وزارة الصحة
Ministry of Health

DSC
مركز سلامة الدواء
Drug Safety Center

Guideline on Backlog Management at the Drug Safety Center

Drug Safety Center

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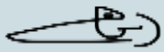
Signature		**Signature**	
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- Ph. Safiya Al Aghbari
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- Ph. Asia Al Bulushi
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Acronyms:

DSC	Drug Safety Center
MAH	Marketing Authorization Holder
ADR	Adverse Drug Reaction
MOH	Ministry of Health
QASM	Quality Assurance and Safety Management Section

Definitions

Backlog	The term backlog is used to indicate work pending beyond standard turnaround time.
Backlog Logbook	A standardized departmental register where all backlog items are logged, tracked, updated, and monitored until resolution.
Escalation	The process of referring unresolved backlogs to higher levels of authority for resolution.
Logging	Documenting backlog items in a centralized system
Tracking	Monitoring backlog items using specific performance indicators
Reporting	Summarizing and presenting backlog data for review and decision-making.

CHAPTER ONE

Introduction

Effective backlog management is fundamental to DSC operations. By addressing backlogs proactively, departments and sections can minimize delays, maintain regulatory compliance, and ensure quality. Each department and section should develop and implement SOPs aligned with this guideline.

Purpose

The purpose of this guideline is to establish a transparent and systematic framework for backlog management across DSC's departments and sections.

Scope

This guideline applies to all DSC departments and sections. It covers every operational activity within the scope of DSC functions.

Each department and section are required to prepare its own SOP on backlog management, adapting the procedures of this guideline to the specific nature of its operations.

Structure

This is the first version of this guideline and is organized into four chapters. CHAPTER ONE covers the Introduction, Purpose, Scope, and Structure. CHAPTER TWO outlines the detailed procedures and methods. CHAPTER THREE defines responsibilities in relation to this guideline. CHAPTER FOUR includes the document history and version control table, references, and the Annex.

CHAPTER TWO

Procedure

2.1 Identifying Backlogs

The DSC Departments and sections are required to review their operational tasks regularly to identify items exceeding agreed timelines. Potential backlogs may be detected through daily operations, audits, or performance reviews. Once identified, the backlog must be recorded immediately in the Backlog Logbook.

2.2 Logging Backlogs

All backlog items must be entered into the Backlog Logbook within five working days of identification. The logbook records essential details such as Task ID, Task Description, Responsible Person, Original Due Date, Reason for Delay, and Current Status. The logbook provides a single reference point for monitoring all outstanding items.

2.3 Prioritization of Backlogs

Backlog entries in the logbook shall be prioritized using the standardized Backlog Prioritization Matrix. Departments shall rank tasks according to public health risk, regulatory deadlines, and resource availability. Prioritization must be reflected directly in the logbook, ensuring transparency and consistency.

2.4 Tracking Backlogs

The Backlog Logbook must be updated monthly to reflect progress, completion, or escalation.

2.5 Backlogs Escalations

Backlogs that remain unresolved beyond 30 working days must be clearly flagged in the logbook and escalated to the department or section head, with notification to the QASM Section.

2.6 Reporting

The Backlog Logbook serves as the source document for all backlog reporting. Departments and sections must submit updated logbooks to the QASM Section biannually.

The QASM Section will consolidate these into a central DSC dashboard, prepare compliance reports, and conduct trend analysis. Recurring issues detected through logbooks will be subject to root cause analysis and corrective action.

CHAPTER THREE

Responsibilities

Department and Section Staff	Record backlog items in the logbook, update entries and provide accurate information for reporting.
Department Directors and Section Heads	Ensure proper use of the Backlog Logbook within their unit and review escalated cases.
QASM Section	Maintaining oversight of all departmental logbooks, verify completeness and accuracy of entries, consolidate data into central dashboards, and prepare quarterly reports for senior management. Also, conducting audits and ensuring corrective actions are implemented.
DG-DSC	Provide strategic oversight, ensure adequate resourcing, and support enforcement of backlog management processes across the Center.

CHAPTER FOUR

Document History and Version Control Table

Version	Description	Review Date
1	**Initial Release**	**October 2025**
2		
3		

References

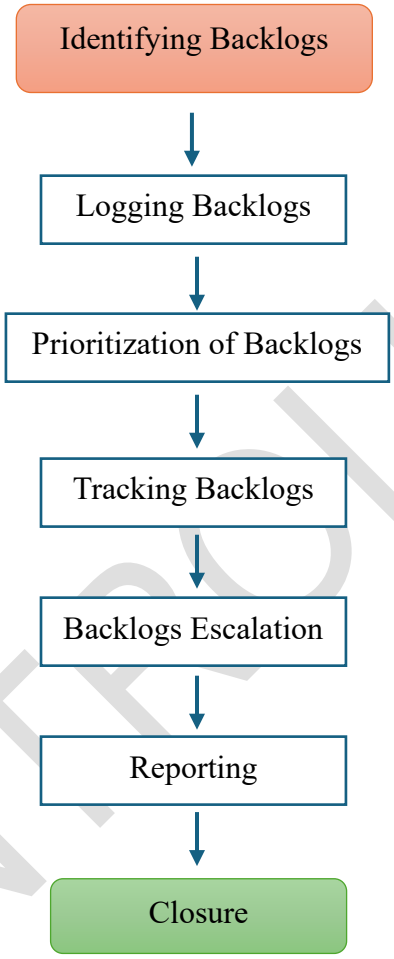
International Council for Harmonization (ICH) (2020) *Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management*.

International Organization for Standardization (ISO) (2015) *ISO 9001:2015 – Quality Management Systems – Requirements*. Geneva: ISO.

USAID PQM+ and MTaPS Programs (2021) *Strengthening Pharmaceutical Systems*. U.S. Agency for International Development.

Annex

Appendix 1: Backlog Process Flow Chart



Appendix 2: Backlog Logbook Excel Contents

Sheet: Instructions

How to use the workbook (steps, submission).

- Explains data entry on Backlog Logbook (A–N).
- Reminds to use dropdowns and avoid editing calculated fields.
- Explains monthly submission to QASM.

Sheet: Backlog Logbook

Primary data-entry table (columns A–N) used for QA consolidation.

- Headers (A–N): Task ID, Department/Section, Task Type, Task Description, Responsible Person, Original Due Date, Revised Due Date, Backlog Reason, Date Logged, Logged By, Current Status, Priority Level, Overdue, Completion Date.
- Validations: Department/Section, Task Type, Reason, Status (Pending/In Progress/Completed), Priority (High/Medium/Low).
- Dates: dd-mm-yyyy for Original/Revised Due, Date Logged, Completion Date.
- Overdue (Yes/No) auto-calculated from due date(s) and status.
- Conditional formatting colors for Status, Priority, and Overdue.

Sheet: Prioritization Matrix

Optional scoring to inform Priority (High/Medium/Low).

- Task ID dropdown sourced from Backlog Logbook column A.
- Enter Risk, Deadline, Resources (1–5).
- Weights in I2:I4; Weighted Total auto-calculated.
- Suggested Priority derived from weighted total.

Sheet: Dashboard

Simple KPIs pulled from the Backlog Logbook.

- Shows counts: Total Backlogs, Completed, Pending, Overdue.
- No manual data entry in this sheet.

Sheet: Lists

Dropdown sources for Department/Section, Task Type, Backlog Reason, Status, and Priority.

Appendix 3: DSC Central Backlog Dashboard Contents

Sheet: **Instructions** — how to paste-append A:N each month and use the dashboard filter.

Sheet: **Lists** — Departments and filter list (includes 'All Departments').

Sheet: **Consolidated Logbooks** — paste departmental A:N data here; helper columns O:Q compute Effective Due Date, Age (days), Resolution Days.

Sheet: **Dashboard** — KPIs (Total, Completed, In Progress, Pending, Overdue), SLA %, Avg Resolution Time; Department filter (E2).

Data Input Structure (Consolidated Logbooks)

Field (A–N)	Notes
A Task ID	Unique; no duplicates.
B Department/Section	Owning unit.
C Task Type	Category of work.
D Task Description	Concise outcome-oriented description.
E Responsible Person	Named owner.
F Original Due Date	dd-mm-yyyy.
G Revised Due Date	dd-mm-yyyy (if re-baselined).
H Backlog Reason	Standard taxonomy.
I Date Logged	dd-mm-yyyy.
J Logged By	Name.
K Current Status	Pending / In Progress / Completed.
L Priority Level	High / Medium / Low.
M Overdue	Yes/No; calculated in departmental BLb (may be pasted as value).
N Completion Date	dd-mm-yyyy (when completed).

Appendix 4: Examples of Backlogs Prioritization for the DSC Departments

Department	Primary Focus	Backlog Prioritization
Pharmaceutical Licensing Department	Licensing and inspection to ensure compliance with practice laws.	1. Pharmaceutical establishment licensing backlogs for urgent/expired cases. 2. Registration/licensing of pharmacists and assistants. 3. Inspection reports and compliance follow-ups for flagged establishments.
Drug Control Department	Regulation of medicines and controlled substances	1. Controlled medicines approvals and monitoring. 2. Registration of new and renewing medicines. 3. 4. Customs clearance for imported medicines. .
Central Quality Control Laboratory	Quality assurance and drug analysis.	1. Analysis of registration samples for market entry. 2. Testing of imported medicine critical to public health. 3. Quality complaints and recalls requiring analysis. 4. Routine surveillance testing.
Pharmacovigilance and Drug Information Department	Post-marketing surveillance and ADR reporting.	1. Serious ADR reports. 2. Medication error reports with safety impacts. 3. High-risk product safety reports (e.g., PSURs, RMPs). 4. Quality Defects Reports
Medical Devices Control Department	Registration, adverse event management, and compliance monitoring.	1. Adverse event reports for medical devices. 2. Registration of high-demand or critical devices. 3. Issuance and follow-up of Field Safety Notices. 4. Monitoring flagged manufacturers for compliance. 5. Routine evaluations for low-risk devices.

This is an example table to ensures clarity in prioritizing tasks within each department based on urgency, risk, and regulatory importance.