Auditing Guide

Annex 2 – Aide Mémoire

Company :	Auditor(s) :
Location, Country :	Date of Audit:

General Remark
Chapters 1 to 19 of this Aide Mémoire refer to the appropriate chapters of ICH Q7 (*Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients)*.Chapter 20 relates to aspects of Quality Management Systems according to ISO 9001 or ICH Q10 Pharmaceutical Quality System.

AIDE MEMOIRE

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
1	**Introduction**								
1.3	**Scope**								
	Has the company designated the point at which the production of the API begins? Can a rationale be provided for this decision? Has the decision been discussed with the respective authority? Are the quality critical steps identified?								
2	**Quality Management**								
2.1	**Principles**								
2.11	A Certified Quality Management System (e.g. ISO 9001) is implemented? (if yes, see chapter 20)								
2.12	Is there a quality policy? How is it brought to the attention of the employees? Is there a Quality Manual or equivalent documentation that describes in detail how the Quality System is implemented? How does Management review effectiveness of quality system								
2.13	Is the Quality Unit (QA/QC) independent of production?								
2.14	Is there an authorized person(s) for the release of IM and APIs? Who is the person(s)?								
2.16	Are all deviations documented and explained? Are critical deviations investigated in a timely manner?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

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		YES	NO	YES	tbi *	No			
	Is there a written procedure for handling investigations (6.53)? Average days for completion?								
2.17	How is it ensured that materials are not released or used before completion of evaluation by the QU? If not done by QU: Is an appropriate system in place?								
2.18	How is management notified of serious GMP deficiencies, quality related complaints and/or product defects? Average time needed for information?								
2.2	**Responsibilities of the QU**								
2.21	Are there procedures that ensure that QU reviews and approves all quality related documents?								
2.22	Non-transferable responsibilities of QU: - release/rejection of APIs and IM (to be sold) - establish system to release/reject materials and labels - review of critical process steps batch records - ensure critical deviations are investigated - approving specifications and master instructions - approving all quality related documents - ensuring conduction of internal audits - approving contract manufacturers - approving changes with quality impact - approving validation documents - ensure complaints are resolved								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

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		YES	NO	YES	tbi *	No			
	- ensuring calibration system is functioning according to procedure executed - ensuring that stability data is generated and reviewed - performing product quality reviews								
2.3	**Responsibilities for Production Activities**								
	- procedure for preparing, reviewing and approving instructions - reviewing batch production records - ensure all deviations and investigations are handled - cleaning of facilities - calibrations performed - validation documents generated - evaluation of proposed changes - ensure that facilities and equipment are qualified								
2.4	**Internal Audits**								
2.40	Are regular audits performed? Is there an audit schedule? Is the schedule followed?								
2.41	Are audit findings and corrective actions documented? Procedure to notify management of audit findings? Are corrective actions completed within agreed time (are there significant delays?)								
2.5	**Product Quality Review**								

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		YES	NO	YES	tbi *	No			
2.50	Are regular Product Quality Reviews conducted for all products? Frequency (dedicated, campaign)? Content (at least): - review of critical IPC and API test results - review of all batches failed - review of all critical deviations - review of process changes and impact on quality - review of changes to analytical methods - review of results of ongoing stability programmes - review of returns, complaints, recalls - review of adequacy of corrective actions defined in previous review								
2.51	Evaluation and assessment for need of additional corrective actions to address recurring issues and/or need for process or cleaning revalidation								
3	**Personnel**								
3.1	**Personnel Qualifications**								
3.10	Adequate number of personnel? Qualification of personnel sufficient at different levels?								
3.11	Are responsibilities of all personnel engaged in manufacture in APIs in writing available? Are responsibilities periodically reviewed to ensure they are current?								
3.12	Is regular training conducted?								

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		YES	NO	YES	tbi *	No			
	Are records of training maintained? Is effectiveness of training evaluated? How?								
3.2	**Personnel Hygiene**								
3.21	Do personnel wear clean clothing suitable for activity? Additional protective apparel where necessary (e.g. Final Product Packing Rooms)?								
3.22	How is it ensured that personnel have no direct contact with IM and APIs?								
3.23	How is it ensured that no smoking, drinking, chewing and storage of food takes place ?								
3.24	How are personnel with infectious diseases or open lesions identified? Is there a procedure in place that these persons have no product contact?								
3.3	Consultants Are consultants used to advise on any GMP related activities? Is there an assessment of consultant's education, training and experience?								
4	**Buildings and Facilities**								
4.1	**Design and Construction**								
4.10	Can cleaning and maintenance be easily performed based on design of equipment and layout of facility? Have production and warehouse facilities been designed to prevent contamination or cross contamination? If not, how is contamination prevented?								

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		YES	NO	YES	tbi *	No			
4.11	Is there adequate space for placement of equipment to prevent mix-up or contamination?								
4.12	Outdoor equipment raises concerns for contamination?								
4.13	Does flow of materials and personnel raise concerns for contamination?								
4.14	Defined areas or control systems in place for the following activities: - receipt, identification, sampling of incoming materials - quarantine before release/reject - Sampling of intermediates or API's - holding of rejected materials before further disposition? - Packaging and labeling operations?								
4.15	Washing facilities and toilets available for personnel?								
4.16	Laboratory areas separated from production?								
4.2	**Utilities**								
4.20	All utilities that could impact on product quality are identified and qualified? Are the utilities monitored and actions taken when alert limits are exceeded?								
4.21	Adequate ventilation, air filtration and exhaust systems in place? Are these systems designed and operated to prevent contamination?								
4.22	Control of re-circulated air sufficient to avoid contamination?								

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		YES	NO	YES	tbi *	No			
4.23	Permanently installed pipework appropriately identified? Is pipework maintained and located in such a way as to prevent contamination?								
4.24	Are drains designed to prevent back-siphonage or microbiological contamination in areas where product is exposed?								
4.3	**Water**								
4.30	Water demonstrated to be suitable for intended use?								
4.31	Is Process water meeting drinking water quality as a minimum standard? Is additional water treatment system in place? Is quality of all grades of process water monitored at points of use for physical/chemical attributes, total microbial counts, objectionable organisms? Are actions taken when limits are exceeded?								
4.32	Tighter specifications needed to ensure quality? What are the specifications?								
4.33	Validation of treatment of (higher) water treatment?								
4.34	If claims are made for sterile or parenteral use: Monitor microbial counts, objectionable microorganisms and endotoxins								
4.4	**Containment**								
4.40	For highly sensitizing materials are dedicated production areas (facilities, air systems, equipment) in use?								

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		YES	NO	YES	tbi *	No			
4.41	Dedicated production area for high pharmacological activity								
4.42	Are there measures to prevent cross-contamination from personnel, materials etc. for example moving from one production area to another?								
4.43	Production of highly toxic, non-pharmaceutical products, for example pesticides excluded from pharmaceutical production facilities?								
4.5	**Lighting**								
	Adequate lighting for e.g. cleaning and maintenance								
4.6	**Sewage and Refuse**								
4.60	Sewage to be removed timely								
4.7	**Sanitation and Maintenance**								
4.70	Buildings to be kept properly maintained, repaired and cleaned								
4.71	Written procedures for cleaning for equipment and facilities in place								
4.72	Procedures for pest control in place?								
5	**Process Equipment**								
5.1	**Design and Construction**								
5.10	Equipment suitably located, easy to clean and maintain?								
5.11	Equipment surfaces do not alter product quality								
5.12	Equipment only used within the qualified operation range?								
5.13	Major equipment and permanently installed pipework identified								

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5.14	Lubricants not in contact with IM and APIs? Otherwise food grade lubricants used?								
5.15	Precautions (measures) taken where equipment is opened to prevent contamination? For example addition of seeds or sampling								
5.16	Are current engineering drawings available for equipment, installations and utility systems?								
5.2	**Equipment Maintenance and Cleaning**								
5.20	Preventive maintenance programme in place? Schedule followed?								
5.21	Written procedures for the cleaning of equipment in place? Do the procedures give sufficient detail to enable operators to clean each type of equipment in an effective and reproducible manner?								
5.22	Are equipment and utensils, such as sampling devices cleaned, stored and where appropriate sanitized or sterilized to prevent contamination or carry-over of a material that would affect the quality of the IM or API?								
5.23	Continuous production or dedicated production facilities: is equipment/ facility cleaned at appropriate intervals to prevent build-up or carry over of contaminants for example degradants or objectionable levels of micro-organisms? Is the cleaning frequency justified and documented?								
5.24	Is equipment cleaned between production of different products?								

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5.25	For multi-purpose equipment is the Maximum Acceptable Carry Over and other Acceptance criteria for residues justified and determined? Are the cleaning procedures validated?								
5.26	Equipment identified as to its content and cleanliness status?								
5.3	**Calibration**								
5.30	Instruments critical for IM and/or API quality are calibrated? How is critical defined? Written procedure in place? Schedule followed?								
5.31	Calibration done with standards that are traceable to certified standards?								
5.32	Records of calibration maintained?								
5.33	Calibration status of instruments known? How (label, electronic)?								
5.34	How is it ensured that instruments out of calibration are not used?								
5.35	If instruments have been shown out of calibration, are deviation investigations performed to determine if this fact has an influence on the release of the IM/API?								
5.4	**Computerised Systems**								
5.40	Are GMP related computer systems validated?								
5.41	IQ, OQ for Hard- and Software available to demonstrate suitability of computer hardware/software to perform task?								

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5.42	Retrospective validation for existing systems if not validated at time of installation?								
5.43	What controls are in place to prevent unauthorized access? What controls are in place to prevent changes to data? What controls are in place to prevent omissions in data? Is there an audit trail / documents available where changes to data are recorded, who made the change, when the change was made and of the previous entry?								
5.44	Written procedures for the operation and maintenance of computerized systems available?								
5.45	Is the manual entry of critical data checked by additional means (second operator or system itself)?								
5.46	Are all quality related incidents and deviations relating to computerized systems investigated according to defined procedures investigated?								
5.47	Changes to the computerized system are made according to a defined procedure?								
5.48	How is data protected in cases of system breakdowns? Back-up system provided? Is Recovery from back-ups tested periodically?								

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		YES	NO	YES	tbi *	No			
6.	**Documentation and Records**								
6.1	**Documentation System and Specifications**								
6.10	Is there a written procedure in place describing preparation, review, approval and distribution of all quality related documents?								
6.11	How is revision, superseding and withdrawal of documents controlled? Is a revision history maintained?								
6.12	Procedure in place for retaining all appropriate documents? Retention period specified?								
6.13	Retention period for APIs with expiry date: 1 year after expiry (min.) Retention period for APIs with retest date: 3 years after complete distribution (min.)								
6.14	Are corrected entries in documents dated and signed? Original entry still readable?								
6.15	Are documents promptly retrievable (copies or electronic means acceptable)?								
6.17	Are specifications for all materials, IM and APIs established?								
6.18	Are electronic signatures authenticated and secure?								
6.2	**Equipment Cleaning and Use Records**								
6.20	Are there records for the major equipment used , cleaning and maintenance showing the following - date - time - product and batch number of each batch								

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		YES	NO	YES	tbi *	No			
	- person who performed cleaning - person who performed maintenance								
6.3	**Records of Raw Materials, IM, API Labeling and Packaging Materials**								
6.30	Records of each delivery should contain: - name of manufacturer/supplier - identity and quantity - supplier control or identification number - number allocated on receipt - date of receipt - acceptable condition of received goods assessed - result of tests and conclusion derived from this - trace of use - review of labels and packaging materials showing conformity with specifications - final decision release or reject								
6.31	Are master labels maintained?								
6.4	**Master Production Instructions**								
6.40	Are Master Production Instructions for each IM/API - prepared - dated - signed - independently checked by QU								
6.41	Do Master Production Instructions contain the following: - name of product including document reference code								

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		YES	NO	YES	tbi *	No			
	- complete list of raw materials - accurate statement of quantities needed or calculation of quantity - production location and major equipment to be used - detailed production instructions including sequences, ranges of parameters, sampling instructions, IPC, time limits, expected yield - instructions for storage								
6.5	**Batch Production Records**								
6.50	Are Batch Production Records checked before issuance for correct version?								
6.51	Are the records showing an unique batch number (not for continuous production)?								
6.52	The batch record should contain the following: - date(s) and times (if appropriate) - identity of major equipment - identification of materials used - actual results - sampling performed - signatures of the person(s) performing the operation - IPC / laboratory test results - actual yield, if appropriate - description of packaging and labels used - deviation/investigation - results of release testing								

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6.6	**Laboratory Control Records**								
6.60	Laboratory records should contain the following: - description of sample including name, batch number or code, date when sample was taken, quantity - reference to test method - cross reference to preparation of reference standards, reagents and/or standard solutions - complete record of all raw data - record of all calculations - statement of test result if they comply with specifications - signature and date of person(s) performing the testing - signature of second person demonstrating review for accuracy, completeness								
6.61	Other records to be maintained: - modification to test method - calibration of laboratory instruments - stability testing performed - OOS investigations								
6.7	**Batch Production Record Review**								
6.70	Is a written procedure for the handling of batch (laboratory) record review available?								
6.71	Are batch (laboratory) records of critical steps reviewed by the QU? Are they reviewed before the release of the API?								

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6.72	Are all deviations, investigations and OOS reviewed as part of the batch record review?								
6.73	Is the QU releasing all IM that are shipped outside the control of the company?								
7	**Materials Management**								
7.1	**General Controls**								
7.10	Are written procedures available for handling of receipt, identification, quarantine, storage, sampling, testing, approval or rejection of materials?								
7.11	System to evaluate suppliers of critical materials in place? Evaluation must show that supplier can consistently provide material meeting specifications (7.31)								
7.12	Materials purchased against agreed specifications? Purchased from an approved (by QU) supplier?								
7.13	If supplier is not the manufacturer, is the original manufacturer known?								
7.14	Change of source/supplier handled according to Change Control procedures (chap. 13)?								
7.2	**Receipt and Quarantine**								
7.20	Upon receipt materials visually examined for - correct labeling - container damage - broken seals - tampering or contamination Are materials held under quarantine until released for use? How is this done?								

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		YES	NO	YES	tbi *	No			
7.21	Incoming materials are released before mixed with existing stocks? Are procedures in place to prevent discharging materials wrongly?								
7.22	If deliveries are made in non-dedicated tankers which assurance is provided to demonstrate no contamination (one or more of the following): - certificate of cleaning - testing for trace impurities - audit of the supplier								
7.24	Is each delivery of materials identified (code or batch number)? Is there a system in place to identify the status of each batch?								
7.3	**Sampling and Testing of Incoming Production Materials**								
7.30	Is at least one test conducted to verify the identity of incoming materials? If suppliers Certificate of Analysis is used instead of testing a system for evaluation must be in place.								
7.31	(see also 7.11) Are 3 full analyses conducted before reducing testing? Is a full analysis performed at appropriate intervals and compared with the suppliers certificate of analysis?								
7.33	How is it demonstrated that samples taken from the material are representative? Are sampling methods described with at least								

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		YES	NO	YES	tbi *	No			
	- number of containers to be sampled - which part of the container - amount of sample to be taken								
7.34	Is sampling done at defined locations preventing contamination?								
7.35	Are containers from which samples are taken identified?								
7.4	**Storage**								
7.40	Is material stored in a manner to prevent degradation and contamination?								
7.41	Are fiber drums, bags and boxes stored off the floor? Is stored material suitably spaced to permit cleaning and inspection?								
7.42	Do materials met their respective storage conditions? Is the FIFO principle followed?								
7.43	In case materials is stored outdoors: - do labels remain legible - are the containers cleaned before opening - is it described in a procedure								
7.44	How are rejected materials held under a quarantine system?								
8	**Production and In Process Controls**								
8.1	**Production Operations**								
8.10	Are weighing and measuring devices of suitable accuracy for their intended use? Are the devices periodically calibrated with certified references?								

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		YES	NO	YES	tbi *	No			
8.11	Do containers with subdivided material contain the following information: - name of material - code or control number - weight, if applicable - retest date, if applicable								
8.12	How are critical weighing, measuring or subdividing operation witnessed? Is an equivalent control used? If so what?								
8.13	Are all other critical operations witnessed or subjected to equivalent control?								
8.14	Are actual yields compared with expected yields at designated steps in production?								
8.16	How is the processing status of major units of equipment indicated?								
8.2	**Time Limits**								
8.20	Are all specified time limits of the operating instructions met?								
8.21	How are storage conditions for IM held for further processing determined?								
8.3	**In-process Sampling and Controls**								
8.30	Are IPC established to monitor the progress and control the performance of the processing steps?								
8.32	Are critical IPC approved by the QU?								
8.33	How is the qualification (training) of the production personnel documented, if they perform the IPC?								
8.34	Are sampling methods for IPC described in writing?								

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		YES	NO	YES	tbi *	No			
8.35	Does in-process sampling not cause the contamination of sample and/or product?								
8.4	**Blending of Batches of IM or APIs**								
8.41	Are OOS batches blended with other batches meeting the specifications? Are all batches individually tested prior to blending? And do they all meet specification?								
8.43	Is the blending process adequately documented and the blended batch tested for conformance to specifications?								
8.44	Does the batch record of the blended batch allow traceability back to the individual batches?								
8.45	Are blending operations validated if physical attributes of the API resulting from this step are known to be critical?								
8.46	How is it demonstrated that the blended batch does not affect stability?								
8.47	Is the expiry/retest date based on the oldest batch in the blend?								
8.5	**Contamination Control**								
8.50	How is it ensured that carryovers (e.g. degradants) into successive batches of the same IM/API do not affect the impurity profile of the API?								
8.51	What measures are taken in production to prevent contamination of IM/API?								
8.52	What specific precautions are taken to avoid contamination of the API after purification?								

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9	**Packaging and Identification Labelling of APIs and IM**								
9.1	**General**								
9.10	Are written procedures available describing - receipt - identification - quarantine - sampling - examination/testing - release of packaging materials and labels ?								
9.11	Are specifications for all packaging materials and labels established? Are suppliers of primary packaging materials in contact with the product qualified?								
9.12	Are records of each delivery of packaging materials and labels kept?								
9.2	**Packaging Materials**								
9.20	Can containers/packaging material used provide adequate protection against deterioration or contamination during transportation?								
9.21	Are containers cleaned so that they are suitable for their intended use?								
9.22	Are written procedures for cleaning in place for re-used containers? Are all previous labels removed or defaced?								
9.3	**Label Issuance and Control**								
9.30	Is access to label storage area limited to authorized personnel?								

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9.31	Are procedures in place to reconcile the quantities of labels issued and used? Are discrepancies investigated and approved by the QU?								
9.32	Are labels bearing batch numbers not used being destroyed? How is it documented?								
9.33	Are all out-dated and obsolete labels destroyed?								
9.34	Are printing devices checked that the imprint conforms to the print specified in batch record? Is an examination done to check if the correct label is on the packed IM/API? (9.45)								
9.36	Is a representative label included in the batch record?								
9.4	**Packaging and Labelling Operations**								
9.40	Are written procedures in place ensuring that correct packaging materials and labels are used?								
9.41	Is physical or spatial separation of labels done when multiple labeling operations are done at the same time?								
9.42	Labels should indicate the following information (at least): - name of product - identifying code and batch number - storage conditions, when such information is critical to assure quality								
9.43	If the IM/API is transferred outside of the control of the manufacturer the label as well as requirements of 9.42 contain:								

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		YES	NO	YES	tbi *	No			
	- name and address of manufacturer - quantity - special transport conditions, if applicable - special storage conditions, if applicable (10.22) - legal requirements, if applicable For APIs with expiry date: date to be included on label and certificate of analysis For APIs with retest date: date to be included on label and/or certificate of analysis								
9.44	Are packaging and labeling facilities inspected before use to ensure that all materials not needed are removed? Is this inspection documented?								
9.46	Are seals and other security measures used that will alert the recipient that the material may have been altered? Please specify.								
10	**Storage and Distribution**								
10.1	**Warehousing Procedures**								
10.10	Are facilities for the storage of materials available supporting the claimed storage conditions (e,g, temperature, humidity)? Are records of the storage conditions kept?								
10.11	Are separate storage areas provided for quarantined, rejected, returned or recalled products? Or is an alternative system used? If so, how is it designed and qualified?								

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		YES	NO	YES	tbi *	No			
10.2	**Distribution Procedures**								
10.20	How is it ensured that APIs/IM are not distributed outside of the company before the release of the QU?								
10.21	How are transportation conditions ensured so that the quality of the product will not be adversely affected?								
10.23	How does the manufacturer ensure that the transporter knows and follows the appropriate transport and storage conditions?								
10.24	Are there systems in place to easily permit a recall? Has its effectiveness been demonstrated?								
11	**Laboratory Controls**								
11.1	**General Controls**								
11.10	Are adequate laboratory facilities available?								
11.12	Are all sampling plans and testing procedures reviewed and approved by the QU?								
11.13	Do the specifications set for the APIs include a control of the impurities? If the API has a specification for microbiological purity and/or endotoxins what appropriate action limits have been established?								
11.15	Are all OOS results investigated? Is resampling after OOS described in a procedure?								
11.16	Are written procedures in place for preparation of reagents and standard solutions?								
11.17	Are primary reference standards stored under appropriate conditions? Is the source of the primary standard documented?								

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11.18	If the primary standard is not obtained from an officially recognized source, is appropriate testing conducted to fully establish the identity and purity of the primary standard?								
11.19	Are procedures in place to prepare, identify, test store and approve secondary reference standards? Is the suitability of the secondary standard determined prior to use by comparing it against the primary standard? Are secondary reference standards periodically re-qualified?								
11.2	**Testing of Intermediates and APIs**								
11.21	Is there an impurity profile established for every API?								
11.22	Is the impurity profile compared at appropriate intervals against the impurity profile in the regulatory submission or against historical data?								
11.3	**Validation of Analytical Procedures**								
	See section 12.8								
11.4	**Certificates of Analysis**								
11.40	Are authentic Certificates of Analysis issued for each batch of IM/API?								
11.41	Information on the Certificate of Analysis: - name of IM/API - batch number and code number? - date of release - expiry date, if applicable - retest date, if desired -								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
11.42	On the Certificate of Analysis, are all tests performed listed, together with acceptance limits and numerical results obtained?								
11.43	Certificates of Analysis should be - dated - signed by authorized personnel of the QU - show name, address and telephone number of manufacturer If Certificate of Analysis is issued by agents (chap. 18) the name, address and telephone number of the agents must be shown.								
11.44	If Certificate of Analysis is issued by agents the name, address and telephone number of the laboratory that performed the tests must be shown. It also should contain a reference to the original manufacturer and to the original Certificate of Analysis.								
11.5	**Stability Monitoring of APIs**								
11.50	Is an on-going stability testing programme conducted? Do the results of the stability programme justify storage conditions and expiry/retest dates (see also 11.61)?								
11.51	Are the test methods used in stability validated and stability indicating?								
11.52	Are the stability samples stored in containers of the same material as the market containers?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
11.53	Are the first three commercial production batches placed on stability?								
11.54	Thereafter, is at least one batch per year added to the stability monitoring programme? Are annually tests performed to confirm stability?								
11.55	For APIs with less than 1 year stability: Is testing performed monthly for the first three months and at three month intervals after that?								
11.6	**Expiry and Retest Dating**								
11.60	Is an expiry/retest date assigned when the APIs are transferred outside of the control of the company?								
11.7	**Reserve/Retention Samples**								
11.71	Are reserve samples stored for 1 year after expiry date or 3 years after distribution (whatever is longer)? For APIs are reserve samples stored for at least 3 years after complete distribution?								
11.72	Are reserve samples stored in same packaging system or more protective than the marketed? Is the amount of sample sufficient to conduct at least 2 full compendial or internal specification analyses?								
12	**Validation**								
12.1	**Validation Policy**								
12.10	Is the company's overall validation policy documented? (Could be combined with 2.12)								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
12.11	Are all critical parameters defined during the development (or from historical data)? Are the operating ranges defined?								
12.12	Are all critical operation steps validated?								
12.2	**Validation Documentation**								
12.20	Is a validation protocol established? Is it approved by the QU?								
12.21	Is the following specified in the validation protocol: - critical process steps - acceptance criteria - type of validation - number of process runs?								
12.22	Is a validation report prepared summarising the results obtained, including recommendation of changes to correct deficiencies?								
12.23	Are variations from the validation protocol documented and justified?								
12.3	**Qualification**								
12.30	Is there policy or procedure for Qualification/Validation?. Is Validation Master Plan available? Is appropriate qualification (DQ, IQ, OQ, PQ) conducted for critical equipment and ancillary systems? Is operational qualification completed before Performance Qualification / process validation activities?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
12.4	**Approaches to Process Validation**								
12.40	Is process validation (PV) conducted before commercial distribution of API batches?								
12.42	Prospective Validation should normally be performed. What is the justification of performing other types? Is the validation completed before commercial distribution of the drug product?								
12.44	If retrospective validation is conducted for well established processes, are the following requirements met: - critical process parameters have been identified - appropriate in-process criteria have been established - no significant process failures have occurred - impurity profiles have been established for the existing API								
12.45	Are batches selected for retrospective validation representative for all batches made during the review period?								
12.5	**Process Validation Programme**								
12.50	Are at least 3 consecutive successful production batches made for prospective and concurrent validation? For retrospective validation are 10 to 30 consecutive batches examined? If fewer batches are examined, what is the justification for it?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
12.52	Has process validation confirmed that the process can be reproducibly controlled within critical operating parameters and the impurity profile is within the specified limits?								
12.6	**Periodic Review of Validated Systems**								
12.60	Are systems and processes periodically evaluated to verify that they are still operating in a valid manner (e.g. through product quality review)?								
12.7	**Cleaning Validation**								
12.70	Are cleaning procedures validated? If not, is there a justification? Is cleaning validation directed to situations where contamination or carryover poses the greatest risk?								
12.71	If various APIs/IM are produced in the same equipment and the same cleaning process is used, is a representative API/IM selected for cleaning validation (on the basis of solubility, difficulty to clean and calculation of residue limits based on potency, toxicity and stability)?								
12.72	Does the cleaning validation protocol include - equipment to be cleaned - procedures - materials used - acceptable cleaning levels - parameters to be monitored - analytical methods - type of samples (swab, rinse) - how samples are collected and labeled								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
12.73	Does the type of sampling detect insoluble and soluble residues? Is the sampling method capable to quantitatively measure levels of remaining residues?								
12.74	Are the analytical methods sensitive enough to detect residues or contaminates? How are residue limits established (on minimum known pharmacological, toxicological or physiological activity or the most deleterious component)?								
12.75	If claims on microbiological and/or endotoxin specifications are made, does the cleaning validation take this into account?								
12.76	Are the cleaning procedures monitored at appropriate intervals to ensure their effectiveness?								
12.8	**Validation of Analytical Methods**								
12.80	Are the analytical methods developed by the company validated? How are Pharmacopoeial methods qualified?								
12.81	How is the degree of analytical validation (e.g. for different steps of production) justified?								
12.82	Is the analytical equipment qualified?								
12.83	Are records of modified validated analytical methods maintained? Is the reason for the modification documented?								
13	**Change Control**								
13.10	Is a formal change control system in place capable of evaluating all changes?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
13.11	Written procedures should be provided for the identification, documentation, review and approval of changes.								
13.12	Are all changes impacting the quality of the API/IM approved by the QU?								
13.13	Are changes classified (e.g. major, minor)? If not, how is the impact on the quality of the API being evaluated? How is level of testing, validation, documentation determined (scientific judgement)?								
13.14	How is it ensured that after a change all affected documents are revised?								
13.15	Are the first batches evaluated after the change has been implemented?								
13.16	If critical changes have been made, has the impact on expiry/retest dates and process validation been evaluated?								
13.17	Are medicinal product manufacturers notified about changes that could impact the API quality (especially physical attributes)?								
14	**Rejection and Re-Use of Materials**								
14.1	**Rejection**								
14.10	Are IM/APIs failing to meet specifications identified? How?								
14.2	**Reprocessing**								
	Are all steps where reprocessing is conducted part of the filing documents?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
14.3	**Reworking**								
14.30	Is an investigation performed before a decision is taken to rework a batch?								
14.31	Have reworked batches been subjected - to appropriate evaluation - stability testing - to show equivalency to original process? Is concurrent validation performed if more than one batch is affected? Is a report issued if only one batch is affected?								
14.32	Is the impurity profile of the reworked batch compared with the one of the established process? If routine analytical methods are inadequate, are additional methods used?								
14.4	**Recovery of Materials and Solvents**								
14.40	Do procedures exist for the recovery of materials? Do the recovered materials meet specifications for their intended use?								
14.41	Do recovered solvents used in different processes meet appropriate standards?								
14.42	Are recovered solvents been tested for suitability before being combined with fresh or approved solvents?								
14.5	**Returns**								
14.50	Are returned APIs/IM identified and quarantined?								
14.51	Are returned materials evaluated on their quality before re-use?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
14.52	Are records of returned goods available containing - name and address of the consignee - API/IM, batch number and quantity - Reason of return - Use or disposal of API/IM								
15	**Complaints and Recalls**								
15.10	Is a written procedure available describing the handling of complaints?								
15.11	Do the complaint records include the following: - name and address of complaint - name and phone number of person submitting the complaint - complaint nature (including name and batch number of API) - date complaint is received - action taken (including person taking the action) - any follow-up, if applicable - response provided to the originator of complaint including date of response - final decision on API -								
15.12	Are the records of complaints retained? For how long? Are trends or recurring complaints evaluated?								
15.13	Is there a recall procedure in place?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
15.14	Does the recall procedure specify - who should be involved - how the recall is initiated - who should be informed - how recalled material is treated								
16	**Contract Manufacturers (including Laboratories)**								
16.10	Is it ensured that all contract manufacturers engaged comply with the GMP requirements of ICH Q7?								
16.11	How is the contract manufacturer evaluated for GMP compliance?								
16.12	Is there a written contract (agreement) with the contract manufacturer? Are the GMP responsibilities defined in detail?								
16.13	Does the contract permit to audit the contract manufacturer?								
16.14	Is subcontracting by the contract manufacturer excluded? If not, how is it ensured that the contract giver is involved in prior evaluation of the subcontractor?								
16.15	Are all records kept at the contract manufacturers site? How is it ensured that these are readily available?								
16.16	Does the contract manufacturer have a change control system? How is it ensured that the contract giver is informed about all intended changes of the contract manufacturer to the process? Does the contract giver approve all changes?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
17	**Agents, Brokers, Traders, Distributors, Repackers, and Relabellers (Agent)**								
17.1	**Applicability**								
17.10	Is this not the original manufacturer of the API? (Then this section applies.)								
17.11	Does the Agent comply with the GMP requirements as defined in ICH Q7?								
17.2	**Traceability of Distributed APIs and IM**								
17.20	Is the following information retained: - identity of original manufacturer - address of original manufacturer - purchase orders - transportation documentation - receipt documents - name or designation of API - manufacturers batch number - distribution records - authentic certificate of analysis, including those of the original manufacturer - expiry/retest date								
17.3	**Quality Management**								
17.30	Has the Agent established a system of managing quality as defined in section 2?								
17.4	**Repackaging, Relabeling and Holding of APIs and IM**								
17.40	How does the Agent ensure that during repackaging, relabeling and holding of APIs/IM no mix-ups and loss of identity and purity of the API/IM occurs? Are these operations conducted under conditions described in Q7?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
17.41	Is repackaging done under conditions to avoid contamination?								
17.5	**Stability**								
17.50	Are stability studies conducted if the API is repacked in a different type of container?								
17.6	**Transfer of Documentation**								
17.60	Does the Agent transfer all quality and regulatory information from the original manufacturer to the customer?								
17.61	Does the agent provide the name of the original manufacturer and the batch number to the customer?								
17.63	Is the specific guidance for Certificates of Analysis described in section 11.4 followed?								
17.7	**Handling of Complaints and Recalls**								
17.70	Does the Agent maintain records of all complaints and recalls that were brought to their attention?								
17.71	Does the Agent review the complaint together with the original manufacturer for determining further action?								
17.72	Do the records of the Agents include responses from the original manufacturer to a complaint?								
17.8	**Handling of Returns**								
17.80	Are returns to the Agent handled in the way described in section 14,52? Is documentation maintained of returned APIs/IM?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

AIDE MEMOIRE

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
18	**Specific Guidance for APIs Manufactured by Cell Culture / Fermentation**								
18.1	**General**								
18.10	Are the GMP principles of the other sections complied with?								
18.13	What measures are taken for Biotech processes to ensure that raw materials (media, buffer components) are no source of microbiological contamination? If applicable, is the bioburden, viral contamination and/or endotoxins controlled at appropriate stages of production?								
18.14	Which controls are performed for steps prior to this guide, e.g. cell banking?								
18.15	Which equipment and environmental controls are used to minimize contamination? Are adequate acceptance criteria for quality and frequency's for monitoring set at the various steps of production?								
18.16	Are the following controls taken into account: - maintenance of WCB - proper inoculation and expansion of the culture - control of critical operating parameters - monitoring the process for cell growth, viability and productivity - harvesting and purification procedures - monitoring of bioburden - viral safety concerns (ICH Q5a)								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
18.17	Is removal of media components, host cell proteins process and product related impurities and contamination demonstrated?								
18.2	**Cell Bank Maintenance and Record Keeping**								
18.20	Is the access to the cell banks limited to authorized personnel?								
18.21	Do the storage conditions of the cell banks ensure that viability is maintained and contamination prevented?								
18.22	Are records of the use of vials from the cell banks and storage conditions maintained?								
18.23	Are cell banks monitored periodically for suitability for use?								
18.24	For handling of cell banks check ICH Q5a								
18.3	**Cell Culture / Fermentation**								
18.30	Are closed and contained systems used when aseptic additions are needed? If open vessels are used which measures and controls are used to minimise risk of contamination?								
18.31	If use of open equipment can cause microbial contamination which environmental controls are done?								
18.32	Are personnel handling the cultures appropriately gowned?								
18.33	Are critical operating parameters including cell growth, viability and productivity monitored?								
18.34	Is cell culture equipment cleaned after use?								
18.35	Is culture media sterilized before use?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
18.36	Are procedures in place to detect contamination and to determine necessary action? Is the impact of the contamination evaluated?								
18.37	Are records of contamination maintained?								
18.38	Is multi-purpose equipment sufficiently tested to minimize contamination?								
18.4	**Harvesting, Isolation and Purification**								
18.40	Are harvesting steps performed in equipment and areas designed to minimize risk of contamination?								
18.41	Can the harvesting and purification procedures remove or inactivate organisms in a way that the API is recovered with consistent quality?								
18.42	Is all equipment cleaned properly after use?								
18.43	Is purification performed under controlled environmental conditions if open systems are used?								
18.44	If equipment is used for multiple products additional controls and testing is to be conducted.								
18.5	**Viral Removal / Inactivation steps**								
18.50	See ICH Q5a								
18.51	Are viral removal and inactivation steps performed within their validated parameters?								
18.52	Are appropriate precautions being taken to prevent viral contamination from pre-viral to post-viral removal/inactivation? Do open processing take place in areas that are separate from other processing activities and have separate air handling units?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
18.53	If equipment is used for different purification steps is it appropriately cleaned?								
19	**APIs for Use in Clinical Trials**								
19.1	**General**								
19.11	Are the controls used consistent with the stage of development? Are procedures flexible enough to provide changes as knowledge of the process increases? If APIs are intended to be used for clinical trials, is the API produced in suitable facilities with appropriate controls to ensure the quality?								
19.2	**Quality**								
19.20	Is there an appropriate GMP concept in place? Is a procedure for approval of batches in place?								
19.21	Is there an independent QU in place?								
19.23	Are raw materials, packaging materials IM and APIs tested?								
19.24	Are process and quality problems evaluated?								
19.25	Does the labeling of APIs for use in clinical trials indicate the material as being for investigational use?								
19.3	**Equipment and Facilities**								
19.30	Is it ensured that during all phases of clinical development the equipment is qualified, instruments calibrated, clean and suitable for it intended use?								
19.31	Are materials handled in a way to minimize contamination?								
19.4	**Control of Raw Materials**								
19.40	Are raw materials evaluated or tested?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

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		YES	NO	YES	tbi *	No			
19.5	**Production**								
19.50	Is the production of APIs for use in clinical trials documented appropriately according to the stage of production? Do these documents include information about materials used, equipment, processing and scientific observations?								
19.6	**Validation**								
19.60	Is the equipment used qualified and the instruments calibrated? (Validation is not expected!)								
19.61	If batches are produced for commercial use, then section 12 is to be applied.								
19.7	**Changes**								
19.70	Are all changes adequately recorded?								
19.8	**Laboratory Controls**								
19.80	Are analytical methods used scientifically sound? (No analytical validation required)								
19.81	Is a system to retain reserve samples in place?								
19.9	**Documentation**								
19.90	Is a system in place to document the information gained during the development?								
19.91	Is the development of analytical methods appropriately documented?								
19.92	Is it ensured that all information is retained for an appropriate length of time?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

AIDE MEMOIRE

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
20	**Quality Management System**								
20.1	**Quality Issues**								
20.10	Has the organization established, documented, implemented and maintained a quality management system in accordance with the requirements of ISO 9000:2000?								
20.11	Is the effectiveness of the quality management system continually improved?								
20.12	Does the organization manage these processes in accordance with the requirements of ISO 9000:2000?								
20.13	Does the quality management system documentation include: - Documented statement of a quality policy and quality objectives - Quality Manual - Documented procedures required by ISO 9000:2000 - Documents needed by the organization to ensure the effective planning, operation and control of its processes - Records required by ISO 9000:2000								
20.14	Are documents required for the quality management system controlled?								
20.15	Has a documented procedure been established identifying the following controls needed: - Approval of documents for adequacy prior to issue - Review, update as necessary and re-approval								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
	of documents - Ensure that changes and the current revision status of documents are identified - Ensure that relevant versions of applicable documents are available at points of use - Ensure that documents remain legible and readily identifiable - Ensure that documents of external origin are identified and their distribution controlled - Preventing the unintended use of obsolete documents, and to apply suitable identification to them if they are retained								
20.16	Have records been established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system?								
20.17	Has a documented procedure been established to define the following controls needed - Identification - Storage - Retrieval - Protection - Retention time - Disposition								
20.2	**Management Responsibility**								
20.20	Has top management provided evidence of its commitment to the development and implementation of the quality management system and for the continual improvement of its effectiveness?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

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		YES	NO	YES	tbi *	No			
20.21	Has top management ensured that customer requirements are determined and met with the aim of enhancing customer satisfaction?								
20.22	Has top management established a quality policy?								
20.23	Has top management ensured that quality objectives are established at relevant functions and levels within the organization?								
20.24	Has top management ensured that responsibilities, authorities are defined and communicated within the organization?								
20.25	Has top management appointed member(s) of management who have responsibility and authority for quality management?								
20.26	Has top management ensured that appropriate communication processes have been established within the organization?								
20.27	Does the top management review the quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness?								
20.28	Do the outputs from the management review include the decisions and actions?								
20.3	**Resource Management**								
20.30	Have the resources for quality management been determined and provided?								
20.31	Is competency for personnel who perform work affecting product quality based on appropriate education, training, skills, and experience?								
20.32	Has the organization determined the necessary								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

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		YES	NO	YES	tbi *	No			
	competency for personnel performing work affecting product quality?								
20.33	Does the organization identify, provide, and maintain the facilities including: Buildings, Workspace and associated utilities, Process Equipment, hardware and software, Supporting services?								
20.34	Has the environment needed to achieve conformity of product requirements been determined and managed?								
20.4	**Product Realisation**								
20.400	Is planning of the organization's product realization consistent with the requirements of the other processes of the quality management system?								
20.401	Has the organization determined requirements specified by the customer, including the requirements for delivery and post-delivery activities?								
20.402	Prior to the commitment to the customer (e.g. submission of tenders, acceptance of contracts or orders or acceptance of change orders) are requirements adequately reviewed?								
20.403	Has the organization determined and implemented effective arrangements for communicating with customers?								
20.404	Are inputs relating to product requirements defined, documented and maintained as a record?								
20.405	Are outputs of the design and development provided in a form that enables verification against the design and development inputs?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

AIDE MEMOIRE

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
20.406	Are systematic reviews performed in accordance with planned arrangements at suitable stages of the design and development?								
20.407	Is design and development verification performed in accordance with planned arrangements to ensure that the design outputs have met the design and development input requirements?								
20.408	Is design and development validation performed in accordance with planned arrangements?								
20.409	Are design and/or development changes identified and recorded?								
20.410	Are the purchasing processes controlled to ensure purchased product (or service) conforms to requirements?								
20.411	Does purchasing information describe the product to be purchased?								
20.412	Have the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements been established and implemented?								
20.413	Are the production and service provision planned and carried out under controlled conditions?								
20.414	Have processes where deficiencies may become apparent only after the product is in use or the service has been delivered been validated?								
20.415	Is the product identified by suitable means throughout product realization?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
20.416	Does the organization exercise care with customer property while it is under the organization's control or being used by the organization?								
20.417	Is conformity of product preserved during internal processing and delivery to the intended destination?								
20.418	Has the organization determined the monitoring and measurement to be undertaken and the monitoring and measurement devices needed to provide evidence of conformity of product to determined requirements?								
20.5	**Measurement, Analysis and Improvement**								
20.50	Have the monitoring, measurement , analysis and improvement processes been planned, and implemented?								
20.51	Is information relating to customer perception monitored by the organization as to whether customer requirements have been met?								
20.52	Are internal audits conducted at planned intervals to determine whether the quality management system: - Conforms to planned arrangements, requirements of ISO 9001 and the quality management system - Is effectively implemented and maintained								
20.53	Are suitable methods applied for monitoring and where applicable, measurement of the quality management system processes necessary to meet customer requirements?								

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** Procedure, SOP, OI, memo, notes (personal), Q-manual

AIDE MEMOIRE

Reference ICH Q7	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
20.54	Are product characteristics monitored and measured to verify that product requirements are met?								
20.55	Is nonconforming product identified and controlled to prevent unintended use or delivery?								
20.56	Is appropriate data determined, collected and analysed to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made?								
20.57	Does the organization continually improve the effectiveness of the quality management system?								
20.58	Are corrective actions taken to eliminate the cause of nonconformities and to prevent recurrence?								
20.59	Has the organization determined actions to eliminate the causes of potential nonconformities in order to prevent occurrence?								

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