What does the QOS consist of?

Answer:

Chemical purity evaluation: this is a critical summary of the information provided in the application dossier. Emphasis will be placed on the suitability of the European Pharmacopoeia monograph to control the quality of the concerned substance, the potential impurities (including nitrosamines and elemental impurities) resulting from the specified manufacturing and the need for alternative methods where appropriate. Particular attention will have to be paid to justifying cases where testing for impurities is omitted (e.g. if an impurity is unlikely to be present due to a particular route of synthesis).

TSE risk evaluation: the QOS should discuss the ability of the system in place to minimise the TSE risk for the substance, especially concerning traceability and the '3 pillars', (countries of origin, animal tissues and method of manufacture) with particular reference to general chapter *5.2.8* of the Ph. Eur., which is identical to the EMA NfG on minimising the risk of transmitting TSEs.