



Regulatory Compliance and Validation Concept For a New Biopharmaceutical Manufacturing Facility

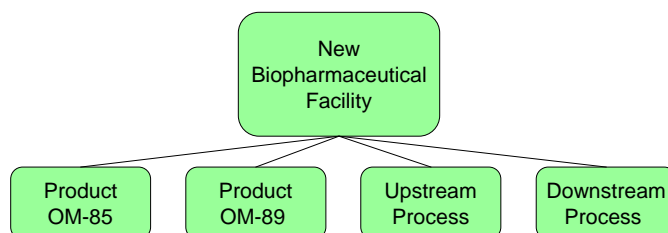
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OM PHARMA

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Facility Requirements




OM-85 : Concentrate – active principal of Broncho-Vaxom®

OM-89 : Concentrate – active principal of Uro-Vaxom®

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Regulatory Basis For Facility Requirements



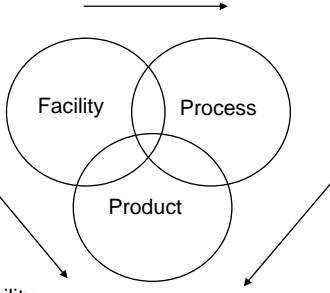
How to make sure that the product will be of the required quality and that facility and process will have the ability to prevent contamination or cross-contamination ?

- Regulatory Requirements

cGMP
Laws
Codes
- Construction Practices


Cost
Time
- Process Know How

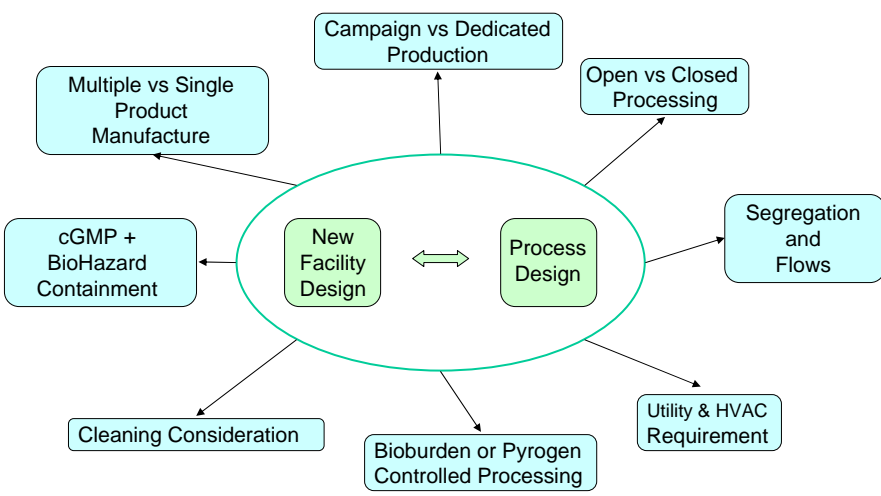
Fiability
Reliability
Reproducibility



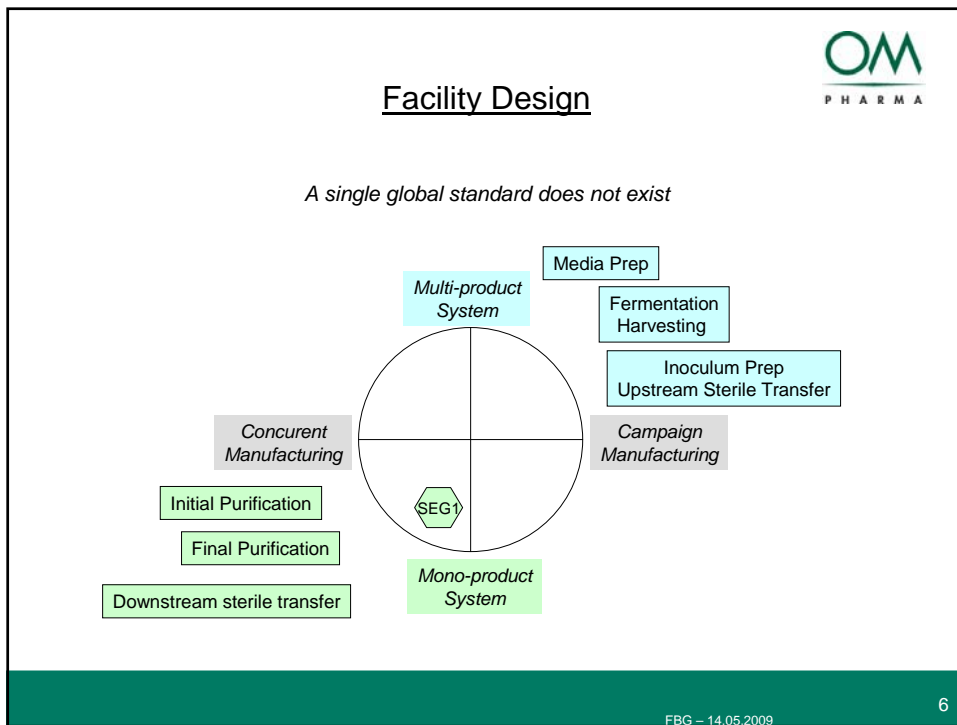
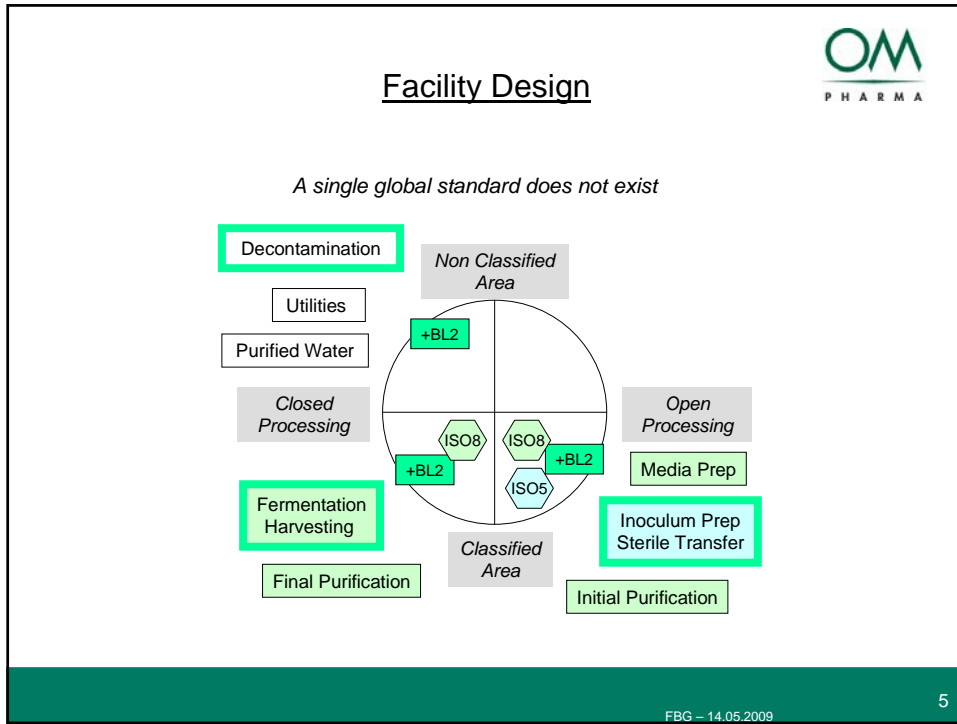
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How to Prevent Contamination ?





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Process Design

Equipment & Piping Design	Critical Process Variables
Closed vs open system	Temperature
Drainability / cleanability	pH
Material of construction	Homogeneity / Uniformity
Surface finish	Sterility
Containment level	Conductivity
Thermal constraints (Sterilization)	Bioburden
Mechanical constraints	Cell concentration
Process Instrumentation	Yield
Equipment arrangements	Purity


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Validation Concept

Facility and equipment design should provide appropriate measures to prevent contamination

Product / process critical parameters and their acceptance criteria must be identified



Define

User Requirement Specifications & Functional Design Specifications


Verify & Confirm

Validation strategy

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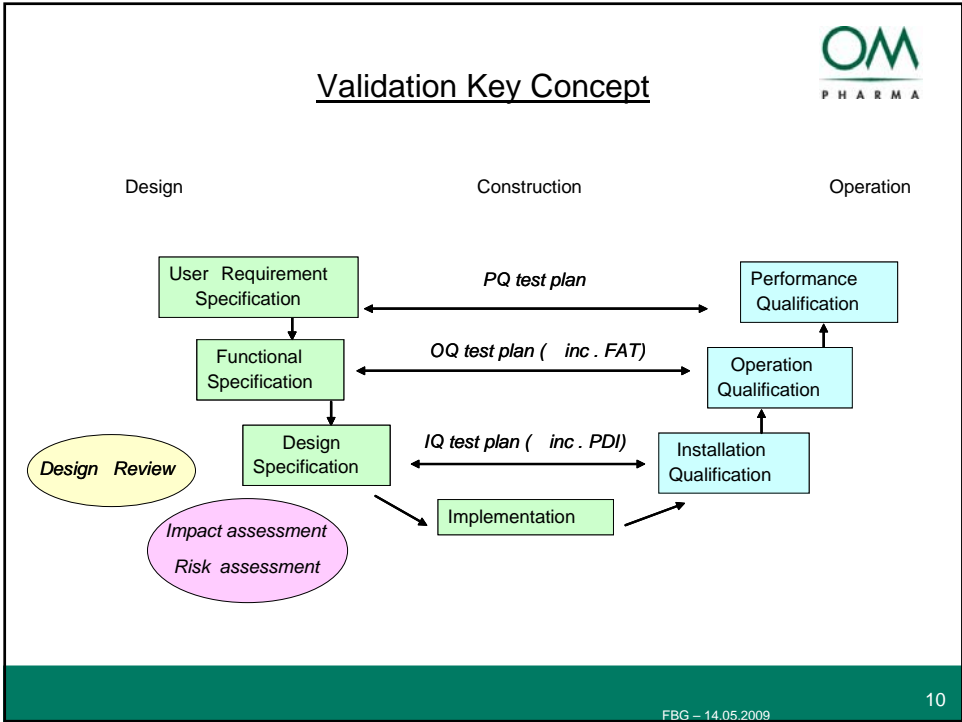
Validation Overview

- The **qualification** should establish and provide documentary evidence that the premises, the supporting utilities, the equipment :
 - Have been designed in accordance with GMP requirements (**DQ**)
 - Have been built and installed in compliance with design specifications (**IQ**)
 - Operate in accordance with functional specifications (**OQ**)


- The **validation process** should establish and provide documentary evidence that a specific process:
 - Have been designed in accordance with GMP requirements (**DQ**)
 - Will consistently produce a product meeting its predetermined specifications and quality attributes (**PQ**)

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Impact Assessment



= Process by which the impact of a system on product quality is evaluated and the critical components within those systems are identified


	CRITICAL	NON CRITICAL
DIRECT IMPACT		
INDIRECT/ NO IMPACT		

Qualification Practices
 Commissioning Practices

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Risk Assessment



= Identify the GMP critical functionality and evaluate them through an index

PRI = Severity (S) × Occurrence (P) × Detection (D)

TRF (Total Risk Factor) = P × S

Ex 1 :

	Occurrence	Minor Severity	Moderate Severity	Critical Severity
Failure Modes Analysis	High			
	Medium			
	Low			
	Remote			

Ex 2 :

	CAT-1	CAT-3	CAT-4	CAT-5
GxP-1				
GxP-2				
GxP-3				
GxP-4				
GxP-5				

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