Creation of clinical developmental labeling documents

Labelling documentation creation as per region wise guidelines

Globally functioning pharmaceutical company

- Creation of labeling documents for US, EU, ASEAN, LATAM, ROW Market (USPI, SmPC etc.)
- QC of labeling documents (involves review of editorial changes, compliance per guidance documents and formatting checks)

Supportive documents

- The labeling content development using Investigator's Brochure (IB), Core Safety Information (CSI), Target Product Profile (TPP), Development Product Label (DPP) provided by client etc.

TEAM SIZE	PHASES / MODEL	PERFORMANCE	BUSINESS IMPACT
20	Phase III clinical trial in vaccine development	Extensive proof reading and labeling specialist review reduced the error rates to less than 1%	• Triaging facilitated meeting tight deadlines • Rigorous QA/QC process helped improve quality of updated labels