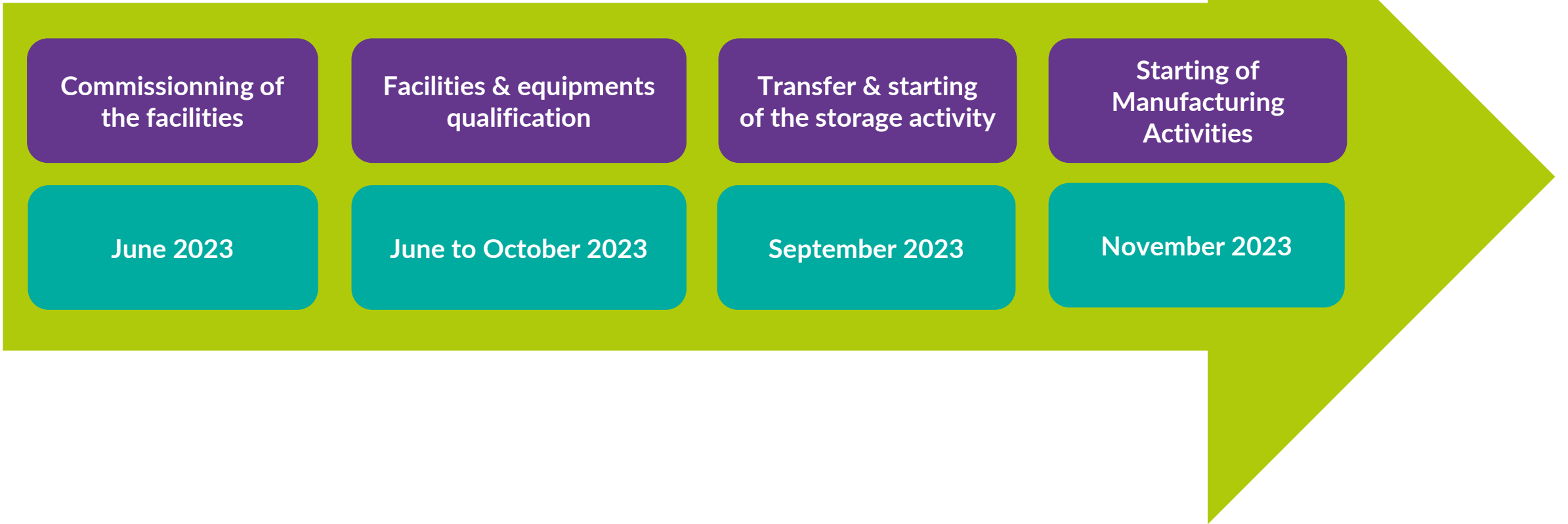
# Customer Communication: Storage & Manufacturing activities



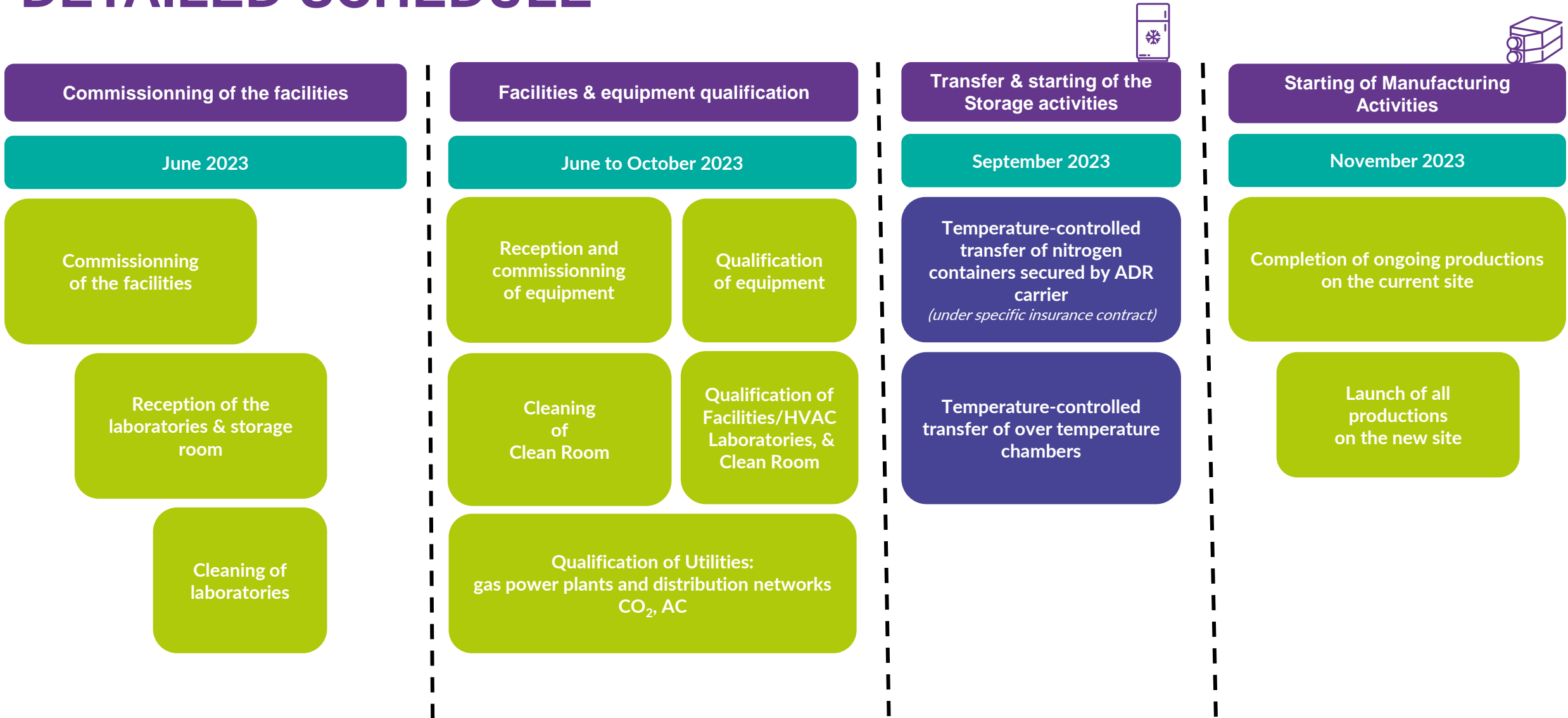
# CHANGE SCHEDULE



Here are the 4 main phases of the site transfer strategy:

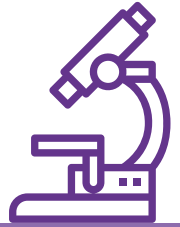


# DETAILED SCHEDULE



# CHANGE CONTROL STRATEGY: CGC 22-61

The control of risks has been taken into account through the CGC 22-61 :

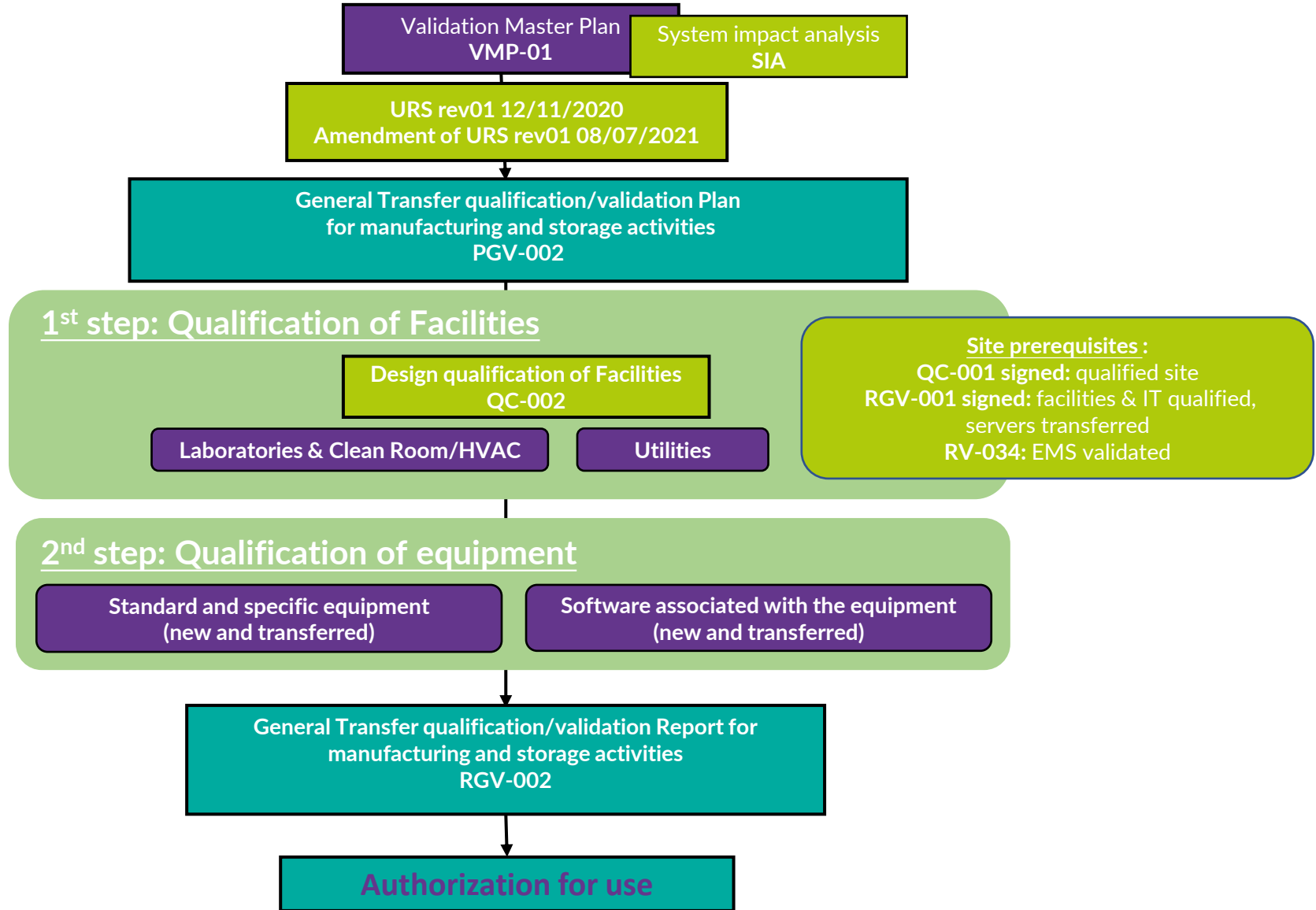


5 M diagram	Document ID	Item
<b>Machine (equipment)</b> <i>(common strategy for the entire site*)</i>	<b>AdR 028/ AdR 058</b>	<b>Transfer of equipment</b>
<b>Manpower</b> <i>(common strategy for the entire site*)</i>	<b>AdR 029/ AdR 030</b>	<b>Training of people</b>
<b>Medium (environment)</b>	<b>AdR 033</b>	<b>Qualification of facilities</b>
<b>Methods</b>	<b>NA</b>	<b><i>Dependent customer</i></b>
<b>Materials</b> <i>(common strategy for the entire site*)</i>	<b>AdR 029/ AdR 030</b>	<b>Transfer of raw materials</b>

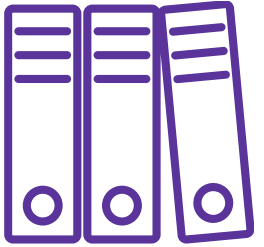
*\*Common documentation to the 1<sup>st</sup> transfer step : qualification/validation strategy for the transfer of quality control activities (CGC 21-03)*

# QUALIFICATION & VALIDATION STRATEGY

The strategy is divided into 2 major steps :



# GENERAL DOCUMENTATION



- List of documents mentioned in the presentation :
  - CGC : change control
  - VMP : Validation Master Plan
  - SIA : System Impact Analysis
  - PGV : General Transfer qualification/validation Plan
  - RQV : General Transfer qualification/validation Report
  - AdR : Risk Assessment

Comment: these documents will be available for consultation on site only during audit.

- Address of CLEAN CELLS new facility starting since February 2023: 4 rue Nicolas Sadi Carnot  
ZA du Point du Jour  
85 600 Montaigu – Vendée  
FRANCE

Start of Storage activities in new facilities :  
September 2023

Start of Manufacturing activities in new facilities :  
November 2023



# THANK YOU !

For any additional information feel free to contact :  
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