are essential for API, drug product, critical excipients, primary packaging components)

- required supplier communication regarding Regulatory Agency activity (inspections, notifications, enforcement activities) impacting the supplied material (including the systems used to manage the material production, testing, handling and storage);
- specifications should include any requirements concerning packaging of the material, (for example tamper-resistant container seals, weight limitations, etc.) labeling (identity, expiration date, lot number, etc.) storage and shipping restrictions (store at XX0F/C , protect from freezing or exposure to heat, etc.);

- supplied certificate of analysis (COA) showing results of evaluation to meet acceptance criteria meeting national/local guidelines, recognized compendia requirements, etc. The COA needs to be supplied in specified client local language and include authorizing signature of an identified (name and position) responsible individual;

- requirements to document compliance with TSE/BSE directives (Applies to ingredients, drug products; product-contact packaging components);

- required documentation and retention samples including the required retention time period and storage conditions, any required review, quantity required (recommend twice the amount needed to perform complete evaluation). This applies to API and drug product samples, process, packaging and testing records. A risk-based evaluation may be used to justify inclusion for other materials;

- stability program (for API, drug product, excipients subject to degradation) to provide data to establish expiry periods, conditions for storage, including transportation, and re-evaluation periods;

- requirements for supplier to notify client of significant non-conformances (deviations, discrepancies, out-of-specification results, etc.). Supplier needs to have an effective system for investigation of non-conformances to encompass documentation, corrective activities, and tracking. (Requirements for API, critical excipients and drug products.);

- expectations regarding qualification activities and documentation required for production processes, test methods and cleaning. (Applies to API, drug product.); -an effective complaint handling system should be in place to monitor complaints received, any corrective activities and observed trends.
(Required for drug product; may be included via risk-based justification for other materials);

 