		API for EU/ US	Bulk Formulated Product/ Drug product for US	Bulk Formulated Product/ Drug product manufactured in or for EU	Finished Product Packaging in or for EU
5.4.1	Summary	√	√	√	√
5.4.2	Batches reviewed	√	√	√	√
5.4.3	Starting / Packaging Materials			√	√
5.4.4	Analytical data	√	√	√	√**
5.4.5	Changes	√	√	√	√
5.4.6	Stability data	√	√	√	√*
5.4.7	Deviations	√	√	√	√
5.4.8	Reprocessed and reworked batches	√	√	√	
5.4.9	Rejected batches	√	√	√	√
5.4.10	Complaints	√	√	√	√
5.4.11	Recalls	√	√	√	√
5.4.12	Returned and Salvaged goods		√		
5.4.13	QA Agreements			√	√
5.4.14	Qualification status of relevant equipment and utilities			√	√
5.4.15	Market Authorization variations submitted / granted / refused			√	√
5.4.16	Post marketing commitments			√	√
5.4.17	Other	**	**	**	**
5.4.18	Comparison with previous review	√	√	√	√
5.4.19	Conclusions and recommendations	√	√	√	√

* For primary packaging and other packaging steps that could affect product quality

** If applicable

Sections of the product review could be combined when practical.
Regular trend reports produced for other purposes (for deviations, complaints, stability, validation, etc.) could be referenced. Critical trends and conclusions from these should be evaluated with all other information in the Product Review.

Bulk Formulated Products and Drug Products.

5.4.14 Qualification Status of Relevant Equipment and Utilities

For EU supplying sites of Bulk Formulated Products, Drug Product and Finished Products, include qualification status of relevant manufacturing equipment and services, e.g. HVAC, water, compressed gases, etc. It is recommended to include equipment with direct product impact. The qualification status can where appropriate be reviewed per production area rather then per product.

5.4.15 Marketing Authorization Variations

For EU supplying sites of Bulk Formulated Products, Drug Product and Finished Products, a listing of all marketing authorization variations submitted / granted / refused must be compiled.

5.4.16 Post-marketing Commitments

For EU supplying sites of Bulk Formulated Products, Drug Product and Finished Products, a listing of all post-marketing commitments must be compiled.

5.4.17 Other

It might be relevant to add in conclusions from trend reports for e.g. water systems or environmental monitoring, major changes in SOPs and Master Batch Records etc.

Sites may also choose to include other activities where this is practical.

5.4.18 Comparison with Previous and Related Reviews

Comparisons of data with previous and, when relevant, related product reviews must be undertaken for each section.

A comparison of the product reviews with the previous product reviews must be undertaken and summarized in the first page summary.

5.4.19 Conclusions and Recommendations

The conclusions must include explanations of key points evident from the review, a statement of validation status and recommendations for any changes and/or revalidation.

5.5 Contract Manufacturer or Contract Laboratory

The QA Agreement between the company and a Contractor must include a section On Product Reviews. Copies of a Contractor's Product Review report must be available at the Lead Team/Site (or other responsible unit)..

The sponsor company must review and agree to any conclusions made by the

