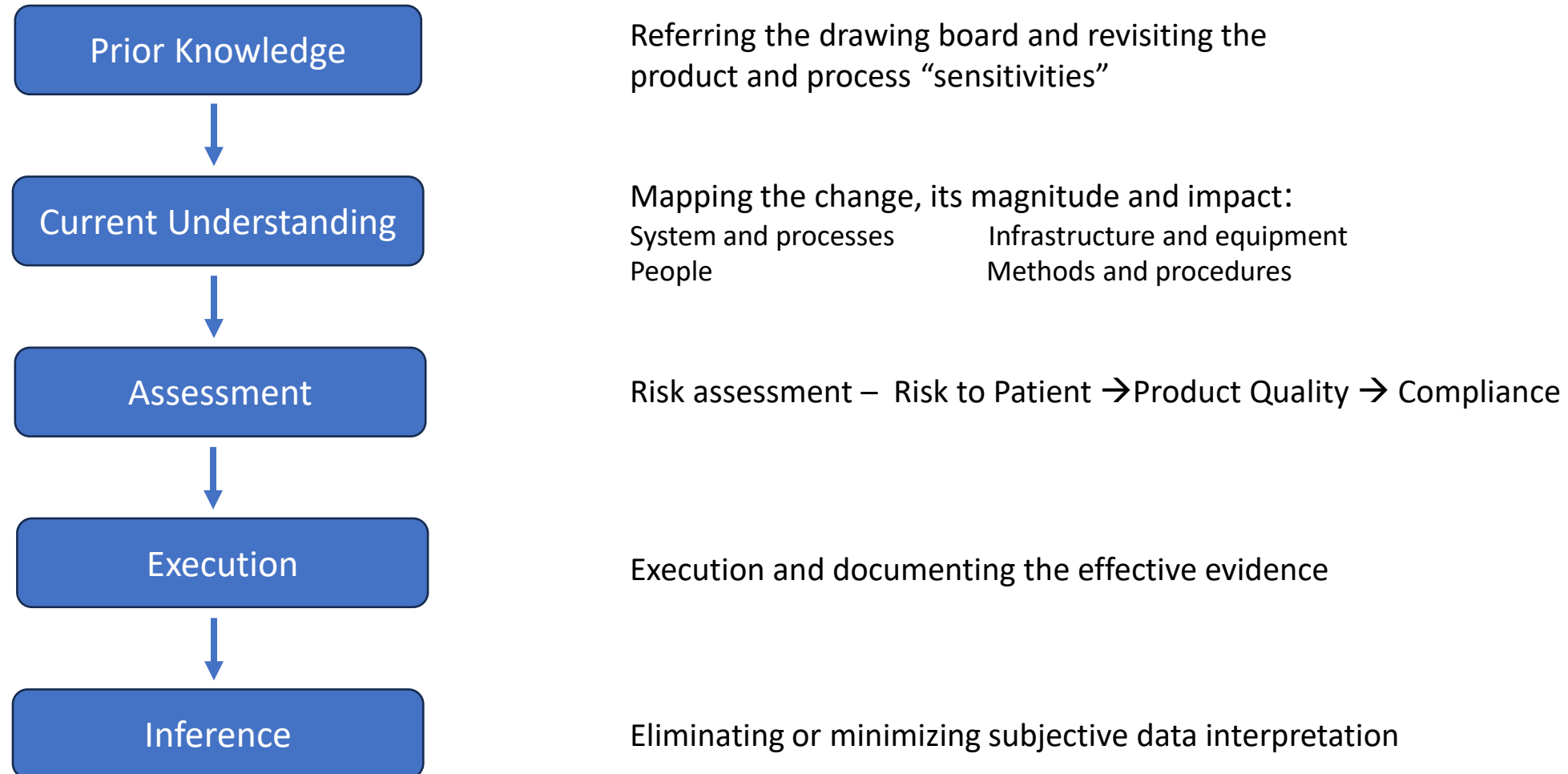


# Effective strategy for executing post approval changes

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



# Select case examples for discussion:

Product	Change	Remarks
<b>Solid Oral drug product</b>	NIR Technology for bulk testing	<ul style="list-style-type: none"><li>• Initial product was adjudicated and approved as PAS</li><li>• Subsequent application for 3 products approved as CBE 30</li></ul>
<b>Sterile drug product (Vial)</b>	Use of alternate manufacturing line to de-bottleneck capacity	<ul style="list-style-type: none"><li>• Submission of comprehensive risk assessment</li><li>• Contextual deliberation on infrastructure similarity, referencing previously approved product</li><li>• Protocol based study execution with supporting information on potential variables (people, processes, product, equipment)</li><li>• PAS approved ahead of time eliminating need of inspection</li></ul>