PRE-LICENSURE MEETING SCHEDULED*

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Gain concurrence with Regulatory Authority on licensure

Pre-licensure meeting(s) in country of manufacture conducted.
(*Specific communication requirements of National Regulatory Authorities (NRA) should be identified upon initiation of the Regulatory Strategy Plan)

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Requirements for pre-licensure meeting(s) in country of manufacture completed; endorsed, submitted to NRA(s)	a) Safety and efficacy data from all clinical trials b) Product release specifications (including pre-approval inspection of manufacturing facilities) c) Stability data to support expiration dating d) Claims and indication statement in the product label e) If applicable, agreement on deferral (or waiver) of pediatric studies f) Plans for any post-approval clinical studies and pharmacovigilance plan g) Information on transition from clinical to commercial-scale manufacture (i.e., establishing comparability of the Phase 3 and commercial products) h) Plans for organizing the content of the application and the submission type (paper vs. electronic) i) Determine if any type of advisory committee meeting will be necessary (if applicable) j) Determine schedule/route of communications with NRA during review process	▪ End of Pre-licensure briefing package
▪ Post-meeting debrief and development strategy adjustment (if required) completed	a) Minutes of meeting prepared by sponsor. NRA minutes obtained (if possible). Review of decisions and recommendations made at the meeting. b) Action plan to address highlighted development issues (if any) prior to filing of application	▪ Regulatory responses to questions