Sakura Bloom Tablets AF Mock

Disclaimer

This AF (Application Form) mock provides an example of the contents in the AF to be intended for the JNDA (New Drug Application in Japan), which was created based on the “Sakura Bloom Tablets P2 Mock” prepared in February 2015. The purpose of this mock is to envision overall image of the AF of drug product using the Quality by Design (QbD) methodology. Note that we are not intending to create any new regulatory requirement or eliminate any existing regulatory requirement, and this AF mock does not include all the elements to be required for the JNDA AF.

“Sakura Bloom Tablets P2 Mock” provided an example of the contents to be included in CTD 2.3.P.2 “Pharmaceutical Development” section for a drug product that had been developed by using the QbD methodology presented in ICH Q8, Q9, Q10 and Q11. It was supposed to be into CTD Module 2.3 (Quality Overall Summary). In addition, in order to help readers’ better understanding, some additional contents corresponding to 2.3.P.3”Manufacture” and 2.3.P.5”Control of Drug Product” were also included in this P2 mock.

It should stress again that the purpose of this AF mock is to envision overall image of the AF using the QbD as an example, and each product could have each quality profile and attribute to be shown in the AF. Additionally, the readers (new drugs’ applicants and CMC regulatory reviewers/GMP inspectors) of this AF mock could consider the current ongoing discussions on ‘what the AF looks like for the JNDA’ and the ICH Q12 (Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management) in the regulatory authorities and the industry experts when they prepare and review the actual JNDA AFs.

Finally hope that this AF mock will help better understanding of the JNDA AF mock with the drug product using QbD and more closely communications and collaborations in the regulatory authorities (CMC reviewers and GMP inspectors) and the industry experts (CMC experts).

Study project for regulatory harmonization & evaluation of drugs etc.
Studies on quality control approach to new development and change in manufacturing of drugs
“Studies on quality assurance throughout the drug product lifecycle”
Sakura Bloom Tablets Mock Sub-group

February 2017