Lexicon of Quality Terms

ASMF/DMF Working Group

Version 1.0 – May 26, 2015

Version	Description of Change	Author	Effective Date
v 1.0	Original publication	ASMF/DMF WG	May 26, 2015

IGDRP ASMF/DMF Working Group
Lexicon of Quality Terms

Version 1.0 (2015-05-26)

It is acknowledged that legal and regulatory terms and phrases are in place in the different jurisdictions for regulatory procedures and documents. This *IGDRP ASMF/DMF Working Group Lexicon of Quality Terms* has been developed to facilitate interactions and the development of work activities through the use of a common vocabulary of Quality-related terms. In the spirit of international cooperation and regulatory convergence, it is recommended that ICH-adopted Quality terms (when available) be used as the default term when developing documentation for the IGDRP activities for the ASMF/DMF Working Group.

Following is a list of ICH Quality terms that should be used in IGDRP materials, together with the corresponding ICH definition (verbatim) as it appears in the relevant ICH Quality guideline. It is acknowledged that some of these ICH definitions may be out-of-date and in need of updating. The ICH definitions are included in this Lexicon of Quality Terms as illustrative purposes only to provide clarity on the term under consideration. Also provided in the table is a list of examples of similar regional terms as they may appear in regional or domestic guidelines. These similar regional terms are included for illustrative purposes only and are not to be used in IGDRP materials.

Similar to procedures at ICH, these ICH/internationally accepted terms could then be transitioned to Regional/Domestic terms once the documentation or activity has been finalised.

ICH-adopted terms:

Preferred (ICH) Quality Term	ICH Definition	Source	Similar Regional Quality Term(s) (not to be used in IGDRP materials)
Accelerated Testing	Studies designed to increase the rate of chemical degradation or physical change of a drug substance or drug product by using exaggerated storage conditions as part of the formal stability studies.	Q1A(R2)	
Acceptance Criteria	Numerical limits, ranges, or other suitable measures for acceptance of the results of analytical procedures.	Q6A	limits, specifications
Active Pharmaceutical Ingredient (API) / Drug Substance *(either could potentially be used, depending on the context)*	API: Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.	Q7	active ingredient, active substance, medicinal ingredient, medicinal substance, pharmaceutical ingredient, pharmaceutical substance
	Drug Substance: The unformulated drug substance that may subsequently be formulated with excipients to produce the dosage form.	Q1A(R2)	
Analytical Procedure	The analytical procedure refers to the way of performing the analysis. It should describe in detail the steps necessary to perform each	Q2(R1)	analytical method, method of analysis, test method

Preferred (ICH) Quality Term	ICH Definition	Source	Similar Regional Quality Term(s) (not to be used in IGDRP materials)
	analytical test. This may include but is not limited to the sample, the reference standard and the reagents preparations, use of the apparatus, generation of the calibration curve, use of the formulae for the calculation, etc.		
API Starting Material	A raw material, intermediate, or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. An API Starting Material can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement, or produced in-house. API Starting Materials are normally of defined chemical properties and structure.	Q7	key starting material, regulatory starting material, starting material
Batch (or Lot)	A specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. In the case of continuous production, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.	Q7	
Container Closure System	The sum of packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the drug product. A packaging system is equivalent to a container closure system.	Q1A(R2)	package, packaging, packaging system
Degradation Product	An impurity resulting from a chemical change in the drug substance brought about during manufacture and/or storage of the new drug product by the effect of, for example, light, temperature, pH, water, or by reaction with an excipient and/or the immediate container closure system.	Q3B(R2)	degradant, decomposition product
	A molecule resulting from a chemical change in the drug molecule brought about over time and/or by the action of e.g., light, temperature, pH, water, or by reaction with an excipient and/or the immediate container/closure system.	Q6A	
Dosage Form	A pharmaceutical product type (e.g., tablet, capsule, solution, cream) that contains a drug substance generally, but not necessarily, in association with excipients.	Q1A(R2)	pharmaceutical form
Drug Product	The dosage form in the final immediate packaging intended for marketing.	Q1A(R2), Q7	finished pharmaceutical product, finished product, medicine, medicinal product, pharmaceutical product
Excipient	Anything other than the drug substance in the dosage form.	Q1A(R2)	auxiliary substance, inactive ingredient, non-medicinal ingredient
Expiry Date or	The date placed on the container label of a drug	Q1A(R2)	

Preferred (ICH) Quality Term	ICH Definition	Source	Similar Regional Quality Term(s) (not to be used in IGDRP materials)
Expiration Date	product designating the time prior to which a batch of the product is expected to remain within the approved shelf life specification if stored under defined conditions, and after which it must not be used.		
	The date placed on the container/labels of an API designating the time during which the API is expected to remain within established shelf life specifications if stored under defined conditions, and after which it should not be used.	Q7	
Identified Degradation Product	A degradation product for which a structural characterization has been achieved.	Q3B(R2)	known degradation product
Identified Impurity	An impurity for which a structural characterization has been achieved.	Q3A(R2) & Q6A	known impurity
Impurity	Any component of the new drug substance that is not the chemical entity defined as the new drug substance.	Q3A(R2)	
	Any component of the new drug substance which is not the chemical entity defined as the new drug substance. Any component of the drug product which is not the chemical entity defined as the drug substance or an excipient in the drug product.	Q6A	
Long term testing	Stability studies under the recommended storage condition for the re-test period or shelf life proposed (or approved) for labeling.	Q1A(R2)	real time testing
Lot	see Batch	Q7	
New Drug Product	A pharmaceutical product type, for example, tablet, capsule, solution, cream, etc., which has not previously been registered in a region or Member State, and which contains a drug ingredient generally, but not necessarily, in association with excipients.	Q6A	new finished pharmaceutical, product, new finished product, new medicine, new medicinal product, new pharmaceutical product
New Drug Substance	The designated therapeutic moiety that has not been previously registered in a region or member state (also referred to as a new molecular entity or new chemical entity). It can be a complex, simple ester, or salt of a previously approved drug substance.	Q3A(R2) & Q3B(R2) & Q6A	new active pharmaceutical ingredient new active ingredient, new active substance, new medicinal ingredient, new medicinal substance, new pharmaceutical ingredient, new pharmaceutical substance
Pilot Scale Batch	A batch of a drug substance or drug product manufactured by a procedure fully representative of and simulating that to be applied to a full production scale batch. For solid oral dosage forms, a pilot scale is generally, at a minimum, one-tenth that of a full production scale or 100,000 tablets or capsules, whichever is the larger.	Q1A(R2)	
Product Lifecycle	All phases in the life of the product from the initial development through marketing until the product's discontinuation.	Q9	
Production batch	A batch of a drug substance or drug product manufactured at production scale by using	Q1A(R2)	commercial batch, industrial batch

Preferred (ICH) Quality Term	ICH Definition	Source	Similar Regional Quality Term(s) (not to be used in IGDRP materials)
	production equipment in a production facility as specified in the application.		
Quality Module / Module 3	[no definition]		Chemistry, Manufacturing, and Controls (or CMC), Chemistry and Manufacturing, Pharmaceutical Chemistry
Re-test period	The period of time during which the drug substance is expected to remain within its specification and, therefore, can be used in the manufacture of a given drug product, provided that the drug substance has been stored under the defined conditions.	Q1A(R2)	
Shelf life	The time period during which a [drug substance or] drug product is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container label.	Q1A(R2)	expiration dating period
Specification	A list of tests, references to analytical procedures, and appropriate acceptance criteria which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a drug substance or drug product should conform to be considered acceptable for its intended use. "Conformance to specifications" means that the drug substance and / or drug product, when tested according to the listed analytical procedures, will meet the listed acceptance criteria. Specifications are critical quality standards that are proposed and justified by the manufacturer and approved by regulatory authorities.	Q1A(R2) & Q6A	specifications
Specified Impurity	An impurity that is individually listed and limited with a specific acceptance criterion in the new drug substance specification. A specified impurity can be either identified or unidentified.	Q3A(R2)	known impurity
Stress Testing (Drug Substance)	Studies undertaken to elucidate the intrinsic stability of the drug substance. Such testing is part of the development strategy and is normally carried out under more severe conditions than those used for accelerated testing.	Q1A(R2)	forced degradation testing/studies
Unidentified Impurity	An impurity for which a structural characterisation has not been achieved and that is defined solely by qualitative analytical properties (e.g., chromatographic retention time).	Q3A(R2)	unknown impurity
	An impurity which is defined solely by qualitative analytical properties, (e.g., chromatographic retention time).	Q6A	
Unspecified Impurity	An impurity that is limited by a general acceptance criterion, but not individually listed with its own specific acceptance criterion, in the new drug substance specification.	Q3A(R2)	unknown impurity

Non-ICH Terms

Following is a list of non-ICH terms that should be used in IGDRP materials, together with definitions, and a list of examples of similar regional terms as they may appear in regional or domestic guidelines. As previously noted, these similar regional terms are included for illustrative purposes only and are not to be used in IGDRP materials.

Preferred Term	Definition	Similar Regional Term(s) (not to be used in IGDRP materials)
Application	The dossier for the drug product submitted to the regulatory body for authorisation	Dossier, Submission
Applicant	The company filing the dossier (application) for the drug product submitted to the regulatory body for authorisation	Marketing Authorisation Holder Product Registrant, Registrant, Sponsor
Applicant's Part / Restricted Part		Open Part / Closed Part Disclosed Part / Restricted Part
"ASMF/DMF"		APIMF, ASMF, CEP Dossier, DMF, MF
ASMF/DMF Holder (e.g., for the ASMF/DMF)	The owner of the ASMF/DMF submitted to the regulatory body	Agent, Owner, Registrant, Sponsor
Assessment		Evaluation, Review
Assessment Report		Evaluation Report, Review Report
Assessor		Evaluator, Reviewer
Authorisation, Authorised		Approval, Approved, Granted, Grant, Registration, Registered
Authorisation Letter		Acceptance letter Approval letter, Opinion Grant letter
CEP Holder	The owner of the CEP dossier submitted to the EDQM	not applicable
Deficiency Letter		Deficiency comments, Deficiency questions, List of Questions, Queries, Query Letter Request for Further Information, Request for Clarification Outstanding points
Prequalified API	APIs that have been assessed by the WHO Prequalification programme and found to meet WHO-recommended quality and GMP standards.	not applicable
Update	A revision, change or replacement for an existing ASMF/DMF	Amendment

Other terms for future consideration (e.g., including discussions with other working groups as appropriate):

Preferred (ICH) Quality Term	ICH Definition	Source	Similar Regional Quality Term(s) (not to be used in IGDRP materials)
Delayed Release	Release of a drug (or drugs) at a time other than immediately following oral administration.	Q6A	gastro-resistant release,
Extended Release	Products which are formulated to make the drug available over an extended period after administration.	Q6A	prolonged release, sustained release
Immediate Release	Allows the drug to dissolve in the gastrointestinal contents, with no intention of delaying or prolonging the dissolution or absorption of the drug.	Q6A	conventional-release, regular-release
Modified Release	Dosage forms whose drug-release characteristics of time course and/or location are chosen to accomplish therapeutic or convenience objectives not offered by conventional dosage forms such as a solution or an immediate release dosage form. Modified release solid oral dosage forms include both delayed and extended release drug products.	Q6A	controlled release
Rapidly Dissolving Products	An immediate release solid oral drug product is considered rapidly dissolving when not less than 80% of the label amount of the drug substance dissolves within 15 minutes in each of the following media (1) pH 1.2, (2) pH 4.0, and (3) pH 6.8.	Q6A	fast melt products, quick dissolving product
Risk	The combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51).	Q9	