ChecklistGuro

Pharmaceutical Annual Product Review (APR) Checklist

Commercial Data Review

Assessment of sales, market trends, and competitive landscape.

Total Sales Revenue (USD)

Enter a number...

Units Sold

Enter a number...

Market Share (%)

Enter a number...

Primary Market Segment

- [ ] Hospital
- [ ] Pharmacy
- [ ] Direct to Patient
- [ ] Wholesale

Last Sales Data Update Date

Enter date...

Summary of Market Trends

Write something...

Quality Performance Evaluation

Review of quality metrics, including deviations, CAPAs, and complaints.

Total Number of Deviations

Enter a number...

Number of CAPAs Opened

Enter a number...

Number of Customer Complaints Received

Enter a number...

Overall Quality System Rating (e.g., Excellent, Good, Needs Improvement)

- [ ] Excellent
- [ ] Good
- [ ] Needs Improvement
- [ ] Unsatisfactory

Last Internal Audit Date

Enter date...

Summary of Significant Quality Trends

Write something...

Were there any critical deviations? (Yes/No)

- [ ] Yes
- [ ] No

Supporting Documentation (e.g., Deviation Reports, Audit Findings)

Upload File

Stability Data Analysis

Evaluation of ongoing stability data to confirm product expiry dates and storage conditions.

Review Date

Enter date...

Batch Number

Enter a number...

Temperature (°C)

Enter a number...

Humidity (%)

Enter a number...

Stability Protocol Followed

- [ ] ICH Q1A
- [ ] Company Specific
- [ ] Other

Visual Inspection Results (Scale 1-5, 1=Excellent, 5=Unacceptable)

Enter a number...

Detailed Observations & Comments

Write something...

Attached Stability Data Reports

Upload File

Manufacturing Process Review

Assessment of manufacturing processes, including efficiency, yield, and quality control.

Overall Yield (%)

Enter a number...

Process Efficiency (%)

Enter a number...

Description of any Process Deviations

Write something...

Equipment Performance Rating (Excellent, Good, Fair, Poor)

- [ ] Excellent
- [ ] Good
- [ ] Fair
- [ ] Poor

Date of Last Equipment Maintenance

Enter date...

Attachment: Process Validation Report (if applicable)

Upload File

Summary of Improvements Implemented This Year

Write something...

Regulatory Compliance Update

Verification of adherence to current regulatory requirements and identification of potential changes.

Last Regulatory Inspection Date

Enter date...

Applicable Regulatory Frameworks (e.g., cGMP, EU GMP)

- [ ] cGMP (US FDA)
- [ ] EU GMP
- [ ] ICH Guidelines
- [ ] Other (Specify in LONG_TEXT)

Summary of Regulatory Updates (new guidelines, interpretations)

Write something...

Number of Significant Regulatory Changes Identified

Enter a number...

Status of Outstanding Regulatory Actions (if any)

- [ ] Open
- [ ] Closed
- [ ] In Progress

Supporting Documentation (e.g., inspection reports, regulatory correspondence)

Upload File

Product Labeling and Packaging Review

Assessment of labeling accuracy, compliance, and packaging integrity.

Labeling Revision Status

- [ ] Original
- [ ] Revised
- [ ] Pending Revision

Primary Label Revision Date

Write something...

Labeling Change Justification

Write something...

Current Primary Label Image

Upload File

Packaging Material Compliance

- [ ] Compliant
- [ ] Non-Compliant
- [ ] Pending Assessment

Tamper-Evident Features Verification (Quantity)

Enter a number...

Packaging Defects Observed (if any)

Write something...

Next Labeling Review Date

Enter date...

Risk Assessment & Mitigation

Identification of potential risks associated with the product and evaluation of existing mitigation strategies.

Identify Potential Risks

Write something...

Risk Priority Score (1-10)

Enter a number...

Risk Category (e.g., Quality, Manufacturing, Regulatory)

- [ ] Quality
- [ ] Manufacturing
- [ ] Regulatory
- [ ] Supply Chain
- [ ] Commercial

Existing Mitigation Strategies

Write something...

Severity Assessment (Select all that apply)

- [ ] Minor
- [ ] Moderate
- [ ] Major
- [ ] Critical

Proposed Additional Mitigation Actions (if needed)

Write something...

Implementation Date of New Mitigation Actions

Enter date...

Reviewer Signature

Post-Market Surveillance Data

Review of adverse event reports and other post-market surveillance data.

Number of Adverse Event Reports Received

Enter a number...

Summary of Significant Adverse Event Trends

Write something...

Review of Periodic Safety Update Reports (PSURs)

- [ ] Completed & Reviewed
- [ ] In Progress
- [ ] Not Applicable

Supporting Documentation (e.g., Trend Analysis Reports)

Upload File

Date of Last PSUR Submission

Enter date...

Signal Detection Activities Performed

- [ ] Literature Review
- [ ] Database Analysis
- [ ] Spontaneous Reporting Analysis
- [ ] Automated Signal Detection

Lifecycle Management Considerations

Discussion of potential product enhancements, line extensions, or discontinuation plans.

Potential Product Enhancements (Formulation, Dosage Form)

Write something...

Potential Line Extensions (New Indications, Patient Populations)

- [ ] New Therapeutic Indication
- [ ] Expanded Patient Population
- [ ] Combination Product
- [ ] Pediatric Formulation

Estimated Market Size for Line Extension (Units/Year)

Enter a number...

Target Date for Line Extension Launch (if applicable)

Enter date...

Potential Product Discontinuation (if applicable)

- [ ] No Discontinuation Planned
- [ ] Discontinuation Considered

Justification for Discontinuation (if applicable)

Write something...

Impact Assessment (if product discontinued)

- [ ] Minimal Impact
- [ ] Moderate Impact
- [ ] Significant Impact

Summary and Recommendations

Consolidation of findings and suggestions for future actions.

Overall Summary of APR Findings

Write something...

Proposed Budget Increase/Decrease (%)

Enter a number...

Date of Next Review

Enter date...

Recommended Actions (select all that apply)

- [ ] Process Optimization
- [ ] Stability Testing Expansion
- [ ] Labeling Update
- [ ] Regulatory Consultation
- [ ] Further Investigation

Responsible Party for Action Implementation

Write something...

Reviewer Signature