National Pharmaceutical Control Bureau
MINISTRY OF HEALTH MALAYSIA

Process Validation (PV)

World Health Organization
WHO Collaborating Centre for Regulatory Control of Pharmaceuticals

PIC/S
Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme

QUALITY SYSTEM
SIRIM
Certified to ISO 9001:2000
Cert. No: AR 2293

STANDARDS MALAYSIA
ACCREDITED LABORATORY
MS ISO/IEC 17025:2005
[illegible]

Q & A

PV Team

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Question No. 1

Are PRH to follow the ASEAN PV requirements, or are there country-specific requirements ?

(eg for P3.4 "Process validation and/or Evaluation" of the Part II document.)

Answer No. 1

PRH are required to follow the ASEAN PV requirements.

Question No. 2

What type of validation data is required for the 1 pilot batch in option 2?

Answer No. 2

The content of the validation data that is required for this 1 pilot batch can refer to the point no. 6 of the ASEAN Guideline on Submission Of Manufacturing Process Validation Data For Drug Registration which is the content of validation report.

Question No. 3

What are the expectations regarding the process validation of a pilot batch?

Answer No. 3

We expect that the data of the pilot scale batches are the data predictive of the production scale product. It may be necessary to further develop and optimise the manufacturing process using pilot scale batches. Therefore, the pilot batch should provides the link between process development and industrial production of product.

Question No. 4

If the drug product is not an orphan drug, but is a very slow moving drug (for example - one production batch per year), is it possible to apply for concurrent validation and concurrent batch by batch approval? In this case, what are the expectations of the concurrent process validation report?

Answer No. 4

Applicant should seek prior consent from DRA first before submitting the application to register any drug product that uses concurrent validation approach. Usually, categories of drugs for which have short lives (e.g. radiopharmaceuticals) and that are medically necessary (e.g. drug used to prevent or treat serious or life-threatening disease or medical condition, for which there is no other available source with sufficient supply of that drug or alternative drug available) may be considered on case by case basis.

Thank You!