

Pharmaceutical Quality Forum

3rd Symposium

# Revised Pharmaceutical Affair Law and Risk Management

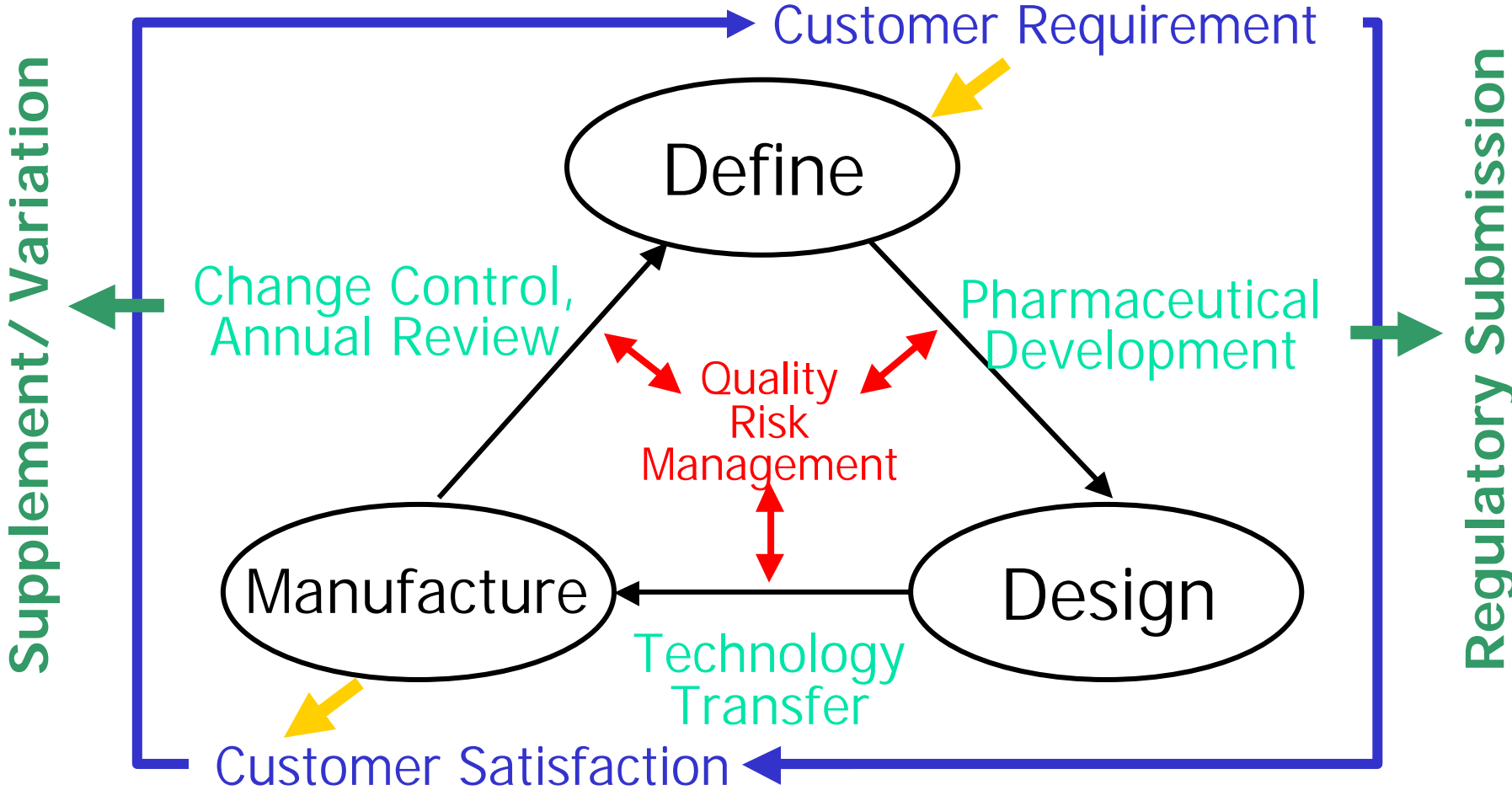


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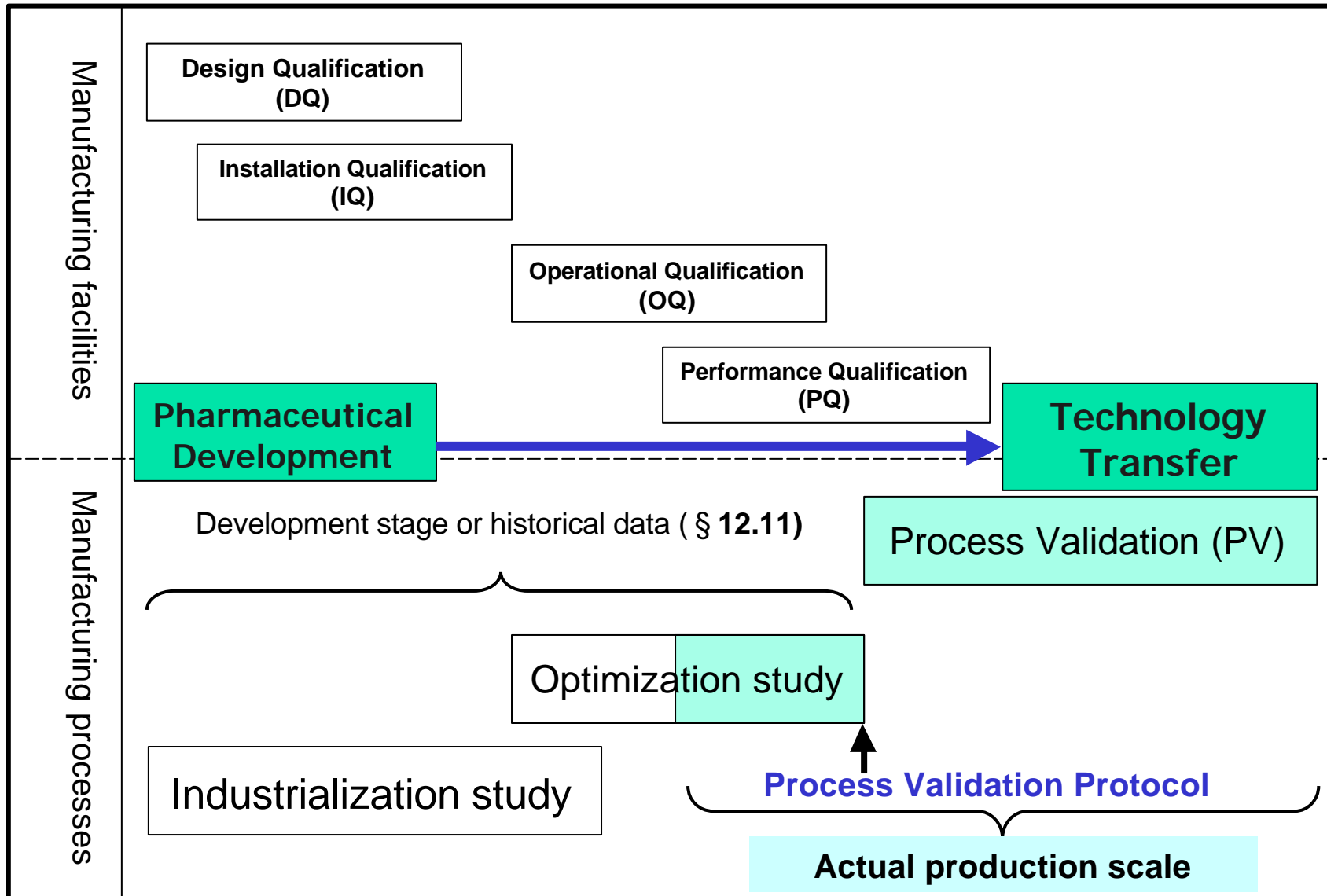
Q9 Topic Leader of JPMA

Takayoshi Matsumura

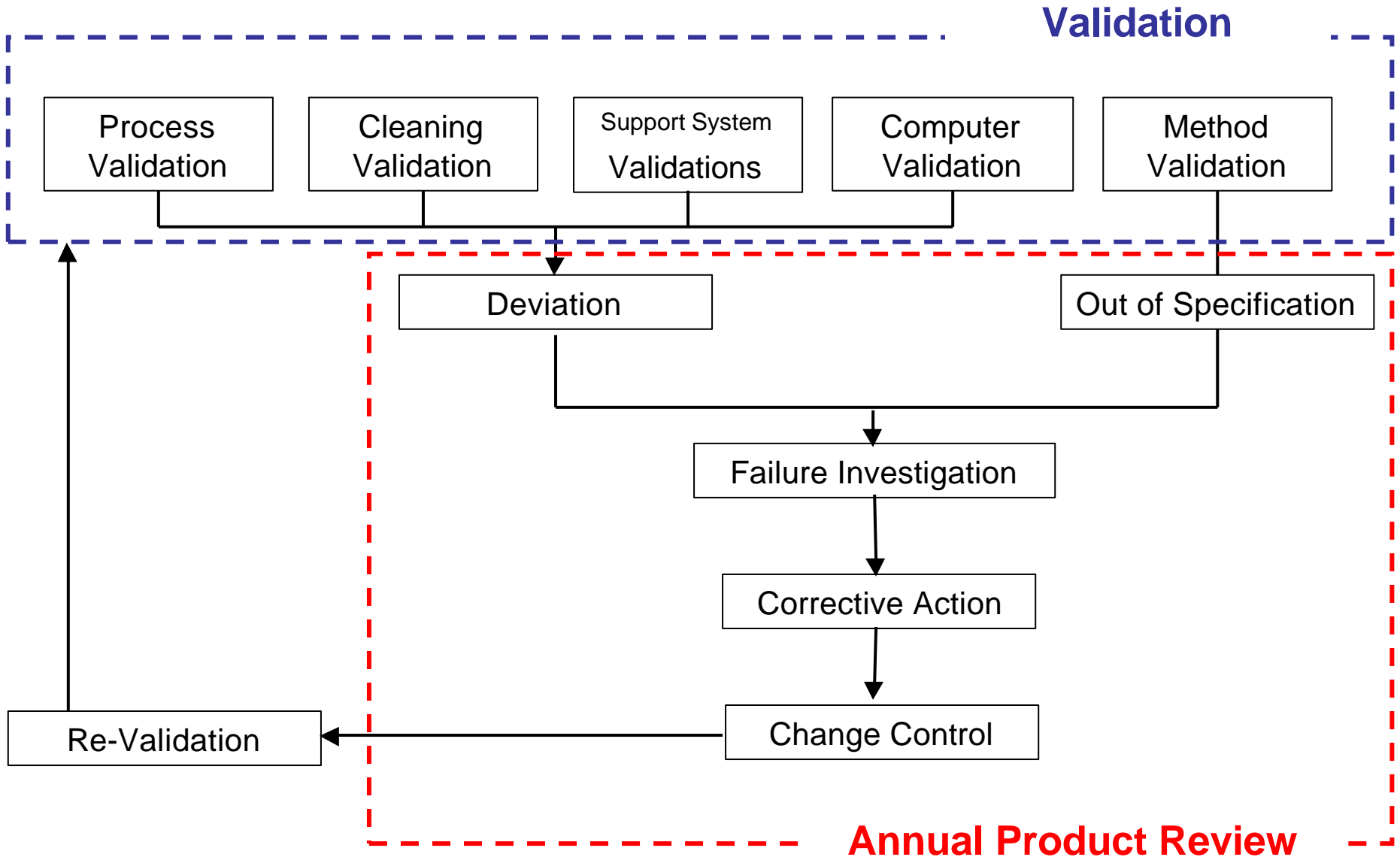
# Continuous Improvement



# Validation of Process



# Quality (Management) System



# Example of Risk Management Evaluation of API Supplier (1)

Type of API

	pharmacoepial	non aseptic	aseptic
High			
Middle			
Low			

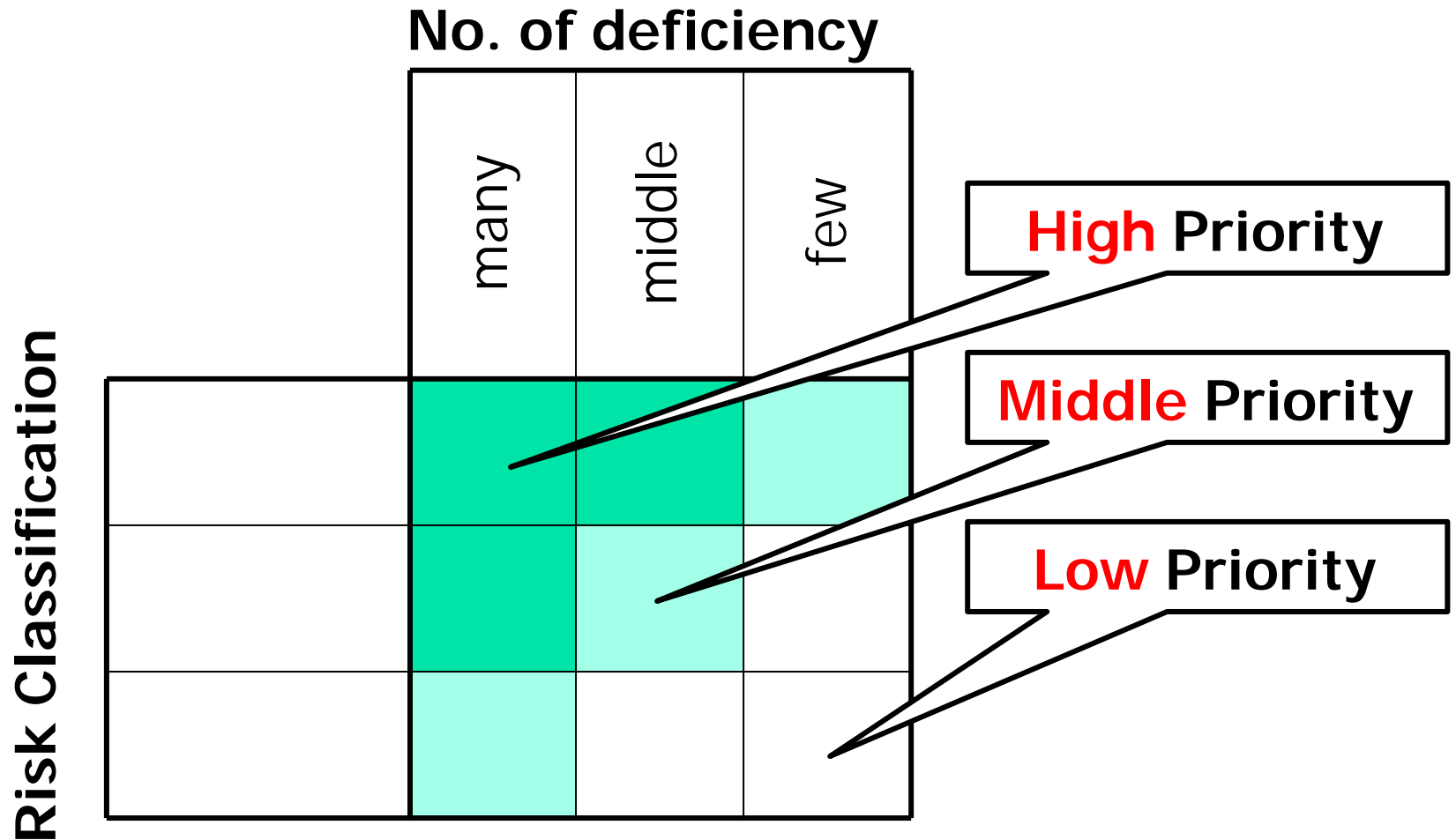
Previous Evaluation

Risk Classification

Risk Classification

Risk Classification

# Evaluation of API Supplier (2)



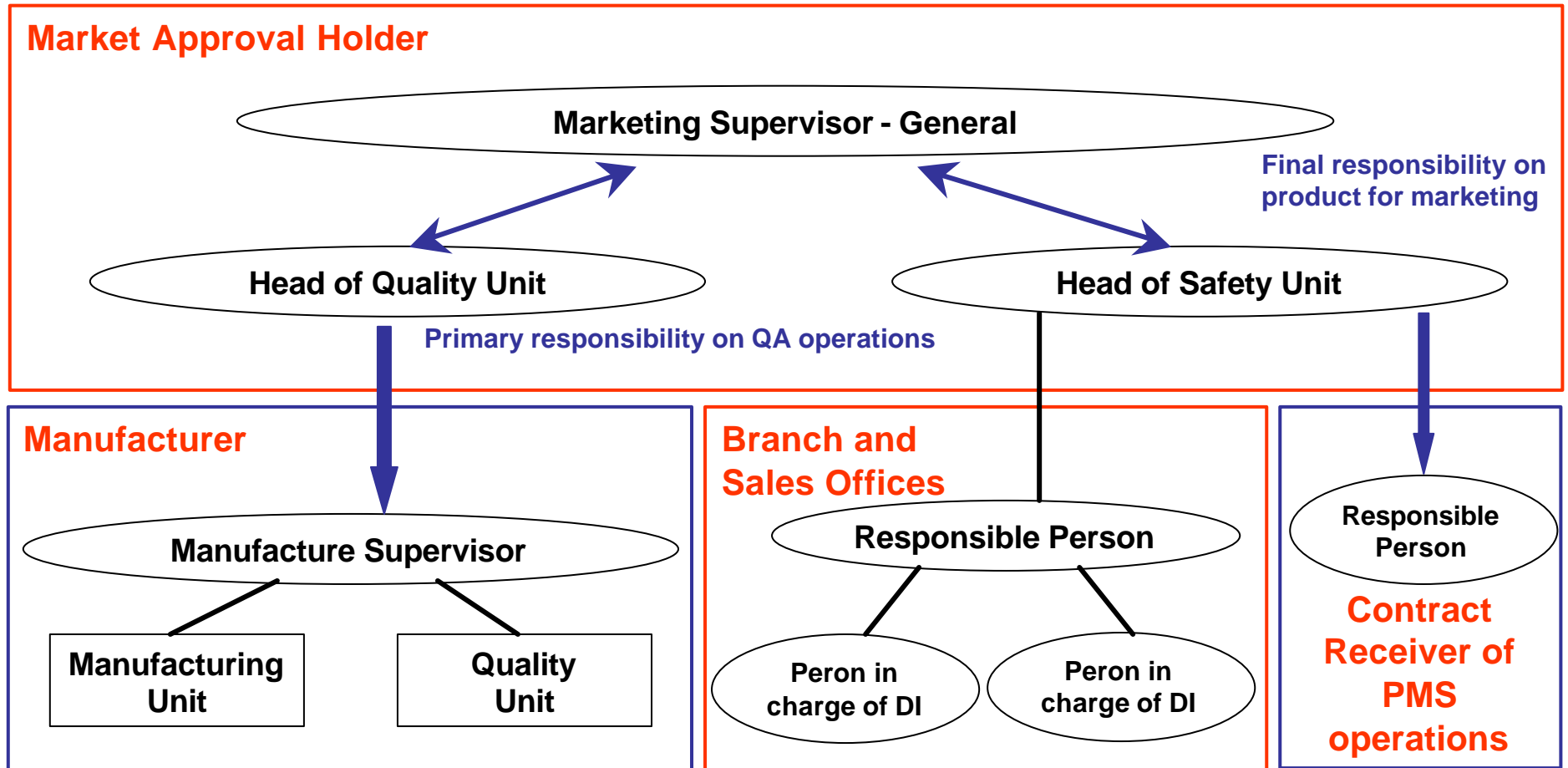


# Revised Pharmaceutical Affairs Law and Current GMP

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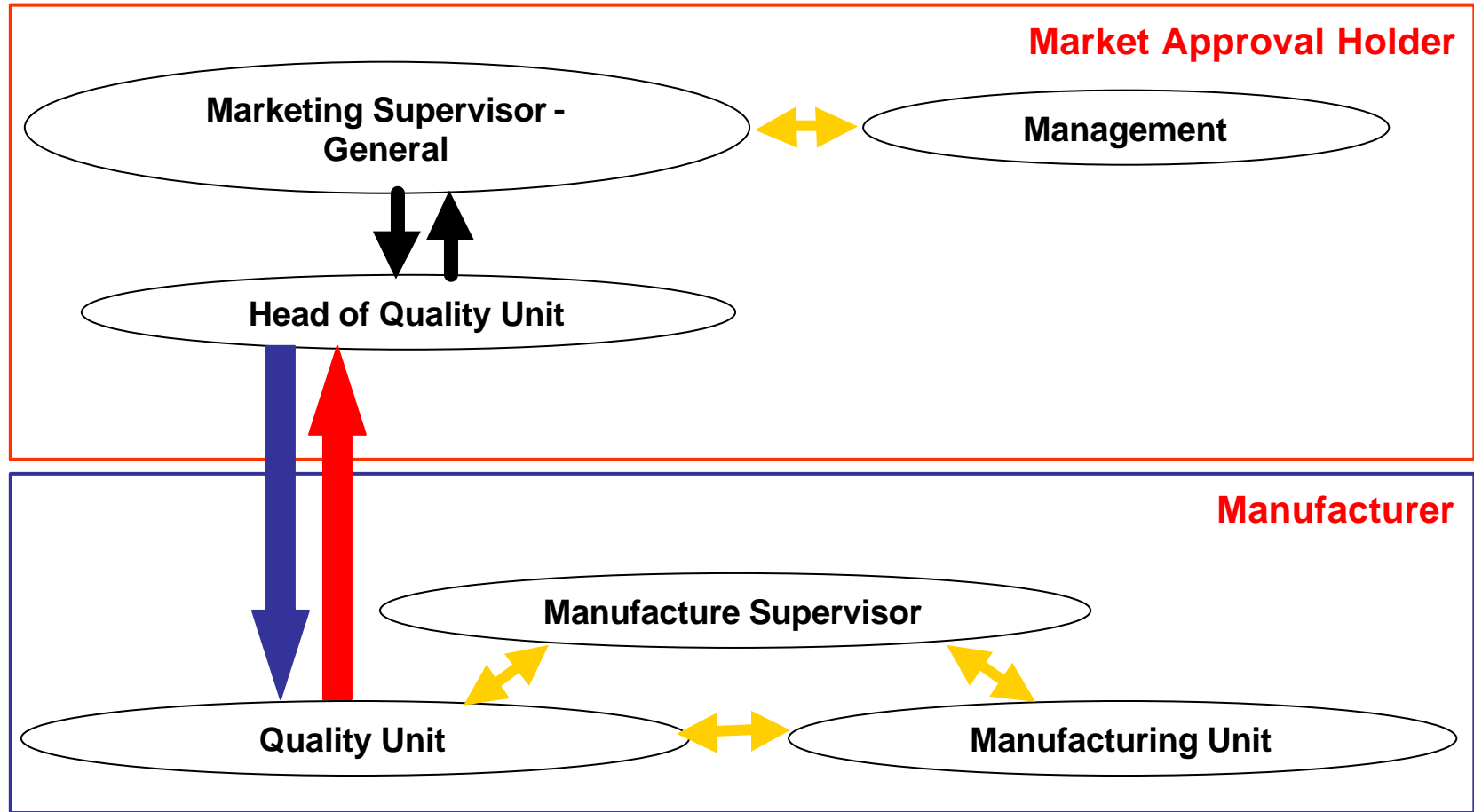
- Communication
  - Deviation
  - Change Control
  - Internal Audits / Self-inspection
  - Validation

# Three Responsible Person in Revised Pharmaceutical Affair Law



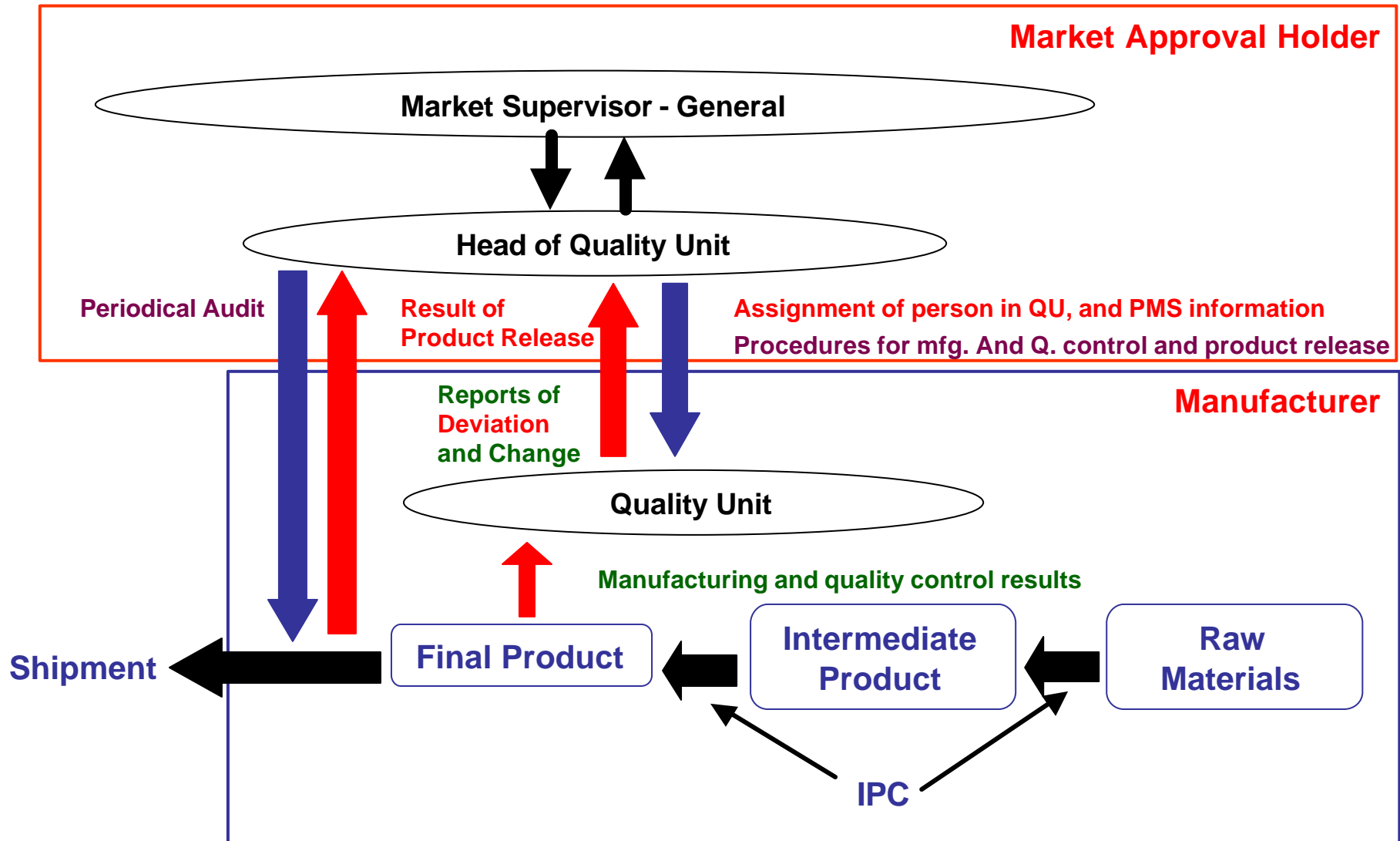


# Quality Management Organization and Communication

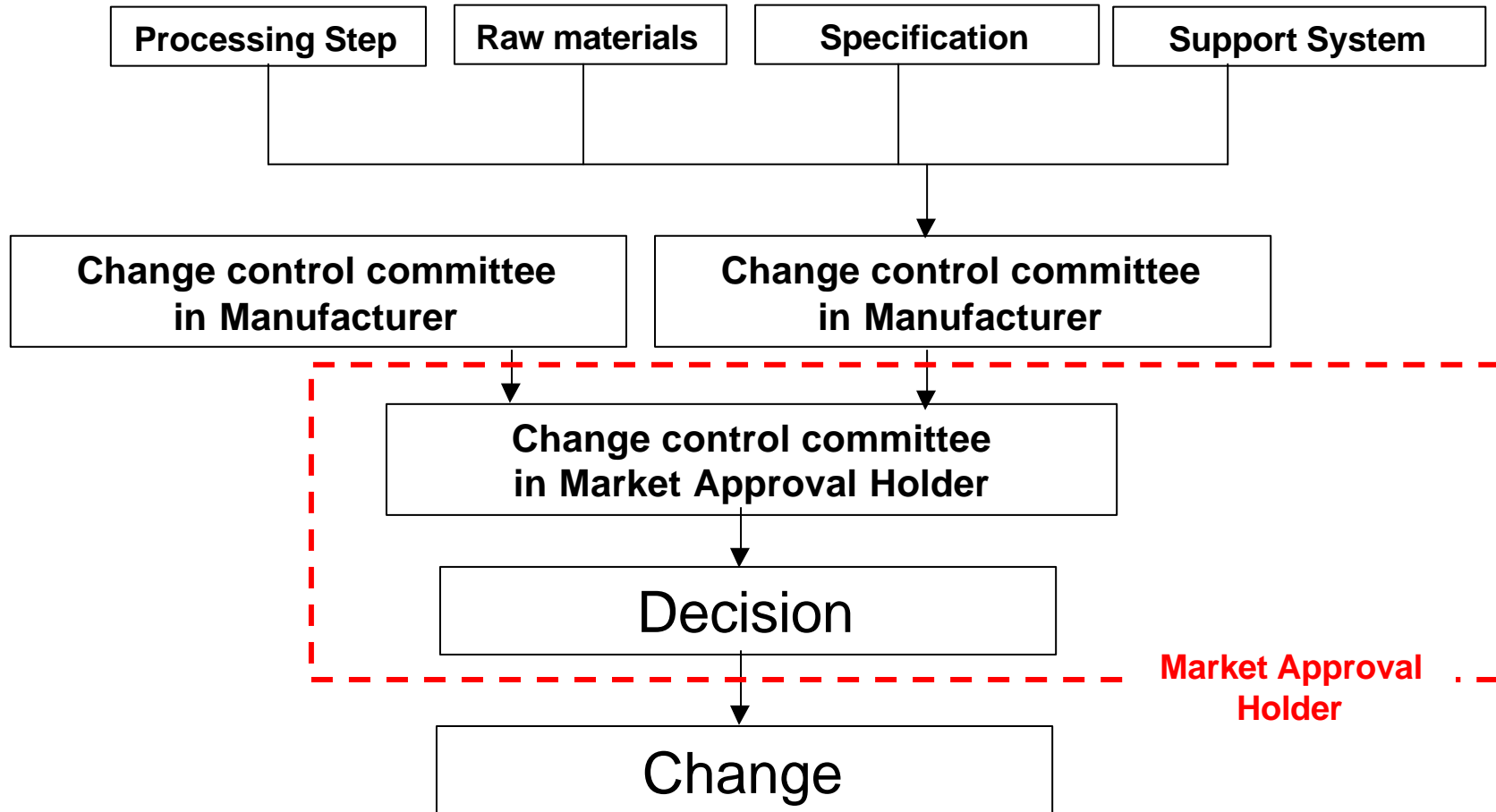


# Manufacturing & Release Procedures

(Released by Quality Unit in Manufacturer)



# Change Control System



# Subjects for Internal Audit / Self-inspection

