g) Is the recall system periodically challenged by mock (dry run) recalls?
Yes ☐ No ☐

### *4.4 Training*

Do you have approved individual job descriptions for your personnel?
Yes ☐ No ☐

Do you have an up to date signature/initial list? Yes ☐ No ☐

Do you have a training concept and program described in a SOP?
Yes ☐ No ☐

Do you have GMP introduction training records for new personnel?
Yes ☐ No ☐

Do you have complete document training files for GMP, SOP and Analytical Method training for your personnel?

Yes ☐ No ☐

Do you perform periodic GMP training (GMP refresher) on GMP trends?

Yes ☐ No ☐

Do you perform periodically specific technical training e.g. new analytical techniques?

Yes ☐ No ☐

### *4.5 Change control*

a) Are all proposed changes to manufacture, packaging, testing and distribution being assessed following a change control procedure before implementation?
Yes ☐ No ☐

b) Is the Quality Assurance Department involved in approving all changes that may have an impact on validation, qualification, process, product or regulatory commitments in the Drug Master File or any other regulatory dossier?
Yes ☐ No ☐

### *4.6 Cleaning validation and Cross contamination Risk*

a) Do you manufacture in your facility or in your near neighborhood any Steroid, Cytotoxic, Antibiotic, Chephlosporin, Penicillin or Semi Synthetic Penicillin?
Yes ☐ No ☐

If yes, please provide full evidence that there is no product(s) of interest contamination risk. You may also attach further documents to the questionnaire.

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b) Have all your cleaning procedures for the equipment used for the product(s) of interest been validated?
Yes ☐ No ☐