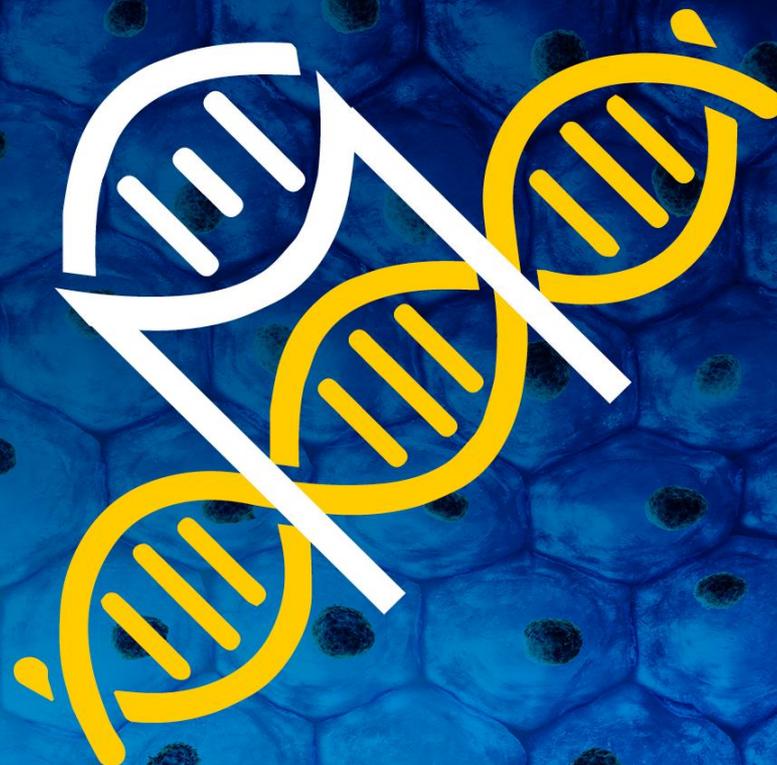




2018 PDA Europe Conference

Advanced
Therapy
Medicinal
Products

ATMPs
10
YEARS



Flexible Gene Therapy Facilities - Current Best Practice



John Dougherty – Lead Process Engineer, DPS Group



DPS Office Locations





What is a Flexible Gene Therapy Facility?



Typical Process Flows



Process Centric Design



Production Modeling



Scale Up Considerations



Single Use Technology



Other Process Support



Containment and Environmental Control



Typical Facility Layout

Budget?

Clinical/Manufacturing?

CDMO or Build?

Single Use?

Maximize Platform-
How Many Products?

Target Location?



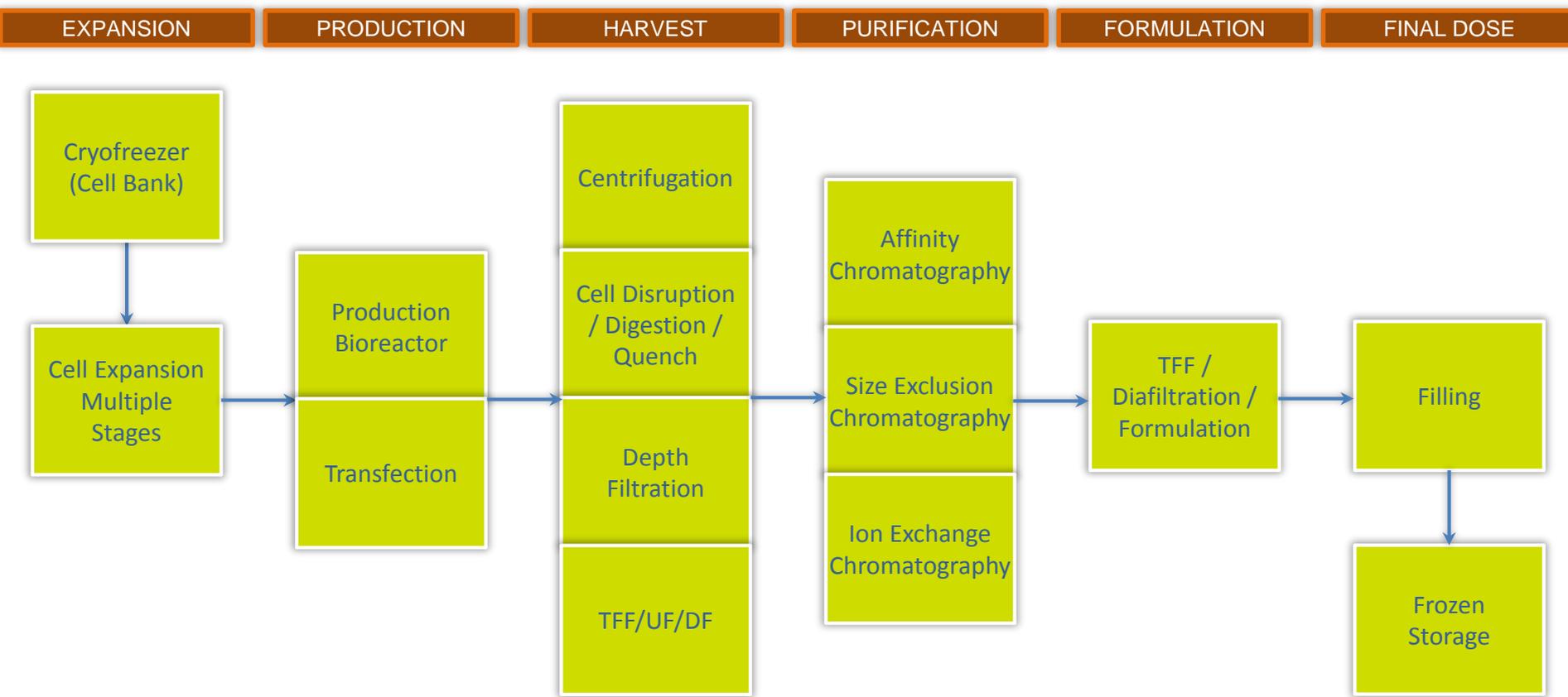
R&D Labs/ PD/ Offices?

Status of PD?

GMP Warehouse



Typical Process Flow





Operating Strategy



Hours of Operation



Block Flow Diagram



Capacity



Product Campaigning vs Parallel Operations



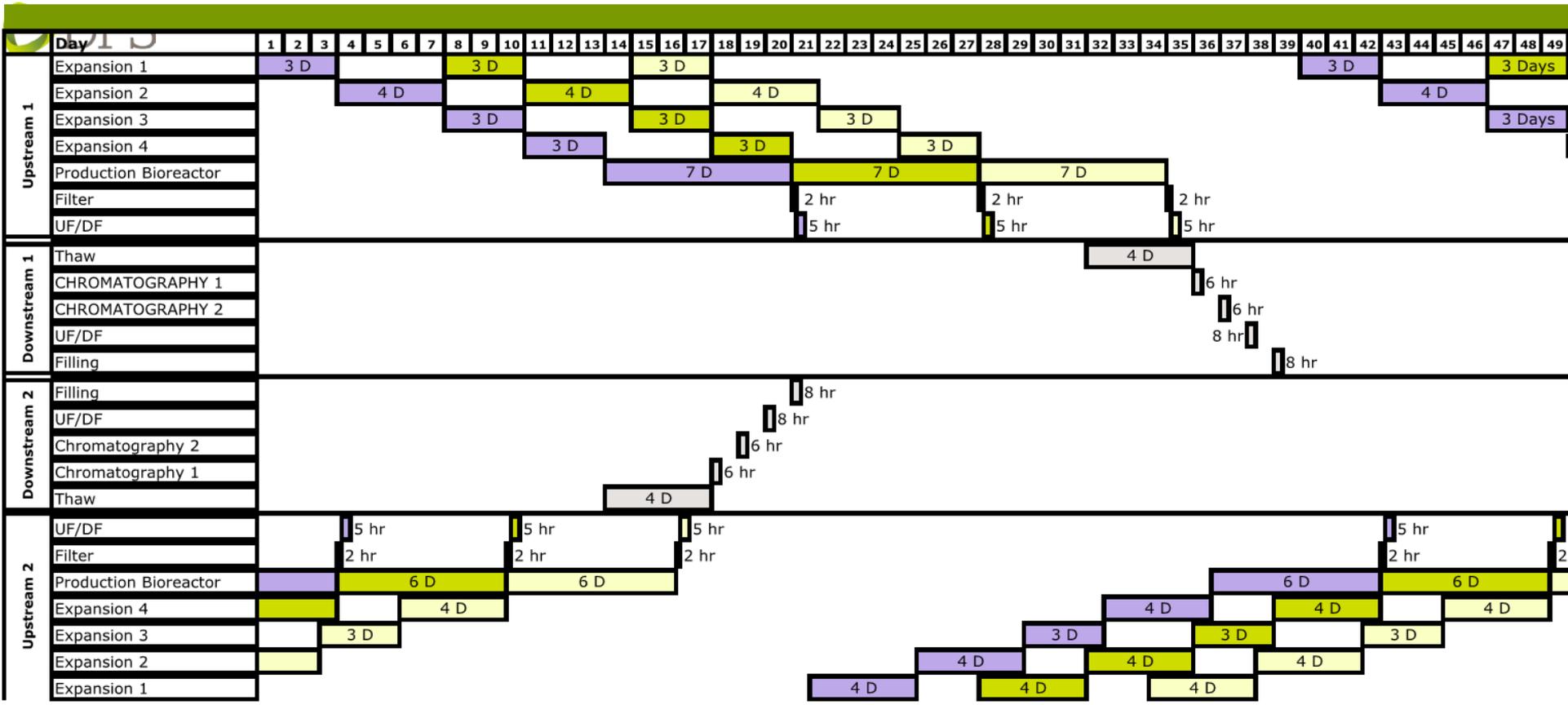
Production Model



High Level Mass Balance



Example of Staggered Production Model

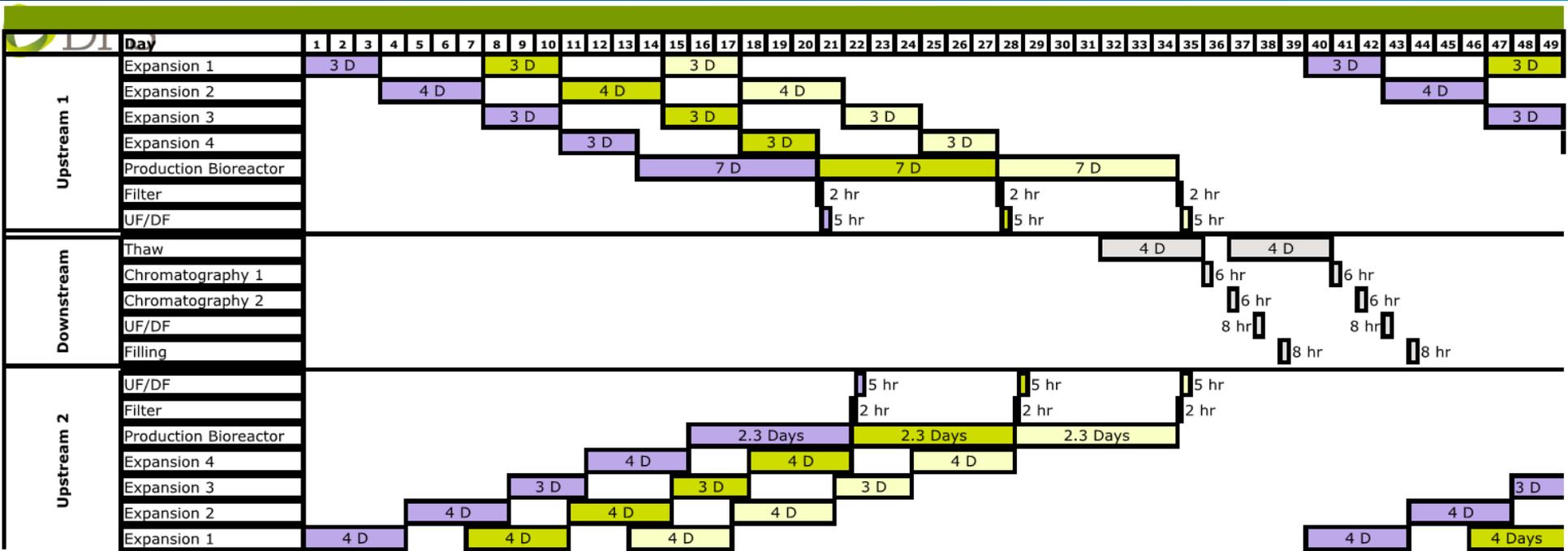


Upstream Utilization – 55%

Downstream Utilization – 6%



Example of Stacked Production Model



One single downstream with clearance and change over.

Flexibility to pool 1 to 5 upstream lots in downstream.

Upstream Utilization – 55%

Downstream Utilization – 16% to 83%

-  Transition from Laboratory to cGMP
-  PD, Manufacturing, Quality, & Design Team Integration
-  Adherent vs. Suspension cultures
-  Harvest Process
-  Chromatography
-  Formulation TFF

Pall Allegro STR™



Sartorius Biostat



GE Wave



Pall iCellis™



Millipore Flexready™



GE Akta Ready™



Pall Allegro™



GE Akta ReadyFlux™





Mobile



Media & Buffer Prep

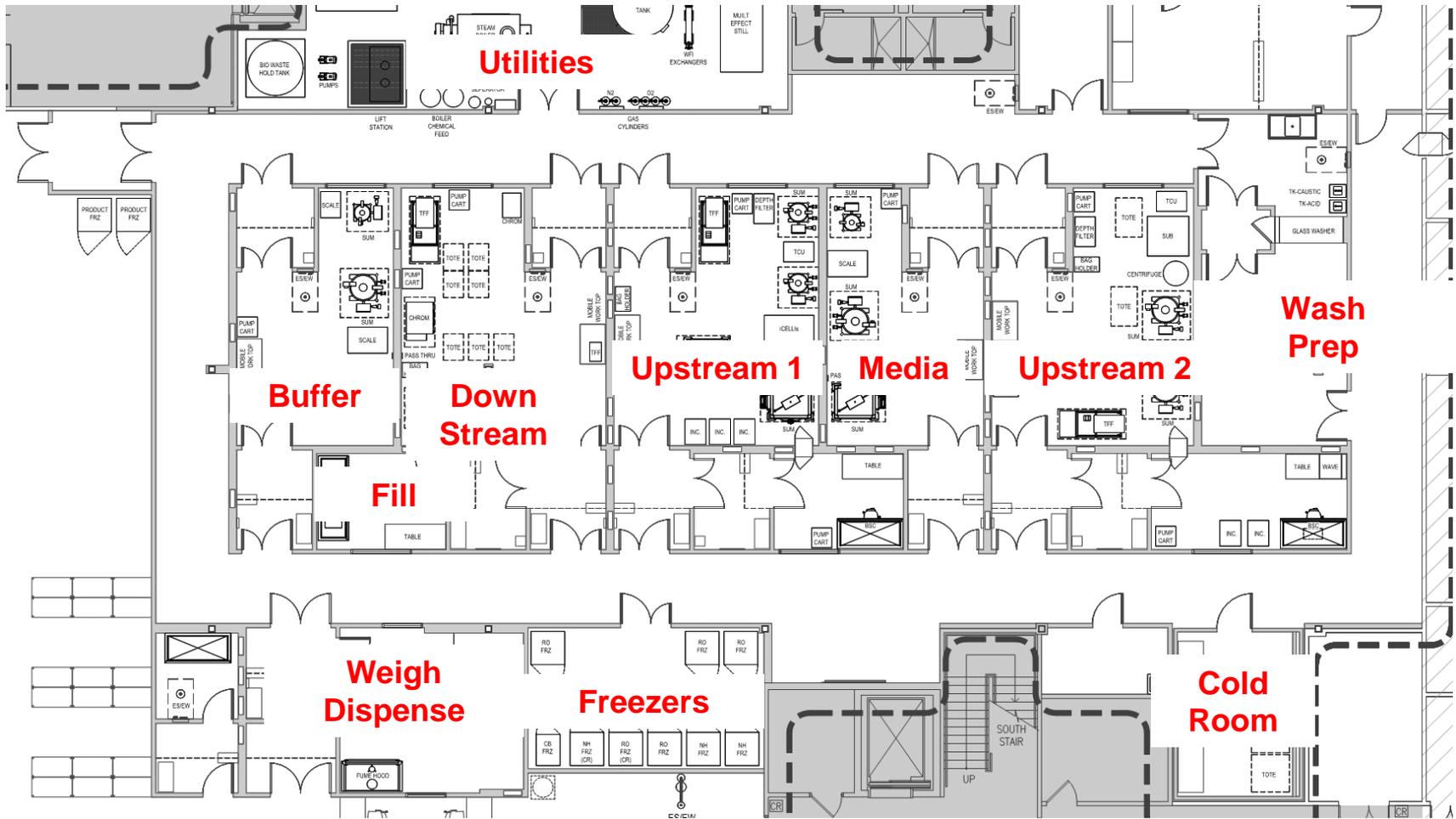


Utilities

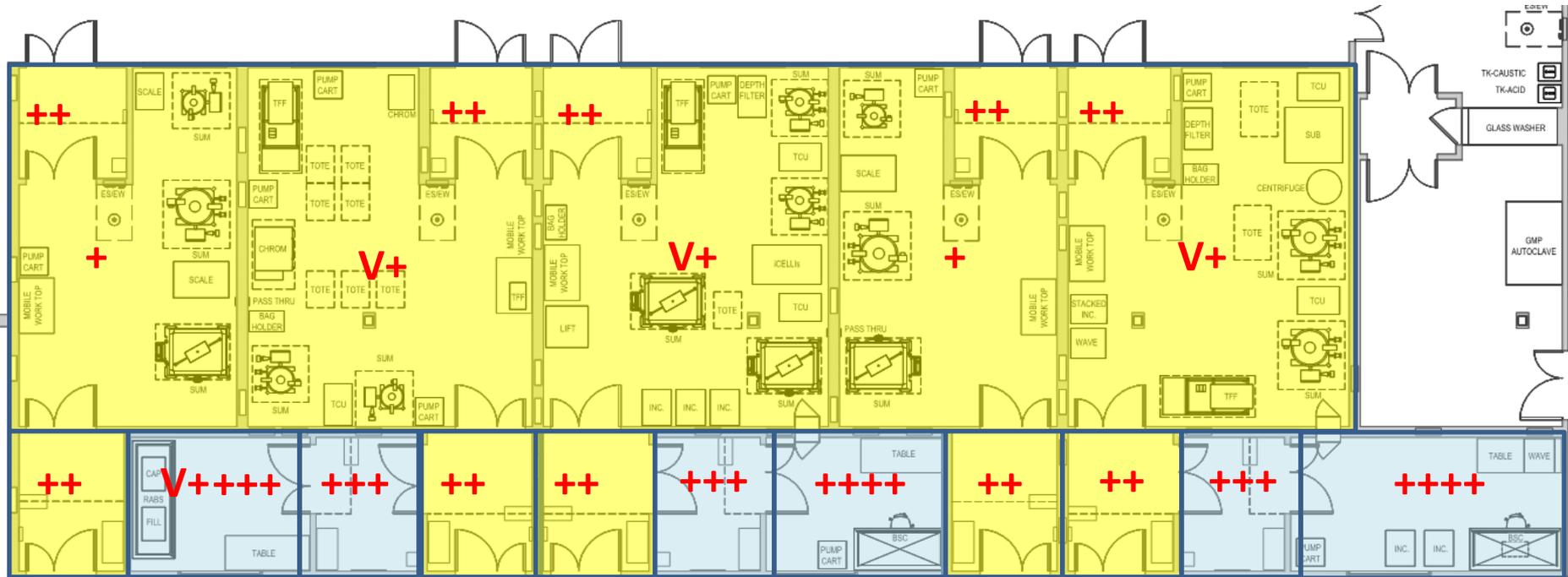


WFI Choices

-  BSL Level 2 (PPE, aerosols in BSC, Showers, eyewash, autoclose doors, waste contamination)
-  Identify V- and V+ spaces
-  Room Classifications (CNC, ISO8, ISO7)
-  Pressurize for Quality and Containment
-  Recirculate air vs. Once through air
-  Use of VHP Sterilization



Warehouse



- What is Flexible Design
- Integrated / Iterative
- Single Use Technology
- Environment Control?

Thank You



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