Quality by Design Checklist for Excipient Users

1. Effective Communication

1. Is the selection of suitable Suppliers discussed and agreed with the Procurement Department?
2. Are contact points at both the Supplier side and the User side identified?
3. Is the existence of a valid confidentiality agreement with right scope and intellectual property status, if required, checked for?
4. Are contacts and confidentiality with the Supplier (Confidential Disclosure Agreement; CDA etc) agreed?
5. Is a Quality agreement addressing change notifications during drug development in place?

2. Development of the Dosage Form

6. Is the pharmaceutical platform and selected excipients defined, i.e. exist information such as target profile of product, development phase, prior knowledge, special requirements (fast disintegration, controlled release etc), type of process (e.g. wet granulation, direct compression) and any specific requirements of the drug substance?
7. Is the function of the excipient in the formulation and which functionality/ functionalities should be added to the dosage form and its process under development, clarified?
8. Are specifications of excipients defined together with the Supplier?
9. Are future needs regarding excipient quantities needed defined?
10. Is the manufacturing site you want to obtain the material from identified?

3. Excipient Critical Quality Attributes

11. Do we have any own, prior knowledge of CQAs of the selected excipients in question and for the process(s) in question?
12. For each excipient chosen, have we agreed on possible CQAs based on User and Supplier experiences from both product and process perspectives?

4. Equipment and Production

13. Are all the agreed CQAs listed in the specifications and actual results given on the CoA by the Supplier? If not, agree on how the CQAs should be measured and controlled (QC).
14. Is it known how the CQAs are set during the excipient manufacturing process and what the process controls are?
15. Is it known if the specification limits for the CQAs are based on monograph limits or on production capability/production history?
16. Is it known what are the expected batch-to-batch and intrabatch (batch uniformity) variation and stability trend in the CQAs?
17. Is it known what the process capability of the excipient is?
18. Are any new CQAs identified during large scale production of the drug product?

5. Supply of samples for development

19. Is it possible to obtain batch sample representative for upper, lower and mid range (so called "QbD kits")?
20. Is it possible to ask for samples of several lots obtained over different time periods?