

WELCOME TO CLEAN CELLS

Site Transfer Management

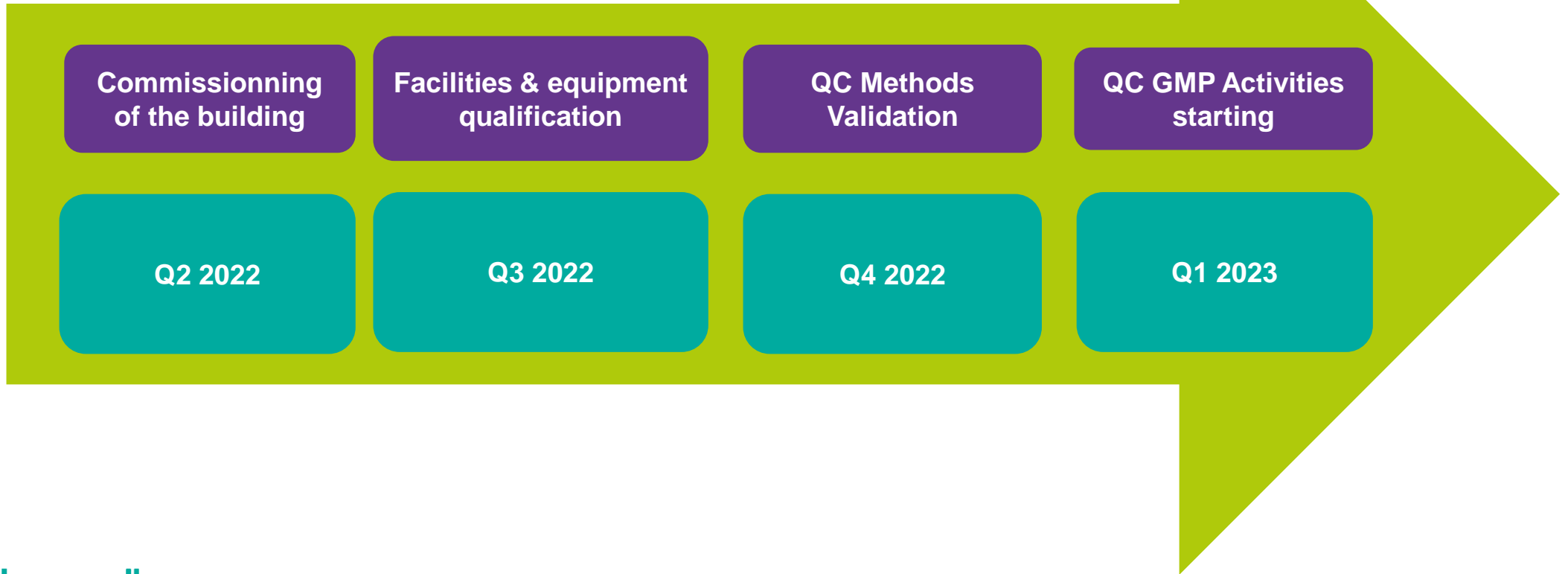
clean cells
SOLUTION FOR BIOLOGICS



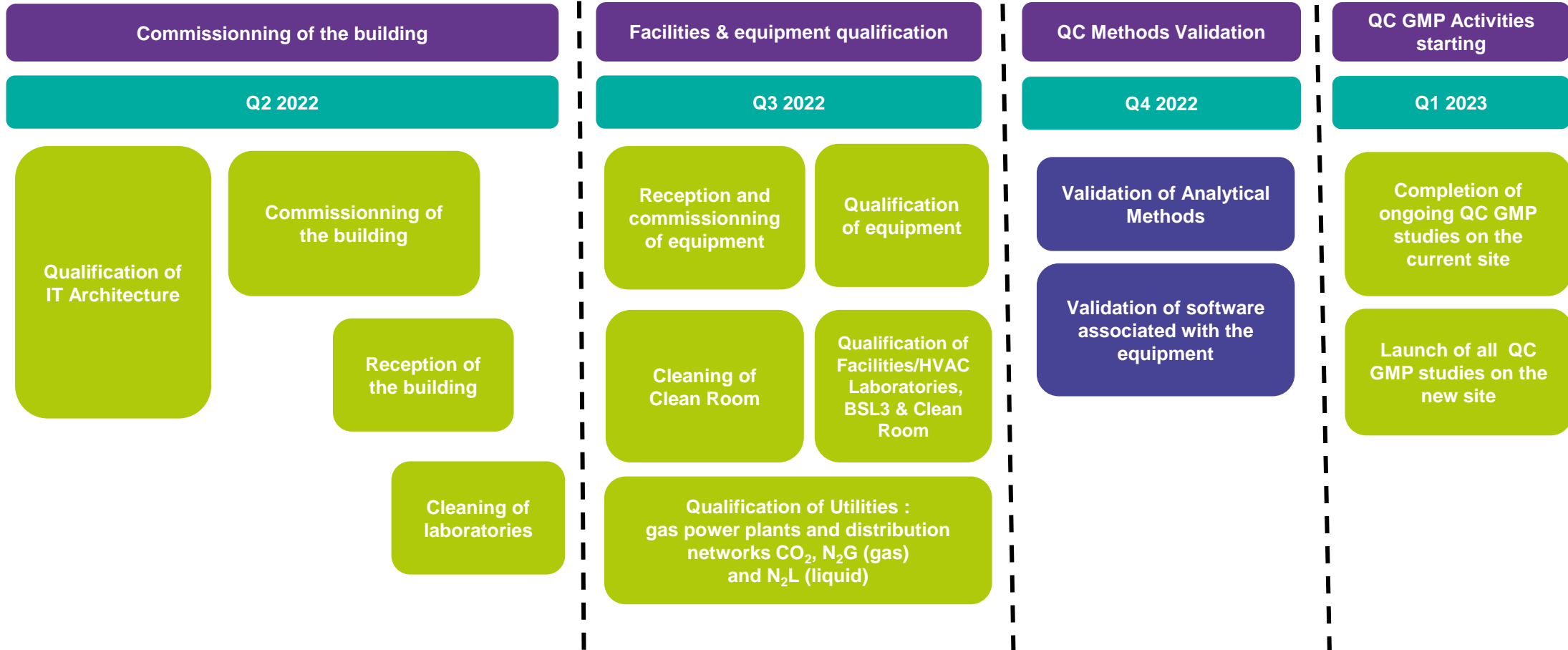
CHANGE SCHEDULE



4 main phases of the site transfer strategy :



DETAILED SCHEDULE



CHANGE CONTROL STRATEGY : CGC 21-03

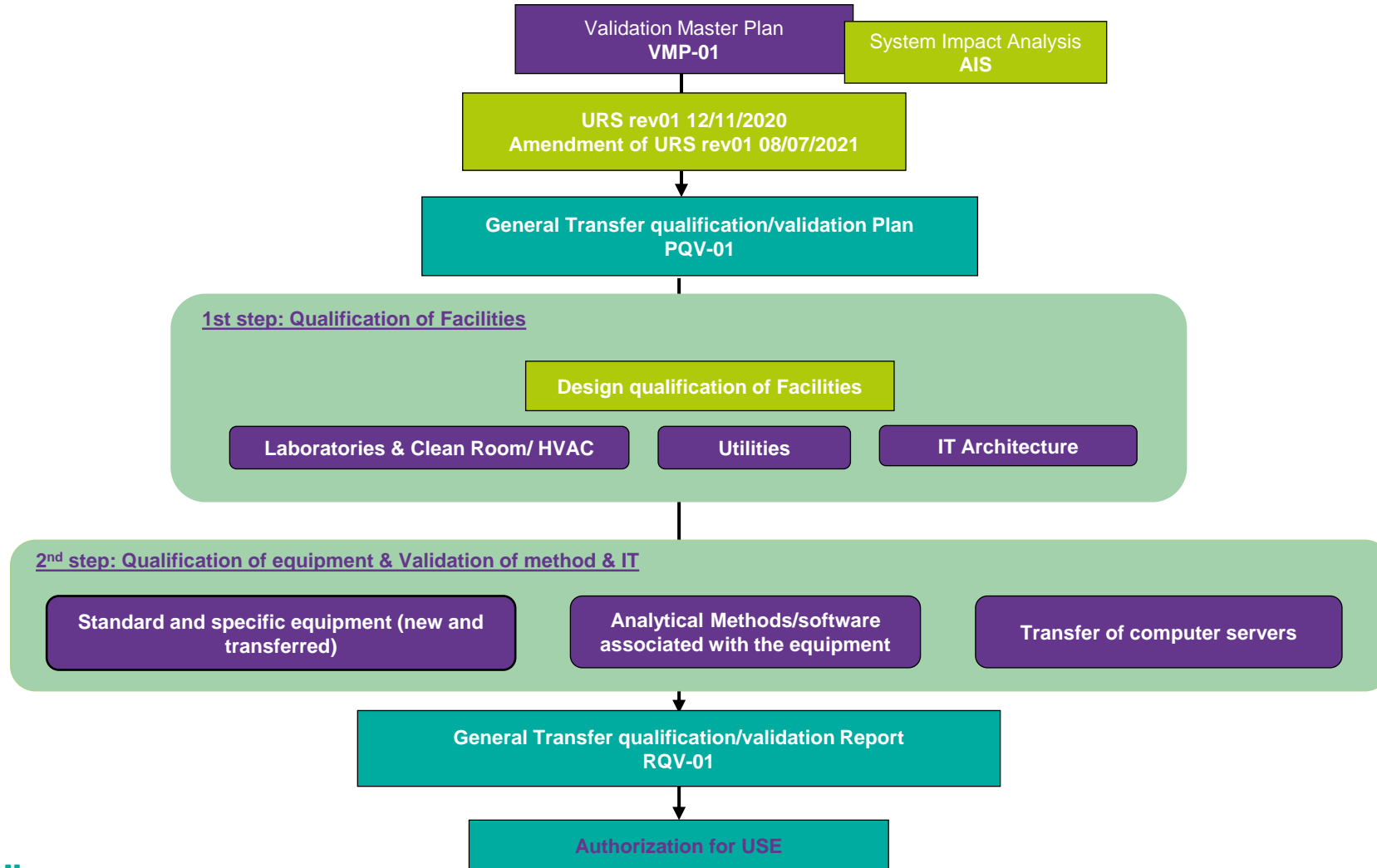


The control of risks has been taken into account through the CGC 21-03 :

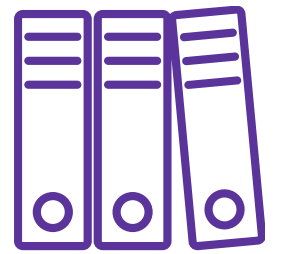
5 M diagram	Document ID	Item
Machine (equipment)	AdR 028	Transfer of equipments
Manpower	AdR 029/ AdR 030	Training of people
Medium (environment)	AdR 029/ AdR 030	Qualification of facilities
Methods	AXT 002	Validation of methods
Materials	AdR 029/ AdR 030	Transfer of consumables, raw materials, samples

- AdR : Risk Assessment
- AXT : Criticality analysis

QUALIFICATION & VALIDATION STRATEGY



GENERAL DOCUMENTATION



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

Comment : these documents will be available for consultation during audit on site or remotely

- Obtention of the new site's Manufacturing Authorization by French authorities (ANSM): 28/03/2022
(MIA number : [2022_071_1](#))
- Address of CLEAN CELLS new facility starting from Q1 2023 :
4 rue Nicolas Sadi Carnot
ZA du Point du Jour
85 600 Montaigu – Vendée
FRANCE
- Next customer communication date : SEPTEMBER 2022

Start of GMP Quality Control Activities in our new facilities : Q1 2023

THANK YOU

For any additional information feel free to contact :

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For more information

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