

Construction in a GMP qualified environment

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Sr. Project Manager
DPS Group



WE SHARE THE KNOWLEDGE

Agenda

- **Introduction**
- **Preparation**
- **Enabling work**
- **Shutdown & CQV**
- **Summary**

Introduction | relevance



Over 200 pharma companies in Benelux



Facility investment levels hundreds of millions euros annually



Majority of projects related to upgrade or refurbishment of facility



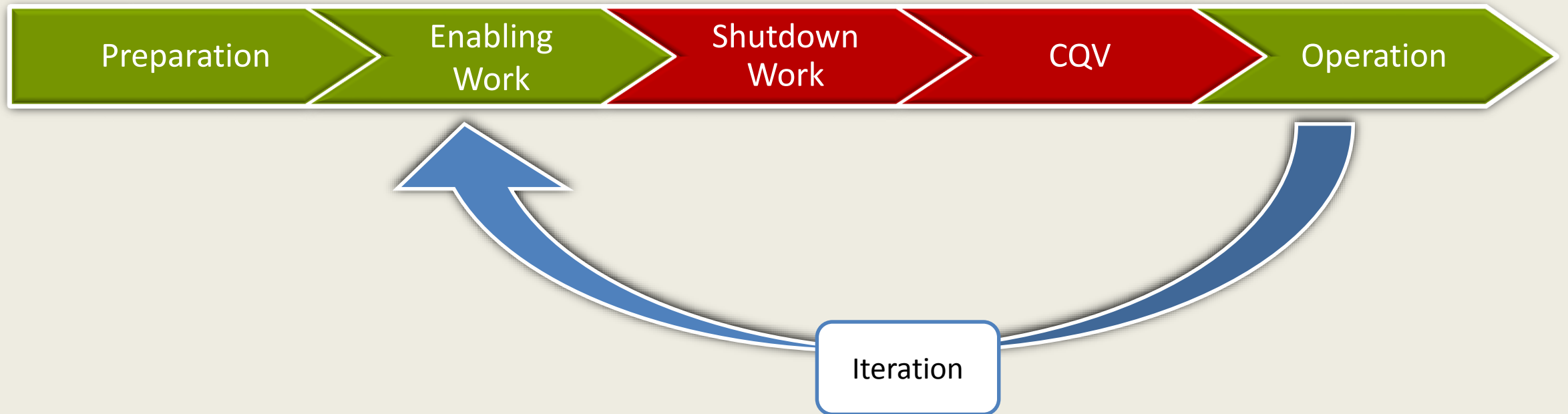
Relevant project experience (recent years):

>> 270M€ of capital investments

>> 1,000,000 construction hours

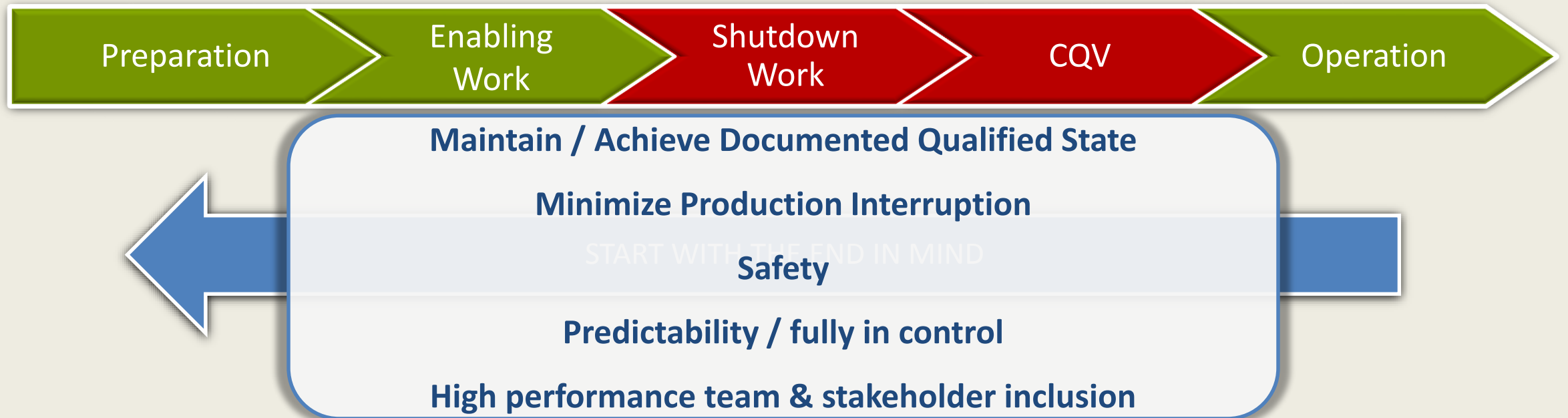
Introduction | framing

Projects involving construction work in an operating production facility

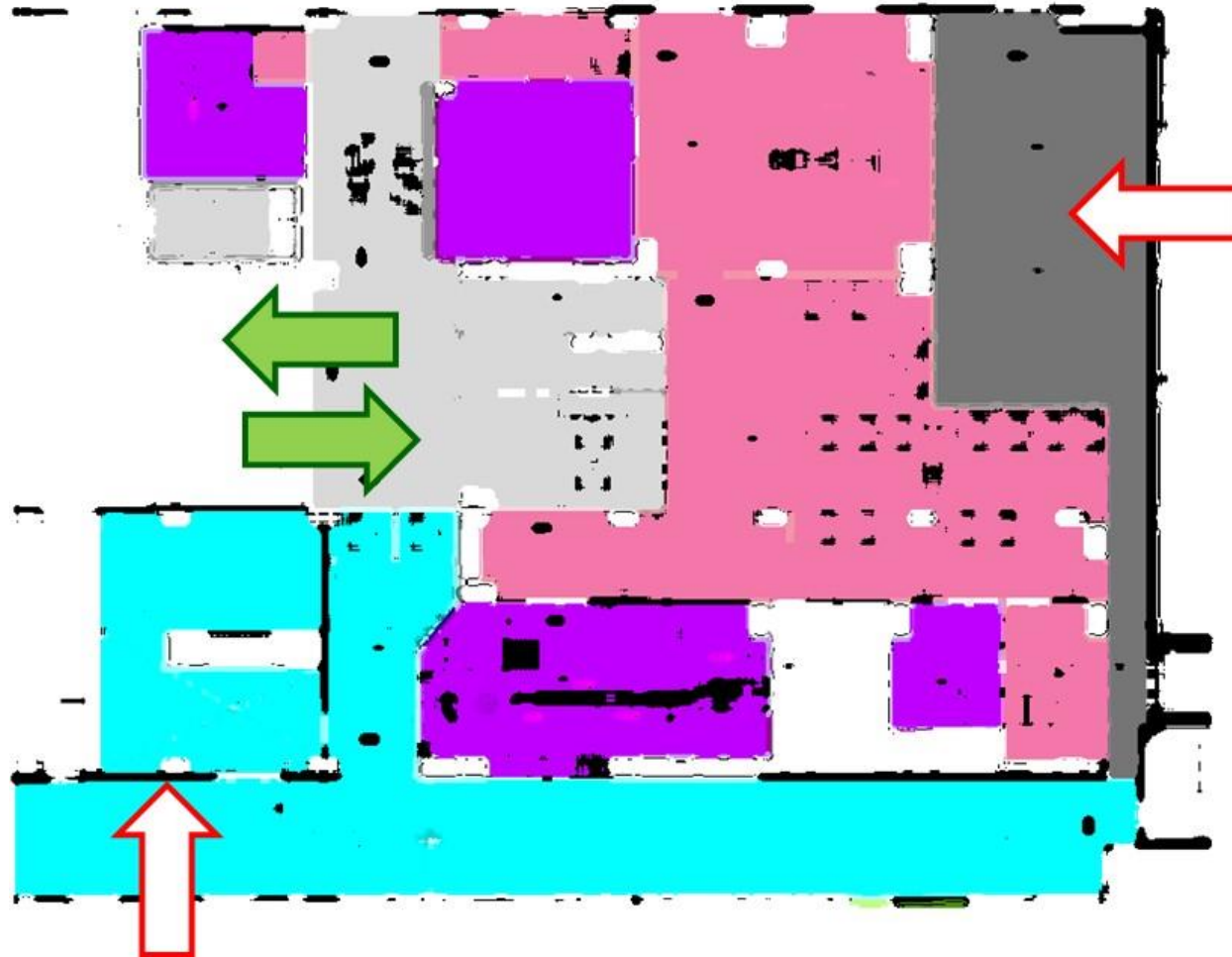


Introduction | framing

Key Success Factors - parallel production & construction



Introduction | framing









Engineering (new + temporary)



Investigations



Project execution planning



Qualification planning

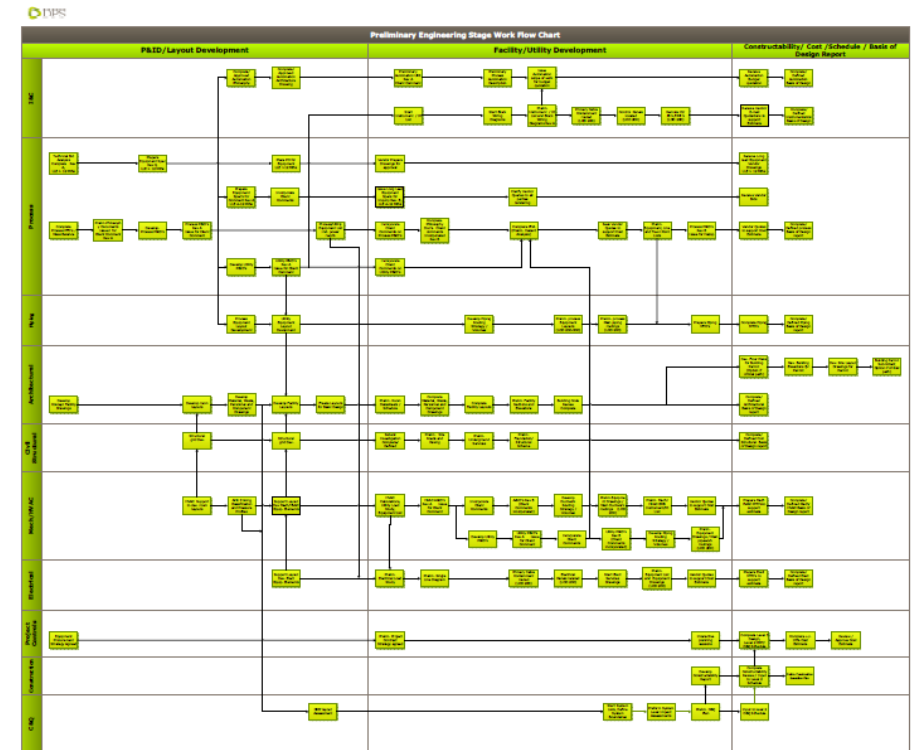


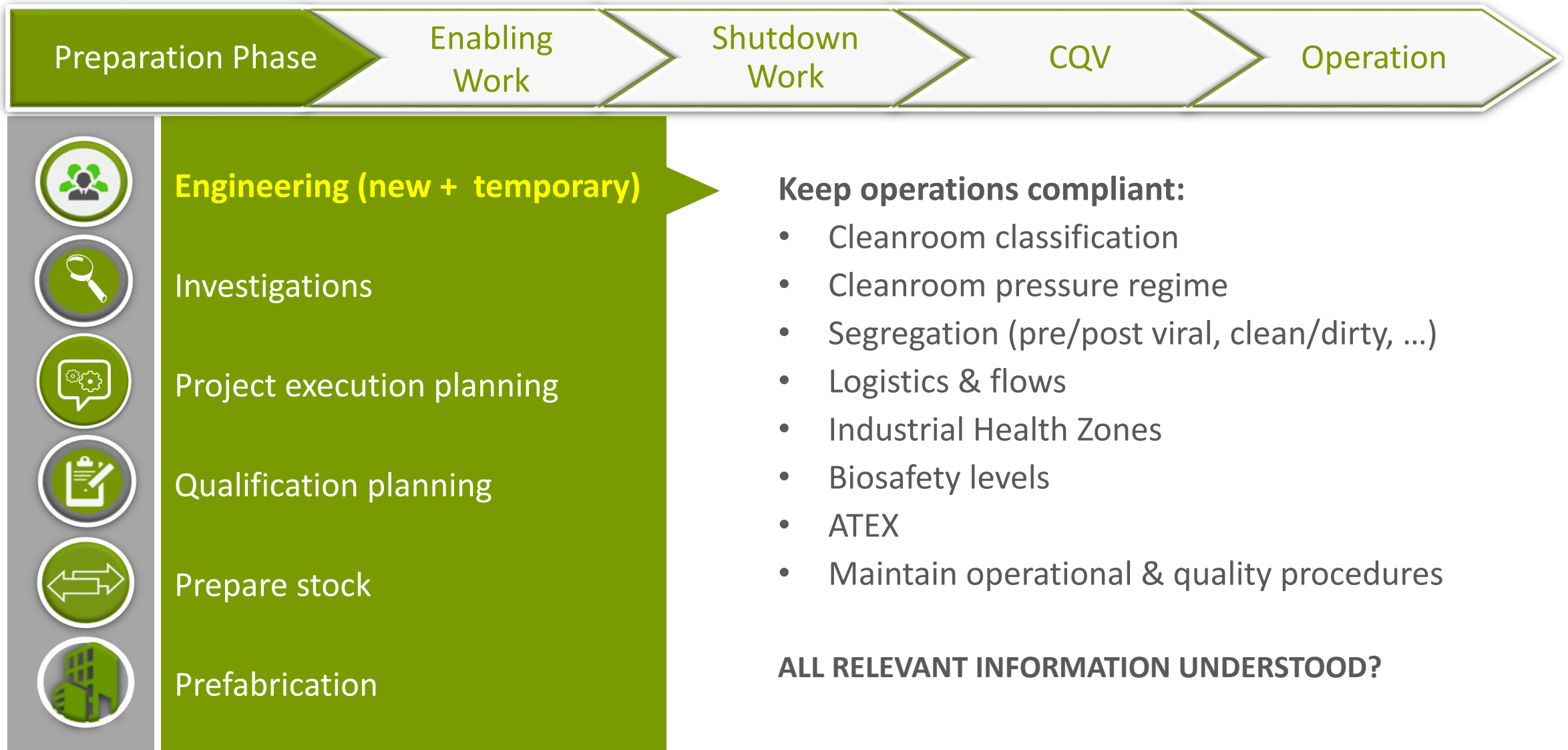
Prepare stock

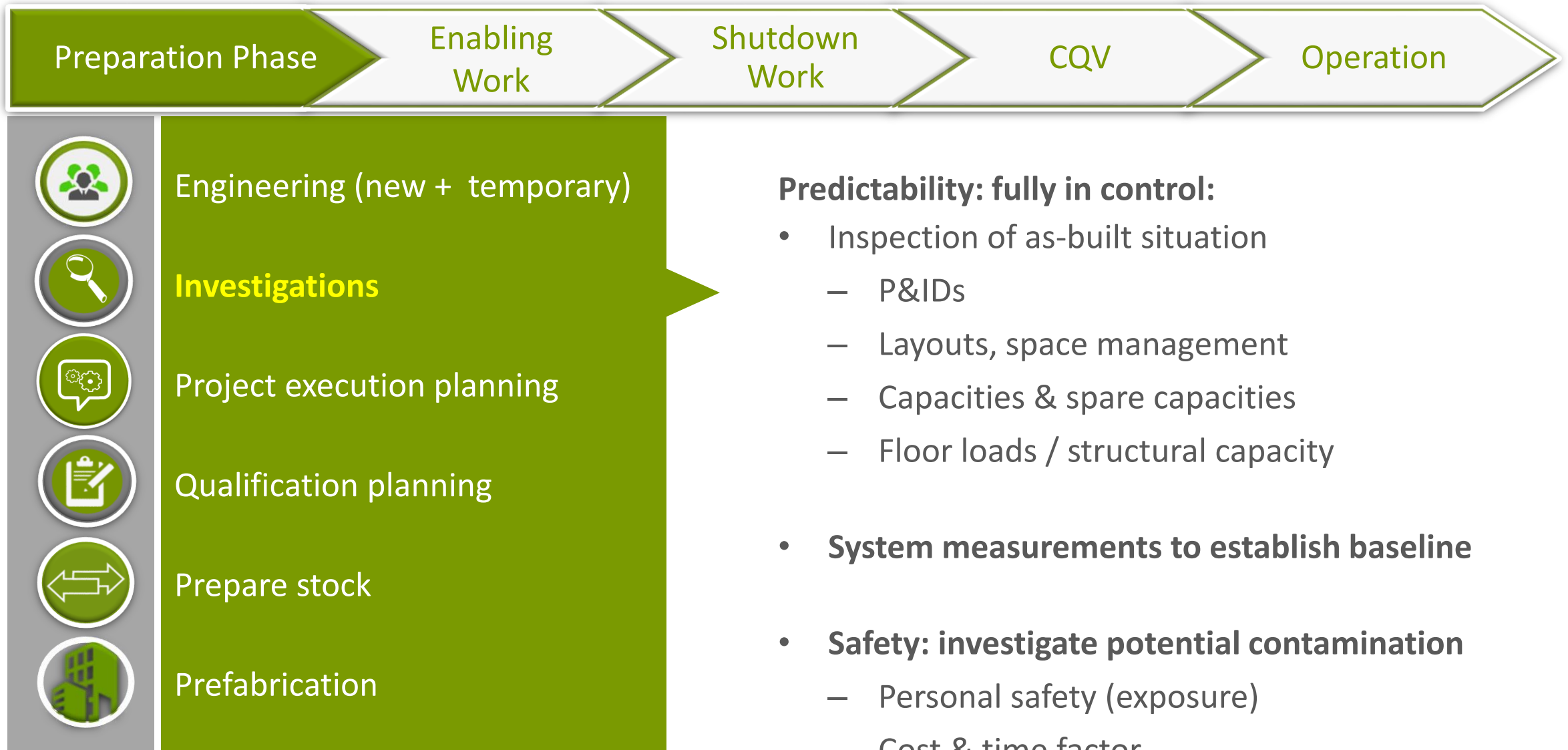


Prefabrication

Engineer for compliance: roadmap







Preparation Phase

Enabling
Work

Shutdown
Work

CQV

Operation



Engineering (new + temporary)



Investigations



Project execution planning



Qualification planning



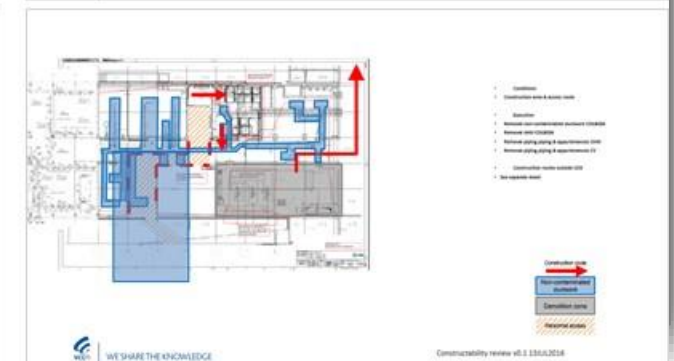
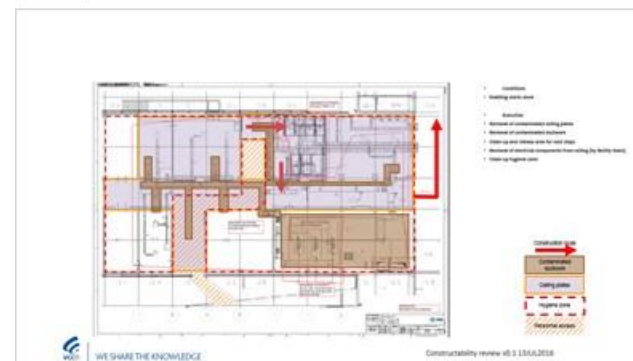
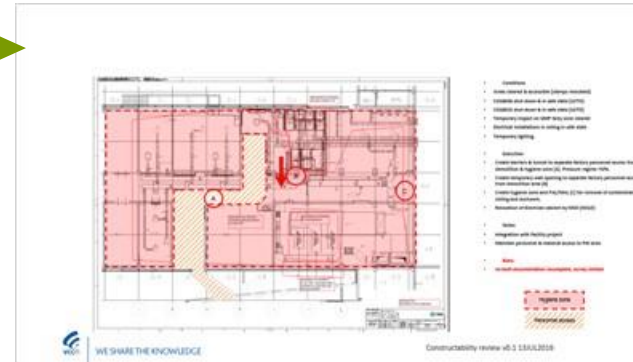
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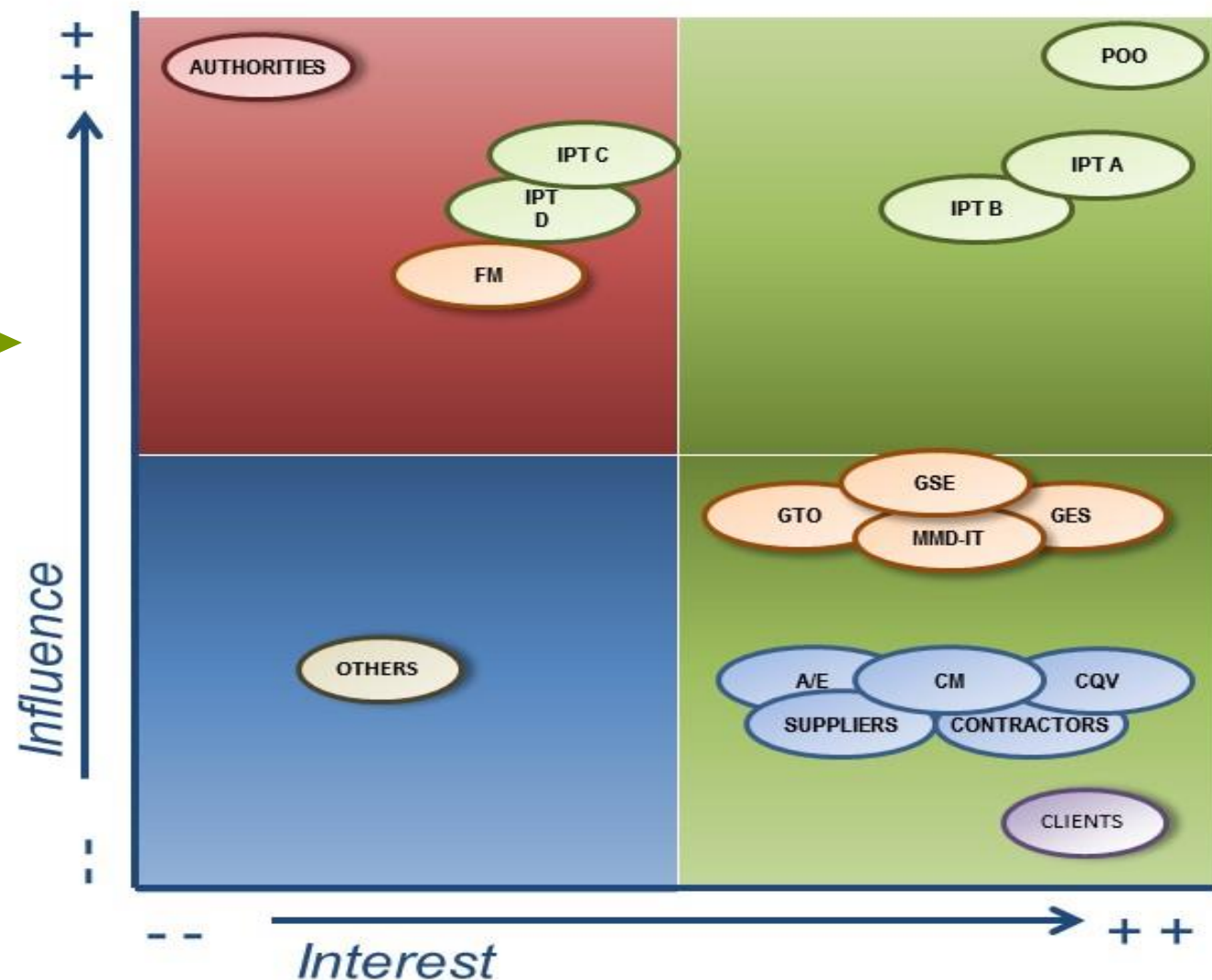


Prefabrication

Plans:

- Project execution plan
- Graphic script (stakeholder alignment)
- Shutdown plans (& risk assessments)







Engineering (new + temporary)



Investigations



Project execution planning



Qualification planning



Prepare stock

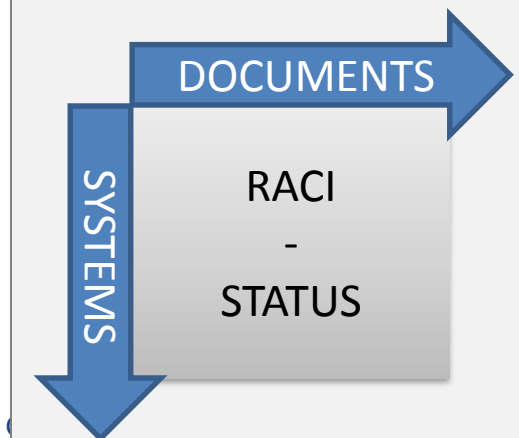


Prefabrication

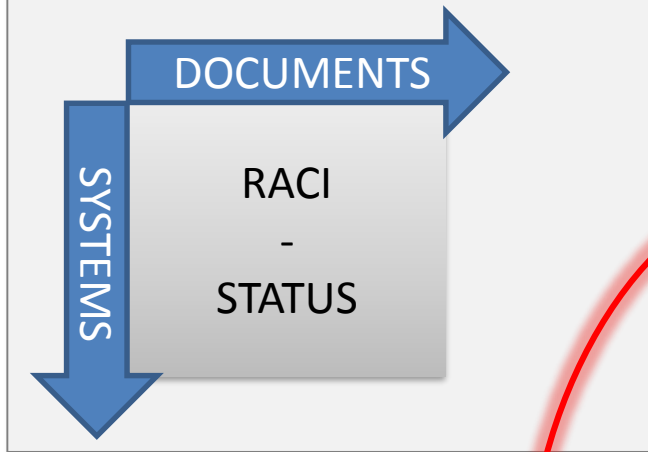
Key aspects:

- Define systems (new, existing, temporary)
- Define requirements (URS → DD)
- Define acceptance criteria
- C&Q strategy / plan
- Develop test protocols (IOC, IOQ, PQ)
- Test Plans (ensure tests are possible)
- VMP

System matrix

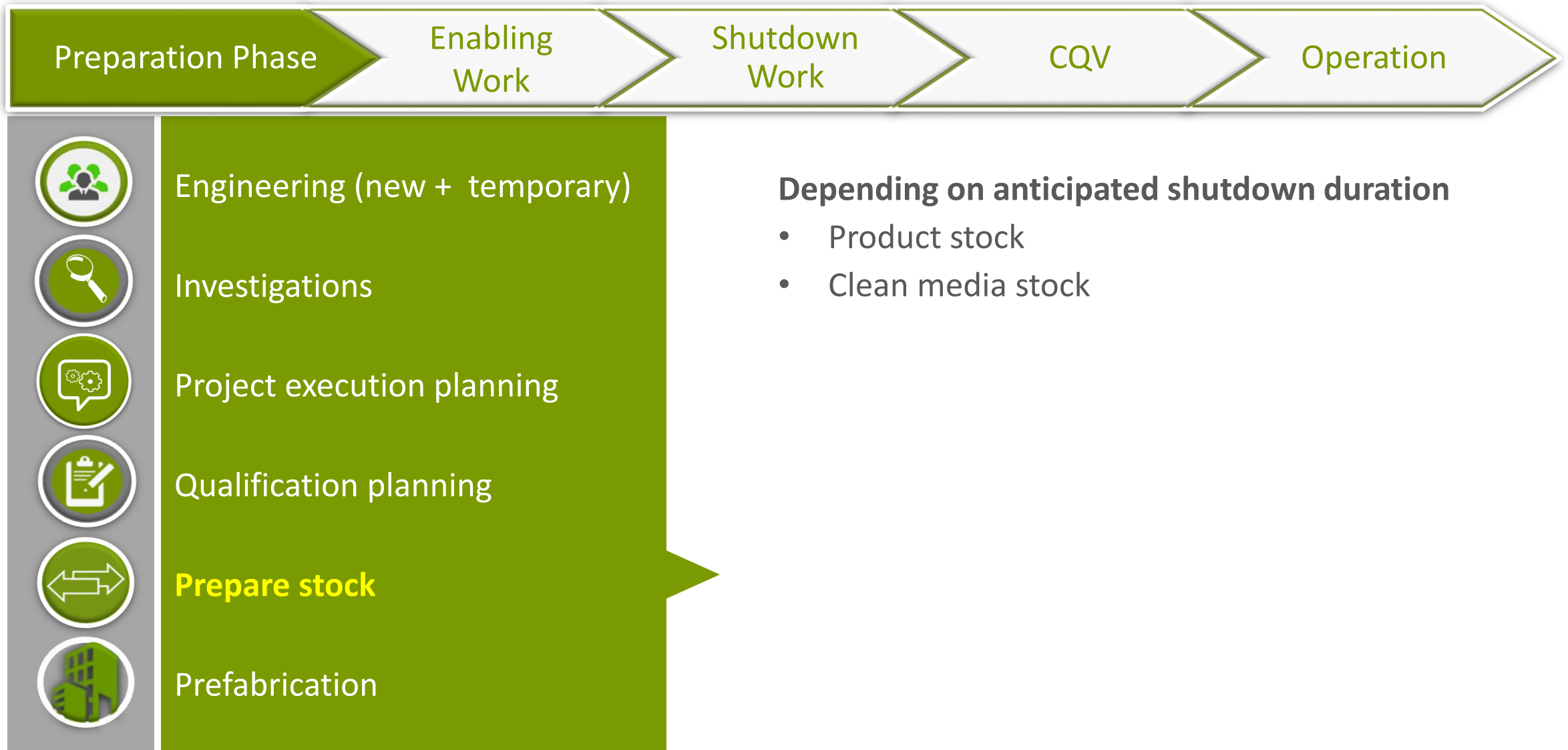


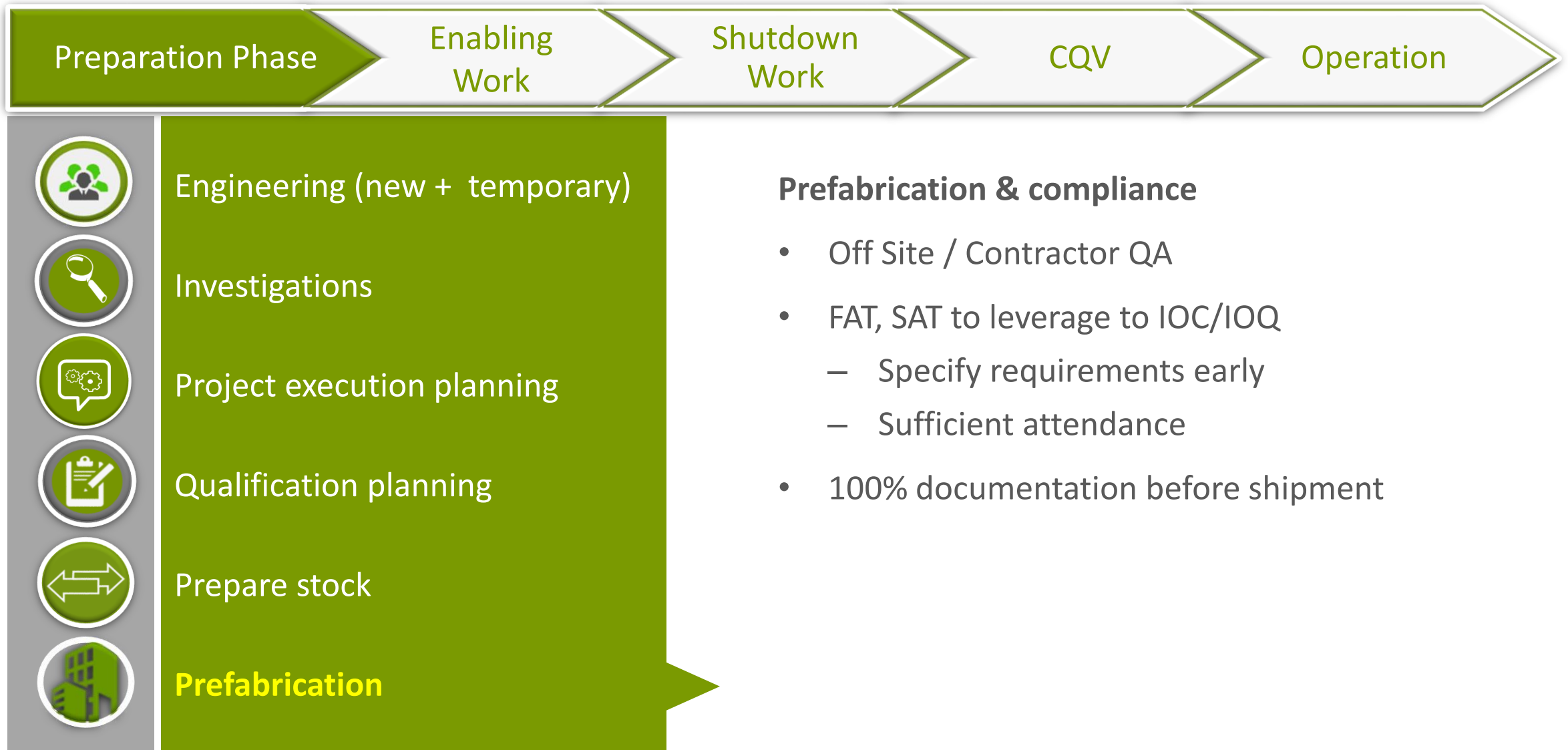
System matrix



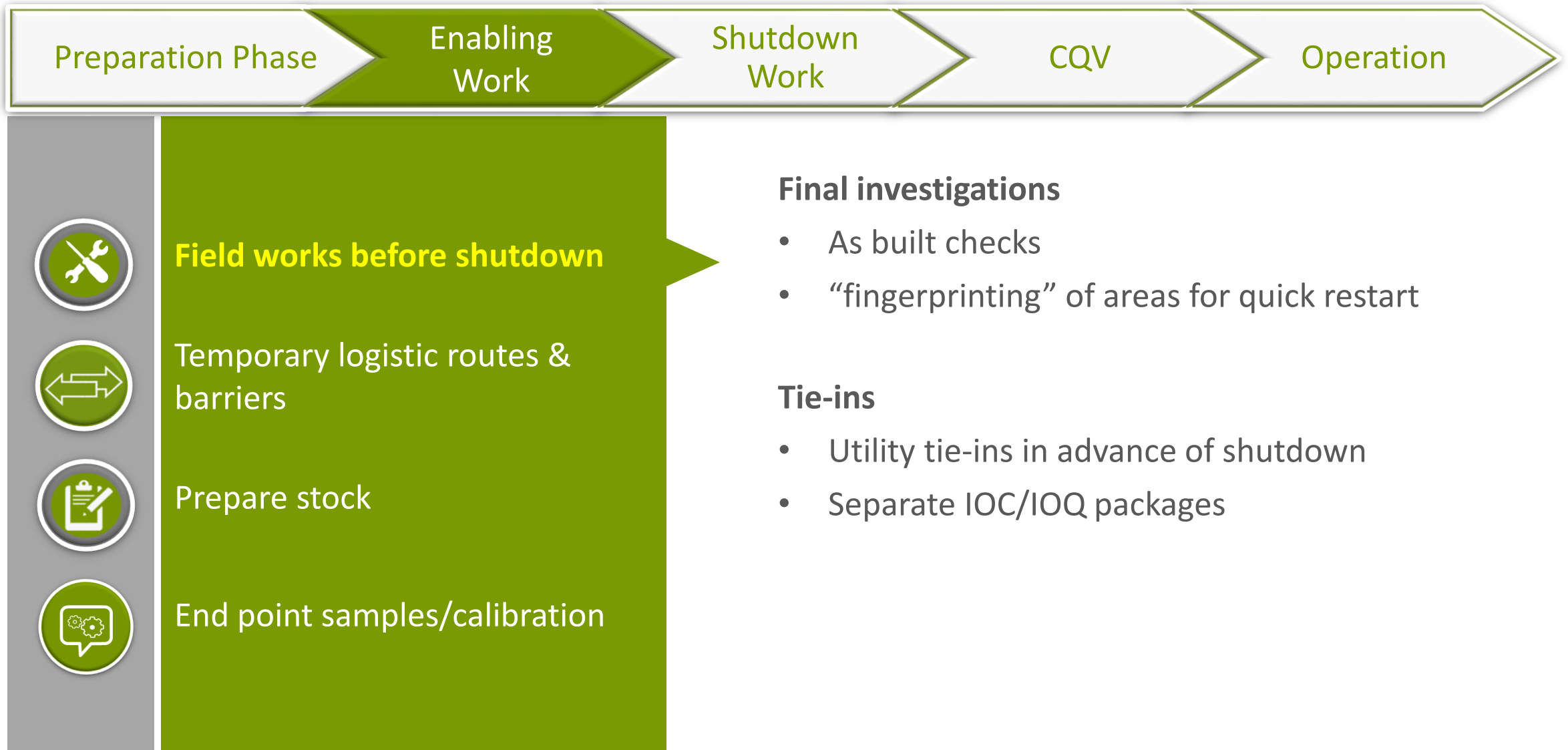
Preparation phase

Systems affected by project																					
Number	Description	Location / Room ID	Type	Change type	(Sub) project	IPT	Responsible team (primaire)	Phase	Priority	Conceptual design	URS		System Boundaries		SIA			SQAP			
										Resp. (action owner)	Status	Resp. (action owner)	Status	Resp. (action owner)	Status	Resp. (action owner)	Status	System Criticality	Resp. (action owner)	Status	
CO2239	Supermarket	CO2230 CO2239	Civil	New	Relocation	Sterile	IPT Ster CO transition	0	1	x	Completed	Hans	Approved			Cor	Reviewed	No Impact			
CO43084	Freezer room new	CO2337	Process equipment	New	Relocation	Solids	IPT Nuv New	0	2		Tebodin	Completed	John	Approved	Cor/Barth	In progress		per SQAP	Direct	John	App
CO43074	Freezer room old	CO2348/1	Process equipment	Removal	Relocation	Solids	Realization	0	2		Tebodin	Performed		NA	Existing			Direct		per	
CO89034-US102	EMS (FOCOG5) CO43084	NA	Automation	New	Relocation	Solids	Realization	0	2		Tebodin		Hans/MMD-IT	per TML	Cor/Barth	Existing	Cor	?	Direct		per
CO89002	EMS (FOCOG1) CO43074	NA	Automation	Removal	Relocation	Solids	Realization	0	2		Tebodin			per TML		Existing		existing	Direct		per
	Fire alarm system	NA	Electra	?	Relocation	FM	Realization	0	2		Tebodin			NA	Cor/Barth		GES	?	No Impact		
	Electrical	NA	Electra	Addition	Relocation	FM	Realization	0	2		Tebodin			NA	Cor/Barth		GES	?	No Impact		
	Sewage	NA	Black piping	Addition	Relocation	FM	Realization	0	2		Tebodin			NA	Cor/Barth		GES	?	No Impact		
CO2200(A)	Corridor (General Access) (including XS pass)	CO2200	Civil	Modification	Relocation	FM	Realization	0	3	x	Completed	Hans			Existing	Cor	Reviewed	No Impact			
CO2206	Container mixing room	CO2302	Civil	Modification	Relocation	Relocation	Realization	0	4		Tebodin	Completed		Existing		Existing		existing	Direct		per
	Ultrasonic bath (temporarily location)	CO2302	Process equipment	Move&Mod	Relocation	Relocation	IPT Nuv transition	0	4		Tebodin	Completed		NA	Existing			existing	Non-Direct		
	Stealconstruction for hoist	CO2302	Process equipment	New	Relocation	Relocation	IPT Nuv transition	0	4		Tebodin	Completed		NA		Cor	?	Non-Direct			











Field works before shutdown



Temporary logistic routes & barriers



Prepare stock



End point samples/calibration

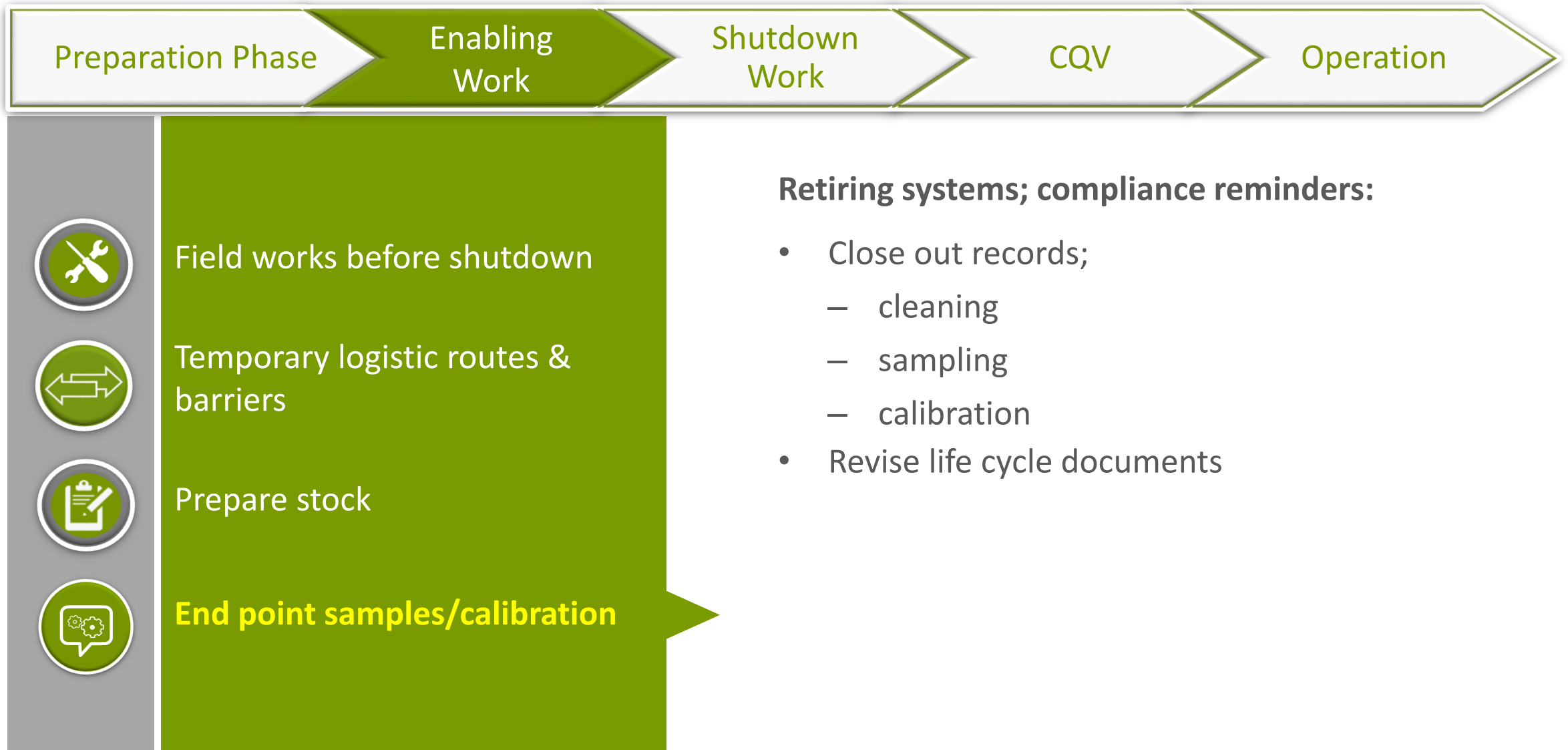
Realize temporary logistic routes

- Construction personnel, materials & waste
- Contaminated waste disposal?
- Current operations

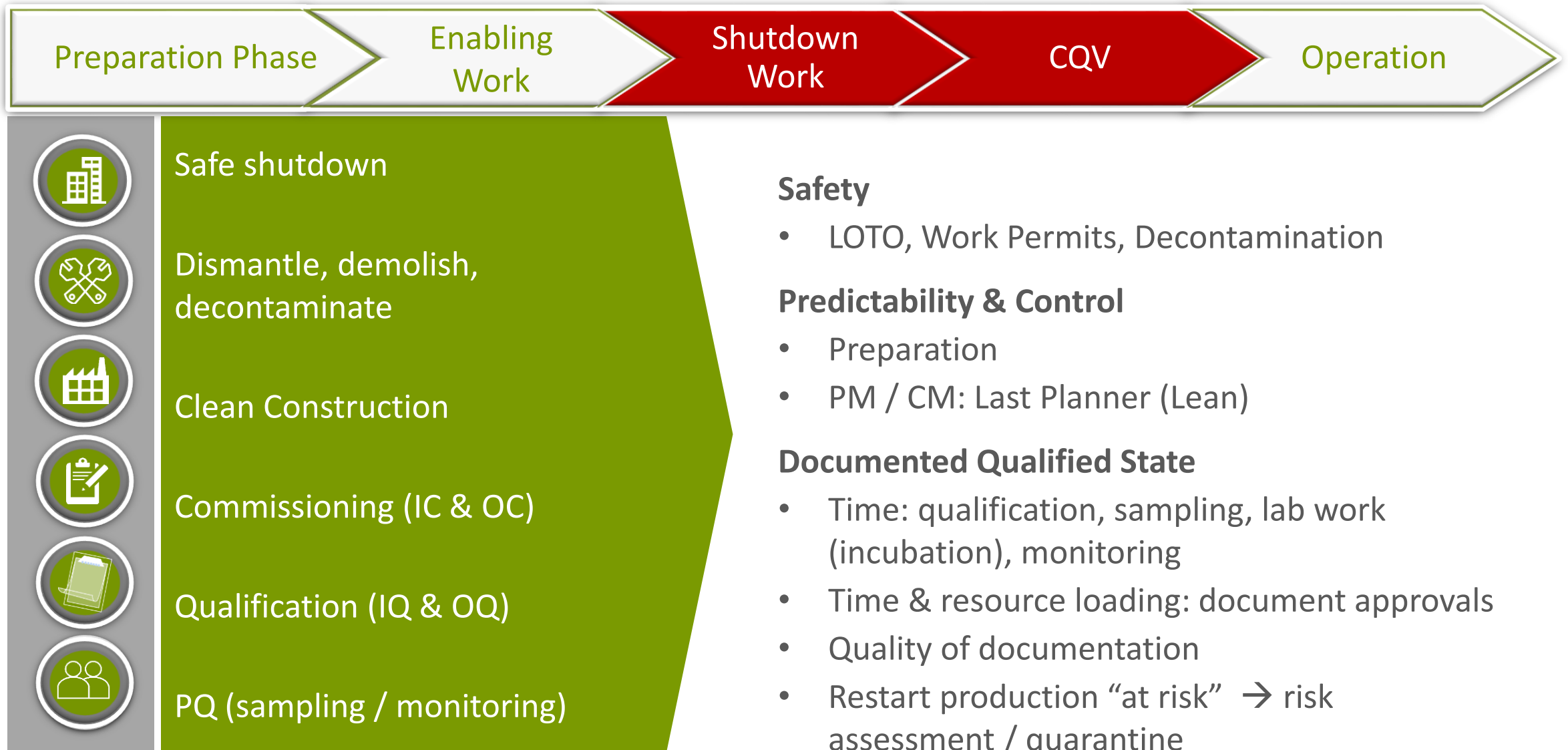
Segregate construction & GMP areas

- Consider **pressure differentials** in view of product protection, cross contamination, ATEX, Industrial Hygiene Zones (HPAPIs)
- Consider **hygienic zones/routes** for removal of contaminated waste
- Consider **HVAC segregation**

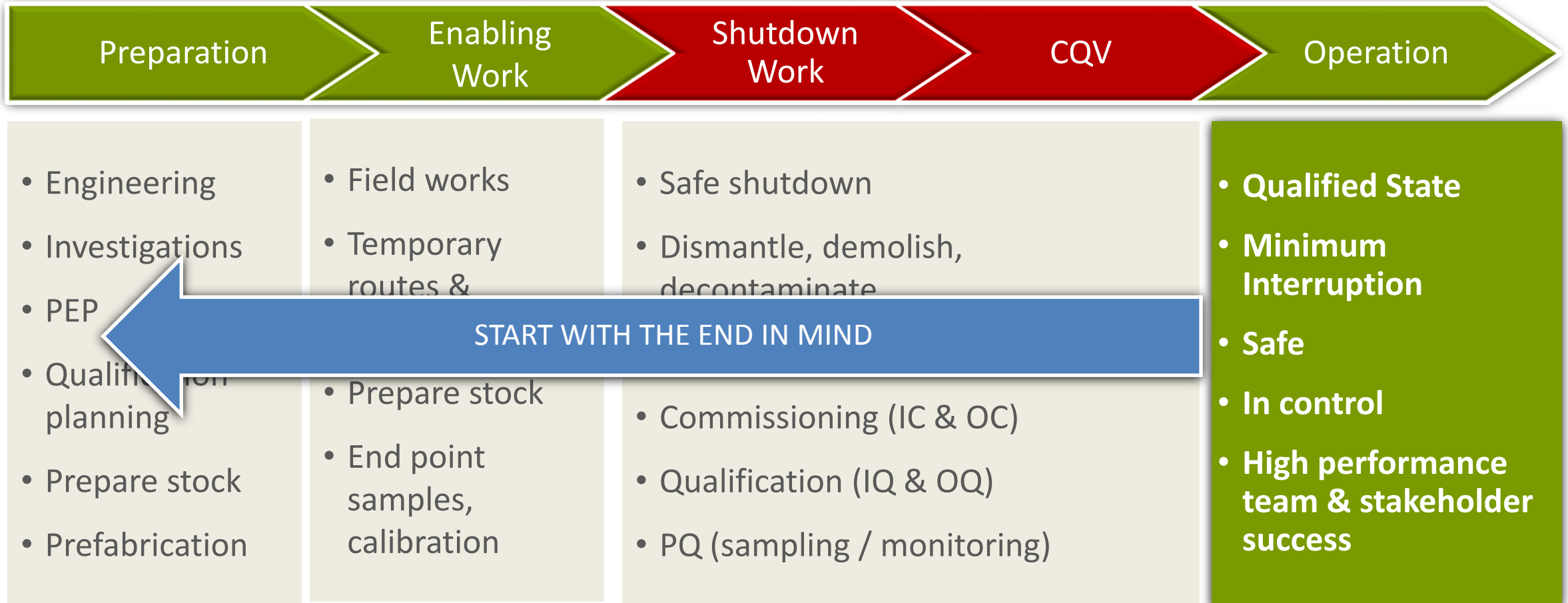
Compliance Documents (QA)







Summary



Summary



Last Planner System

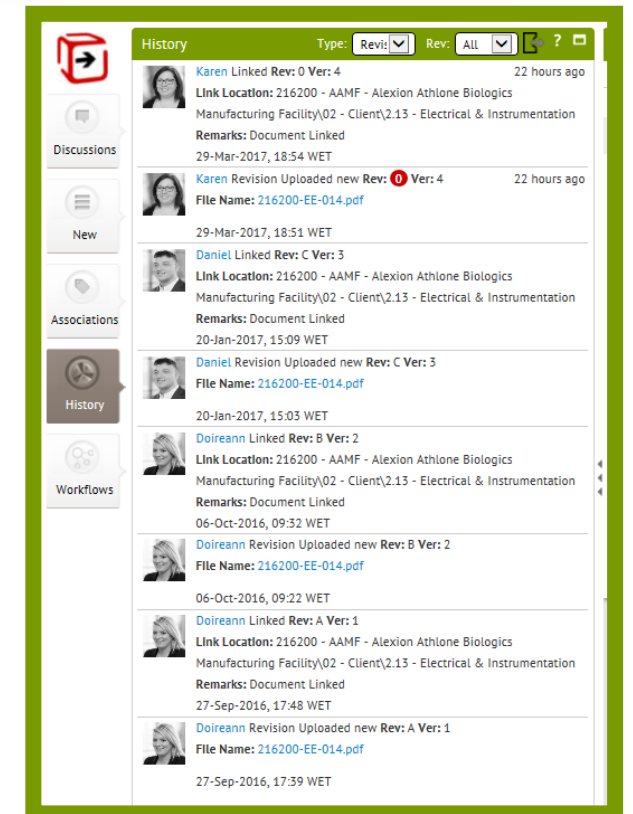


Summary



Document Management System

- Approval of documents and drawings electronically.
- Full visibility of internal comments and number of versions and history.
- Approvers of documents are restricted to appropriate qualified personnel.
- All documents are approved on a cloud based platform to facilitate inter- office execution of projects.
- Documents can be approved with mobile devices.
- Vendor document management.



Summary



“If it is not documented, it didn’t happen”

“C&Q engineers should not have an opinion”

As Built Data is to be fully trusted

“Post hoc ergo propter hoc”

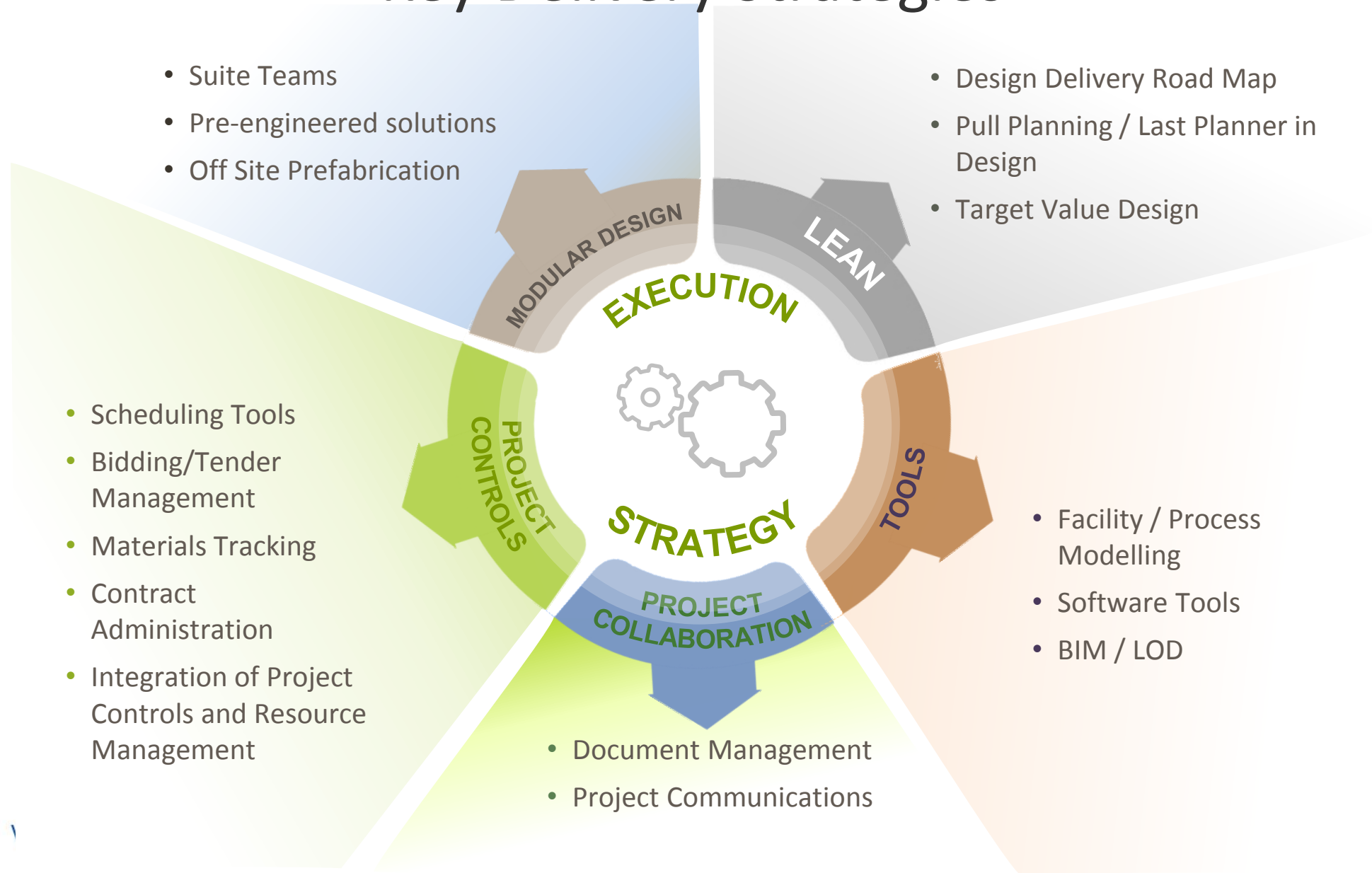
Summary



Any Questions?

BACK-UP SLIDES

Key Delivery Strategies



3D Software Tools

Autodesk Revit

Specifically built for Building Information Modeling (BIM), including features for architectural design, MEP and structural engineering, and construction.

CADWorx Plant

Provides intelligent spec-driven piping design, equipment, ISOGEN isometrics, live database connectivity, model - P&ID synchronization and links to Stress Analysis.

CADWorx Intelligent P&ID

Provides quick and intuitive P&ID creation, large user-modifiable symbol library, spec-driven P&ID's and bi-directional project database.

Autodesk Navisworks Manage

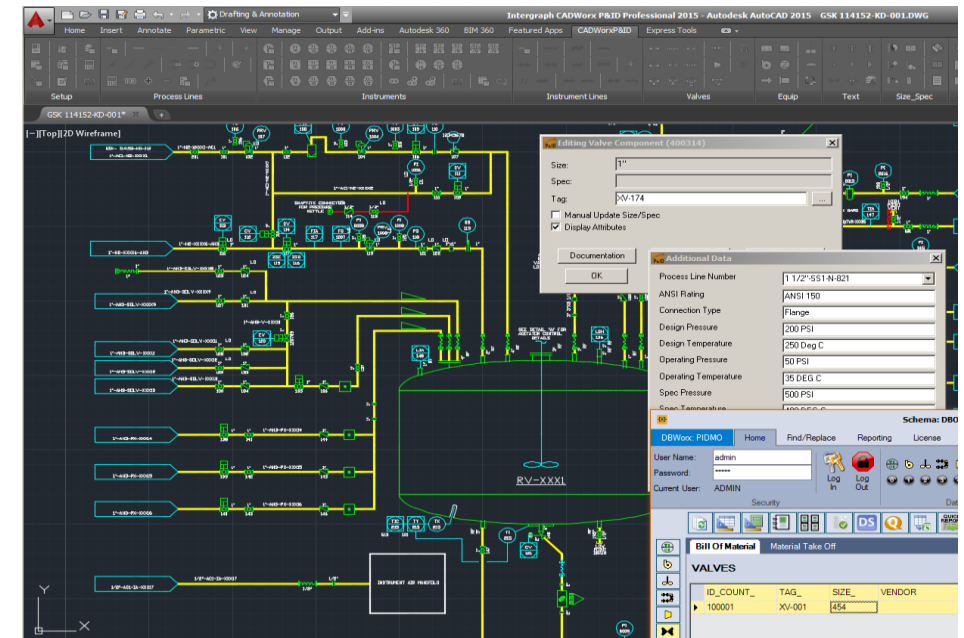
Aggregate models from multiple design packages, model review, clash and interference management, 5D scheduling and quantification.

Autodesk® 3ds Max® Design

Visualisation tools that provides cinema-like image quality to help communicate design intent to clients and win new business.

CADWorx Intelligent P&ID's

- List Capability (Equip, Line, Valve, Instrument etc.)
- Instrument Datasheets
- Instrument Loop Drawings
- Process Equipment Datasheets



WE SHARE THE KNOWLEDGE

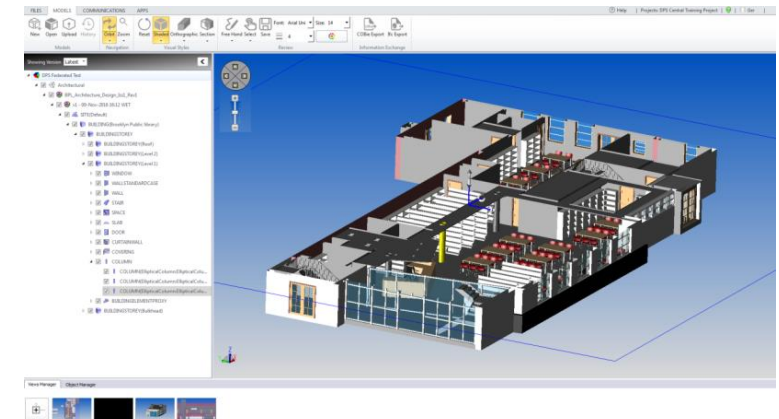
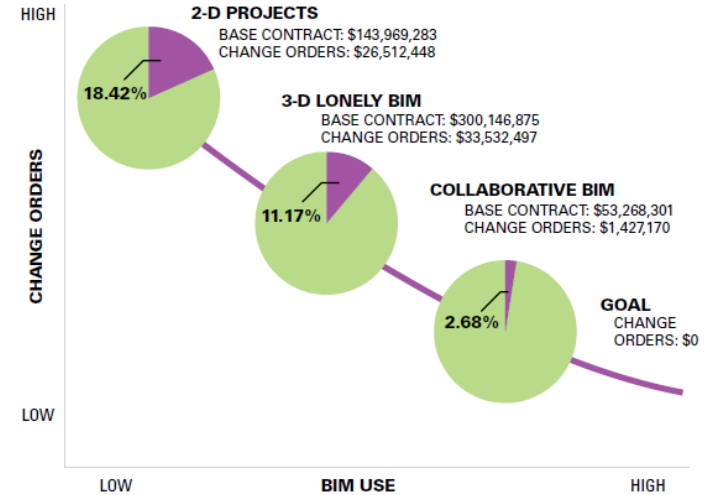
BIM

General

- ▶ BIM Level of development (LOD)
- ▶ Project BIM Execution Plan
- ▶ Model review guidelines
- ▶ Model Sharing Tools
- ▶ Clash management Guideline

BIM 3D, 4D, 5D

- ▶ 3D as standard
- ▶ 4D – Linking components to schedule (Project Specific)
- ▶ 5D – Bills of Material's/Schedules to support cost management. As standard



LOD 200



LOD 300



LOD 350

Document Management System - Asite

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Project Communications - Asite

Intelligent Forms to track key project communications

- ▶ RFI's.
- ▶ Site Query.
- ▶ Field Change Notice (FCN).
- ▶ Technical Design Query – Internal use.
- ▶ Emails.
- ▶ Minutes of Meeting and associated Action Register

Create Form

Project Name

DPS Training Workspace for AAMF

Form Name


Contractor Request for Information

Form Code

CRFI

To :

**** Note ** This RFI is to be sent to the Construction Manager for distribution and review**

DPS

Contractor Request for Information

Date: 31 March 2017

PM Project No	IE0312014	DPS Project Number:	216200
Project Title	AAMF - Biologics Manufacturing Facility		
Contractor Name:	<input type="text"/>	Contract Name:	<input type="text"/>
RFI Title	<input type="text"/>		
Contractor RFI Ref	<input type="text"/>		

Section A - Contractor to Complete:

DPS

Meeting Minutes

Meeting Type :	DESIGN MEETING
Meeting Number :	DES036
Meeting Date :	26/6/2017
Meeting Title :	DESIGN MEETING - 24/06/2017 - DES036
Meeting Location :	Cork
Meeting Administrator :	Carlota Fenelly - DPS Engineering
Next Meeting Date :	29/6/2017

ATTENDANCE For 24/06/2017 DESIGN MEETING # DES036

Representative	Status	Company	Title	Cell#	Email
Mark Walsh, DPS Engineering	Present	DPS Engineering	021 7302102		mark.walsh@dpsengineeringbiol.co.uk
Alan Phillips, DPS Engineering	Present	DPS Engineering	021 730 2002		alan.phillips@dpsengineeringbiol.co.uk
Carlota Fenelly, DPS Engineering	Present	DPS Engineering	003217302046		carlota.fenelly@dpsengineeringbiol.co.uk

AGENDA For 24/06/2017 DESIGN MEETING # DES036

#	Agenda Points
1	Material Training database - review meeting

MEETING MINUTES For 24/06/2017 DESIGN MEETING # DES036

Action	Action#	Description	Organisation	Responsible	Actions
<input type="checkbox"/>	1	Agreed to have standard set of drawings	DPS Engineering	Overseer	
<input type="checkbox"/>	2	Review Tables print set up	DPS Engineering	Overseer	Alan Phillips - DPS Engineering forward 20/06/2017
<input type="checkbox"/>	3	Logic page and call cycles M3P	DPS Engineering	Overseer	Alan Phillips - DPS Engineering forward 20/06/2017
<input type="checkbox"/>	4	Create linked curves for wall foot, not available for general view	DPS Engineering	Overseer	Alan Phillips - DPS Engineering forward 20/06/2017
<input type="checkbox"/>	5	Create schedule for project set up	DPS Engineering	Overseer	Alan Phillips - DPS Engineering forward 20/06/2017

Last Planner System In Design

Last Planner System



1. **Weekly Work Planning** – Project schedule lookahead is published to Design Leads to plan works.
2. **Weekly Planning Co-Ordination** – Activities are broken down into daily commitments per Design and any conflicts are identified and resolved. A WWP schedule is agreed.
3. **Weekly Constraint Identification** – Roadblocks to achieving these Activities are identified (P&ID, Specs, Clashes etc) and an owner identified to resolve.
4. **Daily Huddle** – Activities and Variances are tracked. Designs performance is measured.
5. **Weekly Review.** – Constraints, Performance and impacts from previous week reviewed. Improvements identified and implemented.