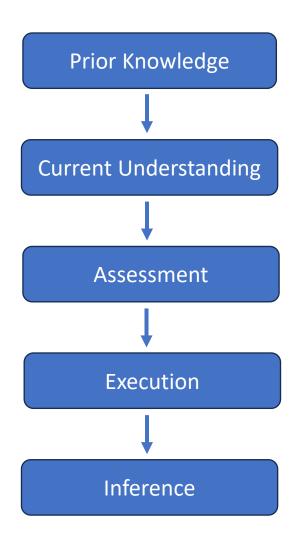
Effective strategy for executing post approval changes

Knowledge-based approach to execute the change v/s "Do it and justify" tactic enables timely approval, and delivers efficiency throughout product lifecycle.....



Referring the drawing board and revisiting the product and process "sensitivities"

Mapping the change, its magnitude and impact:

System and processes Infrastructure and equipment

People Methods and procedures

Risk assessment – Risk to Patient \rightarrow Product Quality \rightarrow Compliance

Execution and documenting the effective evidence

Eliminating or minimizing subjective data interpretation

Select case examples for discussion:

Product	Change	Remarks
Solid Oral drug product	NIR Technology for bulk testing	 Initial product was adjudicated and approved as PAS Subsequent application for 3 products approved as CBE 30
Sterile drug product (Vial)	Use of alternate manufacturing line to de-bottleneck capacity	 Submission of comprehensive risk assessment Contextual deliberation on infrastructure similarity, referencing previously approved product Protocol based study execution with supporting information on potential variables (people, processes, product, equipment) PAS approved ahead of time eliminating need of inspection