Quality by Design Checklist for Excipient Manufacturers/Suppliers

1. Effective Communication

1.1. It is defined who within the company is responsible for customer communication with the customer on QbD related topics?
1.2 Should it be necessary, is there a process to review and discuss customer 'special' specifications?
1.3 Does the change notification procedure include changes which may affect the results for the CQAs even if there is no change to the overall specification?
1.4 Is a Confidential Disclosure Agreement needed to protect proprietary information?

2. Development of the Dosage Form

2.1 Is it understood what the customer application is for the excipient and have they selected the most appropriate material or grade?
2.2 Can any of the variables be categorised as not being Critical Quality Attributes in the customer's specific application and have the relevant Functionality related Characteristics been identified?
2.3 Is the customer using the selected excipient at the correct level in the formulation to optimise robustness?

3. Excipient Critical Quality Attributes

3.1 Have all potential chemical and physical variables for the excipient been identified?
3.2 Is the manufacturing process under sufficient control to be able to relate process parameters to physical or chemical attributes in the product?

4. Equipment and Production

4.1. Is the manufacturing process optimised to minimise variability in the product?
4.2 Is the manufacturing process sufficiently robust and understood to be able to manage variability in the starting materials?
4.3 Is the inherent variability in the starting materials understood, monitored and controlled as much as possible?
4.4 Are all the identified CQAs listed in the specification and actual results given on the CoA?
4.5 If some parameters identified as CQAs are not monitored routinely in the final product, what is the level of confidence that they are under control?
4.6 Are the specification limits for the CQAs based on monograph limits or on production capability/production history?

5. Supply of samples

5.1 Are samples for customers available which represent the product at the edges of the published specification limits?
5.2 Is the customer willing to work with manipulated samples or 'non pharma' grade samples to assist define the product design space?