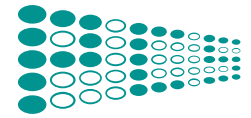
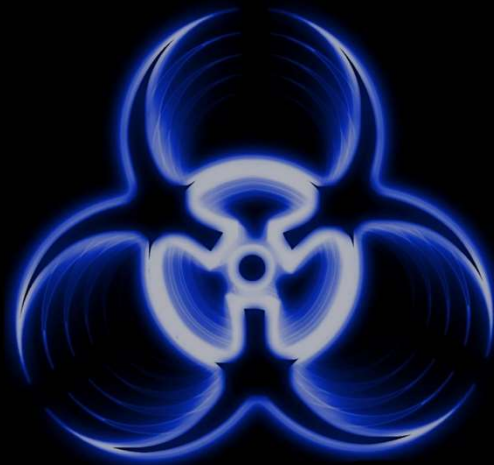


BSL/GMP Q-SYSTEMS

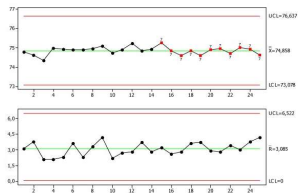


PHARMACEUTICAL
CONSULTANCY
SERVICES



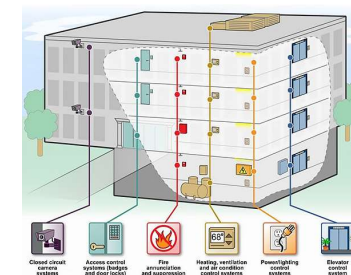
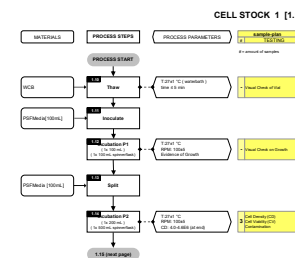
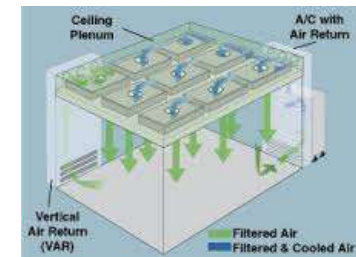
What is a Quality-System ?

A Quality System is holistic, there is no exception (it's all)



- Systems
- People
- Equipment
- Buildings/Premises
- Utilities
- Products
- Processes

.....



Your Pharmaceutical QMS should assure that the above assets delivers a product consistent according specification, fit for purpose.



QUALITY SYSTEM ELEMENTS

- Documentation
- Training
- Deviations
- Change Management
- Equipment Management
- Vendor management
- Sample management
- Out of Specification
- Stability
- Etc.



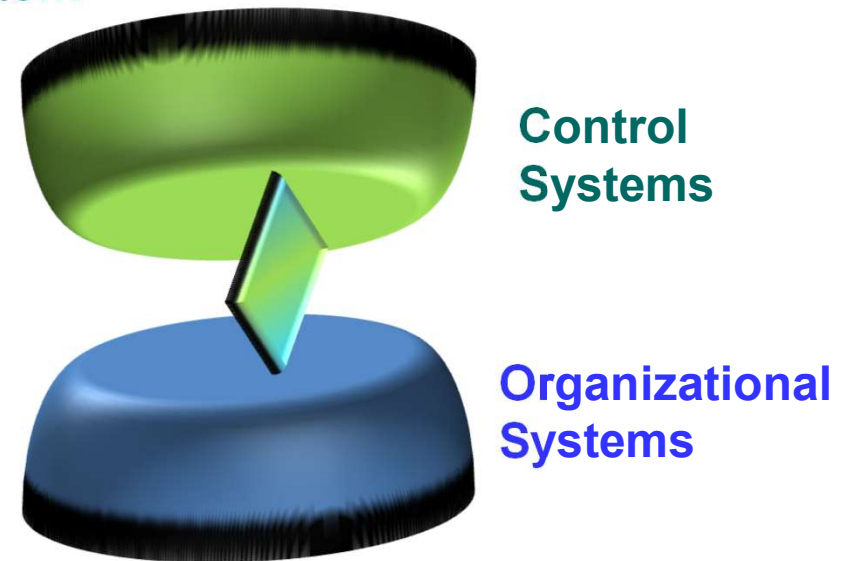
The above mentioned Quality System Elements should assure that the principle stated in former slide manages the assets properly.



QMS (ANOTHER VIEW)

- Material Control System
- Production and Process Control System
- Records and Document Control System
- Facility and Equipment Control System
- Laboratory Control System
- Divergences Control System
- Validation
-

- Responsibilities
- Management Review**
- Continuous Compliance
-



RM



PROCESS



FP

Essentials

Quality Risk Management

Validation

RM

Facilities control OJT/HR

PROCESS

FP

UNDERSTANDING

CQP/CQA, Batch Records

Essentials

Quality Risk Management

Validation



Essentials

Quality Risk Management

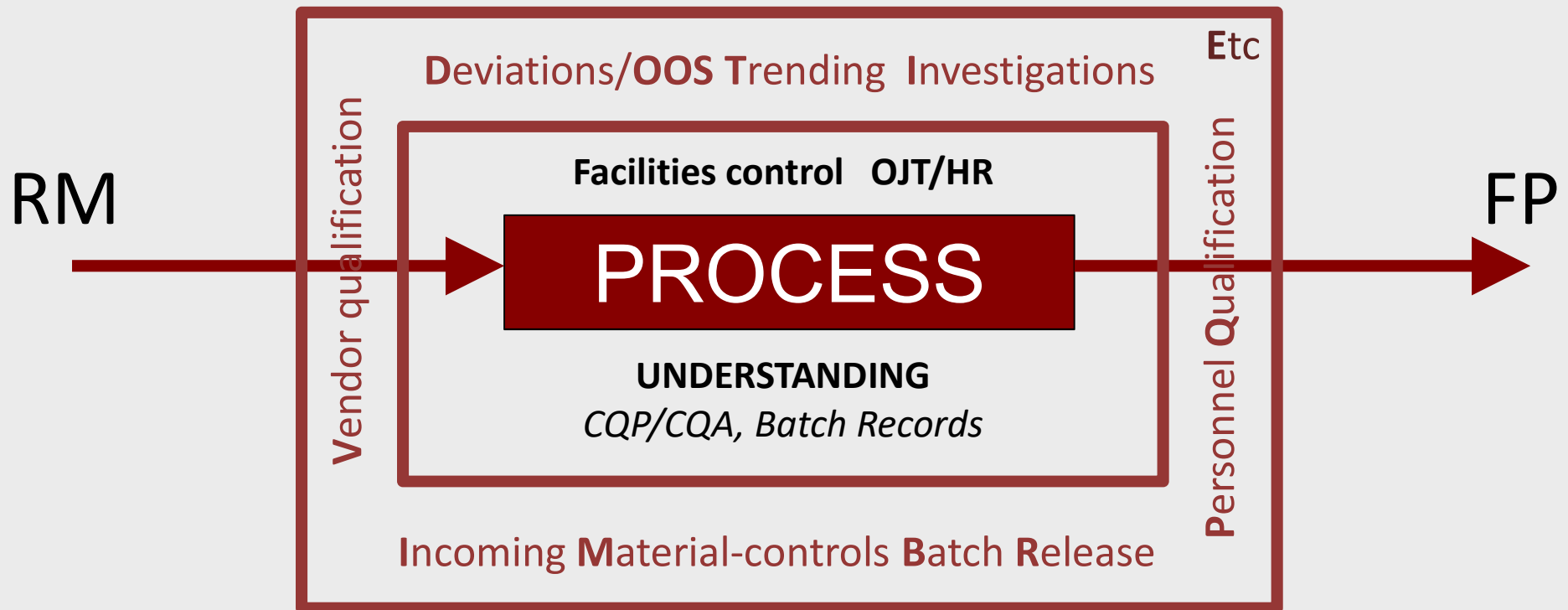
Validation



Essentials

Quality Risk Management

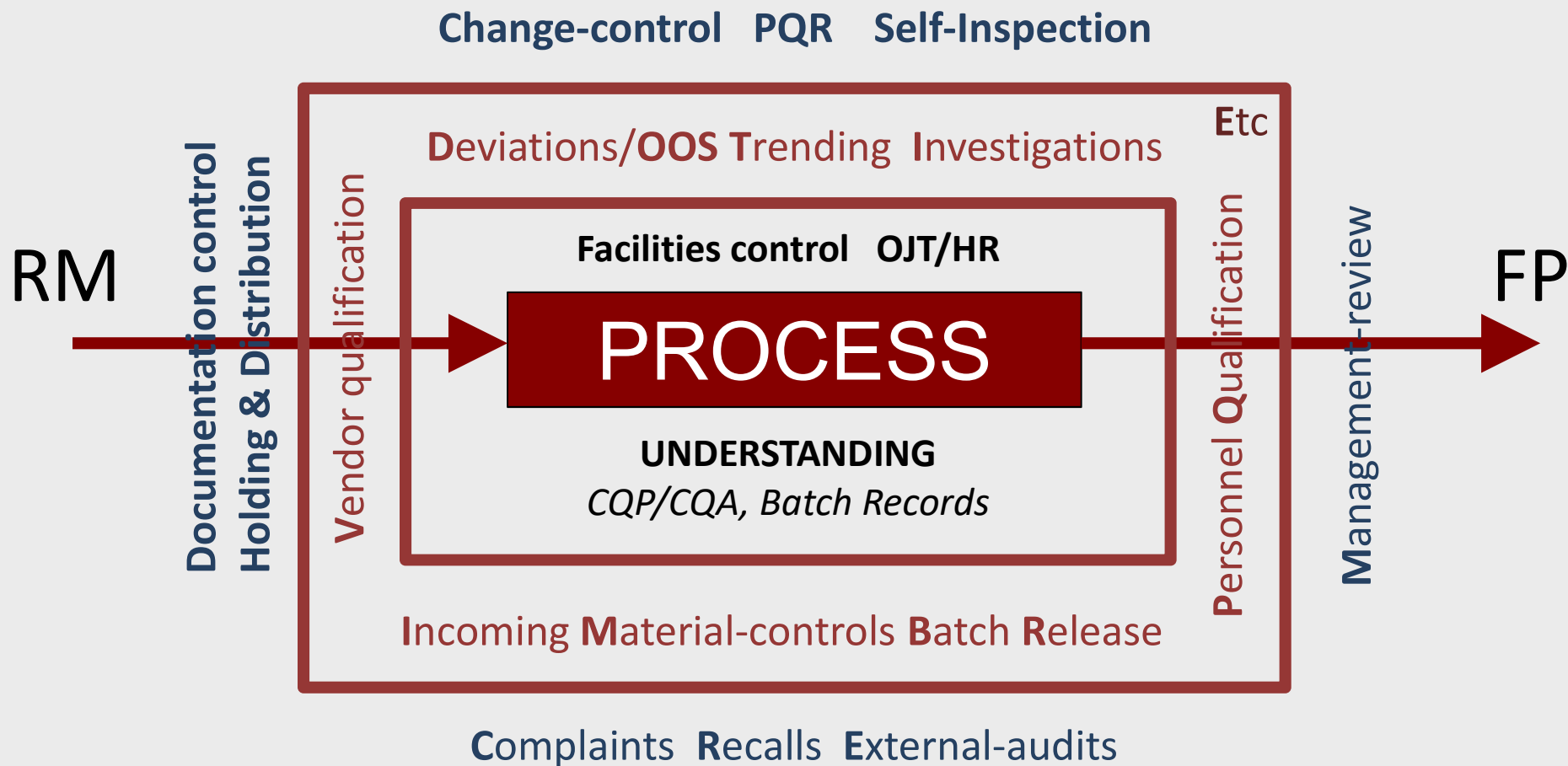
Validation



Essentials

Quality Risk Management

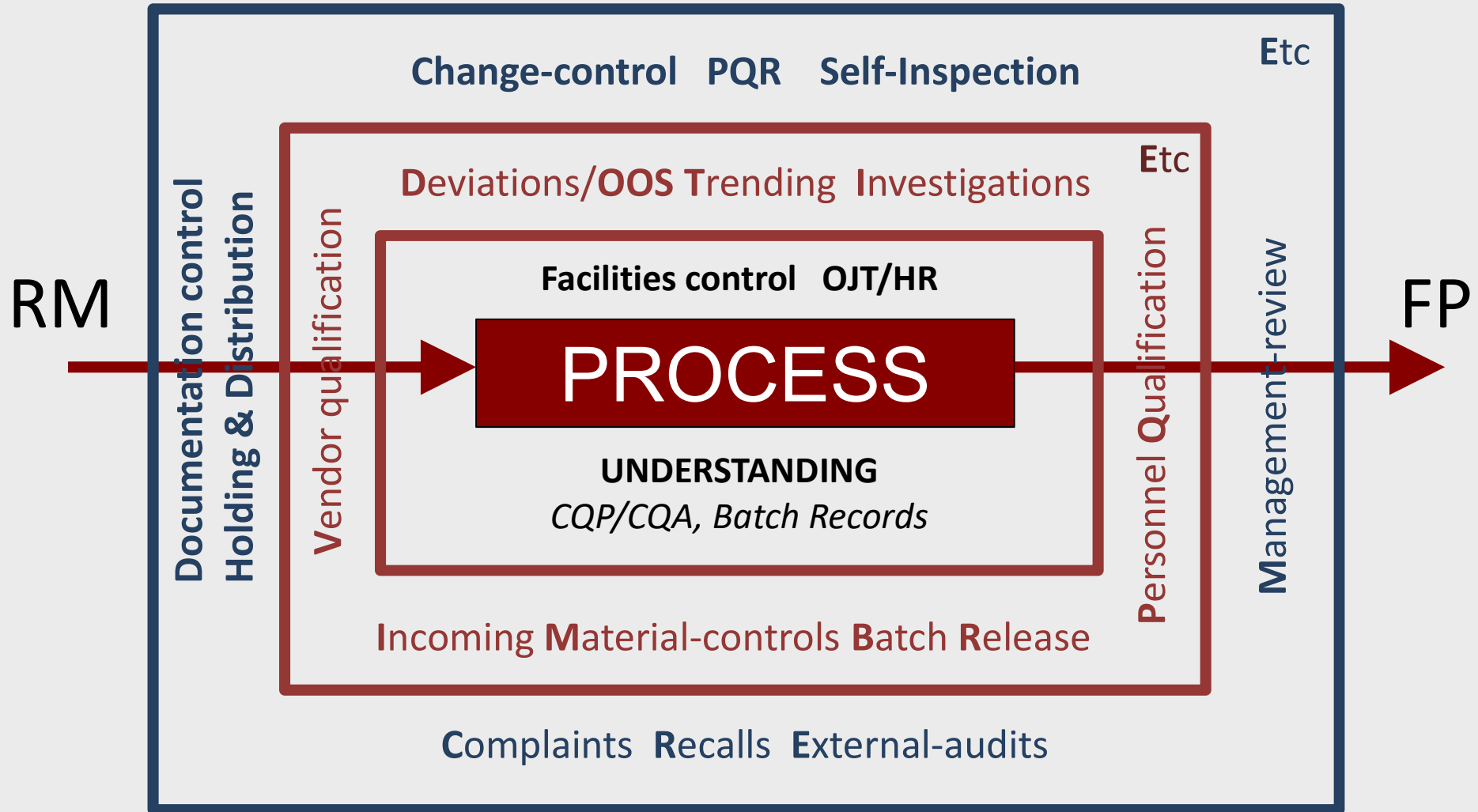
Validation



Essentials

Quality Risk Management

Validation

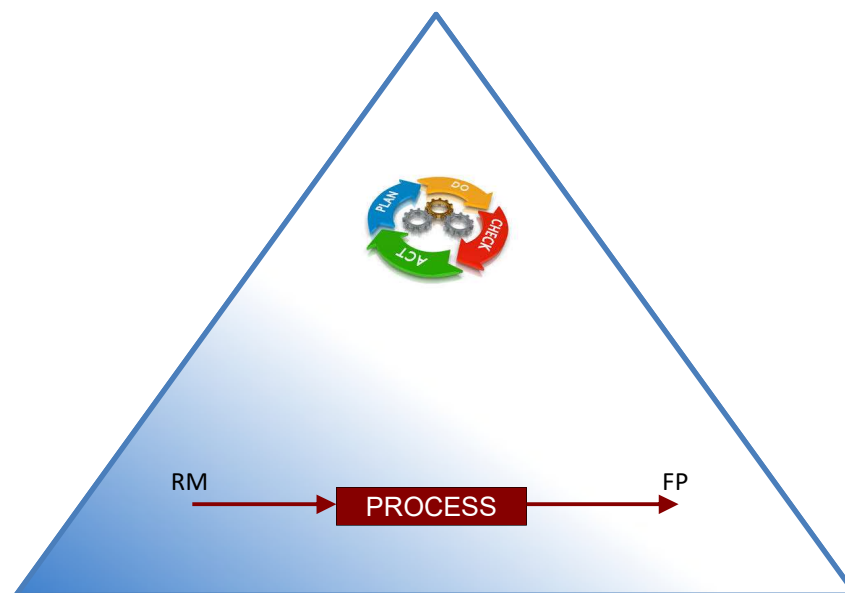


Essentials

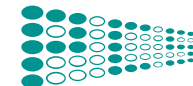
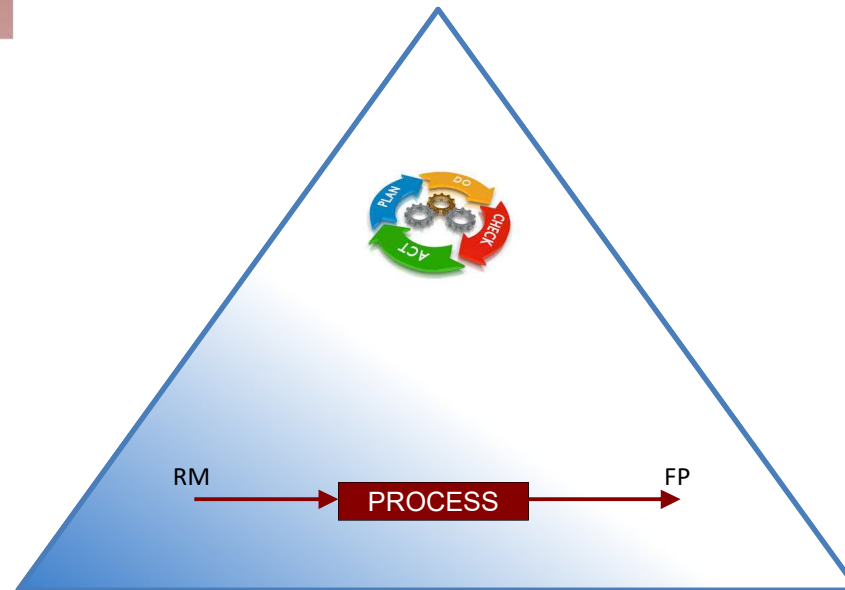
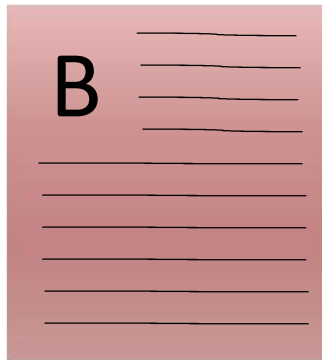
Quality Risk Management

Validation

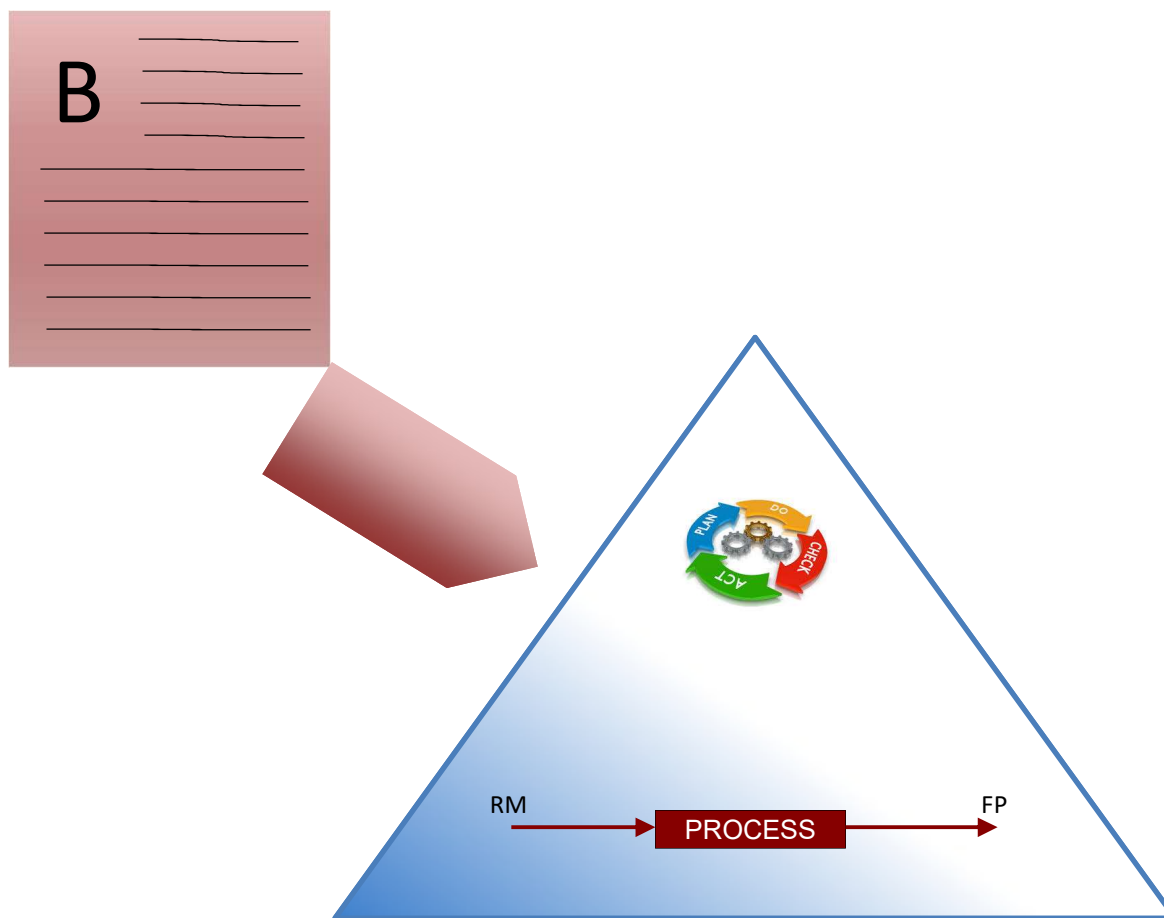
BSL & GMP REQUIREMENTS IN QMS



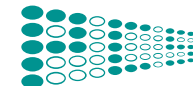
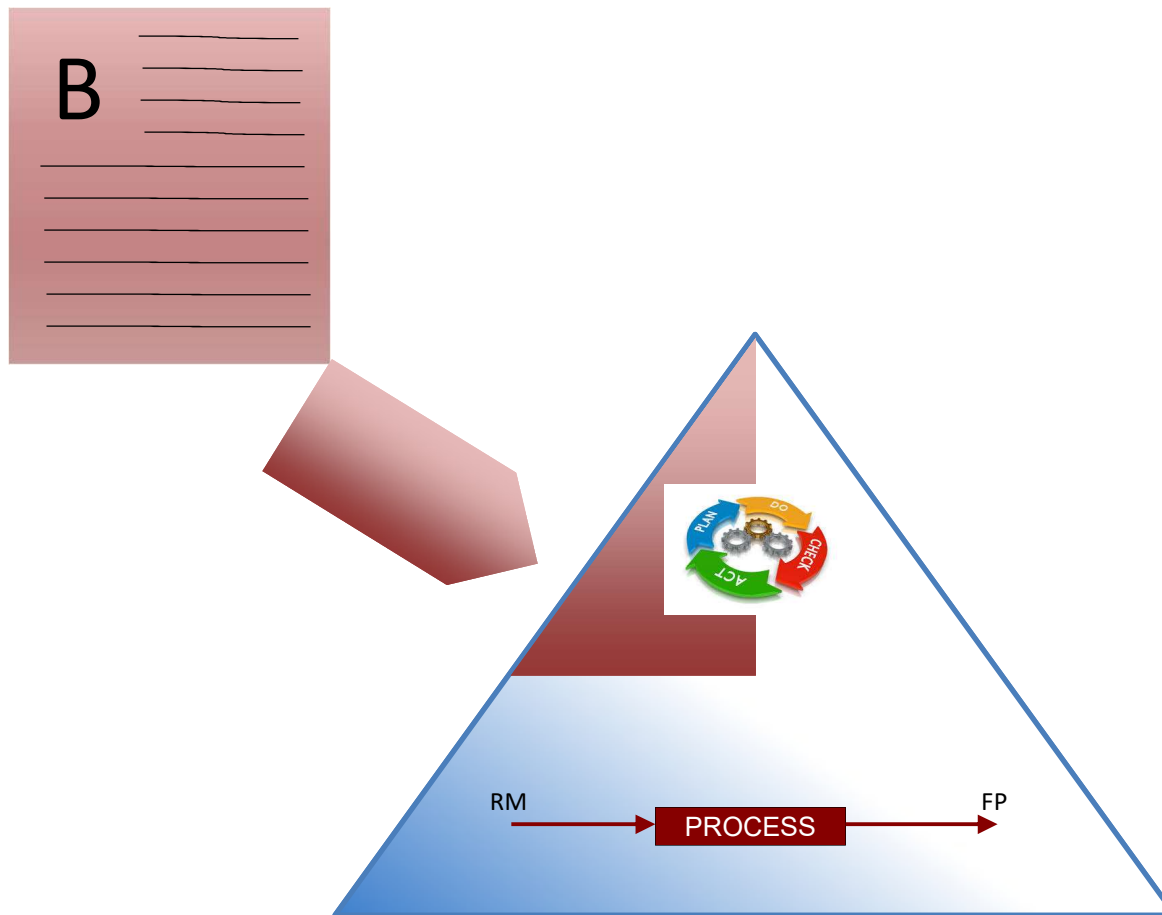
BSL & GMP REQUIREMENTS IN QMS



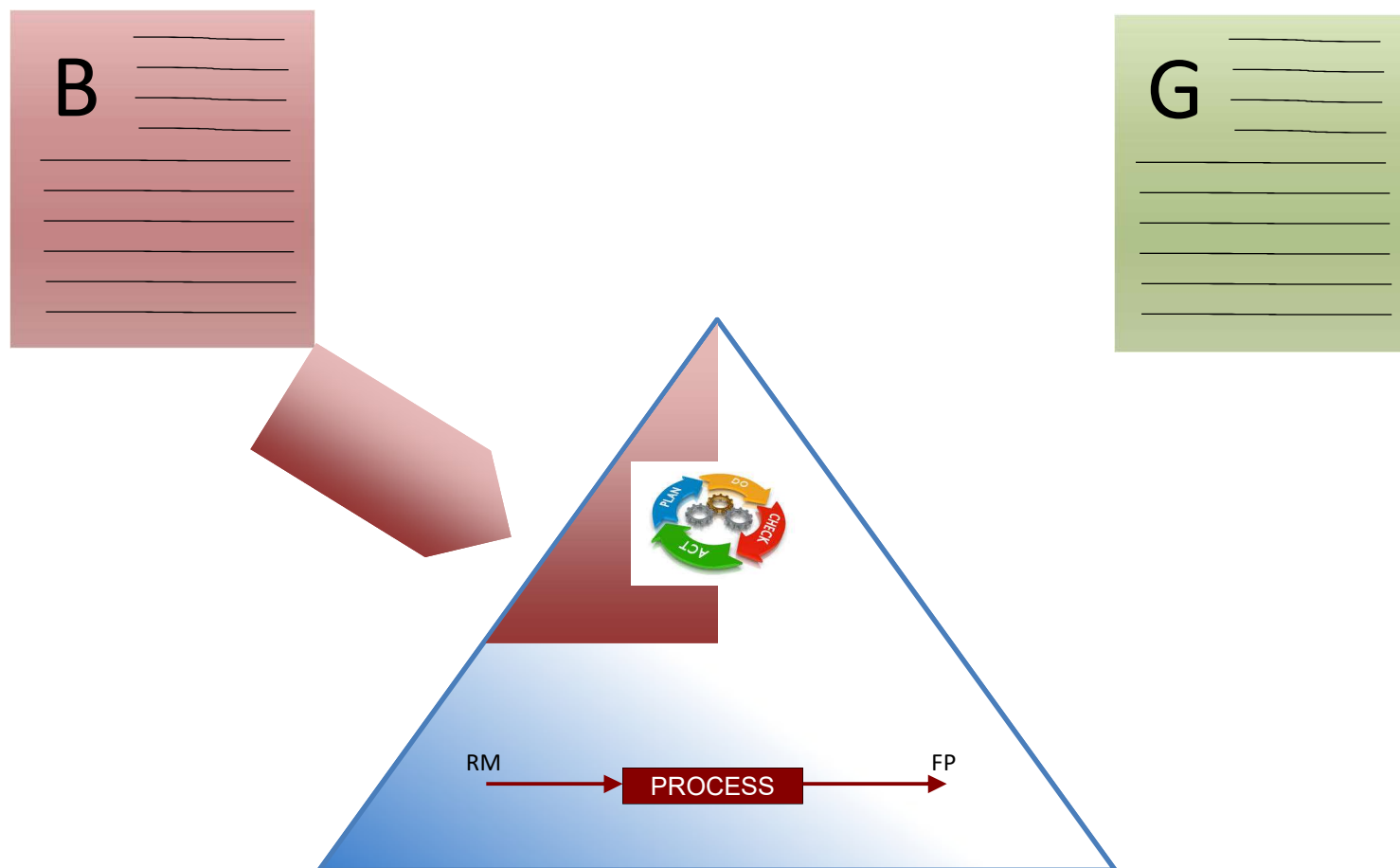
BSL & GMP REQUIREMENTS IN QMS



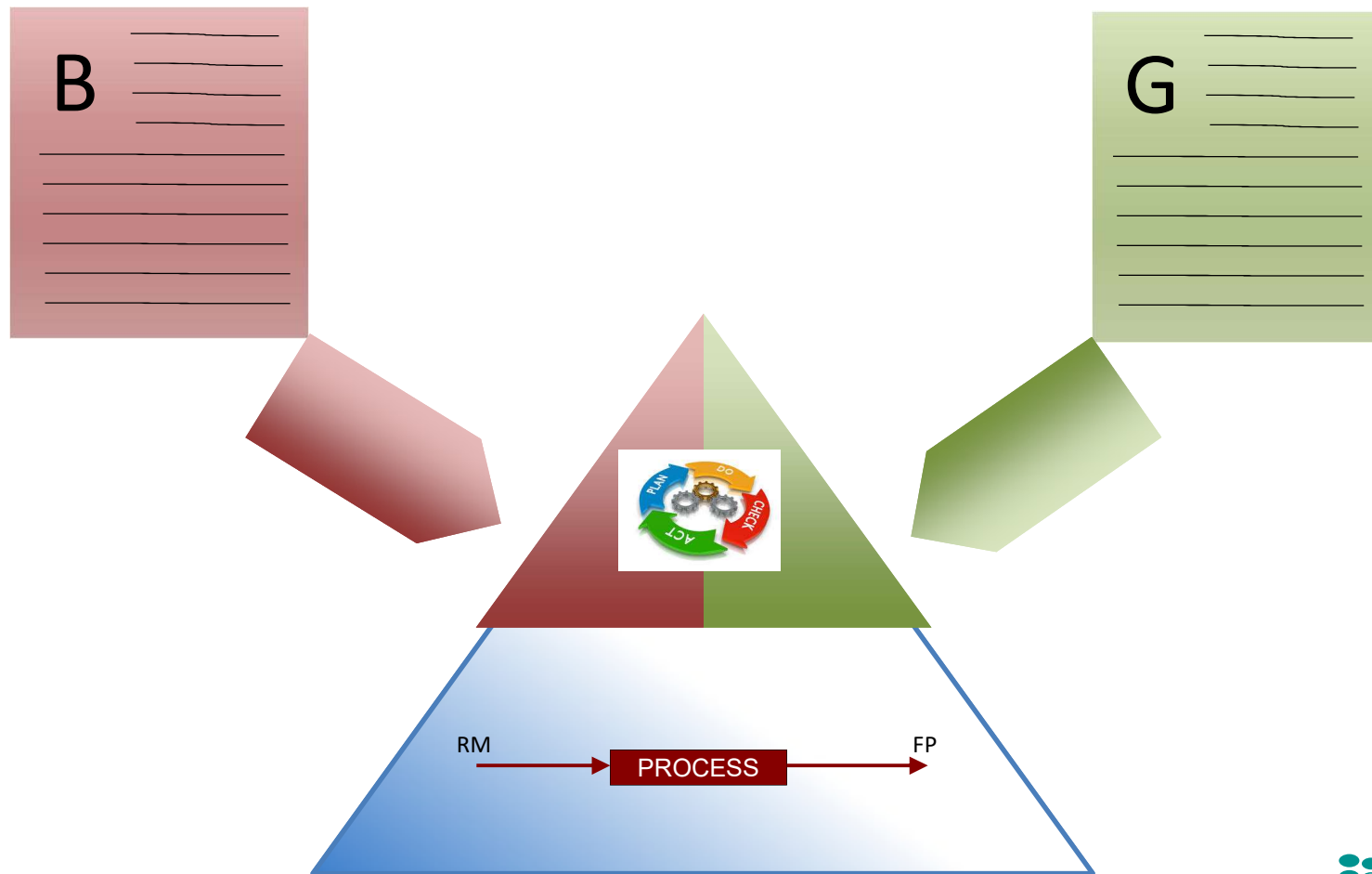
BSL & GMP REQUIREMENTS IN QMS



BSL & GMP REQUIREMENTS IN QMS



BSL & GMP REQUIREMENTS IN QMS



START WITH BSL (& GMP)

“URS”

Closed process

- e.g. no centrifuge

Early inactivation

Etc.



START WITH BSL (& GMP)



“URS”

Closed process

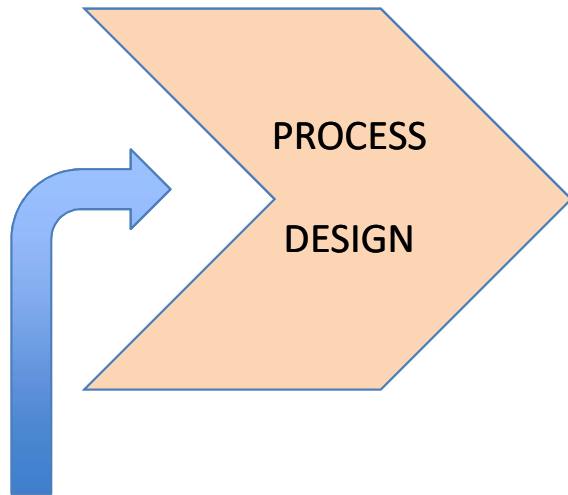
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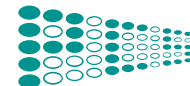
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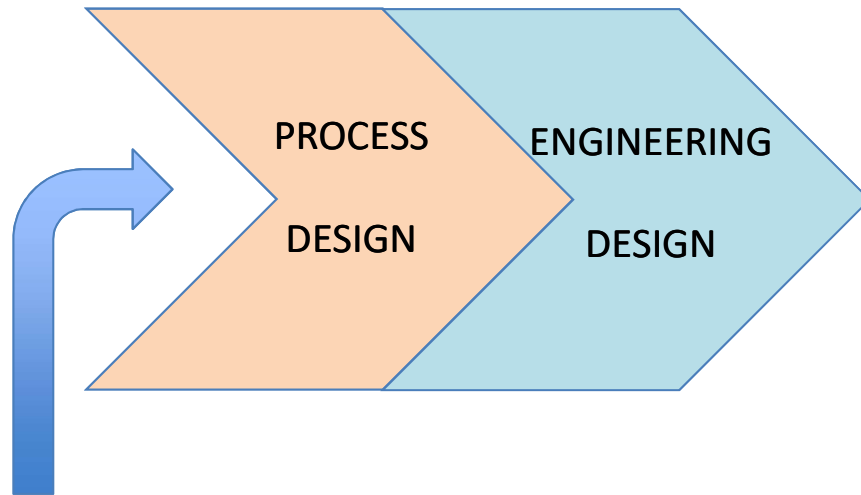
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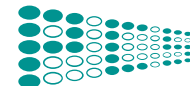
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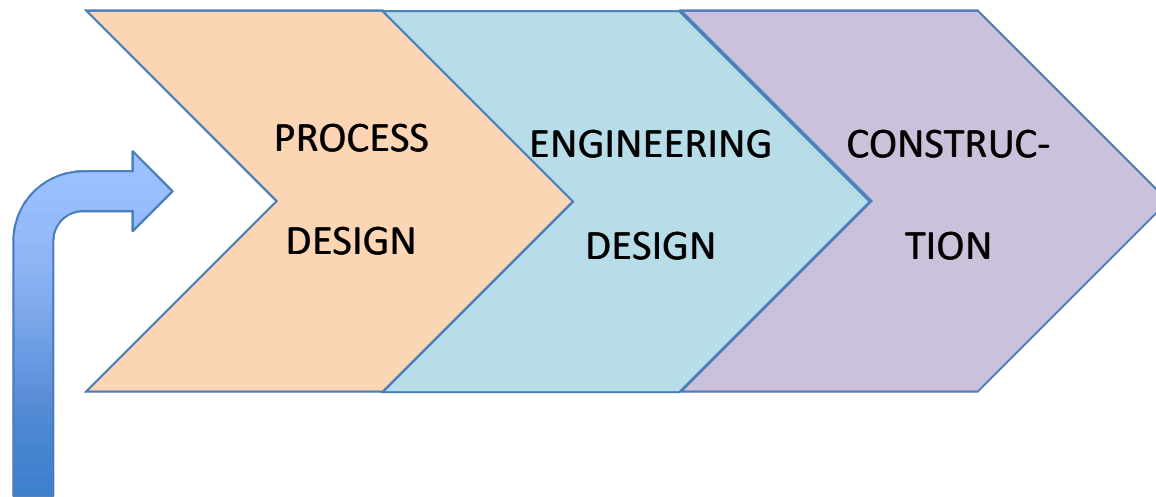
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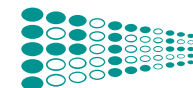
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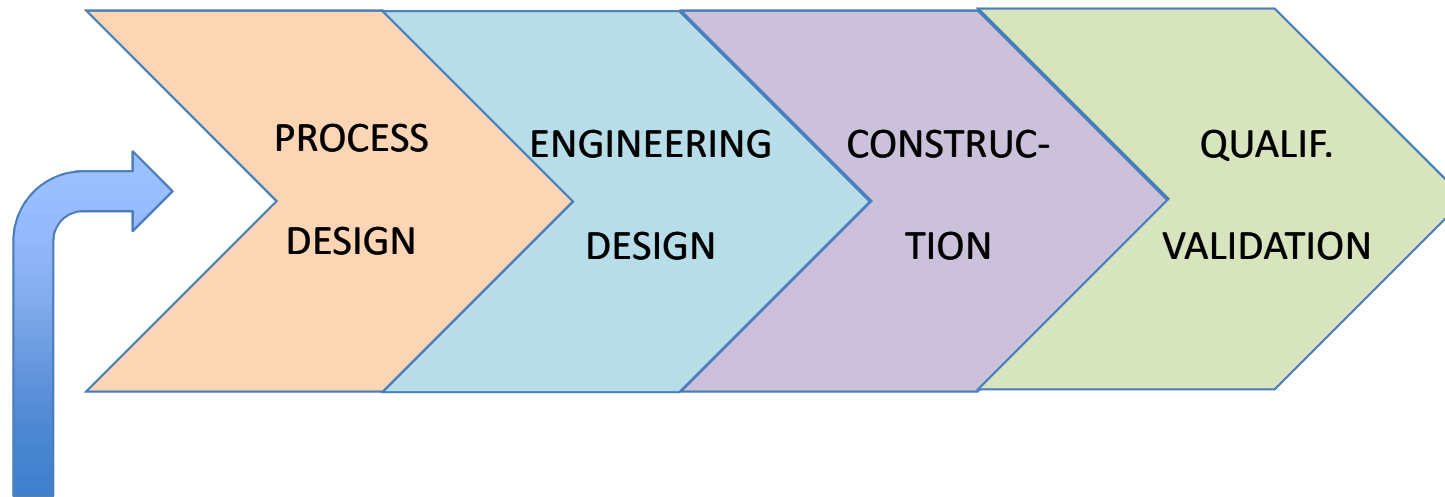
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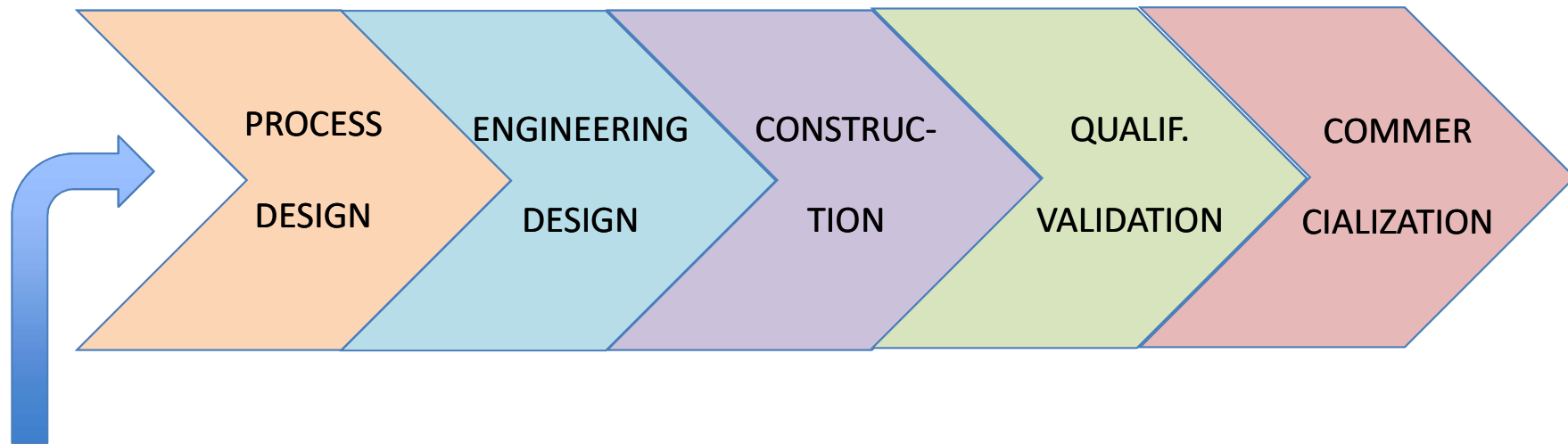
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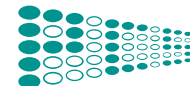
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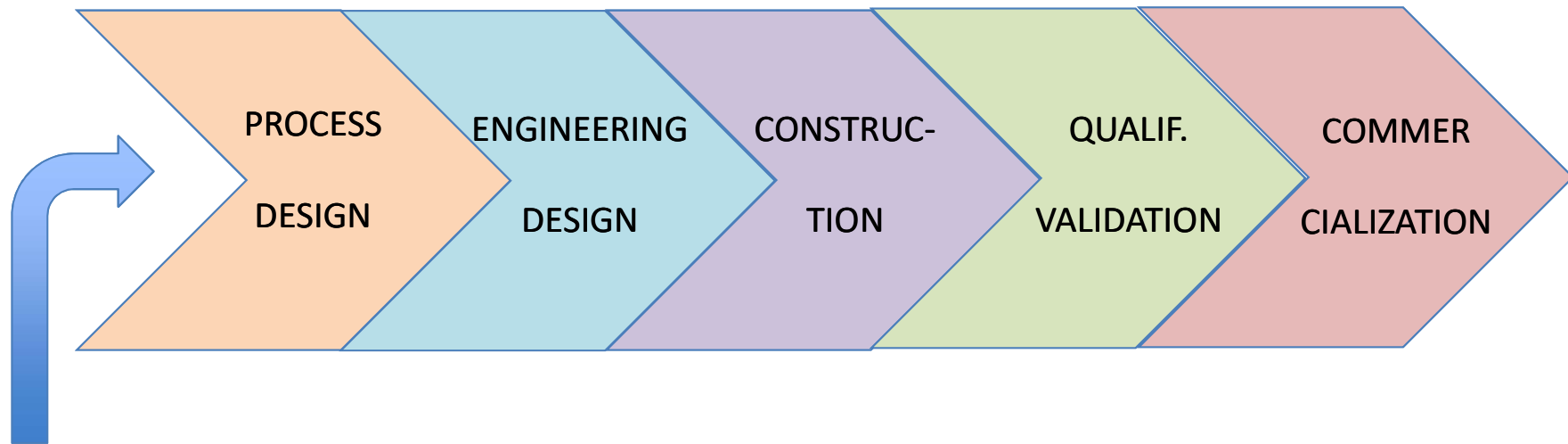
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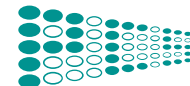
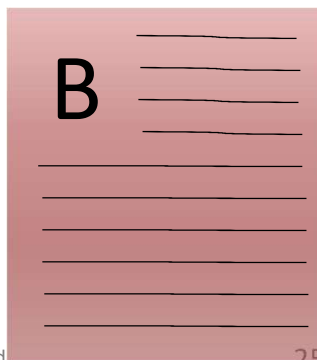


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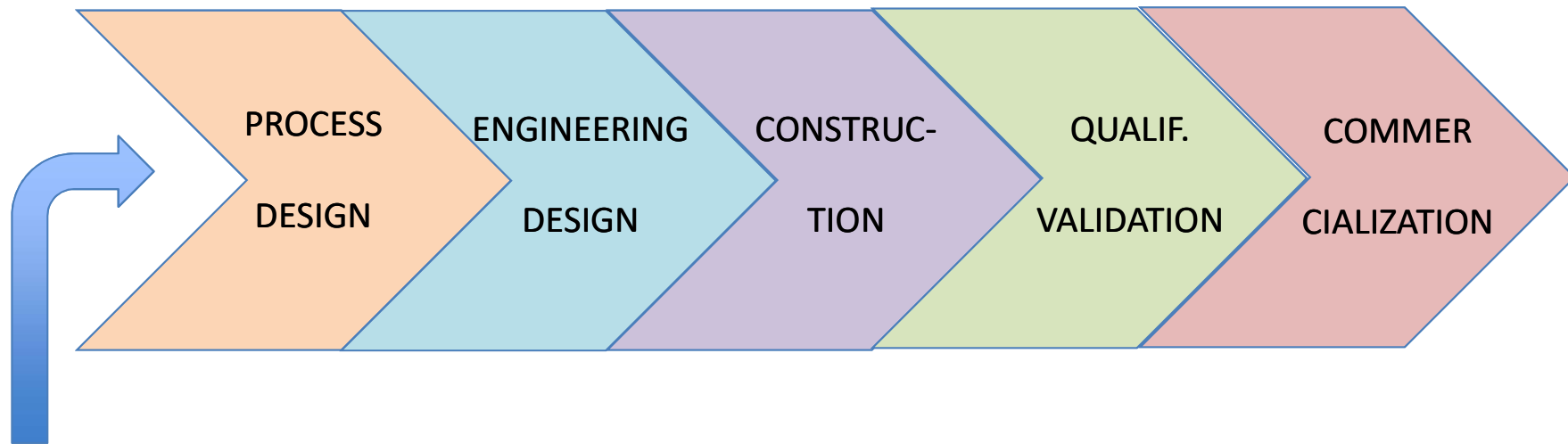


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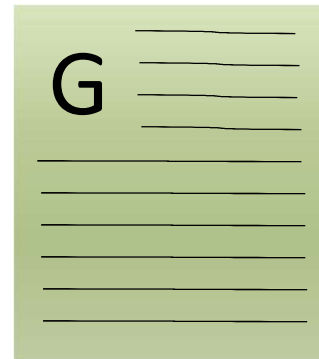
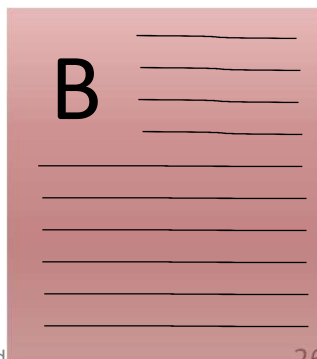


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