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

INFECTED BLOOD INQUIRY

EXHIBIT WITN2989004 TO WRITTEN STATEMENT OF SUSAN O'REILLY

1.0 Purpose

This document describes the Baxter Quality Management System (QMS) requirements for quality document control, safeguarding restricted/highly restricted information, good documentation practices (GDP) and record retention.

2.0 Scope and Applicability

This document applies to Entities, Functions, Regions and personnel that perform or support QMS related activities.

3.0 Associated Documents

3.1 Parent

CQM02 Data and Documentation Management

3.2 Related

CP-IP-04 Global Information Classification and Trade Secret Policy

EudraLex – The Rules Governing Medicinal Products in the European Union, Volume 4, Good Manufacturing Practice – Medicinal Products for Human and Veterinary Use, Annex 11: Computerized Systems

21 Code of Federal Regulations (CFR) Part 11 Electronic Records; Electronic Signatures

4.0 Definitions

Baxter Practice: Baxter defined standard that is not related to a Regulation or Industry Standard.

Data: Information derived or obtained from raw data (e.g., reported analytical result), including metadata (e.g., date, time and other information about the data).

Document: A version controlled document that establishes a requirement or process, which can be superseded or made obsolete.

Electronic signature: Consists of a compilation of computer symbols that represent a person's handwritten signature. An electronic signature must be unique to one individual and must not be used by or reassigned to anyone else.

Legal Hold: A notification issued by Baxter's Legal Department as a result of current or anticipated litigation, audit, government investigation or other matter that suspends normal disposition or processing of records.

Metadata: System related attributes associated with a document or record (e.g. Document Title, Number, Owner Code, etc.).

Raw Data: Original records and documents, retained in the format in which they were originally generated.

Record: A record provides objective evidence from a point in time for requirements or processes, which are not version-controlled and cannot be made obsolete until dispositioned per retention policy.

Redaction: To obscure or remove sensitive information from a document prior to distribution.

When Not In Use (Safeguarding Restricted/Highly Restricted Information): The period of time excluding an employee's working hours.

For additional definitions see the GLOSSARY *(Baxter's Glossary)*.

5.0 Responsibility

Role	Responsibility
Management	• Ensure compliance with the requirements described in this document. • Ensure timely completion of periodic review. • Assume document ownership or establish new owners, as necessary. • Identify personnel responsible for record retention activities. • Ensure record retention activities are completed and data and documentation from these activities are compliant with this document. • Ensure record destruction is suspended or prevented when informed by Baxter Legal of a legal hold on records. • Establish procedures, when needed, to describe GDP concepts not described in this document including, but not limited to calculations, time recording, data transcription, damaged data handling, and records and unit of measure.
Baxter Regular and Non-Baxter Temporary and Contract Employees	• Comply with the requirements described in this document. • Ensure the legibility, traceability, credibility and validity of data, information, signatures and dates within the records.
Owner	Create, revise or obsolesce the document, related documents (e.g. forms) and complete Periodic Review.
Change Initiator	Collaborate with the owner to create new documents and revise or obsolesce existing documents.
Reviewer / Approver	Review recommended document and/or changes and any supporting data for accuracy, technical validity, and compliance with procedural requirements for area of expertise.

Role	Responsibility
Approver	Review recommended document and/or changes and any supporting data for accuracy, technical validity, and compliance with procedural requirements and then approve or reject the change for area of responsibility and expertise.
Document Change Management Function	Establish and maintain procedures to control document changes and manage record retention activities.

6.0 General Requirements

6.1 Good Documentation Practices (GDP)

- Records must be created in accordance with good documentation practices:
  - — Records must be clear and legible.
  - — Data and observations must be entered as they occur – not before or delayed.
  - — Temporary documentation of data to later transcribe is not allowed.
  - — Records must not be pre-dated or post-dated.
  - — Handwritten entries must be created in indelible ink; the use of pencil is not allowed.
  - — Use of another person's initials, signature or equivalent (e.g., stamp) is not allowed and considered falsification.
  - — All fields must be completed in a form. If appropriate, a field can be marked as not applicable (NA). When further entry is not required or there are controlled decision steps (e.g., checkboxes), sections or fields can be left blank.
  - — Forms must be used as-is whereas templates can be modified for the intended use.
  - — Ditto marks and arrows must not be used to document process steps, raw data, test results or signatures.
  - — All entries must be verified as complete and correct.
  - — Pages must be numbered in a format that ensures the record is complete.
  - — Dates must include month, day, and year.
  - — If an error is made or detected on a record, it must be corrected in such a way that the original entry is not lost (normally by drawing a single line through the incorrect entry) and the correction must be signed and dated by the person making the correction. If appropriate, the reason for the correction must be recorded, signed and dated.
- Falsification of data or records is not allowed.
- Original data must not be obliterated by use of any means (i.e., ink, pen, marker, or correction fluid). If redacting for legal or clinical purposes, a copy must be used.
- An individual must only sign for work he/she completes or for which he/she is authorized to sign.

- Delegation authorization is allowed with signed approval to any qualified individual who is able to perform the function being delegated.
- Corrections must be made by the individual that made the original entry. Exceptions are allowed when information used to correct the document was retrieved from an approved document or record.
- If changes or corrections are made to data that required verification by a second person, the change or correction must be re-verified.
- If changes are made after approvals, the data and/or record must be re-approved.
- If missing data is not retrievable from objective evidence, a non-conformance must be initiated.
- In conditions where only two (2) approval signatures are necessary on a record, the same person cannot give both signatures.
- Signatures or initials must include the current date and allow for identification of the individual(s) that signs the record.
- Paper signed records including raw data as applicable can be transmitted without the need to retain the original record, if the electronic record is stored in a secure format (i.e., PDF) in a validated system.
- In the case where a stamp is used as a signature, controls must be in place to ensure the stamp is unique to the individual and is protected from use by others.
- Electronic signatures

  Electronic records and electronic signatures must be validated and controlled according to the requirements of 21 Code of Federal Regulations (CFR) Part 11, EudraLex Vol 4 Annex 11, and local legal requirements, as applicable.

  When an individual uses an assigned electronic signature in a computerized system, they understand and accept the following conditions related to electronic signature usage:

  — The electronic signature that has been assigned to them is the legally binding equivalent of their handwritten signature.

  — They shall not transmit nor disclose their electronic signature and associated password to another person.

  — They shall not use the electronic signature of another person.

  — Misuse of electronic signatures is considered falsification of records.
- Calculations performed using non-validated software must be verified.
- Calculations must follow significant figure and rounding rules.

- Significant Figures

  Significant Figures, also known as Significant Digits, must be considered significant if any of the following exists:

  — In a given number, each non-zero digit is significant.

  — When a zero (0) marks the quantity in the position in which it stands, it is significant. If a zero (0) is used only to designate a decimal place, it is not significant.

  — For multiple operations, the number of significant figures must be calculated in the same order as the operations: first operations inside parentheses, then multiplication and division and last, addition and subtraction.

- Rounding

  When rounding rules are described by a country pharmacopeia, the country pharmacopeia rules must be followed or use the rounding requirements identified below:

  — When a number is compared to a procedure limit, the specified number of decimal places must be rounded before judging pass or fail.

  — Rounding must take place at the end of the mathematical operation which is the final answer, not intermediate results.

  — Data generated from an instrument must not be rounded if the value will be used in a calculation.

6.2 Quality Document Control

- **Document Elements:**

  — Document identification must minimally include a document title and a unique identification number or designation, and be readily identifiable and legible.

  — All documents must have an owner.

  — The document must include an applicable confidentiality statement per CP-IP-04.

  — Printed copies of documents must show the effective date.

- **Document Review/Changes:**

  — Periodic review must be completed every three (3) years on minimally Standard Operating Procedure (SOP), Manual, and Procedural Specification type documents.

  — A document change must be supported by: the description of change, reason for change and as necessary product related change information.

  — A document change due to an audit observation must be traceable to the audit observation response.

  — If documents are translated, content must not be changed with the exception of language-related differences. The translated document must reference the original document.

— A document change that impacts requirements or processes within another document must be coordinated for issuance and effectivity.

— A document change is administrative when there is no change to document content, intent, requirement, numerical formula, specification, process, regulatory requirement, material or design change or document obsolescence.

— Administrative changes can be used for, but are not limited to, the following types of changes:

  - Metadata
  - Format, spelling, grammar, typographical errors
  - Removal of obsolete references
  - Document processing errors
  - Updating regulation references
  - Document owner

— Administrative changes do not require training and must be approved by Quality at a minimum and

— Quality system documents must be reviewed and approved before issuance by, at a minimum, Quality and the same function or organization that performed the original review and approval of the document.

— Appropriate time must be allowed for training on new and revised documents.

- **Document Effectivity:**

  — The document owner must determine the effectivity date.

  — Quality procedures with global or multi-site applicability cannot be issued and effective on the same or next day (e.g., zero or one day effectivity).

  — An entity or function cannot be removed from distribution of a document without approval of the entity or function to be removed.

  — If an entity does not implement a quality procedure with global applicability by the effective date, a non-conformance must be opened to document and address the late implementation.

  — Effective revisions of documents must be available for use at all designated locations.

  — Superseded or obsolete printed documents must be removed from all points of use or otherwise controlled to prevent unintended or unauthorized use and must be marked or indicated as superseded or obsolete.

6.3 Safeguarding Restricted/Highly Restricted Information

NOTE: Refer to CP-IP-04 for additional details on classification and protection of information.

- Electronic information must be protected by appropriate access controls based on the sensitivity of the information.

- Paper or other hard copy information must be physically secured when not in use (see Definitions section for definition of 'when not in use').

6.4 Record Retention

NOTE: Non-quality record retention information can be found on Baxter Legal Record Management Intranet Site.

- Records must be established and retained to demonstrate adherence to requirements and procedures.
- Procedures must be established to ensure the following controls are implemented:
  - — Records have a person or a department responsible for Record Management.
  - — Records are correctly identified, traceable, indexed, stored and are quickly accessible for retrieval and disposition as needed.
  - — Records are protected from change, damage, loss and unauthorized access during storage.
  - — Suppliers used for off-site storage must be approved.
    - Records must be retained minimally for the periods listed in Appendixes to this document.
    - Records that have more than one retention time frame must be kept for the longest time frame.
    - Records must not be assigned an indefinite retention period if a regulatory requirement exists for the record category.
    - Official records must not be destroyed before the end of the retention period or while under legal hold.
    - When a record is available in a validated electronic system and the electronic record is verified to be complete and accurate, the electronic record is considered the official record. In all other cases the physical record is the official record.
    - Records must be destroyed in such a way that maintains Baxter's confidentiality. Electronic records must no longer be available for general use.
    - Objective evidence must be available for record destruction.

Appendix A

Document / Record Types	Device	Biologic	Therapeutic / Drug	Reference
483 Certification	**All Entities/Functions/Regions:** • 3 years after the completion of the last corrective action.			Baxter Practice
Advertising and Marketing (e.g. product information bulletins, advertising, promotional materials)	Retirement + 1 year **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			Europe Exception: Medical Device: MDD 93/42/EEC
Annual Product Review	**All Entities/Functions/Regions:** 1 year after the expiry date of the batch to which it relates or at least 5 years after certification of the batch by the Qualified Person, whichever is the longer. For APIs with retest dates, records should be retained for at least 3 years after the batch is completely distributed			21 CFR Part 211.80(a)&(b) Eudralex 4-4.11 ICH Q7
Audits* - Internal Audit Plans, Audit Reports, Responses including extension requests	**All Entities/Functions/Regions:** Whichever is longer: --Subsequent audit verified all Corrective Actions CAs implemented or --Issue date + 4 years **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			Baxter Practice Europe Exception: Medical Device: MDD 93/42/EEC
Audits* - All other internal audit documentation including auditor notes	**All Entities/Functions/Regions:** • Until issuance of the Audit Completion Notice			
Audits* - Internal Audit Schedule and amendment, audit completion notices	**All Entities/Functions/Regions:** • 10 Years after Audit Completion Notice **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			
Audits - External	**All Entities/Functions/Regions:** • Not less than 4 years or until next assessment/inspection, whichever occurs earlier. **Exceptions:** • Baxter medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			
Records related to Biologics*: such as Blood Components=RBCs, plasma, etc.	N/A	**All Entities/Functions/Regions:** Whichever is longer: --manufacturing records complete + 5 years OR --latest exp date of individual product + 6 months	N/A	21 CFR Part 606.160(d)
Records related to Biologics*: such as Plasma services / Donor Information (e.g. donor files, rejection files, collection, processing, testing)	N/A	**All Entities/Functions/Regions** 34 years from record creation **Exception:** EU: 30 years from record creation	N/A	Baxter Practice Europe Exception: EU Directive 2005/61/EC
Records related to Biologics: such as Donor Center Inspection and Correspondence Files	N/A	Whichever comes first: -- Completion of next assessment OR -- 3 years from record creation	N/A	Baxter Practice

An asterisk (*) indicates Japan Requirements exceptions are outlined in Appendix B.

Appendix A

Document / Record Types	Device	Biologic	Therapeutic / Drug	Reference
Calibration Records*	Retirement + longest shelf life of affected products **Exception:** Australia - Whichever is longer: -Lifetime of device (LOD) or -Last date of manufacture + 5 years Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			Medical Device: 21 CFR Part 820.180 Australia: Australian Regulatory Guidelines for Medical Devices (ARGMD) Biologic: 21 CFR Part 600.12(b) Drug / Therapeutic: 21 CFR Part 211.180(a)&(b) Europe Exception: Medical Device: MDD 93/42/EEC
CAPA* Records including Gambro Nonconformance Records (NCR's) / Deviation	Closure Date + 10 years **Exception:** • Baxter Medical Devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			Baxter Practice Europe Exception: Medical Device: MDD 93/42/EEC
Certificate of Compliance (CoC) and/or Certificate of Implementation (CoI) Records	**All Entities/Functions/Regions:** • Closure of COC and COI records + 1 year minimum.			Baxter Practice
Complaints*	**All Entities/ Functions/Regions:** Whichever is longer: --Lifetime of Product (LOP) + 2 years or --Date of report + 2 years. **Exceptions:** Medical Device Reports (MDRs) must be maintained for the time period above even when the device is no longer distributed. Europe - A period ending at least 5 years after the last product has been manufactured. A period ending at least 15 years after the last product has been manufactured for implantable devices. Australia - Whichever is longer: -Lifetime of device or -Last date of manufacture + 5 years	**All Entities/Functions/Regions:** Whichever is longer: --Expiration (EXP) + 1 year or -- Receipt of complaint + 1 year		Medical Device: 21 CFR Part 803.18(d)&(e) MDR Exception: 21 CFR Part 803.18(d)&(e) Europe Exception: MDD 93/42/EEC Australia: Australian Regulatory Guidelines for Medical Devices (ARGMD) Therapeutic/Drug/Biologic: 21 CFR Part 803.18(d)&(e)

An asterisk (*) indicates Japan Requirements exceptions are outlined in Appendix B.

Appendix A

Document / Record Types	Device	Biologic	Therapeutic / Drug	Reference
Correction and Removal and Product Holds*	**All Entities/ Functions/Regions:** Report date + 2 years and beyond expected LOP **Exceptions:** Europe - 5 years, for implantable devices, after Last product manufacturing Date + 15 years	Whichever is longer: --Date Of Manufacture (DOM) + 5 years OR --EXP for individual product + 1 year OR --last batch product produced + 1 year	Whichever is longer: --ROM complete + 5yrs or --EXP + 1 year	Medical Device: 21 CFR Part 806.20 Europe Exception: MDD 93/42/ECC Biologic: 21 CFR Part 600.12 Drug / Therapeutic: 21 CFR Part 211.180(a)&(b)
Design Control Records*/ Design History Files (DHF)	**All Entities/ Functions/Regions:** Design and Lifetime of Product (LOP), at least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured Implantable devices - last product manufactured date + 15 years For medical devices containing human blood derivatives, follow the respective requirements **Exceptions:** If recalled - date of last product removed + 15 years End Of Life - 1.) If the active or passive device uses a proprietary disposable, the design documentation and other quality documentation can be destroyed 15 years after disposable lifetime. 2.) If the product uses standard disposables the design documentation can be destroyed at whichever is the longest period of time: 15 years after End of Life communication or the published expected life of the product is met.	**All Entities/ Functions/Regions:** Whichever is longer: --Manufacturing records complete + 5 years OR --latest exp date of individual product + 6 months **Exceptions:** Europe: Donation time + 30 years for plasma derived product. A link from donation/donor to finished product should be maintained for at least 30 years. France: EXP + 40 years	**All Entities/ Functions/Regions:** Design and lifetime of product **Exceptions:** Plasma or blood derived meds sold in EU: Donation time + 30 years Compounded product: EXP + 5 years France blood derived product: EXP + 40 years	Medical Device: MDD 93/42/EEC Related : 21 CFR Part 820.180(b) and ISO13485 Product Recall and EOL: ISO13485 4.2.4, CMDR Section 55, CFR 820.180(b), and Japan 2004 Ministerial Ordinance No. 169 Article 72 Biologics: 21 CFR Part 600.12(b) EU Directive 2002/98/EC EMA/CHMP/BWP/-706271/2010 French Public Health Code Articles R.5121-195 Therapeutics / Drugs: 21 CFR Part 211.180(a)&(b), C.02.021 European Exceptions: EMA/CHMP/BWP/-706271/2010 France Exception: French Public Health Code Articles R.5121-195 Canada Exception: Canadian Regulation C.02.022 to C.01A.003

An asterisk (*) indicates Japan Requirements exceptions are outlined in Appendix B.

Appendix A

Document / Record Types	Device	Biologic	Therapeutic / Drug	Reference
Device History Record (DHR) / Batch Records*	**All Entities/ Functions/Regions:** Design and Lifetime of Product (LOP), but in no case less than 2 years from the date of release for commercial distribution by the manufacturer. Implantable devices – last product manufacturing date + 15 years **Exceptions:** If recalled - date of last product removed + 20 years EOL - LOP + 20 years	**All Entities/ Functions/Regions:** Whichever is longer: --manufacturing records complete + 5 years OR --latest exp date of individual product + 6 months **Exceptions:** Europe: Donation time + 30 years for plasma derived product France: EXP + 40 years	**All Entities/ Functions/Regions:** EXP + 1 year **Exceptions:** European Products: Whichever is longer: --EXP + 1 year or 5 years Plasma or blood derived meds sold in EU: Donation time + 30 years Compounded product: EXP + 5 years France blood derived product: EXP + 40 years Canada Admixture Batch Records: EXP + 1 year	All Facilities/Regions: CFR Part 211.180(a) & (b) CFR Part 820.180(b) Canadian Regulation C.02.021 Exceptions: Europe: EMA/CHMP/BWP/706271 /2010 France: French Public Health Code Articles R.5121-195 Canada: Canadian Regulation C.02.022 to C.01A.003
Management Review Records*	Not less than 5 years **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			21 CFR Part 820.181 Europe Exception: Medical Device: MDD 93/42/EEC
Non-Batch Related Records*: room cleaning records, facility maintenance	Date of record creation + 5 years **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			Baxter Practice Europe Exception: Medical Device: MDD 93/42/EEC

An asterisk (*) indicates Japan Requirements exceptions are outlined in Appendix B.

Appendix A

Document / Record Types	Device	Biologic	Therapeutic / Drug	Reference
Non-clinical Laboratory Studies, Policies, and Procedures*	**All Entities/Functions/Regions:** • Minimum of 2 years following the date on which an application for a research or marketing permit, in support of which the results of the nonclinical laboratory study were submitted, is approved by the FDA. **Exception:** This requirement does not apply to studies supporting investigational new drug applications (IND's) or applications for investigational device exemptions (IDE's). • Minimum 5 years following the date on which results of the nonclinical laboratory study are submitted to the FDA in support of an application for a research or marketing permit. • Minimum 2 years where the nonclinical laboratory study does not result in the submission of the study in support of an application for a research or marketing permit to the FDA is completed, terminated, or discontinued. • Wet specimens (except those obtained from mutagenicity tests and wet specimens of blood, urine, feces and biological fluids), samples of test and control articles and specially prepared material, which are relatively fragile and differ markedly in stability and quality during storage shall be retained only as long as the quality of the preparation affords evaluation.			21 CFR Part 312.57 21 CFR Part 58.195(b)(2)&(c) Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with (TGA) Therapeutic Goods Administration comments
Non-product related policies and procedures - Quality System Policy and Procedures, Document Change Control	Document obsolescence + 5 years **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			Baxter Practice Europe Exception: Medical Device: MDD 93/42/EEC
Pharmacovigilance Records*	N/A	**All Entities/ Functions/Regions:** New Drugs, not part of an approved application **Drugs, submitted for FDA approval Biologics** 10 years **Exceptions:** Canada - Date of creation + 25 years Europe - --Product related Marketing authorization existence + 30 years --System related, system authorization master file existence + 10 years Change for japan: • Special Biological Products: 30 years • Biological Products: 10 years • All other: 5 years	**All Entities/ Functions/Regions:** 10 years for records and reports concerning adverse drug events on marketed prescription drugs for human use without approved new drug applications. **Exceptions:** Canada - Date of creation + 25 years Europe - --Product related Marketing authorization existence + 30 years --System related, system authorization master file existence + 10 years	Therapeutic / Drug: 21 CFR Part 310.305(f) 21 CFR Part 314.80(c) 21 CFR Part 600.80(i) Canada Exception: Canadian Regulation C.01.017 to C.01.019 Europe Exception: European Regulation
Product Distribution Records	Whichever is longer: - Distribution + 5 years - Product expiration date + 2 years **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			Baxter Practice Europe Exception: Medical Device: MDD 93/42/EEC

An asterisk (*) indicates Japan Requirements exceptions are outlined in Appendix B.

Appendix A

Document / Record Types	Device	Biologic	Therapeutic / Drug	Reference
Product Related Procedures and Specifications*	Design and expected Lifetime of Device (LOD), but in no case less than 2 years from date of release for commercial distribution. **Exception:** Europe: manufactured and or distributed - -Date of last product manufacture + 5 years -implantable devices - Date of last manufacture + 15 years	Whichever is longer: -Release of Material (ROM) complete + 5 years -Over the counter drug - distribution of last lot + 3 years **Exception:** - Europe: Donation time + 30 years for plasma derived product. A link from donation/donor to finished product should be maintained for at least 30 years. France: EXP + 40 years	Whichever is longer: -Release of Material (ROM) complete + 5 years - Latest EXP of last batch produced + 1 year -Over the counter drug - distribution of last lot + 3 years **Exception:** - Plasma or blood derived meds sold in EU: Donation time + 30 years	Medical Device: 21 CFR Part 820.180(b) ISO 13485 Europe Exception: MDD 93/42/EEC Biologic/Therapeutic/Drug : 21 CFR Part 211.180 (a) & (b) EMA/CHMP/BWP 706271/2010 Europe Exception: European Exceptions: EMA/CHMP/BWP/-706271/2010
Regulatory: Device and Drug Establishment Registrations, Submissions, Correspondence, Device and Drug Listings, Decision Strategies	Whichever is longer: - LOP + 10 years - 30 years			Baxter Practice
Regulatory: Federal and State Licenses	US Requirement: -EXP + 4 years			Baxter Practice
Regulatory: FDA User Fee Documentation	N/A	US Requirement: - Date of payment of particular user fee + 5 years		Baxter Practice
Regulatory Labeling: Company Core Data Sheets, Company Core Safety Information	**All Entities/Functions/Regions:** Prior to archival or destruction of records a documented risk assessment shall be conducted. The risk assessment shall assess: • Whether expiration has occurred for the last manufactured lot of product affected • Whether market withdrawal is complete • Baxter otherwise has no regulatory responsibility for the product in any market			MHRA Good Pharmacovigilance Practice Guide

An asterisk (*) indicates Japan Requirements exceptions are outlined in Appendix B.

Appendix A

Document / Record Types	Device	Biologic	Therapeutic / Drug	Reference
Regulatory: Product Labeling / Artwork	**Labeling Centers** At minimum, the current product label/artwork and the immediate obsolete version, if one exists. **All Facilities, Functions, or Regions:** • Prior to archiving or destruction of obsolete product labeling/artwork, verify that retention of the label/artwork is not required by regulation in any country in which the product is marketed. **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			Baxter Practice Europe Exception: Medical Device: MDD 93/42/EEC
	Design and Lifetime of Product (LOP), but in no case less than 2 years from the date of release for commercial distribution by the manufacturer. **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured		EXP of last batch + 1 year **Exception:** in the case of certain Over the Counter (OTC) drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, 3 years after distribution of the last lot of drug product incorporating the component or using the container, closure, or labeling.	Medical Device: 21 CFR Part 820.180(b) Biologic/Therapeutic/ Drug: 21 CFR Part 211.180(b) Europe Exception: Medical Device: MDD 93/42/EEC
Research & Development*: Product Development Documentation	Until end of lifetime of product **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			Baxter Practice Europe Exception: Medical Device: MDD 93/42/EEC
Research & Development: Product Research and Development Protocols	Whichever is longer: -EXP of last batch + 1 year -ROM complete + 5 years			Baxter Practice
Research & Development: Non-research and development, Non-product specific laboratory records	5 years			Baxter Practice

Appendix A

Document / Record Types	Device	Biologic	Therapeutic / Drug	Reference
Service Records*	**All Entities/ Functions/Regions:** Design and Lifetime of Product (LOP), but in no case less than 2 years from the date of release for commercial distribution by the manufacturer. **Exception: Europe** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured For medical devices containing human blood derivatives, follow the respective requirements **Exceptions:** If recalled - date of last product removed + 15 years	**All Entities/ Functions/Regions:** Whichever is longer: --Manufacturing records complete + 5 years OR --latest exp date of individual product + 6 months **Exceptions:** Europe: Donation time + 30 years for plasma derived product. A link from donation/donor to finished product should be maintained for at least 30 years. France: EXP + 40 years	N/A	Medical Device: MDD 93/42/EEC Related : 21 CFR Part 820.180(b) and ISO13485

An asterisk (*) indicates Japan Requirements exceptions are outlined in Appendix B.

Appendix A

Document / Record Types	Device	Biologic	Therapeutic / Drug	Reference
Supplier Quality Audits and SCARS*	**All Entities/Functions/Regions:** Whichever is longer: --Subsequent audit verified all Corrective Actions CAs implemented or --Issue date + 4 years **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			Baxter Practice Europe Exception: Medical Device: MDD 93/42/EEC
Supplier Quality Records* (e.g. agreements, purchased goods or services, consulting, lease, etc.)	- Date Supplier is removed from active service list + 5 years -Longer if required by the agreement, Internal Revenue Service or the legal review in other countries than US **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			Baxter Practice Europe Exception: Medical Device: MDD 93/42/EEC
Therapeutics: Microbiological Media Preparation Records	N/A		10 years	Baxter Practice
Training Records	Termination date + 7 years **Exceptions:** • Medical Device Employees: Retain for a period of time equivalent to the design and expected lifetime of the device, but not less than 2 years from date of release for commercial distribution. **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured	Termination date + 7 years	Termination date + 7 years	**Medical Device:** 21 CFR Part 820.180(b) **GLP:** 21 CFR Part 58.195(b) Europe Exception: Medical Device: MDD 93/42/EEC
Training Records - Training Materials: PowerPoint, e-Learning files	**All Entities/Functions/Regions:** • Retain for 5 years after last date of use. **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			Baxter Practice Europe Exception: Medical Device: MDD 93/42/EEC
Validation Records*	**All Entities/Functions/Regions:** • Minimum of 7 yrs. past system decommissioning. (Retention requirements should be assessed based on system intended use/purpose.) **Exception:** • Baxter Medical devices Manufactured and/or Distributed in Europe: At least 5 years, and in the case of implantable devices at least 15 years, after the last product has been manufactured			21 CFR 820.180 ISO 9001 4.2.4 21 CFR 314.80 Europe Exception: Medical Device: MDD 93/42/EEC

An asterisk (*) indicates Japan Requirements exceptions are outlined in Appendix B.

Appendix B

Document / Record Types	Device	Biologic	Therapeutic / Drug	Reference
Japan Records - All types except the following rows	From date of obsolescence for procedure documents, date of creation for all others: 1.) Special Maintenance control medical device or implantable device: 15 years or 1 year after the expiration, whichever is longer 2.) Special Biological medical device product or biological medical device products containing human blood: 30 years after the expiration 3.) Biological medical device products or cell tissue medical device products: 10 years after the expiration 4.) All other medical device products (Control Medical Device and General Medical Device): 5 years or 1 year after the expiration, whichever is longer	From date of obsolescence for procedure documents, date of creation for all others: 1. Special Biological (contains components of human origin or rFVIII) Product or Biological Products containing human blood: 30 years after the expiration 2. Biological Products or cell tissue products: 10 years after the expiration	From date of obsolescence for procedure documents, date of creation for all others: • All other medical drug products than biological or cell tissue products: 5 years or 1 year after the expiration, whichever is longer	Japan MHLW Ordinance See Japan Reference Index for the specific ordinance referenced for record type.
Biological Medical Devices designated by the MHLW Minister	For the period designated by the Minister. Proviso: This provision shall not apply when the records are maintained properly by the biological raw material collectors etc. for the period under the contract closed between the manufacture and the biological raw material collectors etc.	—	—	MHLW Ordinance No.169 Article 79

Appendix B

Document / Record Types	Device	Biologic	Therapeutic / Drug	Reference
Active Pharmaceutical Ingredient (API)	—	From date of obsolescence for procedure documents, date of creation for all others: 1. Special Biological (contains components of human origin or rFVIII) Product or Biological Products containing human blood: 30 years after the expiration 2. Biological Products or cell tissue products: 10 years after the expiration	—	1.) MHLW Ordinance No. 136 Article 16.1.3.1; MHLW Ordinance No. 179 Article 30.1.2 2.) MHLW Ordinance No. 136 Article 16.1.3.2; MHLW Ordinance No. 179 Article 30.1.3 3.) MHLW Ordinance No. 136 Article 16.1.3.3; MHLW Ordinance No. 179 Article 30.1.1
Active Pharmaceutical Ingredient (API) continued		—	From date of obsolescence for procedure documents, date of creation for all others: 1 year after the expiration or 3 years after the date of completion of the release of the lot from the manufacturing site for API for which the date of retesting has been provided and replaced the shelf life.	MHLW Ordinance No. 179 Article 20
Clinical Studies	—	1.) 3 years from marketing approval (or date notification) or, discontinuation or completion of the clinical trial, whichever is longer 2.) 5 years from the date of completion of the re-examination or reevaluation		1.) MHLW Ordinance No. 28, Article 25 2.) MHLW Ordinance No. 28, Article 56
	1.) 3 years from marketing approval (or date notification) or, discontinuation or completion of the clinical trial, whichever is longer 2.) 5 years from the date of completion of the re-examination or reevaluation	—		1.) MHLW Ordinance No. 36, Article 34 2.) MHLW Ordinance No. 36, Article 76
Non-clinical Laboratory Studies	From date of marketing approval: 1.) Evidence for marketing approval application documents: 5 years from Marketing Approval or, until completion of reexamination if required and exceeding 5 years. 2.) Evidence for marketing approval re-examination application documents: 5 years from completion of re-examination except for those set forth under 101.1. 3.) Evidence for marketing approval reevaluation application documents: 5 years from completion of reevaluation except for those set forth under 101.1 and 101.2			1.) Law for Pharmaceuticals, Medical Devices, etc., Enforcement Regulations Article 101.1 2.) Law for Pharmaceuticals, Medical Devices, etc., Enforcement Regulations Article 101.2 3.) Law for Pharmaceuticals, Medical Devices, etc., Enforcement Regulations Article 101.3
Research & Development: Product Development Documentation				

Appendix B

Document / Record Types	Device	Biologic	Therapeutic / Drug	Reference
Post-Marketing Surveillance	1.) Records related to re-examination or re-evaluation:5 years from date of completion of the re-examination or re-evaluation in question. 2.) Records other than those specified in Item 1): 5 years from the last date of use, or from the final entry in the records in question.			1.) MHLW Ordinance No.171, Article 11(1) 2.) MHLW Ordinance No.171, Article 11(2)

Japan Reference Index

Document / Record Types	Reference
Biologics: Blood Components=RBCs, plasma, etc.	1.) MHLW Ordinance No. 136, Article 16.3.1; MHLW Ordinance No. 179 Article 30.2; MHLW Ordinance 169 Article 78.1.1, Article 78.2 2.)MHLW Ordinance No. 136 Article 16.3.2; MHLW Ordinance No. 179 Article 30.3; MHLW Ordinance No. 169 Article 78.1.2, Article 78.2
Biologics*: Plasma services / Donor Information (e.g. donor files, rejection files, collection, processing, testing)	Japan MHLW Ordinance 169, 2004
Complaints	**Medical Device:** 1.) MHLW Ordinance No.169 Article 68.1.1 2.) MHLW Ordinance No.169 Article 78.1.1, 78.2 3.) MHLW Ordinance No.169 Article 78.1.2, 78.2 4.) MHLW Ordinance No.169 Article 68.1.2 **Biologic:** 1.) MHLW Ordinance No. 136 Article 16.1.3.1; MHLW Ordinance No. 179 Article 30.1.2 2.) MHLW Ordinance No. 136 Article 16.1.3.2; MHLW Ordinance No. 179 Article 30.1.3 3.) MHLW Ordinance No. 136 Article 16.1.3.3; MHLW Ordinance No. 179 Article 30.1.1 **Therapeutics:** MHLW Ordinance No. 136 Article 16.1.3.3, MHLW Ordinance No. 179 Article
Audits: --Internal Audit Plans, Audit Reports, Responses including extension requests --All other internal audit documentation including auditor notes --Internal Audit Schedule and amendment, audit completion notices	**Medical Device:** 1.) MHLW Ordinance No.169 Article 68.1.1 2.) MHLW Ordinance No.169 Article 78.1.1, 78.2 3.) MHLW Ordinance No.169 Article 78.1.2, 78.2 4.) MHLW Ordinance No.169 Article 68.1.2 **Biologic:** 1.) MHLW Ordinance No. 136 Article 16.1.3.1; MHLW Ordinance No. 179 Article 30.1.2 2.) MHLW Ordinance No. 136 Article 16.1.3.2; MHLW Ordinance No. 179 Article 30.1.3 3.) MHLW Ordinance No. 136 Article 16.1.3.3; MHLW Ordinance No. 179 Article 30.1.1 **Therapeutics:** MHLW Ordinance No. 136 Article 16.1.3.3, MHLW Ordinance No. 179 Article 20.1.3
CAPA Records including Gambro Nonconformance Records (NCR's) / Deviation	
Non-Batch Related manufacturing Records: room cleaning records, facility maintenance	
Validation Reports	
Calibration Records	**Medical Device:** 1.) MHLW Ordinance No.169 Article 68.1.1 2.) MHLW Ordinance No.169 Article 78.1.1, 78.2 3.) MHLW Ordinance No.169 Article 78.1.2, 78.2 4.) MHLW Ordinance No.169 Article 68.1.2 **Biologic:** 1.) MHLW Ordinance No. 136 Article 16.1.3.1; MHLW Ordinance No. 179 Article 30.1.2 2.) MHLW Ordinance No. 136 Article 16.1.3.2; MHLW Ordinance No. 179 Article 30.1.3 3.) MHLW Ordinance No. 136 Article 16.1.3.3; MHLW Ordinance No. 179 Article 30.1.1 **Therapeutics:** MHLW Ordinance No. 136 Article 16.1.3.3, MHLW Ordinance No. 179 Article 20.1.3
Correction and Removal and Product Holds	
Design Control Records	
Device History Record (DHR) / Batch Records	
Management Review Records	**Medical Device:** 1.) MHLW Ordinance No.169 Article 68.1.1 2.) MHLW Ordinance No.169 Article 78.1.1, 78.2 3.) MHLW Ordinance No.169 Article 78.1.2, 78.2 4.) MHLW Ordinance No.169 Article 68.1.2
Supplier Quality Records: --Audits and SCARS --Agreements, purchased goods or services, consulting, lease, etc.	

Document / Record Types	Reference
Product Related Procedures and Specifications	**Medical Device:** 1.) MHLW Ordinance No.169 Article 67.1 2.) MHLW Ordinance No.169 Article 78.1 3.) MHLW Ordinance No.169 Article 78.2 4.) MHLW Ordinance No.169 Article 67.2 **Biologic:** 1.) MHLW Ordinance No. 136 Article 16.3.1; MHLW Ordinance No. 179 Article 30.2 2.) MHLW Ordinance No. 136 Article 16.3.2; MHLW Ordinance No. 179 Article 30.3 3.) MHLW Ordinance No. 136 Article 16.3.3; MHLW Ordinance No. 179 Article 30.1 **Therapeutics:** MHLW No. 136 Article 16.3.3, MHLW Ordinance No. 179 Article 20.3, 30.1
Service Records	**Medical Device:** 1.) MHLW Ordinance No.169 Article 68.1 2.) MHLW Ordinance No.169 Article 78.1 3.) MHLW Ordinance No.169 Article 78.2 4.) MHLW Ordinance No.169 Article 68.2
Pharmacovigilance Records	1.) MHLW Ordinance No. 135 Article 16.1.2 2.) MHLW Ordinance No.135 Article 16.1.1 3.) MHLW Ordinance No.135 Article 16.1
Regulatory: Product approval holder records for Biological product sales, rental, or transfer	Ordinance for Enforcement of PAL Article 241.1, 241.2

CHANGE INFORMATION			
DCR/CP Number:	CP0777864	**Local Change Request Number:**	☒ N/A

Description of Change

ADD APR RECORD TYPE AND CORRECT VERBIAGE AND/OR TIMEFRAMES AS NEEDED IN APPENDIX A.
ADD 3 REQUIREMENTS FOR JAPAN RETENTION IN APPENDIX B.

Reason for Change

THIS DOCUMENT WAS REFORMATTED TO SUPPORT INTEGRATION ACTIVITIES AND THE GLOBAL QUALITY MANAGEMENT SYSTEM (QMS) SIMPLIFICATION INITIATIVE. ADDITIONALLY, ADDITIONS WERE MADE TO THE RETENTION TABLE TO SUPPORT A REGULATORY COMMITMENT TO TUV AND TO SUPPORT THE HARMONIZATION EFFORTS. RETENTION TABLE CORRECTIONS AND ADDITIONS WERE MADE BASED ON ENTITY FEEDBACK.

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

APPROVALS			
Document Owner/SME:	Bishop, David	**Quality Approver:**	Loeffler, Christine
		Processor:	Bennett, Stacey

HISTORY

Revision	DCR/CP Number	Issue Date	Local Change Request Number	Reason for Change
F	CP0706139	03-OCT-2014	N/A	TO PROVIDE GREATER VISIBILITY TO THE SAFEGUARDING REQUIREMENT AND TO CLARIFY RETENTION REQUIREMENTS.
E	CP0593744	28-JUN-2013	N/A	1. TO PROVIDE CORPORATE DIRECTION ON DOCUMENT AND RECORD CONFIDENTIALITY. 2. DEFINITIONS FOR THESE ITEMS DID NOT HAVE CURRENT DEFINITIONS AVAILABLE. 3. INFORMATION ON NON-QUALITY RECORDS WAS NOT INCLUDED IN PREVIOUS VERSION. 4. FOR EASE OF CUSTOMER USE. RETENTION PERIODS ARE NOW ASSIGNED PER GLOBAL, COUNTRY OR REGULATORY BODY GUIDANCE. 5. TO GIVE CLEAR DIRECTION ON HOW TO MANAGE RECORDS ON LEGAL HOLD. 6. THE RETENTION SCHEDULE WAS ORGANIZED BY BUSINESS FUNCTION OR QUALITY SYSTEM, RECORD TYPE, RETENTION REQUIREMENT AND THE REFERENCE THAT ESTABLISHED THE RETENTION REQUIREMENT. IT ALSO IS SEPARATED BY TYPE OF PRODUCT, MEDICAL DEVICE, THERAPEUTIC OR BIOLOGIC AS TO THE RETENTION PERIOD.
D	CP0437076	12-JUL-2010	N/A	**Administrative change issued on 26-JUL-2011 with CP0437076.**

Document Status: Issued and Effective

				Current Document Owners listed for the documents are no longer with Baxter. **Original changes were made on CP0371031, issued on 12-JUL-2010. Those changes were as follows:** Update format per new requirement. 5.1, 5.2, 6.1 & 6.2 Clarification Section 8.0 added storage requirements Updated the COC to COI to reflect new process.

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