

# Standard Operating Procedure

**Title:** Product Quality Reviews for Contract Manufactured Products

<b>Department</b>	<b>Quality Management</b>	<b>Document no</b>	<b>QMS-170</b>
<b>Title:</b> Product Quality Reviews for Contract Manufactured Products			
Prepared by:		Date:	
Checked by:		Date:	
Approved by:		Date:	

## 1.0 DOCUMENT OWNER

Technical/Quality Manager

## 2.0 PURPOSE

The purpose of this procedure is to describe a process for the preparation, review and approval of Product Quality Reviews (PQR) for products that are the responsibility of Contract Operations Management of Quality Assurance Team.

## 3.0 SCOPE

This procedure applies to products manufactured or packaged by a contract manufacturer managed by Contract Operations - [Quality Assurance](#).

## 4.0 RESPONSIBILITY \ BUSINESS RULES

4.1 It is the responsibility of the contract manufacturer to either:

4.1.1 Provide PQR report/s as per agreed PQR schedule, Or

4.1.2 Provide data as per Quality Agreement to enable PQR to be prepared.

4.2 It is the responsibility of the QA Officer or delegate to ensure that:

4.2.1 The PQR schedule is prepared based on [approved Quality Agreements](#).

4.2.2 PQRs for contract manufactured or packed products are completed in compliance with the established PQR schedule.

4.2.3 The contract manufacturer generated PQR, including conclusions and recommendations, are reviewed, where available.

4.2.4 An Sponsor site PQR report is generated, where applicable.

4.2.5 A PQR executive summary is compiled for both Sponsor site and contract manufacturer PQR reports and submitted to monthly Site Quality Team meetings for review.

4.2.6 An action plan to address recommendations is established and progress is tracked.

4.2.7 The completed PQR and executive summary is forwarded to Key Site Principals for approval.

4.3 It is the responsibility of the Site Quality Team and/or Key Site Principals to:

4.3.3 Review the PQR executive summary and recommendations.

4.3.4 Make or endorse recommendations, if necessary, for preventative or corrective actions that would lead to product quality improvements.

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5.4.2 Identify any significant trends in regard to the type of complaint and the batch number

## 5.5 Market Actions and Recalls

5.5.1 Record and review any recalls or market actions for the product initiated during the review period.

5.5.2 Summarise the reason for recall, extent of recall (batch numbers and area recovered from), percentage of units retrieved and the current status of the product recall.

## 5.6 Deviations

5.6.1 Summarise any manufacturing, packaging or analytical (including stability) deviation reports, which were raised by the contractor.

5.6.2 Summarise any Sponsor site deviations raised in relation to any contractor activities.

5.6.3 Identify any trends or repeating issues, which may require corrective actions to eliminate reoccurrence.

## 5.7 Out-of-specification (OOS)

5.7.1 Summarise any significant OOS results obtained during QC testing for both release and stability testing, if available.

5.7.2 Identify any trends or repeating issues, which may require corrective actions to eliminate reoccurrence.

## 5.8 QC Data and Statistical Analysis

5.8.1 Record the chemical analytical data for the finished product in a tabular or graphical format.

5.8.2 Evaluate the data against the registered specifications. Identify and investigate any adverse trends in the data during the review period.

5.8.3 Statistical analysis is to be conducted on the finished product data for the API assays and any other critical parameters using Minitab (a statistical software program).

5.8.4 The normality plot, Individual Value-Moving Range (I-MR) charts and process capability analysis should be applied where possible. Process Capability analysis can only be applied when both the data is normally distributed and in a state of control.

5.8.5 Review microbial data against the release and/or registered specifications for compliance.

5.8.6 Review the raw material (API) QC data for those materials supplied by Gmp Australia to the relevant contractor for manufacture of Gmp products.

## 5.9 Stability Data

5.9.1 Summarise all ongoing stability studies initiated and conducted during the review period by either the [contract manufacturer](#) or Sponsor site's QC laboratories. This responsibility is outlined in the relevant Quality Agreement.

5.9.2 Summarise all evaluation stability studies initiated and conducted during the review period and identify the reason for the evaluation study.