Annexes 1-12 to SOP QS-026 Product Quality Review engl

QS-026-Annex 1	Template 1.1 Starting materials used in the product, especially those from new sources Template 1.2 Packaging materials used in the product, especially those from new sources
QS-026-Annex 2	Template 2.1 Results from in-process controls of critical process parameters Template 2.2 Testing results of the finished product
QS-026-Annex 3	Template 3 All batches that failed to meet established specification and their related investigation
QS-026-Annex 4	Template 4 Significant deviations or non-conformances, their related investigations and the effectiveness of resultant corrective and preventive actions taken
QS-026-Annex 5	Template 5.1 Changes carried out to the manufacturing procedures Template 5.2 Changes carried out to the testing procedures
QS-026-Annex 6	Template 6 Marketing Authorisation variations, submitted / granted / refused, including those for third country (export only) dossiers
QS-026-Annex 7	Template 7 Results of the stability monitoring program and any significant adverse trends
QS-026-Annex 8	Template 8 Quality-related claims (returns, complaints) and recalls and related investigations
QS-026-Annex 9	Template 9 Adequacy of corrective actions performed on the production process or equipment (not required for the first Review)
QS-026-Annex 10	Template 10 Check of requirements imposed by the regulatory authorities in connection with Marketing Authorisation or variations to Marketing Authorisation
QS-026-Annex 11	Template 11 Status of qualification of relevant equipment and media, e.g. ventilation, air conditioning, water, compressed gases (e.g. compressed air)
QS-026-Annex 12	Template 12 Check of being up-to-date: Agreements on contract manufacturing for medicinal products, agreements on contract testing for medicinal products