Questionnaire of GPFI seminar
21-Apr-16
Hotel Bidakara, Jakarta

PT. CMPlus Consulting Indonesia
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| No | Question | | CMP Answer |
|---|---|---|---|
| | Bahasa Indonesia | English | English |
| 1 | Apakah semua personel yang bekerja di area produksi/QC harus dikualifikasi? Jika perlu, bagaimana cara menentukan personel tersebut terkualifikasi? | Are all personnel who working in production/QC area need to qualified? How to identify those personnels are qualified or not? | All personnels shall receive the necessary training and they shall be qualified. Manufacturers should define necesarry skill and knowledge for each position and technical field, and qualify indivisuals through their training history and job experiences (OJT). |
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| 2 | Salah satu dasar konsep GMP adalah meminimalkan cross contamination. Bagaimana jika personel flow menuju area produksi tidak uni-directional? | One of the basic concept of GMP is to minimize cross contamination. How about the personnel flow to production area that not uni-directional? | Cross-contamination through operators' clothes, shoes, etc. can be prevented by one-way personnel flow, and necessity of one-way depends on material feature (e.g. highly potent / sensitizing / toxic) and process operation (e.g. powder |
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| 3 | Apakah setiap sampling room harus memiliku sampling booth? | Does all sampling room must have a sampling booth? | Sampling booth is not always necessary when cleanliness of the room is equivalent to production area. However, local exhaust ventilation is recommended to prevent material spreading in the room. |
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| 4 | Bahan pembersih/hand soap harus dikualifikasi oleh QC. Bagaimana standar kualifikasinya? | Detergent/hand soap shall qualified by QC. What the qualification standard? | Safety should be considered, but common qualification standards are not available. Residual detergent should be evaluated when used for product contact surface (see PIC/S GMP Annex 15, 10.6). |
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| 5 | Terkait training personel (operator, staff, dll), bagaimana cara membuat matrix kebutuhan training? | How to make a matrix for training needs for personnel training (operator, staff, etc)? | Expected capability and required training differ depending on position and technical field of personnel. For example, conceptual skill is important for seneor management; wide technical knowledge is important for managers; specific technical skill is important for operators. |
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| 6 | Bagaimana dengan contoh MBR yang baik? Apakah perlu mencantumkan detail? | How to make a good MBR? It is necessary to describe in details? | Insufficient description may cause operators' human error, and too much description will result in huge batch records which are difficult to be reviewed. Contents, expressions and layout of MBR should be operator-friendly and also reviewer-friendly. See PIC/S GMP Part I, 4.1-4.6 and 4.17-4.19. |
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| 7 | Secara organisasi, apakah IPC berada dibawah QA atau QC? | In a organization chart, whether IPC under QA or QC? | Routine sampling and testing are performed by QC personnel or Production personnel trained and qualified by QC/QA. Such procedures should be reviewed and approved by QA. In addition, QC and QA activities may be included in a combined quality unit according to size of organization. |

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| 8 | | Should Quality Risk Management be applied only for deviation control? | QRM is a concept that any decisions on quality, including deviation control, should be made according to risk-based scientific consideration. Be careful that QRM is not limited to statistical procedures but also include use of informal processes (see, ICH Q9, Chapter 1, last paragraph), and such informal processes are useful as well (see, ICH Q9, Chapter 5, 2nd paragraph). |
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| 9 | | Can production personnel perform IPC testing when the test result is used for product release? | If the test item is included in Marketing Authorization, the test should be performed by QC personnel. However, samples for such test may be taken by production personnel (trained and qualified by QC/QA) when such procedure is documented. |
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| 10 | (Additional question after seminar) | Sampling and dispensing of raw materials that will be used for sterile product (terminal sterilization), should it be done in clean room? Or can it be done under dispensing booth with D-class environment surrounding? | A booth in Grade D room is acceptable unless high risk of contamination is concerned. See PIC/S GMP Annex 1, paragraphs 17 and 28-30. |