Sneak Peek

Process Scale-up & Tech Transfer for Injectables

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Protea,
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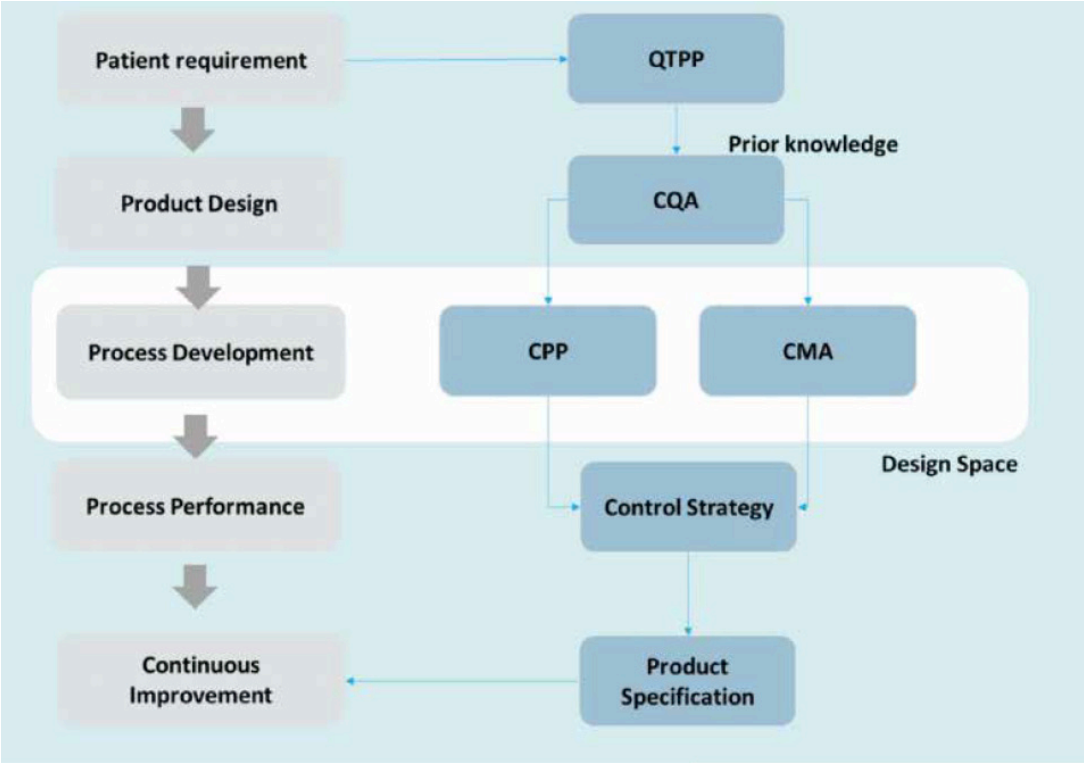
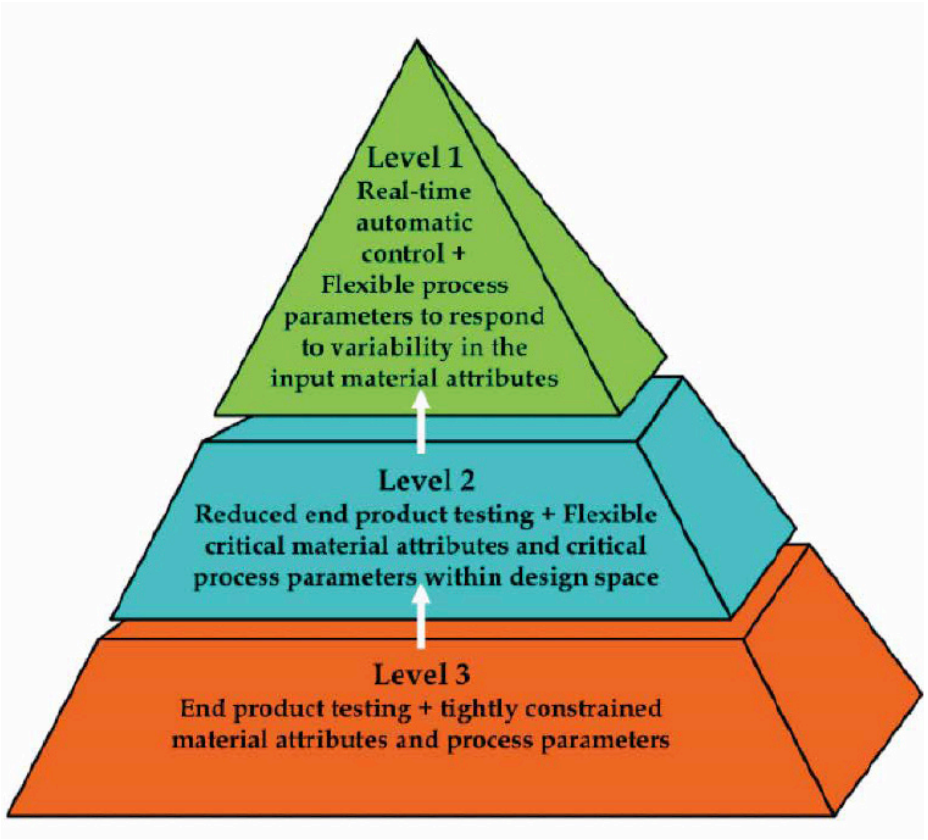
ONLINE
TRAINING

Road to Success

- Build in success from the start (e.g. containment, robust process, automation);
- Control quality from start to finish (in raw materials and operators too);
- Excellent teamwork between different disciplines;
- People (train, lead by example, walk the talk);
- Excel at managing risks proactively.



Impact on Post-Approval Changes

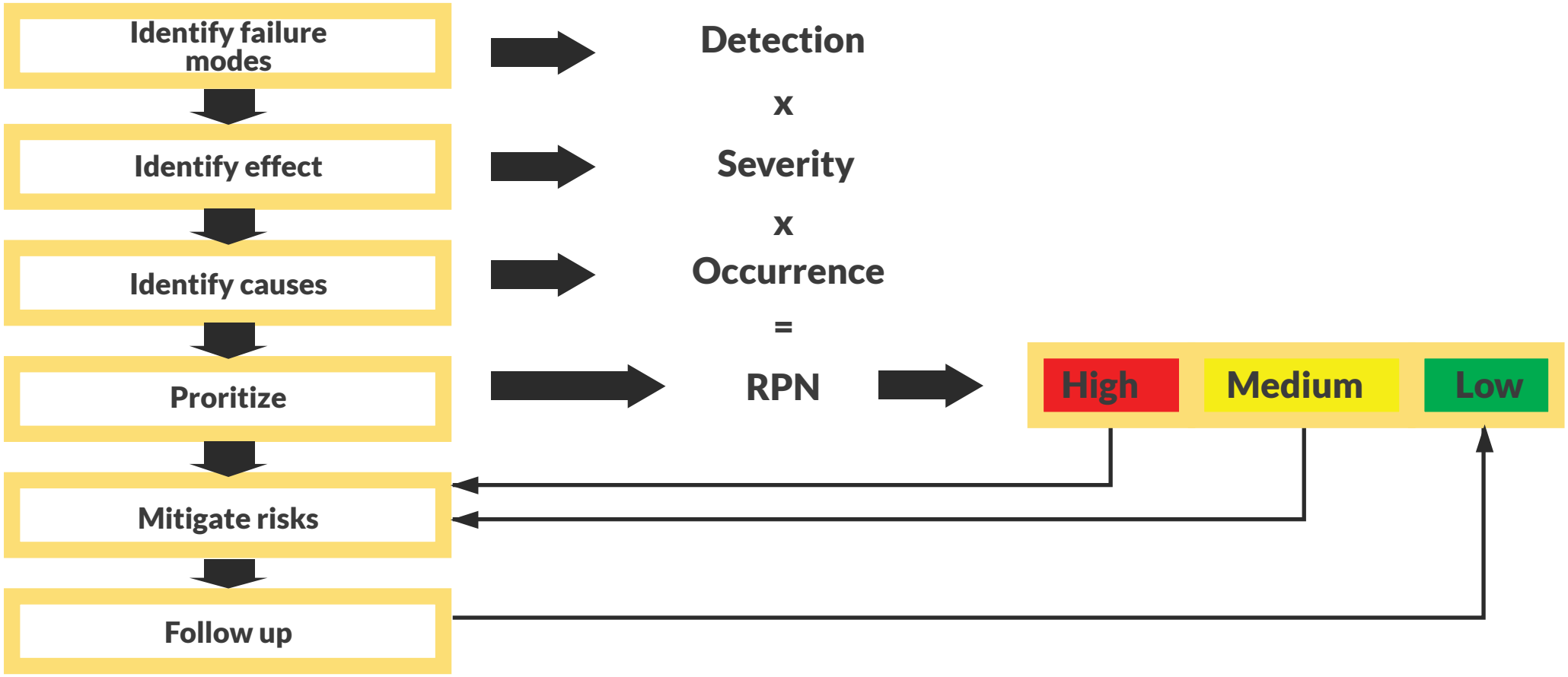


Control Strategy Implementation Options

- Level 1: **flexible** input material attributes and process parameters; **real-time automatic controls** assure that CQAs consistently conform to the established acceptance criteria
- Level 2: flexible material attributes and process parameters **within** the established design space
- Level 3: **any significant change** in these MAs and PPs warrants regulatory oversight

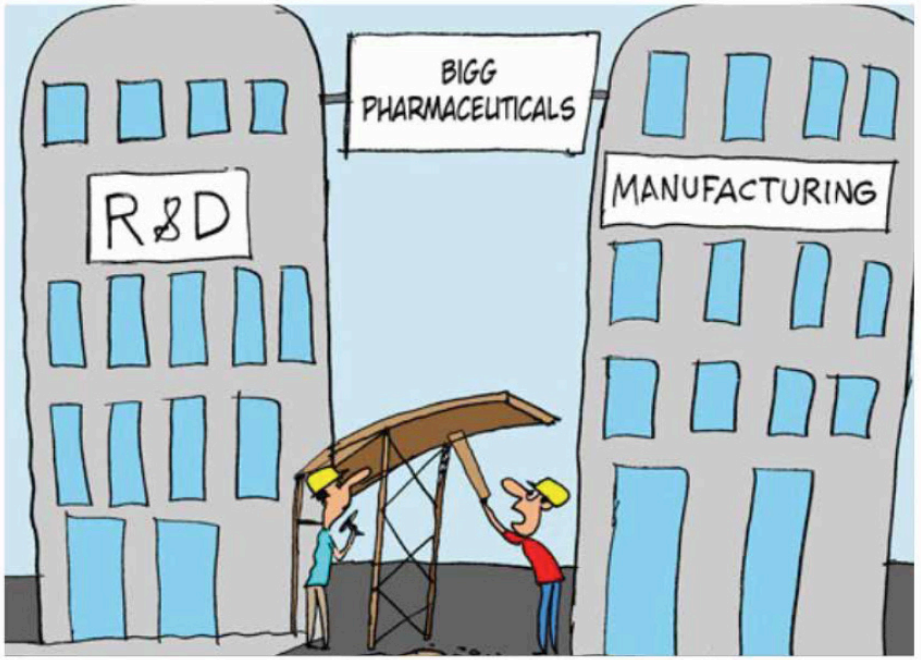
Yu, et al. Understanding Pharmaceutical Quality by Design, The AAPS Journal, 2014, 16(4): 771-783

FMEA Approach



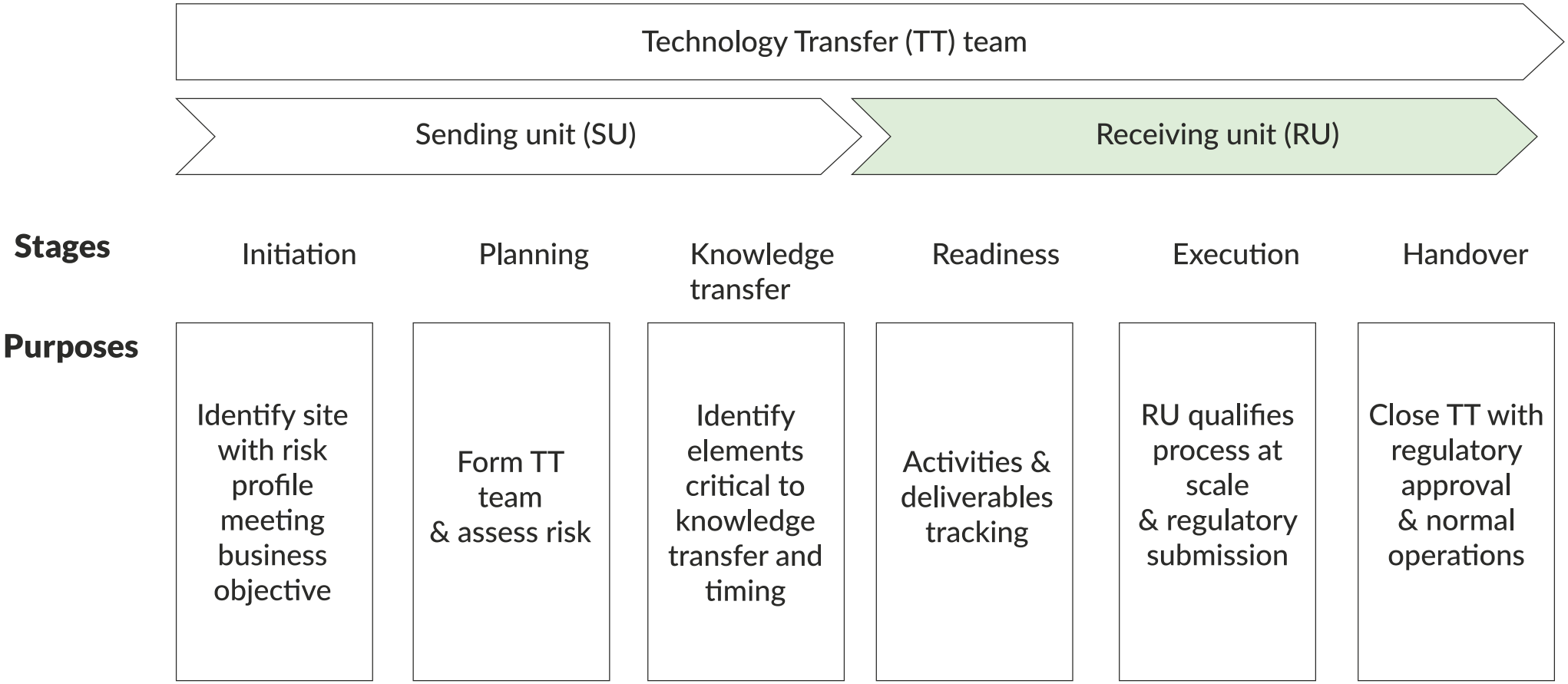
Tech Transfer: When & Why

- From R&D to large scale production;
- From site to site;
- Capacity harmonisation or optimisation;
- Site area changes;
- Productivity or financial efficiency of the site/company.



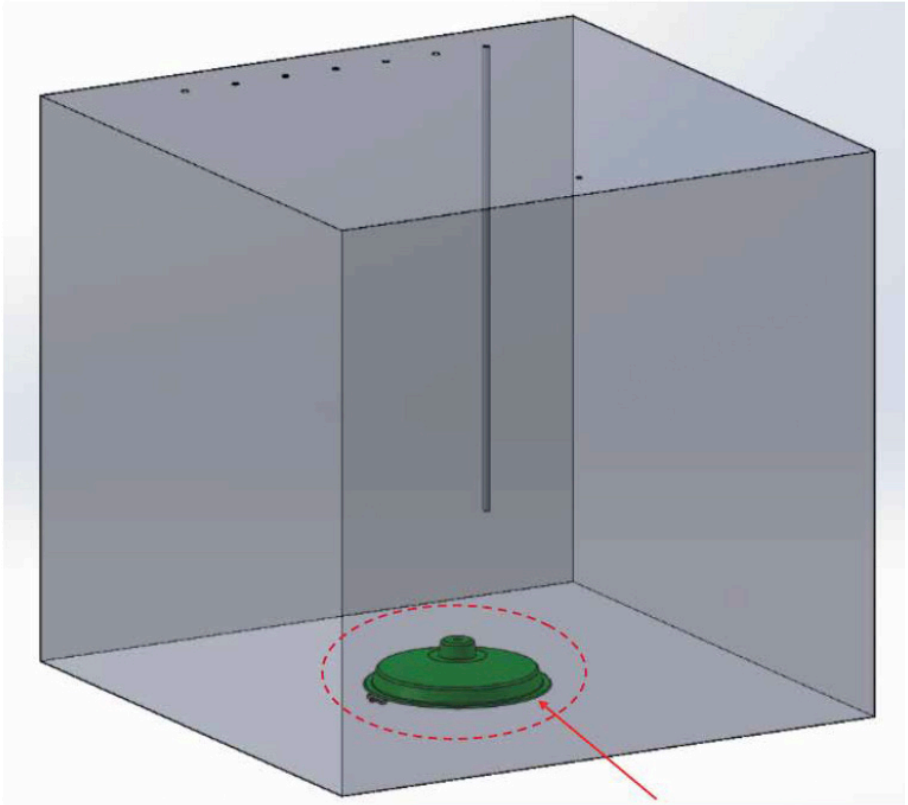
At any stage of the lifecycle!!

Technology Transfer Stages



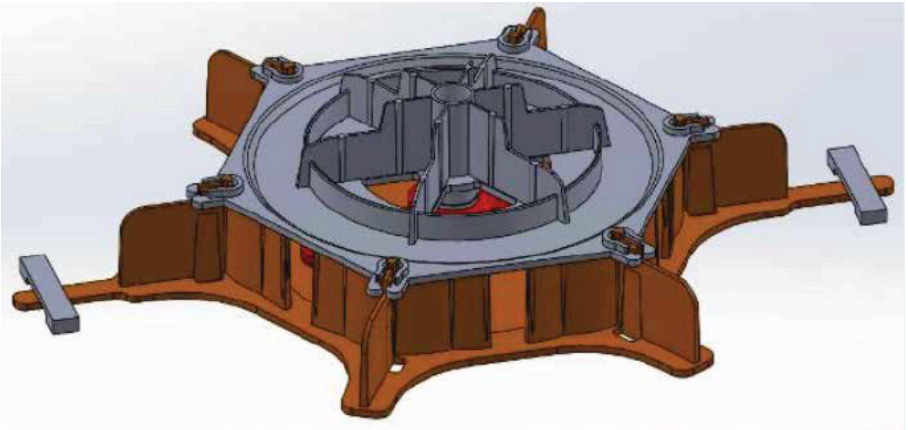
Mathematical Models for Mixing Scale Up

3D CAD Model of Bag, Dip Tube and Jet mixer

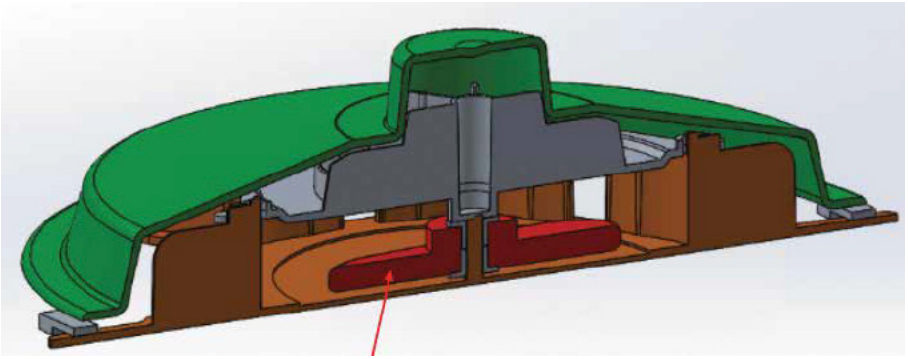


Jet mixer

3D View of Jet mixer



Cross-sectional View of Jet mixer



Impeller

Note: This 3D CAD model was created by Griffin based upon the 2D drawings.

EMA vs FDA Guidance

FDA		EMA		
PV Guideline Jan 2011 (Submission and GMP		Annex 15 Mar 2011 (GMP)	PV drug product Feb 2014 (Submission)	PV Biotech API Apr 2016 (Submission)
Stage 1	Process Design (Process understanding and strategy for process control)	Ref: ICH Q8, 9, 10, 11, CQA, CPP, Control Strategy	Ref: ICH Q11, enhanced or traditional sampling	Ref: ICH Q11, enhanced or traditional sampling
Stage 2	Process Qualification: 2a (Equipment/ Utility) + 2b (Process Performance Qualification). Confirm Stage 1. Justify no of batches	URS, DQ, FAT, SAT, IQ, OQ, PQ	ANNEX 15	ANNEX 15
		PV (traditional, continuous approach, hybrid) If traditional, min 3 batches	PV (traditional, continuous approach, hybrid) If traditional, min 3 batches	PV (Process Evaluation and verification). An 'appropriate' no of batches
Stage 3	Continued Process Verification (CPV)	Ongoing Process Verification	Ongoing Process Verification	Ongoing Process Verification

Registration

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for Injectables

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