Submitted on behalf of Shire Pharmaceuticals Limited
Witness Name: S. O'Reilly
Statement No.: WITN2989001
Dated: 4 September 2019

INFECTED BLOOD INQUIRY

EXHIBIT WITN2989006 TO WRITTEN STATEMENT OF SUSAN O'REILLY

1.0 Purpose

The purpose of this document is to describe the Baxter Quality Management System (QMS) requirements for US Supply Chain record retention and storage.

2.0 Scope and Applicability

This document applies to all US Supply Chain employees.

3.0 Associated Documents

Parent

CQP0202001	Document and Record Management Requirements

Reference

DDM002	Management of Archived Records
Corporate Record Retention Guideline & Schedule	http://corporate.inbaxter.com/law/recordmgmt/htdocs/record_policy_schedules.html
CQP0302003	Supplier Lifecycle Management Process
GLOSSARY	Baxter's Glossary

4.0 Definitions

See Baxter GLOSSARY

5.0 Responsibility

5.1 Management Personnel is responsible for the following:

- Identifying personnel responsible for record retention and ensuring proper training is completed.
- Maintaining overall responsibility for compliance with the requirements described in this document.
- Ensuring procedure is effective and sustainable.

5.2 US Supply Chain Personnel who generate records are responsible for the following:

- Ensuring that record retention activities and the resulting data and documentation are compliant with this document.
- Suspending or preventing record destruction when notified by the Baxter Law Department of the need for legal holds on records.

6.0 General Requirements for Quality and Business Records

All Records shall remain legible, readily identifiable, and retrievable.

Retention times shall be maintained based upon the document content, regardless of record type (i.e. paper, electronic).

Year one of the record retention period begins in the next calendar year from the year in which the record was created.

Example: A record created on April 5, 2013 with a two year retention period would be retained until January 1, 2016.

If record storage space is not available then records can be sent to off-site storage facility. Refer to the following documents for instructions:

US Supply Chain: Refer to DDM002, Management of Archived Records

Off-site storage suppliers must be approved per CQP0302003.

Records stored off site must be maintained in secure storage facilities that provide a suitable environment to prevent loss and minimize deterioration and damage.

7.0 Procedure - Business Records

Business Records should be maintained in accordance with CQP0202001, Appendix A (below), or in accordance with specific department retention procedures.

8.0 Procedure – Quality Records

Quality Records shall be established and maintained to provide evidence of conformity to requirements and the effective operation of the Quality Management System. These records shall be maintained in accordance with CQP0202001 or Appendix A.

8.1 Identification, Collection, and Tracking

All Quality Records shall be identified and processed in a manner which controls tracking and allows for efficient retrieval.

Quality Records shall be submitted to or collected by the appropriate personnel to ensure records are complete and accurate. They shall be indexed or tracked in an orderly manner to facilitate control, retrieval, and disposition.

Indefinite retention periods are to be considered only when there is no governing regulation that defines the record retention period. Records assigned an indefinite retention period must be reviewed at regular intervals to evaluate potential for record destruction.

8.2 Filing / Access

Quality Records shall be protected against unauthorized changes, deletion, alteration, access and use and shall remain legible and readily identifiable. They shall be:

- Filed and maintained in secure and controlled locations to restrict access to unauthorized personnel.

  Example: Store in a locked metal file cabinet with keys only available to authorized personnel.

- Stored in a location that provides a suitable environment to prevent loss and minimize deterioration and damage.

  Example: Store in a metal file cabinet in a building with fire protection.

- Electronic records must be maintained within a validated system that requires a user name and login to access in order to protect against unauthorized changes, deletion, alteration, access and use.

Quality Records shall be retained for the required retention time identified in Appendix A.

Access to record storage areas must be controlled and restricted to authorized personnel.

8.3 Destruction

Records shall **not** be destroyed when the following situations exist:

- Legal holds for the records are in effect
- Document has not met the retention period guidelines
- Known investigations regarding the records have not been concluded
- Regulations or laws are known to have become effective that establish longer retention periods than established by the Retention Schedule
- Retention period is established as indefinite
- Business requirements which dictate longer requirements

See CQP0202001, Document and Record Management Requirement for additional information.

Timing of record destruction is based on the record retention period.

Paper records must be shredded, pulped, or disposed of in any other manner in such a way as to maintain Baxter's confidentiality.

Destruction of electronic records must result in the record no longer being available for general access.

Records are not required to be destroyed on the exact date that destruction is due but should be destroyed based on a regular review after their specified destruction date.

In the event records are covered by more than one time period, the records shall be retained for the longer period of time.

Review and destruction of records should be completed on an annual basis.

8.3.1 Paper Record Destruction

Paper records shall be shredded, pulped, or disposed of in any other environmentally sound manner in such a way as to maintain Baxter's confidentiality. All known copies of paper records shall be destroyed along with the original.

Any vendor providing this service must shred paper records.

8.3.2 Electronic Record Destruction

Electronic records scheduled for destruction shall be permanently destroyed along with known copies.

9.0 Records on Legal Hold

A legal hold is a notification by the Legal Department that all records, non-records (copies, duplicates), e-mails, and data that could be relevant to a legal action or anticipated legal action must be retained by staff until further notice by the Legal Department.

During this time, all destruction activities for the impacted records are suspended until notice by the Legal Department.

When the legal hold has been removed, records will continue to follow their applicable retention requirements.

Appendix A - US Supply Chain Quality Record Retention Requirements

SEE PARENT CQP0202001, DOCUMENT AND RECORD MANAGEMENT REQUIREMENTS, FOR ALL RETENTION REQUIREMENTS NOT INCLUDED BELOW.

Record	Retention Period (Applies to all entities/functions unless approved local procedure is used)	Reference
Advertising and Marketing		
Competitor Information Records	Two (2) years	US Supply Chain Practice
Corrective and Preventive Action (CAPA) Records		
CAPA Review Board (CRB) Rosters/Meeting Minutes	No less than 5 years from date of meeting.	US Supply Chain Practice
General Quality System Records		
Siebel Down Time Forms	2 years	US Supply Chain Practice
Pedigree Documents	3 years	Florida State Regulations 21 CFR § 203.60
General Records	2 years	US Supply Chain Practice
Patient Records/Pharmacy		
Patient Prescriptions	10 years from the date of prescription expiration	FDA
Temporary Prescription Change Request Authorization Form	10 years	Board of Pharmacy
Patient Medication Disease Profiles	10 years	Board of Pharmacy
Drug Utilization Reviews	10 years	Board of Pharmacy
Patient Consultations	10 years	Board of Pharmacy
Daily Dispensing Logs	10 years	Board of Pharmacy
Regulatory Affairs & Pharmacovigilance		
Risk Evaluation and Mitigation Strategy (REMS) Extraneal PD Solution Records	2 years after record initiation	US Supply Chain Practice

CHANGE INFORMATION			
DCR/CP Number:	CP0906474	**Local Change Request Number:**	☒ N/A

Description of Change

Administrative change released on 11-JAN-2017.
UPDATED REFERENCE DOCUMENT FROM 1188239 TO DDM002

Original changes were made on CP0813517, issued on 18-NOV-2015. Those changes were as follows:
REMOVED ALL INFORMATION INCLUDED IN PARENT DOCUMENT, AND ONLY INCLUDED ADDITIONAL REQUIREMENTS APPLICABLE TO US SUPPLY CHAIN RECORDS.

Reason for Change

Administrative change released on 11-JAN-2017.
DOCUMENT 1188239 HAS BECOME OBSOLETE.

Original changes were made on CP0813517, issued on 18-NOV-2015. Those changes were as follows:
TO ENSURE INFORMATION STAYS CURRENT AND IS EASY TO FIND

Change Category:	☐ Major	☒ Administrative	
Additional Information for Document User:			☒ N/A
Training:	☐ Required	☒ Not Required	☐ N/A

APPROVALS			
Document Owner/SME:	Gregory, Erica	**Quality Approver:**	Gladwell, Christine
		Processor:	Markovics, Rita

HISTORY

Revision	DCR/CP Number	Issue Date	Local Change Request Number	Reason for Change
C	CP0813517	18-NOV-2015	N/A	TO ENSURE INFORMATION STAYS CURRENT AND IS EASY TO FIND
B	CP0616197	27-SEP-2013	N/A	ALL CHANGES MADE TO BETTER ALIGN WITH PARENT DOC CQP0202001
A	CP0574988	09-APR-2013	N/A	Document created to support US Supply Chain's implementation of 1QSys

(REF. CHGHIST) Issue Date: 06-DEC-2013

Document Status: Issued and Effective