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The LA experience: Post-approval



Expedited Report

SUSAR/Local SAEs

Spanish/Portuguese
Online submission/E-mail or Fax

Various timelines (SAEs 7Wd; 10Wd and non-serious q 2months)

Periodic Report

PSUR/Line Listings/CIOMS

Spanish/Portuguese
Hard copy-Hand delivery/Online submission/E-mail

Various timelines (q 2 months/6 months, yearly PSUR in Mexico all others specific template and LL)

RMPs in MEX ARG, PER and BRA

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