June 23, 2016

Seminar Question Sheet (Quiz)

Please read the following statement and write your answer (○ = Correct Statement and × = False Statement) on your answer sheet.

Q1 : Premises and equipment must be designed, constructed, adapted, and maintained to suit the operations. ✓

Q2 : Repair and maintenance operations are not related to validation. Therefore, no need for re-validation. ✗

Q3 : In a closed system, it is not having to worry about the environment conditions. ✗

Q4 : Steps should be taken in order to prevent the entry of unauthorised people. ✓

Q5 : Dedicated and self-contained facilities must be available for the production of particular medicinal product, such as highly sensitizing materials (e.g. penicillin) or biological preparations (e.g. from live micro-organisms). ✓

Q6 : There is no problem to have process room not in a logical order, since it is not required by GMP. ✗

Q7 : Where starting and primary packaging materials, intermediate or bulk products are exposed to the environment, interior surfaces (walls, floors, and ceilings) should be smooth, free from cracks and open joints, and should not shed particulate matter and should permit easy and effective cleaning and, if necessary, disinfection. ✓

Q8 : Drain should not be installed in the grade-B room. ✓

Q9 : Weighing of starting materials usually should be carried out in a separate weighing room designed for that use. ✓

Q10 : In the area where dust is generated, local ventilation and airlock (AL) shall be created in order to avoid leakage from the process room. ✗ ✓

Q11 : The provisions for mix-ups or cross-contamination are not necessary in the secondary packing of the packing facilities. X

Q12 : For visual inspection, lighting validation is required. ✓

Q13 : Bigger space is necessary to store separately of materials and products, such as in quarantine, released, rejected, returned or recalled. So, to reduce space, any kinds of materials is better to be put together in one place (no separation). X

Q14 : Temperature monitoring point in the storage areas, shall be placed where the administrator can see easily. X

Q15 : No need to pay attention to the weather if the materials are sealed. X

Q16 : Sampling, where contamination doesn't affect to the test items, can be carried out at anywhere (any places). X

Q17 : Segregated areas should not be required for the storage of rejected, recalled or returned material or products if there is an indication. X

Q18 : Printed carton and insert document (instruction sheet), which describes the product name and lot number, have to be stored in the locked place. ✓

Q19 : The toilets are placed next to the process room and storage room, so that the employees can be accessed easily. X

Q20 : There are only two primary types of documentation used to manage and record GMP compliance: site master file and instructions (directions, requirements). X

record

Q21 : Documents containing instructions should be approved, signed and dated by appropriate and authorised persons. ✓

Q22 : Since the contents of the documents is the important one, the documents layout and style (imperative mandatory style or not) can be ignored. X

Q23 : Records should not be handwritten. X

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Q24 : Handwritten entries should be made in clear, legible, indelible way. The thermal paper, which the character may disappear with time is excluded. X

Q25 : Specific requirements apply to batch documentation which must be kept for three years after expiry of the batch to which it relates or at least ten years after certification of the batch by the Authorised Person, whichever is the longer. X

End of Quiz.