EU GMP – Chapter 4: Documentation	
Versione corrente	**Nuova versione per commenti (emessa 8 aprile 2008)**

Principle	Principle
Good documentation constitutes an essential part of the quality assurance system. Clearly written documentation prevents errors from spoken communication and permits tracing of batch history. Specifications, Manufacturing Formulae and instructions, procedures, and records must be free from errors and available in writing. The legibility of documents is of paramount importance.	Good documentation constitutes an essential part of the quality assurance system. The various types of documents and media used should be fully defined in the manufacturing authorisation holder's Quality Management System (QMS). Documentation may exist in a variety of forms, including paper-based, electronic or photographic media. Clearly prepared documentation can minimise communications errors e.g. from spoken communication.
	There are two primary types of documentation used to manage and record GMP compliance: (a) instructions, (b) records.

	The recording of data in support of development activities, and product manufacture, quality control and distribution rely upon good documentation practices. GMP requires the maintenance of a variety of documents and associated records. Some examples follow: • Data collection, processing, security and storage • Data to support dossiers to competent/regulatory bodies in relation to operations, investigational medicinal products and marketing authorisation applications and ongoing compliance with those dossiers. • Master files (for materials and sites) • Contracts or technical agreements, given and received • Qualification, validation, stability testing, clinical trial and other reports • Change management and controls • Procurement, development, manufacture, testing, inventory and distribution • The delivery of training and the evaluation of its effectiveness • Summary and exception reports from automated systems (e.g. process analytical technology related) • The investigation and reporting of non-conformances • The tracking and trending of changes, non-compliances, complaints, deviations and rejected materials • Process and systems improvements • Audit Reports • Certification for batch release • Pharmacovigilance and adverse reactions
	The accuracy and integrity of documents is a fundamental pre-requisite and a 'document management system'[1] should be in place to ensure that proper controls are implemented over all categories of QMS documents to ensure compliance. Documents such as specifications, manufacturing and packaging formulae and instructions, procedures, and records must be free from errors and available in writing. The legibility, accuracy and integrity of documents are of paramount importance for both internal use and for possible examination by competent authorities.
	To facilitate control, traceability and referencing, each document should carry a unique identification 'label' for title and version. Control measures should be in place to ensure adherence to instructional documents.

General	General
4.1 *Specifications* describe in detail the requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation. *Manufacturing Formulae, Processing and Packaging Instructions* state all the starting materials used and lay down all processing and packaging operations. *Procedures* give directions for performing certain operations e.g. cleaning, clothing, environmental control, sampling, testing, equipment operation.	4.1 The following section provides some examples of typical GMP documentation elements by type, but it is not intended to be an exhaustive list. 4.1(a) **'Instructions' (directions, or requirements) type:** **Specifications** describe in detail the requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation. **Manufacturing Formulae, Processing, Packaging and Testing Instructions** detail all the starting materials, equipment and computerised systems (if any) to be used and specify all processing, packaging sampling and testing instructions. In-process controls, process analytical technologies and metrics to be employed will be specified where relevant, together with acceptance criteria and requirements for summary and exception reports. **Procedures** (otherwise known as Standard Operating Procedures, or SOPs), give directions for performing certain operations e.g. cleaning, garbing, environmental control, sampling, testing, equipment operation. **Protocols** give instructions for performing and recording certain controlled operations. (E.g. supply of Investigational Medicinal Products for clinical trials; validation/ qualification work; on-going stability trials) **Technical Agreements** are agreed between contract givers and acceptors for subcontracted services in relation to requirements under licences or authorisations. They contain details of the particular services to be provided, the main contacts, specifications, methods, reporting arrangements and limits of responsibility for the two parties, inter-alia.
Records provide a history of each batch of product, including its distribution, and also of all other relevant circumstances pertinent to the quality of the final product.	4.1(b) **'Records' type** **Records** provide a historical record of various actions taken to demonstrate compliance with instructions, e.g. activities, events, investigations, reports and in the case of manufactured batches a history of each batch of product, including its distribution. Records are essential to chronicle the quality and disposition of the resulting medicinal product or IMP. Records include the raw data which is used to generate other records. **Certificates of Analysis** provide a summary of testing results on samples of products or materials[2] together with the evaluation for compliance to a stated specification. **Reports** give an account of the conduct of particular exercises, projects or investigations, together with results, conclusions and recommendations.

	All types of document elements should be defined and adhered to. The requirements apply equally to all forms of document media types. For networked systems, **shared files and databases** (with multiple users having 'write' or 'modify' rights), adequate control should be in place that reflect the systems complexity. Change logs and audit trails for the management of documents ensure their integrity and protection from inadvertent or unauthorised changes. For an electronic document management system (EDMS), all forms of electronic documentation system elements have to be defined, including embedded or linked programs (e.g. objects, hyperlinks or macros) and metadata. (See also GMP Annex 11 clause 5). The programmable processes acting upon electronic documentation elements need to be understood, well documented, validated and controlled within a secure information management system. "Programmable processes" are determined not just by the specific application but also by the links, controls, permissions and settings for the totality of the computerised system's functionality.
	Information security management fundamentals are outlined in various Information Technology standards and guidelines[3]. Many documents (instructions and/or records) may exist in hybrid forms, i.e. some elements as electronic and others as paper based. Relationships and control measures for master documents, official copies, data handling and records need to be clearly stated for both hybrid and homogenous systems.
4.2 Documents should be designed, prepared, reviewed and distributed with care. They should comply with the relevant parts of the manufacturing and marketing authorisation dossiers.	4.2 Documents should be designed, prepared, reviewed and distributed with care. They should comply with the relevant parts of Product Specification Files**,** or Manufacturing and Marketing Authorisation dossiers, as appropriate
4.3 Documents should be approved, signed and dated by appropriate and authorised persons.	4.3 Documents should be approved, signed and dated by appropriate and authorised persons. For the use of electronic authorisations or signatures, the precise technologies and controls in place should be documented and validated. Further guidance on these aspects is found in GMP Annex 11.
4.4 Documents should have unambiguous contents; title, nature and purpose should be clearly stated. They should be laid out in an orderly fashion and be easy to check. Reproduced documents should be clear and legible. The reproduction of working documents from master documents must not allow any error to be introduced through the reproduction process.	4.4 Documents should have unambiguous contents; title, nature, purpose and version should be clearly stated. They should be laid out in an orderly fashion and be easy to check. The style and language of documents should fit with their intended use. It is logical for Standard Operating Procedures, Work Instructions and Methods to be written in an imperative mandatory style. It is also important for all related documents to cross-refer to each other. Reproduced documents should be clear and legible. The reproduction of working documents from master documents must not allow any error to be introduced through the reproduction process.

4.5 Documents should be regularly reviewed and kept up-to-date. When a document has been revised, systems should be operated to prevent inadvertent use of superseded documents.	4.5 Documents should be regularly reviewed and kept up-to-date. The issuance, revision, superseding and withdrawal of all documents should be controlled and documented, e.g. in revision histories.
4.6 Documents should not be handwritten; although, where documents require the entry of data, these entries may be made in clear, legible, indelible handwriting. Sufficient space should be provided for such entries.	4.6 Documents should not be hand-written; although, where documents require the entry of data, these entries may be made in clear, legible, indelible handwriting. Sufficient space should be provided for such entries.
4.7 Any alteration made to the entry on a document should be signed and dated; the alteration should permit the reading of the original information. Where appropriate, the reason for the alteration should be recorded.	4.7 Any alteration made to the entry on a document should be signed and dated; the alteration should permit the reading of the original information. Where appropriate, the reason for the alteration should be recorded. Changes made to electronic records should be visible both on-screen and on printouts. It should be possible to view the prior entry as space on a computer screen is limited.
4.8 The records should be made or completed at the time each action is taken and in such a way that all significant activities concerning the manufacture of medicinal products are traceable. They should be retained for at least one year after the expiry date of the finished product.	4.8 Records should be made or completed at the time each action is taken and in such a way that all significant activities concerning the manufacture of medicinal products are traceable. They should be retained for at least one year after the expiry date of the finished product.
4.9 Data may be recorded by electronic data processing systems, photographic or other reliable means, but detailed procedures relating to the system in use should be available and the accuracy of the records should be checked. If documentation is handled by electronic data processing methods, only authorised persons should be able to enter or modify data in the computer and there should be a record of changes and deletions; access should be restricted by passwords or other means and the result of entry of critical data should be independently checked. Batch records electronically stored should be protected by back-up transfer on magnetic tape, microfilm, paper or other means. It is particularly important that the data are readily available throughout the period of retention.	4.9 Data may be processed and recorded by validated, secure, electronic data processing systems, photographic or other reliable means, but detailed procedures relating to the system in use should be available and the accuracy of the records checked. Validated, secure controls must be in place for programmable processes used for documentation applications. For any critical documentation elements (data) handled by electronic data processing methods, only authorised persons should be able to enter or modify such data and there should be an audit trail i.e. a record of changes and deletions, (even at System Administrator level). Access should be restricted by secure identification systems, passwords or other equally effective means. The result of entry of critical data should be independently checked. **A systematic, accurate, secure audit trail is required**. Data and records (e.g. batch records) and other Quality System related documentation elements, electronically stored, should be protected by validated duplication, or back-up and transfer on magnetic tape, disks, microfilm, paper or other validated, secure media to avoid loss or damage of data. Audit trails also need to be maintained for such transfers. It is particularly important that the data are readily available throughout the period of retention. (The current PIC/S document PI011 provides further guidance in these matters.)

	Note: Where a validated process is continuously monitored and controlled, then automatically generated reports may be limited to compliance summaries and exception/ out-of-specification (OOS) data reports as required by specifications derived from process analytical technologies detailed in approved marketing authorisations.
Documents required	**Documents required**
	The following section only gives some examples of required documents. It is not intended to be a complete listing. The manufacturing authorisation holder's quality management system will be expected to detail the complete set, hierarchy and index of all necessary controlled documents to ensure regulatory compliance.
Specifications 4.10 There should be appropriately authorised and dated specifications for starting and packaging materials, and finished products; where appropriate, they should be also available for intermediate or bulk products.	**Specifications** 4.10 There should be appropriately authorised and dated specifications for starting and packaging materials, and finished products; where appropriate, they should be also available for intermediate or bulk products.
Specifications for starting and packaging materials 4.11 Specifications for starting and primary or printed packaging materials should include, if applicable: a) a description of the materials, including: — the designated name and the internal code reference; — the reference, if any, to a pharmacopoeial monograph; — the approved suppliers and, if possible, the original producer of the products; — a specimen of printed materials; b) directions for sampling and testing or reference to procedures; c) qualitative and quantitative requirements with acceptance limits; d) storage conditions and precautions; ***e)*** the maximum period of storage before re-examination.	**Specifications for starting and packaging materials** 4.11 Specifications for starting and primary or printed packaging materials should include, if applicable: a) a description of the materials, including: — the designated name and the internal code reference; — the reference, if any, to a pharmacopoeial monograph; — the approved suppliers and, if possible, the original producer of the products; — a specimen of printed materials; b) directions for sampling and testing or reference to procedures; c) qualitative and quantitative requirements with acceptance limits; d) storage conditions and precautions; **e)** the maximum period of storage before re-examination.
Specifications for intermediate and bulk products 4.12 Specifications for intermediate and bulk products should be available if these are purchased or dispatched, or if data obtained from intermediate products are used for the evaluation of the finished product. The specifications should be similar to specifications for starting materials or for finished products, as appropriate.	**Specifications for intermediate and bulk products** 4.12 Specifications for intermediate and bulk products should be available if these are purchased or dispatched, or if data obtained from intermediate products are used for the evaluation of the finished product. The specifications should be similar to specifications for starting materials or for finished products, as appropriate.

Specifications for finished products 4.13 Specifications for finished products should include: a) the designated name of the product and the code reference where applicable; b) the formula or a reference to; c) a description of the pharmaceutical form and package details; d) directions for sampling and testing or a reference to procedures; e) the qualitative and quantitative requirements, with the acceptance limits; f) the storage conditions and any special handling precautions, where applicable; g) the shelf-life.	**Specifications for finished products** 4.13 Specifications for finished products should include: a) the designated name of the product and the code reference where applicable; b) the formula or a reference to; c) a description of the pharmaceutical form and package details; d) directions for sampling and testing or a reference to procedures; e) the qualitative and quantitative requirements, with the acceptance limits; f) the storage conditions and any special handling precautions, where applicable; g) the shelf-life.
Manufacturing Formula and Processing Instructions	**Manufacturing Formula and Processing Instructions**
Formally authorised Manufacturing Formula and Processing Instructions should exist for each product and batch size to be manufactured. They are often combined in one document.	Formally authorised Manufacturing Formula and Processing Instructions should exist for each product and batch size to be manufactured. They are often combined in one document.
4.14 The Manufacturing Formula should include: a) the name of the product, with a product reference code relating to its specification; b) a description of the pharmaceutical form, strength of the product and batch size; c) a list of all starting materials to be used, with the amount of each, described using the designated name and a reference which is unique to that material; mention should be made of any substance that may disappear in the course of processing; d) a statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable.	4.14 The Manufacturing Formula should include: a) the name of the product, with a product reference code relating to its specification; b) a description of the pharmaceutical form, strength of the product and batch size; c) a list of all starting materials to be used, with the amount of each, described using the designated name and a reference which is unique to that material; mention should be made of any substance that may disappear in the course of processing; d) a statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable.

4.15 The Processing Instructions should include: a) a statement of the processing location and the principal equipment to be used; b) the methods, or reference to the methods, to be used for preparing the critical equipment (e.g. cleaning, assembling, calibrating, sterilising); c) detailed stepwise processing instructions (e.g. checks on materials, pre-treatments, sequence for adding materials, mixing times, temperatures); d) the instructions for any in-process controls with their limits; e) where necessary, the requirements for bulk storage of the products; including the container, labelling and special storage conditions where applicable; f) any special precautions to be observed.	4.15 The Processing Instructions should include: a) a statement of the processing location and the principal equipment to be used; b) the methods, or reference to the methods, to be used for preparing the critical equipment (e.g. cleaning, assembling, calibrating, sterilising); c) detailed stepwise processing instructions (e.g. checks on materials, pre-treatments, sequence for adding materials, mixing times, temperatures); d) the instructions for any in-process controls with their limits; e) where necessary, the requirements for bulk storage of the products; including the container, labelling and special storage conditions where applicable; f) any special precautions to be observed.
Packaging Instructions	**Packaging Instructions**
4.16 There should be formally authorised Packaging Instructions for each product, pack size and type. These should normally include, or have a reference to, the following: a) name of the product; b) description of its pharmaceutical form, and strength where applicable; c) the pack size expressed in terms of the number, weight or volume of the product in the final container; d) a complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types, with the code or reference number relating to the specifications of each packaging material; e) where appropriate, an example or reproduction of the relevant printed packaging materials, and specimens indicating where to apply batch number references, and shelf life of the product; f) special precautions to be observed, including a careful examination of the area and equipment in order to ascertain the line clearance before operations begin; g) a description of the packaging operation, including any significant subsidiary operations, and equipment to be used; h) details of in-process controls with instructions for sampling and acceptance limits.	4.16 There should be formally authorised Packaging Instructions for each product, pack size and type. These should normally include, or have a reference to, the following: a) name of the product; b) description of its pharmaceutical form, and strength where applicable; c) the pack size expressed in terms of the number, weight or volume of the product in the final container; d) a complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types, with the code or reference number relating to the specifications of each packaging material; e) where appropriate, an example or reproduction of the relevant printed packaging materials, and specimens indicating where to apply batch number references, and shelf life of the product; f) special precautions to be observed, including a careful examination of the area and equipment in order to ascertain the line clearance before operations begin; g) a description of the packaging operation, including any significant subsidiary operations, and equipment to be used; **h)** details of in-process controls with instructions for sampling and acceptance limits.

Batch Processing Records	Batch Processing Records
4.17 A Batch Processing Record should be kept for each batch processed. It should be based on the relevant parts of the currently approved Manufacturing Formula and Processing Instructions. The method of preparation of such records should be designed to avoid transcription errors. The record should carry the number of the batch being manufactured. Before any processing begins, there should be recorded checks that the equipment and work station are clear of previous products, documents or materials not required for the planned process, and that equipment is clean and suitable for use. During processing, the following information should be recorded at the time each action is taken and, after completion, the record should be dated and signed in agreement by the person responsible for the processing operations: a) the name of the product; b) dates and times of commencement, of significant intermediate stages and of completion of production; c) name of the person responsible for each stage of production; d) initials of the operator of different significant steps of production and, where appropriate, of the person who checked each of these operations (e.g. weighing); e) the batch number and/or analytical control number as well as the quantities of each starting material actually weighed (including the batch number and amount of any recovered or reprocessed material added); f) any relevant processing operation or event and major equipment used; g) a record of the in-process controls and the initials of the person(s) carrying them out, and the results obtained; h) the product yield obtained at different and pertinent stages of manufacture; i) notes on special problems including details, with signed authorisation for any deviation from the Manufacturing Formula and Processing Instructions.	4.17 A Batch Processing Record should be kept for each batch processed. It should be based on the relevant parts of the currently approved Manufacturing Formula and Processing Instructions. The method of preparation of such records should be designed to avoid transcription errors. The record should carry the number of the batch being manufactured. Before any processing begins, there should be recorded checks that the equipment and work station are clear of previous products, documents or materials not required for the planned process, and that equipment is clean and suitable for use. During processing, the following information should be recorded at the time each action is taken and, after completion, the record should be dated and signed in agreement by the person responsible for the processing operations: j) the name of the product; k) dates and times of commencement, of significant intermediate stages and of completion of production; l) name of the person responsible for each stage of production; m) initials of the operator of different significant steps of production and, where appropriate, of the person who checked each of these operations (e.g. weighing); e) the batch number and/or analytical control number as well as the quantities of each starting material actually weighed (including the batch number and amount of any recovered or reprocessed material added); f) any relevant processing operation or event and major equipment used; g) a record of the in-process controls and the initials of the person(s) carrying them out, and the results obtained; h) the product yield obtained at different and pertinent stages of manufacture; **i)** notes on special problems including details, with signed authorisation for any deviation from the Manufacturing Formula and Processing Instructions. (See also GMP 5.62 – 5.65).

Batch Packaging Records	Batch Packaging Records
4.18 A Batch Packaging Record should be kept for each batch or part batch processed. It should be based on the relevant parts of the Packaging Instructions and the method of preparation of such records should be designed to avoid transcription errors. The record should carry the batch number and the quantity of bulk product to be packed, as well as the batch number and the planned quantity of finished product that will be obtained. Before any packaging operation begins, there should be recorded checks that the equipment and work station are clear of previous products, documents or materials not required for the planned packaging operations, and that equipment is clean and suitable for use. The following information should be entered at the time each action is taken and, after completion, the record should be dated and signed in agreement by the person(s) responsible for the packaging operations: a) the name of the product; b) the date(s) and times of the packaging operations; c) the name of the responsible person carrying out the packaging operation; d) the initials of the operators of the different significant steps; e) records of checks for identity and conformity with the packaging instructions including the results of in-process controls; f) details of the packaging operations carried out, including references to equipment and the packaging lines used; g) whenever possible, samples of printed packaging materials used, including specimens of the batch coding, expiry dating and any additional overprinting; h) notes on any special problems or unusual events including details, with signed authorisation for any deviation from the Manufacturing Formula and Processing Instructions; i) the quantities and reference number or identification of all printed packaging materials and bulk product issued, used, destroyed or returned to stock and the quantities of obtained product, in order to provide for an adequate reconciliation.	4.18 A Batch Packaging Record should be kept for each batch or part batch processed. It should be based on the relevant parts of the Packaging Instructions and the method of preparation of such records should be designed to avoid transcription errors. The record should carry the batch number and the quantity of bulk product to be packed, as well as the batch number and the planned quantity of finished product that will be obtained. Before any packaging operation begins, there should be recorded checks that the equipment and work station are clear of previous products, documents or materials not required for the planned packaging operations and that equipment is clean and suitable for use. The following information should be entered at the time each action is taken and, after completion, the record should be dated and signed in agreement by the person(s) responsible for the packaging operations: a) the name of the product; b) the date(s) and times of the packaging operations; c) the name of the responsible person carrying out the packaging operation; d) the initials of the operators of the different significant steps; e) records of checks for identity and conformity with the packaging instructions including the results of in-process controls; f) details of the packaging operations carried out, including references to equipment and the packaging lines used; g) whenever possible, samples of printed packaging materials used, including specimens of the batch coding, expiry dating and any additional overprinting; h) notes on any special problems or unusual events including details, with signed authorisation for any deviation from the Manufacturing Formula and Processing Instructions; **i)** the quantities and reference number or identification of all printed packaging materials and bulk product issued, used, destroyed or returned to stock and the quantities of obtained product, in order to provide for an adequate reconciliation.

Procedures and records	Procedures and records
	A **list of Standard Operating Procedures** and associated records should be maintained. Relevant documents should be made readily available during inspections by regulatory authorities. **Certain records, (e.g. complaints, process deviations, OOS events, rejected batches) should be summarised for review and inspection purposes,** (see also GMP Chapter 1 for annual product reviews, etc.). The summary should include key information, such as the date of recording each item, description of each item, an indication as to whether each item is open or closed, root cause classification, date of closure and trend summaries.
Receipt 4.19 There should be written procedures and records for the receipt of each delivery of each starting and primary and printed packaging material. 4.20 The records of the receipts should include: a) the name of the material on the delivery note and the containers; b) the "in-house" name and/or code of material (if different from a); c) date of receipt; d) supplier's name and, if possible, manufacturer's name; e) manufacturer's batch or reference number; f) total quantity, and number of containers received; g) the batch number assigned after receipt; h) any relevant comment (e.g. state of the containers).	**Receipt** 4.19 There should be written procedures and records for the receipt of each delivery of each starting material, (including bulk, intermediate or finished goods), primary, secondary and printed packaging materials. 4.20 The records of the receipts should include: a) the name of the material on the delivery note and the containers; b) the "in-house" name and/or code of material (if different from a); c) date of receipt; d) supplier's name and, if possible, manufacturer's name; e) manufacturer's batch or reference number; f) total quantity, and number of containers received; g) the batch number assigned after receipt; h) any relevant comment (e.g. state of the containers).
4.21 There should be written procedures for the internal labelling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate.	4.21 There should be written procedures for the internal labelling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate.
Sampling 4.22 There should be written procedures for sampling, which include the person(s) authorised to take samples, the methods and equipment to be used, the amounts to be taken and any precautions to be observed to avoid contamination of the material or any deterioration in its quality (see Chapter 6, item 13).	**Sampling** 4.22 There should be written procedures for sampling, which include the person(s) authorised to take samples, the methods and equipment to be used, the amounts to be taken and any precautions to be observed to avoid contamination of the material or any deterioration in its quality (see Chapter 6, item 13).

Testing 4.23 There should be written procedures for testing materials and products at different stages of manufacture, describing the methods and equipment to be used. The tests performed should be recorded (see Chapter 6, item 17).	**Testing** 4.23 There should be written procedures for testing materials and products at different stages of manufacture, describing the methods and equipment to be used. The tests performed should be recorded. (See also GMP Chapter 6, item 17).
Other 4.24 Written release and rejection procedures should be available for materials and products, and in particular for the release for sale of the finished product by the Qualified Person(s) in accordance with the requirements of Article 51 of Directive 2001/83/EC[1]. [1] Article 55 of Directive 2001/82/EC	**Other** 4.24 Written release and rejection procedures should be available for materials and products, and in particular for the release for sale of the finished product by the Qualified Person(s) in accordance with the requirements of Article 22 of Directive 75/319/EEC. (For clinical supplies or Investigational Medicinal Products also see GMP Annex 13 to this Guide). All records should be available to the Qualified Person for review when requested although appropriate records should routinely be provided to the Qualified Person for batch certification purposes.
4.25 Records should be maintained of the distribution of each batch of a product in order to facilitate the recall of the batch if necessary (see Chapter 8).	4.25 Records should be maintained of the distribution of each batch of a product in order to facilitate the recall of the batch if necessary (see Chapter 8).
4.26 There should be written procedures and the associated records of actions taken or conclusions reached, where appropriate, for: — validation; — equipment assembly and calibration; — maintenance, cleaning and sanitation; — personnel matters including training, clothing, hygiene; — environmental monitoring; — pest control; — complaints; — recalls; — returns.	4.26 There should be written plans, policies, procedures, protocols and reports and the associated records of actions taken or conclusions reached, where appropriate, for the following examples (which is not an exhaustive list): — validation and qualification of processes, equipment and systems; — equipment assembly and calibration; — technology transfer — maintenance, cleaning and sanitation; — personnel matters including training in GMP and technical matters, clothing and hygiene and verification of the effectiveness of training. — environmental monitoring; — pest control; — complaints; — recalls; — returns. — change control — investigations into deviations and non-conformances — internal quality / GMP compliance audits — supplier audits

4.27 Clear operating procedures should be available for major items of manufacturing and test equipment.	4.27 Clear operating procedures should be available for major items of manufacturing and test equipment.
4.28 Log books should be kept for major or critical equipment recording, as appropriate, any validations, calibrations, maintenance, cleaning or repair operations, including the dates and identity of people who carried these operations out.	4.28 Log books should be kept for major or critical equipment recording in chronological order, as appropriate, any use of the equipment, validations, calibrations, maintenance, cleaning or repair operations, including the dates and identity of people who carried these operations out.
4.29 Log books should also record in chronological order the use of major or critical equipment and the areas where the products have been processed.	4.29 Log books should also record in chronological order the use of major or critical equipment and the areas where the products have been processed.
	[1] An 'electronic document management system', (EDMS), may be required for critical electronic records and other documents. [2] Alternatively the certification may be based, in-whole or in-part, on the assessment of real time data (summaries and exception reports) from batch related process analytical technology (PAT), parameters or metrics as per the approved marketing authorisation dossier. [3] See in particular ISO 17799 (A Code of Practice for Information Security Management), and PIC/S publication PI 01 1-3(Good Practices for Computerised Systems in GxP Regulated Environments).

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