Procedure: Annual Review of Drug Products

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# Purpose

The purpose of this procedure is to specify the requirements for annual Product Quality Reviews of defined products manufactured at [Company], against the Guide to Good Manufacturing Practice for Medicinal Products (PE 009-11) (PIC/S) .

# Scope

The scope of this procedure includes annual Product Quality Reviews for all licensed medicinal products (including export-only products).

# Responsibilities

Amend to reflect company structure.

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Manager  or delegate | Performs the assessment  Produces a review report  Ensures all actions are tracked, documented and completed in a timely manner |
| Quality Manager | Approves the final review report |
| Managing Director and executive management | Reviews Annual Product Quality Review as part of the Management Review process |
| Department Managers | Provide input and information for the review  Approve reviews as required |

# Procedure

## General requirements

It is a requirement that all medicinal products be assessed for continued compliance with the original approved specifications. Regular periodic quality reviews of all licensed medicinal products, including export only products, are conducted with the objective of verifying the consistency of the existing process, the appropriateness of current specifications for both starting materials and finished product to highlight any trends and to identify product and process improvements.

## Frequency

Product Quality Reviews are conducted annually and take into account previous reviews to assess product and process robustness over time.

Each review is evaluated and assessed with respect to need (or otherwise) for corrective and preventative actions, re-validation, etc. and clear actions are documented in the review to this end.

Each product quality review must be conducted within three (3) months of the completion of the review period for each product/process to identify and address any current issues in a timely manner.

[It is good practice to track product reviews, review dates, grouping, etc in an annual product quality review register (MS Excel is acceptable). Reviews should be conducted within a pre-defined time of the completion of the review period and this should be documented and controlled to ensure reviews are conducted in a timely manner. Three months is suggested as an industry guide but should align with company policy].

## Product grouping criteria

Allowance is given for the grouping of reviews by product type (e.g. solid dose, sterile, etc.) where scientifically justified. Justification for specific product grouping must be assessed, documented and approved by appropriate staff and the Quality Manager and filed with the product annual review documentation.

**Important:** Each individual licensed product must be reviewed and assessed fully, even when part of a grouped report.

## Annual product review

Reviews, as a minimum, must consider the following:

* A review of starting materials including packaging materials used in the product, especially those from new sources
* A review of critical in-process controls and finished product results
* A review of all batches that failed to meet established specification(s) and their investigation outcome
* A review of all significant deviations or non-conformances, their related investigations, and the effectiveness of resultant corrective and preventative actions taken
* A review of all changes carried out to the processes or analytical methods
* A review of Marketing Authorisation variations submitted/granted/ refused, including those for third country (export only) dossiers
* A review of the results of the stability monitoring programme and any adverse trends
* A review of all quality-related returns, complaints and recalls and the investigations performed at the time
* A review of adequacy of any other previous product process or equipment corrective actions
* For new marketing authorisations and variations to marketing authorisations, a review of post-marketing commitments
* The qualification status of relevant equipment and utilities, e.g. HVAC, water, compressed gases, etc.
* A review of any contractual arrangements to ensure that they are up to date

Ensure that appropriate subject matter experts from different aspects of the product manufacture are consulted during the review.

Maintain a list all the products on the annual product quality review. For each of these products, complete the review checklist in **Appendix 1 – Annual product quality review checklist** and document accordingly.

## Review documentation

Document the results of the reviews for each product in a report which includes the collation of the information collected from the checklist provided in **Appendix 1**.

In addition to the requirements specified in Section 4.4, include in the report the:

* product name and code
* pack size(s) / formats
* specifications
* review period
* date review is completed and report finalised
* next review required by
* conclusions
* actions

The annual product quality review should be documented by the Quality function with input from other departments as required (e.g. Laboratory, Production, Regulatory, etc.). The report is reviewed by relevant department managers and the Quality Manager with conclusions as to the suitability of the product for continued sale and actions to be taken, if any, to rectify any issues raised. All conclusions as to the suitability of the product are to be addressed individually and appropriate actions taken or the reason for no action documented. The report is to be filed and retained for a minimum of two years after expiry of the current product under test.

Complete records of the annual product quality review and associated qualification specifications/requirements must be documented and maintained as a controlled record.

Appendices

# Appendix 1: Annual product quality review checklist

|  |  |
| --- | --- |
|  | Use the checklist below to facilitate the product quality review: |
|  | Review each batch of all raw materials used for the product, including packing materials, to ensure they meet specification. |
|  | Perform an assessment of results of critical in-process checks and finished product results. Where quantitative data is available, perform statistical analysis to measure process capability and robustness. |
|  | Report all batches failing to meet specifications and the results of the investigations. |
|  | Review batch records for the year’s production and identify any trends. |
|  | List revisions of batch instructions used during the year and assess for adequacy. |
|  | Review any retest results, determine any trending or potential underlying issues. |
|  | Assess and trend the yield results for the product. |
|  | Confirm that there is a current MSDS for the product and that all storage, processing and handling is completed in an appropriate manner for the compound. |
|  | Review any deviations or non-conformances for the product, summarise related investigations and report on the effectiveness of corrective and/or preventative actions. Determine the status of any resolutions. |
|  | Review all the analytical methods used in determining quality of raw materials, primary packaging, in-process and final release testing. Report on any changes to analytical methods. |
|  | Determine if there are any known problems, issues, or changes made to the methods of manufacture, packing or testing by discussing with appropriate staff (for example, manufacturing, packing and QC personnel). |
|  | List all the change controls associated with the product, process or equipment in the review period and the current status of individual change controls. |
|  | Review and report on all Marketing Authorisation variations (if applicable). |
|  | Review stability data for the product and assess the results for the range of process parameters; perform a trend analysis of these results for ease of assessment and report on any adverse trends. |
|  | Confirm that the storage conditions used and monitored for the product are correct and as specified. |
|  | List and review all quality-related returns, complaints and recalls and their respective investigations. |
|  | Review all corrective actions for the product, process or equipment for adequacy. |
|  | Review any post-marketing commitments for new marketing authorisations and/or variations. |
|  | Review and report on the qualification status of relevant process equipment and services/utilities. |
|  | Review any contractual arrangements for currency. |

[Consider converting this checklist into a form to be completed for each product quality review. If using a form in this manner, ensure that it is filed as part of the annual product review documentation.]

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

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| Revision | Modified by | Change Control No. | Description of Change |
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| Associated forms and procedures | |
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| Doc. No. | Document Title |
| PE 009-11 | PIC/S Guide to Good Manufacturing Practice for Medicinal Products |
|  |  |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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