

ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE (APIC)

Quality Agreement for Laboratories

Guideline & Templates

Version 1.0

April 2012

Disclaimer

This document represents voluntary guidance for API manufacturers and their Contract Laboratories and the contents should not be interpreted as regulatory requirements. Alternative approaches than those described here may be used.

Foreword

The CEFIC* Sector Group APIC (the Active Pharmaceutical Ingredients Committee) was founded in 1992 as a direct consequence of the rapidly increasing European regulatory requirements affecting the manufacture of Active Pharmaceutical Ingredients (APIs).

APIC represents producers of APIs and API intermediates in Europe. Its membership consists of more than 60 companies, located all over Europe, and of several national industry associations. For around 2/3 of its members, selling APIs and intermediates is their major business while ca. 1/3 of the members are primarily marketing final medicinal products.

APIC's focus is on worldwide Quality, Good Manufacturing Practice (GMP) and Regulatory matters relating to APIs and intermediates. Through the years APIC has developed into a high-profile industry association with an excellent, worldwide reputation.

APIC has already developed a series of guidance documents and position papers (see <http://apic.cefic.org/>). This document offers best industry practice and guidance in the establishment of a Quality Agreement between an API manufacturer and its contract laboratory. The guideline highlights the factors to consider when concluding such an agreement between both parties.

If you have any comments or suggestions for further improvement please contact the APIC Secretary at:

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** CEFIC (the European Chemical Industry Council): The Brussels-based organisation that represents the European Chemical Industry*

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Quality Agreement for Contract Laboratory Work

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2. Introduction

One of the biggest issues facing the pharmaceutical industry and patients today is quality, integrity and security of the pharmaceutical supply chain. As outsourcing of services such as analytical work along the supply chain is a common practice Supplier Quality Management have come into focus in the recent past. A suitable supplier qualification program has hence to be implemented by each user of purchased services. A major element of such a supplier qualification program is the **Quality Agreement** between the manufacturer of the API/intermediate and the contract laboratory in order to increase transparency and traceability.

2.1 What is a Quality Agreement?

A Quality Agreement under the scope of this guideline is a legally binding agreement that is mutually negotiated and concluded between (the Quality Departments of) the service requestor and the Quality responsible at the service providing laboratory. It is intended to define, in a formalised manner, responsibilities relative to quality tasks to assure the supply of safe materials (APIs or intermediates) acceptable for pharmaceutical use. A Quality Agreement is based on the quality procedures in place at both the service requestor and the service providing laboratory. The Quality Agreement also includes commitments between the parties regarding (a) the provision of information, documents, or samples, and (b) communication and notification rules including contacts. It creates mutual understanding of the quality & regulatory requirements relevant to the analysis of material and both parties respective obligations related to quality. By clearly delineating responsibilities, costly product quality issues resulting from miscommunication can be reduced or eliminated.

A Quality Agreement is a major element of a supplier qualification program but, of course, it is not a substitute for the supplier qualification processes, including audits as necessary, and for understanding the supplier processes and capabilities. A Quality Agreement must not contain any commercial or liability related terms, which should exclusively be dealt with in a Supply Agreement.

2.2 The Issue

Due to the increasing desire to have Quality Agreements in place, there has been a trend to use templates to get a large number of agreements in place quickly. Many companies have developed their own generic Quality Agreement templates. Unfortunately, these individual templates have often been designed to cover multiple types of services (stability testing, raw material testing, API testing) or products (APIs, intermediates, pharmaceutical excipients, and even packaging components). As a consequence, there have been extensive discussions between companies, and **significant time and resources spent** during all the review loops. At the end the **complexity** on both sides has considerably increased due to the high degree of diversity of agreements to be maintained. It is a real challenge for all organisations to keep control over all the individual agreements and commitments made between the various parties (as regards, e.g., timelines, document provisions, notifications vs. prior approvals).

2.3 The Solution

The issues mentioned above could be resolved by the use of **standardised templates**. Since APIC is committed to improve the relationship between the different stakeholders in the production process of safe API, APIC has developed this Quality Agreement Guideline including the corresponding templates. The APIC Task Force that did the work consisted of members from both specialised API/intermediate manufacturers and companies primarily making finished drug products. Hence APIC believes that the result represents best industry practice considering the needs and requirements that enter into such a Quality Agreement.

3. Purpose and Scope

3.1 Purpose

This document intends to provide expert guidance to the Analytical Laboratories analysing APIs and intermediates and its customers for the implementation and maintenance of appropriate Quality Agreements.

It is obvious that consistent standards for such agreements will provide the following **benefits** to the industry:

- Lower workload (by reduced drafting time)
- Faster implementation (by reduced review times)
- Less complexity (by reduced diversity)
- Clear roles and responsibilities
- Compliance with current regulations

Following this document will provide the “state of the art” for Quality Agreements for analytical services in the pharmaceutical (API/intermediate) supply chain.

The APIC Quality Agreement Guideline and corresponding templates are designed to be a flexible model for preparing Quality Agreements. It defines the appropriate items that should be addressed in a Quality Agreement. The template is designed to be global in scope and contents, thus being suitable for the use in all regions.

3.2 Scope

The guideline and templates cover agreements between the API/intermediate manufacturer and the Analytical Laboratory providing any kind of analytical service. It does not cover agreements between API/intermediate manufacturer and their customers.

4. Legal Requirements

Although Quality Agreements have become a common tool in our business and are intensively demanded by the authorities to be implemented they are not described in broad in the current guidelines.

Written contracts/agreements defining the responsibilities and communication processes for quality-related activities of the involved parties are mandatory for “**outsourced activities**” (see ICH Q10 Guideline, chapter 2.7). In principle, it is the responsibility of the contract giver to request the closure of such a contract/agreement with its contract acceptor(s).

Although there is no binding regulation on European level, there seem to be some countries that force to have such an agreement. For instance, France is requiring a Quality Agreement between the API/ excipient manufacturer and the pharmaceutical manufacturer in case the incoming testing for the raw materials shall be delegated to the API/ excipient manufacturer according to French law.

In the United States, Quality Agreements are simply assumed but not necessarily a (legal) requirement of the Food and Drug Administration (FDA). Although FDA issues no guidelines specifically for Quality Agreements in the pharmaceutical industry, nor is issuing a final rule on the subject, expectations of having implemented Quality Agreements are now relatively common.

5. Format and Structure of a Quality Agreement

5.1 General Aspects

The introduction and general provisions sections address the scope and terms and conditions of the agreement. The compliance section addresses the main quality and regulatory points and responsibilities that should be included in an appropriate Quality Agreement. The template in this APIC guideline represent the compliance section (see typical structure of an agreement given further below).

The template does, however, not mention every item of the pharmaceutical quality system since quality requirements that are sufficiently covered by reference to the applicable quality/GMP standard do not need to be reiterated in the agreement.

The format of the templates is intended to be flexible with the templates offering all the single elements needed for the compliance section of most Quality Agreements.

There are different possibilities how both parties may benefit from the use of a standardised template:

- The template may **completely replace** an own agreement
- The template may be **used as a basis** for a (slightly) modified, customised draft agreement
- **Certain sections** of the template may be used when drafting an own agreement
- The templates' wording may be **used to resolve dispute** if mutually understood as good industry practice

Hence the templates constitute the ideal common starting point for any further negotiations on a Quality Agreement.

Modifying the templates should, however, be done with care and only as necessary to avoid lengthy negotiations. It is suggested that Contract Giver prepares in advance a Quality Agreement based on the APIC guideline to begin the negotiation process with its contract Laboratory when a Quality Agreement is requested.

Where necessary or requested by either party, country-specific or product-specific requirements may be added to the standard text.

It would significantly facilitate the discussion if any such alterations are clearly indicated by the drafting party to the other party (e.g., by coloured text) as this will help to achieve one of the major aims of the APIC project – speedier agreements.

Timelines mentioned in a Quality Agreement may be given in a descriptive way (most common terms: immediately, promptly, without undue delay, in a timely manner, within a reasonable period of time) or by a precise figure. Widely accepted definitions of the descriptive terms can be found in the glossary of this document. Time differences between the regions involved should be considered.

5.2 Standard Structure

The following sections should normally be included in a Quality Agreement for contract laboratory:

I. Introduction/Purpose/Scope

I.1 Parties to the agreement

Example wording:

This Quality Agreement is by and between <full manufacturer name> located at <full manufacturer address>, hereafter referred to as Contract Giver and <full Laboratory name> located at <full Laboratory address>, hereafter referred to as CONTRACT LABORATORY. Whereas, Contract Acceptor provides analytical results suitable for pharmaceutical use to Contract Giver.

Note: The following definition of “Affiliate” may be added to the preceding paragraph or listed in the Definitions section.

For the purposes of this Quality Agreement, the term “Affiliate” shall mean any company controlling, controlled by or under common control with the respective party. The term “control” shall mean the possession, directly or indirectly, of more than 50 % of the respective shares or the power to direct the management or policies of such company or party.

I.2 Material covered by the agreement

Example wording:

This Quality Agreement pertains to the following Material(s), hereafter referred to as Product: <list or see attachment>.

I.3 Site(s) involved

Note: Sites at which SUBSTANCE(s) are analysed should be mutually agreed upon. The Contract Acceptor sites involved can be specified here if needed (or may refer to an appendix). If the sites involved are not listed in this agreement, it should be indicated where the agreed sites are specified. The sites can also be sites of affiliates of the Contract Acceptor (see also I.1).

I.4 Definitions and abbreviations (optional)

Example wording:

Unless this Quality Agreement will expressly provide to the contrary, the following terms used herein, whether used in the singular or plural, will have the respective meanings set forth below:

<List definitions/abbreviations>

II. Compliance Section

The appropriate Quality Agreement template is inserted here.

Use instructions for the Quality Agreement templates:

Text highlighted in yellow indicates alternative or optional wordings.

Text highlighted in blue indicates a link to one of the Annexes with additional information.

Notes in grey boxes are for information/explanation purposes only, and they would not appear in the actual Quality Agreement.

Text in green boxes represents specific conditions for Materials still under development.

III. General Provisions

Note: The general provisions mentioned hereunder are required for a stand-alone Quality Agreement.

III.1 Term of agreement

Example wording:

This Quality Agreement shall become effective and binding upon the date of the final signature and shall remain in effect until 2 years after the last service provided by contract laboratory by Contract Giver to Contract Acceptor unless the Parties specifically agree in writing an extension of the Quality Agreement. Either Party may terminate this Quality Agreement by giving 6 months written notice to the other Party.

Note: In case the effective date is not determined by the final signature, the effective date should be given elsewhere in the Quality Agreement.

III.2 Assignment

Example wording:

Neither Party shall have the right to assign any or all of its rights or obligations under this Quality Agreement without the other Party's prior written consent, which consent shall not unreasonably be withheld. The foregoing notwithstanding, prior written consent shall not be required (i) in case of an assignment of rights or obligations to an Affiliate of the assignor (optional extension: provided that the assignor procures that any such Affiliate assigns such rights back to the assignor immediately before ceasing to be an Affiliate of the assignor), or (ii) in connection with a merger, consolidation, or a sale of all or substantially all of Party's assets to a third Party, except if such merger, consolidation or sale is with a competitor of the other Party.

Note: Detailed obligation related to the activities under the Agreement is case specific and should be in line with mutual agreed terms under "6. Change Management" and "7. Subcontracting" in the Quality Agreement for Contract Laboratory Work.

III.3 Related agreements

Example wording:

If other agreement is in place between Contract Giver and Contract Acceptor, and there are any inconsistencies between the agreements, the Quality Agreement will take precedence in all quality related matters.

III.4 Confidentiality (optional)

Note: It is recommended to refer to separate documents pertaining to confidentiality, e.g. confidentiality agreement (also referred to as a confidential disclosure agreement) but may be defined here according to Contract Giver policy.

III.5 Choice of Law (optional)

Note: If a reference shall also be included in the Quality Agreement the following wording is recommended:

“The Parties agree that this Quality Agreement shall be governed by and construed in accordance with the law applicable to the supply agreement between the Parties or their Affiliates pertaining to the Service(s).”

Typically the law of the country where the Contract Laboratory is located is chosen. For instance, in Europe (except Denmark and the UK), the new EU Regulation No. 593/2008 - "Rome I" - will apply as of December 17, 2009, and as most of the jurisdictions it declares that the law of the country where the party required to effect the characteristic performance of the contract has its habitual place of residence shall govern the contract.

III.6 Survival Clause

Example wording:

The <list particular provisions> shall survive <give number> years from expiration or termination of this Quality Agreement.

Note: This clause relates to provisions that by their sense or context are intended to be continued beyond termination of the Quality Agreement, for instance the right to audit, maintenance of lot traceability, responses to complaints or authority requests, ongoing stability studies, or document/record/sample retention.

IV. Signatories

V. Quality Contacts

Note: List the relevant contact persons (name, position, phone number, e-mail) from each party that will be responsible for communications related to this Quality Agreement. This information can be provided in an attachment.

VI. List of Appendices

Examples of documents typically attached to a Quality Agreement (list not exhaustive) e.g. product specification(s), example CoA(s), list of sub-contractors.

6. Quality Agreement Review and Maintenance

6.1 Negotiation, Review and Approvals

The negotiation and review of a Quality Agreement should always be a collaborative effort of different departments of the parties involved: Quality representatives negotiate and review the quality sections, and Legal representatives negotiate and review the legal provisions. Other departments (e.g., Purchasing, Marketing) may be involved, as appropriate. It is recommended that in the negotiation phase a sole functional unit, preferably the Quality Unit, acts as the voice of the entire company.

The Quality representatives at API/intermediate manufacturer and contract laboratory (analytical service provider) must assure that the quality provisions can be met, i.e., that the obligations of the agreement are consistent with the quality systems established at the respective sites [*Note: this is very important in case multiple sites or affiliates at either party are affected by the agreement*], and both parties must understand the impact of the agreement provisions on patient safety and product quality.

In order to allow review of any modified wording or any requirements added during the negotiation phase and to ensure transparency and traceability the “track changes mode” should be used. A “cleaned” version would be created only directly before signature, after all parties are satisfied with the draft agreement.

Clarity of language in the Quality Agreement is essential. Quality Agreements have no room for ambiguity. It is generally recommended that the wording of Quality Agreements is kept “simple” or “non-legal” since it is primarily written for Quality people, and these people have to understand and follow the provisions.

A Legal review of the final draft agreement is a “must”, irrespective if the Quality Agreement is a stand-alone document or if the Supply Agreement is negotiated at the same time. Not having the Quality Agreement undergo a qualified review by Legal department may expose the company to potential liability. It is, however, not the Legal representatives’ task to interpret GMPs and change the language unless potential liability exists. It is their job to look at the document from the point of view of someone who is providing a level of protection to the company.

The following wording recommendations aim to avoid future dispute and unexpected liability with respect to requirements and commitments in Quality Agreements, and they have been considered in the APIC templates:

- Do not use expressions such as “SERVICE PROVIDER guarantees”, “SERVICE PROVIDER represents and warrants”, or “SERVICE PROVIDER ensures”, in Quality Agreements. “Guarantee”, in particular, triggers extended rights of the purchaser, liability without any fault, and leads to extended statute of limitations.
- Instead use “neutral” expressions like “SERVICE PROVIDER shall”, “SERVICE PROVIDER undertakes”, or “SERVICE PROVIDER shall make reasonable endeavours” (but not “best” endeavours).

Since all Quality Agreements require legally binding signatures, it is the responsibility of each party to assure the signatures in the Quality Agreement reflect the legally binding signatures representing each party. Depending on the signing rules in each company two or

even more signatures might be required. At least one signature should come from an authorised Quality representative.

6.2 Maintaining Agreements

Any Quality Agreement should be readily available to all persons or units with obligations stipulated in the agreement. It is recommended to have a system in place for tracking commitments originating from the various Quality Agreements.

Once approved all Quality Agreements must be kept current by both parties during the entire effective period. An amendment/addendum process should allow for simple updating, e.g., for contact or specification updates. Any amendment/addendum should be maintained with the original agreement.

Basically, there are different options to define the review frequency for an established Quality Agreement: periodic review (e.g., during the compilation of the annual PQRs) or frequency based on risk. A combination of both options might be the best solution, namely a 3-years review period in the absence of serious quality incidents.

7. References

1. EU GMP Guide Part I
2. Good Manufacturing Practice (GMP) expectations for Active Pharmaceutical Ingredients (APIs), UK MHRA, October 2008
3. Good Trade and Distribution Practices for Pharmaceutical Starting Materials. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-eighth report. Geneva, World Health Organization, 2004 (WHO Technical Report Series, No. 917), Annex 2
4. ICH Q7 Guideline “Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients”, November 2000
5. ICH Q10 Guideline “Pharmaceutical Quality System”, June 2008
6. Sandhya Mohan: “How to Write a Quality Agreement”, Journal of GxP Compliance, Vol 9, No 3, April 2005
7. The IPEC Quality Agreement Guide and Template 2009, www.ipeceurope.org/index.php?option=com_docman&task=doc_download&gid=280&&Itemid=46
8. Other APIC Quality Agreement Guidelines

8. Glossary

Active Pharmaceutical Ingredient (API) - Any substance or mixture of substances, intended to be used in the manufacture of a drug (or 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 or any function of the body of man or animals.

Adverse trend – A trend in the values of any measure of the quality of product or process which is outside the normal process capability or which indicates a reasonable probability that the product will fail to comply with specification before the end of its assigned shelf-life or retest period.

Agreement – Arrangement undertaken by and legally binding on parties.

(Governmental) Authority – Any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (a) any government of any country, (b) a federal, state, province, or other political subdivision thereof, or (c) any supranational body including without limitation the European Agency for the Evaluation of Medicinal Products (EMA).

Business day – Any day of the week, other than Saturday, Sunday, or day on which the party required to take action is regularly closed for business, i.e., Monday to Friday (European working hours) except any official national or regional bank holidays or shut down of the plant.

CEP – A certificate issued by the European Directorate for the Quality of Medicines which demonstrates that the Product complies with the requirements of the European Pharmacopoeia monograph and / or Transmissible Spongiform Encephalopathy (TSE) requirements. Also known as “CoS” = Certificate of Suitability.

Certificate of Analysis (or Analytical Report) – A document identified as such, provided by the supplier signed by its Responsible Person, or produced by a computer system which provides a degree of control equivalent to that given by a signature, which sets forth the analytical test results, obtained from testing of a representative sample, against the specifications for the batch to be delivered.

Certificate of Conformance (or Certificate of Compliance) – A document identified as such, provided by the supplier and signed by a nominated representative of its Quality Unit, or produced by a computer system which provides a degree of control equivalent to that given by a signature, which certifies that each analysis of Material was performed in compliance with the agreed analytical method against mutual agreed specifications, cGMP, and the relevant pharmacopoeial monographs, as applicable.

Contract – Business agreement for supply of goods or performance of work at a specified price.

Critical deviation – A departure from an approved instruction, a standard operation, or a predefined critical parameter, or an unanticipated event that could have an adverse impact, respectively, on the final SUBSTANCE quality and/or stability and/or physical characteristics.

DMF – Drug Master File. The API manufacturer’s dossier for providing confidential information to a regulatory authority about facilities, processes, or articles relating to product (usually an API) used in the manufacturing, processing, packaging, and storing of one or more drug (or: medicinal) products.

GDP – Good Distribution Practice. GDP deals with the distribution of products, including requirements for purchase, receiving, storage and export. GDP regulates the movement of products from the premises of the manufacturer to the end user, or to an intermediate point by means of various transport methods.

GMP – Good Manufacturing Practice. Requirements for the Quality System under which drug (or: medicinal) products and their (active) ingredients are manufactured. Current Good Manufacturing Practice (cGMP) is the applicable term in the United States. For the purposes of this guideline, the terms GMP and cGMP are equivalent.

Immediately – Generally no more than twenty-four (24) business hours. This period may be exceeded due to events or circumstances beyond the reasonable control of the responsible party.

Laws – All laws, statutes, rules, regulations (including, without limitation, cGMPs, NDA regulations, and other relevant provisions enforced by any applicable governmental authority), ordinances and other pronouncements having the binding effect of law of any governmental authority.

“Manufacturing” License – With respect to a country, any regulatory authorisation required to perform analytical testing of material or classes of material as granted by the relevant governmental authority.

Non-conformance –Departure of a quality characteristic from its intended level or state such as to cause an associated material or activity not to comply with its specification, cGMP, marketing authorisation or applicable law.

OOE – Out-of-expectation. A value obtained that still meets the set requirements but is significantly different from the previous values or former trend

Promptly – Generally no more than three (3) business days. This period may be exceeded due to events or circumstances beyond the reasonable control of the responsible party.

Quality Agreement – A legally binding agreement that is mutually negotiated and concluded between (the Quality Departments of) API/intermediate manufacturers and a contract laboratory. It is intended to define, in a formalised manner, responsibilities relative to quality tasks to assure the supply and use of safe materials acceptable for pharmaceutical use. It may also include commitments between the parties regarding (a) the provision of information, documents, or samples, and (b) communication and notification rules including contacts.

Quality Incident – An incident relating to an issue or defect which is not necessarily detected by the specification parameters but which potentially could result in a non-conformance. A “critical” quality incident is relating to a defect or fault that makes a product unsuitable for use and which could potentially result in a recall, retrieval or withdrawal.

Record – Document stating results obtained and/or providing evidence of activities performed. The medium may be paper, magnetic, electronic or optical, photography etc. or a combination thereof.

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Responsible Person – The person(s) within the Quality Unit at the supplier who is accountable for the release of analytical results.

Sample – A part or parts of the product taken to show the quality of the whole.

Site – A location where the analytical Service is performed. This may be any operational area within the supplier's facility referred to in the section "Parties to the agreement" of the Quality Agreement, or at a remote facility that may be the facility of an affiliate of the supplier or a sub-contractor.

Supplier – Person or company providing any kind of services on request. For the purpose of this guideline, a supplier is the contract laboratory providing analytical services.

Supply chain – For the purpose of this guideline, supply chain is defined as all steps in the entire chain of distribution starting from the point at which an API or intermediate is transferred outside the control of the original manufacturer's material management system downstream to the final user(s).

Timely manner – As soon as can be expected considering the typical operations and processes at manufacturers, the defined responsibilities and the agreed communication pathways. A "reasonable period of time" is considered as practically synonymous. The exact period of time depends on the respective subject.

Without undue delay – Generally no more than five (5) business days. This period may be exceeded due to events or circumstances beyond the reasonable control of the responsible party.

Note: For all other GMP-relevant terms it is referred to the glossary of the ICH Q7 Guideline

Quality Agreement for Contract Laboratory Work

Between

CONTRACT GIVER
street
Zip, state, Country

Subsequently named as 'CONTRACT GIVER'

and

CONTRACT LABORATORY
XXXX
XXXX
XXXX

as Contract Acceptor, subsequently named 'CONTRACT LABORATORY'

'Party' hereafter means either CONTRACT LABORATORY or CONTRACT GIVER, 'Parties' means both CONTRACT LABORATORY and CONTRACT GIVER.

Content of the Quality Agreement:

	PREAMBLE
1.	OBJECT AND BASIS OF THE QUALITY AGREEMENT
2.	PERSONS TO WHOM COMMUNICATIONS SHOULD BE ADDRESSED
3.	SECREC
4.	AUDITS AND INSPECTION
5.	PROCEDURES AND DOCUMENTS
6.	CHANGE MANAGEMENT
7.	SUBCONTRACTING
8.	TEST SAMPLES, STORAGE
9.	INSTRUMENT CALIBRATION AND VALIDATION
10.	REAGENTS, MATERIALS
11.	PERSONNEL
12.	TESTING OF PRODUCT
13.	REVIEW AND STORAGE OF RAW DATA AND REPORTS
14.	DEVIATIONS FROM TESTING INSTRUCTIONS AND OOS RESULTS
15.	REFERENCE STANDARDS
16.	FORMAT OF THE FINAL REPORTS
17.	RESULT TRANSFER
18.	FINAL PROVISIONS
19.	ANNEX

Approved CONTRACT LABORATORY (Dat/Vis)	Approved CONTRACT GIVER (Dat/Vis)

PREAMBLE

The following 'Quality Agreement for Contract Laboratory Work' (hereafter referred to as 'Quality Agreement') defines the roles and responsibilities of the Parties related to analytical testing under contract by CONTRACT LABORATORY for CONTRACT GIVER, in accordance with current Good Manufacturing Practice (cGMP) and any other applicable requirements.

1. OBJECT AND BASIS OF THE QUALITY AGREEMENT

This Quality Agreement concerns **the validation and transfer of test methods** and the testing of samples of the contract products listed in **Annex B** to this Quality Agreement (subsequently called 'Product') by CONTRACT LABORATORY for CONTRACT GIVER under GMP requirements. CONTRACT GIVER will define rules and procedures to be followed during quality control specified in **Annex D** (per Product) and in **Annex E** (for general application).

Any previous arrangements (except for business/commercial arrangements, if they are defined in a separate contract) for contract laboratory work between the Parties are replaced by this Quality Agreement.

CONTRACT LABORATORY will test and handle Product in compliance with the recognized pharmaceutical rules and relevant legal provisions, in its current edition, as follows:

- European Union Directive 2001/83/EC, and its amendments, including but not limited to the EU Guidelines to Good Manufacturing Practice,
- PIC/S; Guide to Good Manufacturing Practice for Medicinal Products,
- **FDA; Current Good Manufacturing Practice (cGMP), US Code of Federal Regulation (21 CFR 210f and 21 CFR 211),**
- ICHQ7 Good Manufacturing Practice guide for Active Pharmaceutical Ingredients,
- **Any applicable national guidelines at the place of testing,**

hereafter collectively referred to as 'GMP Regulations'.

If CONTRACT GIVER further wishes that any special regulations or directives are followed, that are not generally known and recognized under the above GMP Regulations, CONTRACT GIVER shall notify CONTRACT LABORATORY correspondingly and the Parties shall discuss in good faith how to proceed."

CONTRACT LABORATORY's approved facilities are duly authorized by the appropriate authorities for the activities that are subject to this Quality Agreement. This is approved by a Manufacturing License and GMP certificate or an equivalent authorization from the corresponding authority. CONTRACT LABORATORY is obliged to inform CONTRACT GIVER without delay of any restriction to the authorization for the activities covered by this Quality Agreement.

The detailed responsibilities of each Party are defined in **Annex C, Delimitation of Responsibilities under GMP**.

Approved CONTRACT LABORATORY (Dat/Vis)	Approved CONTRACT GIVER (Dat/Vis)

2. PERSONS TO WHOM COMMUNICATIONS SHOULD BE ADDRESSED

Persons who may be contacted by CONTRACT LABORATORY and CONTRACT GIVER in matters of sample analysis and other aspects of this Quality Agreement are defined in Annex A. The Parties shall notify each other of any change in its relevant contact persons.

3. SECRECY

A separate confidentiality agreement was signed between the Parties on XXXX.

4. AUDITS AND INSPECTION

CONTRACT GIVER has the right to inspect the facilities and the analyses of Product at CONTRACT LABORATORY to ensure that the activities under this Quality Agreement are carried out in accordance with the GMP Regulations. After consent by CONTRACT LABORATORY, CONTRACT GIVER is allowed to hand over its audit report to customers if required by them. CONTRACT LABORATORY further agrees that CONTRACT GIVER's customers, if previously coordinated and consented by CONTRACT GIVER, or competent authorities also have the right to inspect the facilities and the analyses of Product at CONTRACT LABORATORY. CONTRACT LABORATORY agrees to inform CONTRACT GIVER in writing and without delay about planned inspections in advance and about problems found at inspections by authorities related to testing of CONTRACT GIVER's Product. Audits will be performed on dates and times mutually agreed between the Parties, provided, however, that audits for investigational reason ('for cause audits') may be performed at any time during normal business hours.

5. PROCEDURES AND DOCUMENTS

CONTRACT LABORATORY's directives and operating procedures shall be used unless otherwise laid down in Annex D for Product specific requirements and in Annex E for general application. All documents expressly mentioned in these Annexes are binding to CONTRACT LABORATORY. CONTRACT GIVER defines the analytical testing methods to be used in the analytical order. In this case CONTRACT LABORATORY's directives may only be used upon CONTRACT GIVER's written approval. CONTRACT LABORATORY is responsible for maintenance and update of its own SOPs to ensure that the processing and testing of the samples of Product is done in compliance with the GMP Regulations and the directives referenced in the Annexes.

6. CHANGE MANAGEMENT

Changes are variations to this Quality Agreement, including its Annexes, and to any activity hereunder, relevant to the regulatory status of Product and to the application of the GMP Regulations. Each intended major change must be drawn up in writing and accepted by both Parties. Change requests directly induced by governmental authorities activities shall not be refused without good reason. For each major change approval by CONTRACT GIVER is necessary, prior to implementation. Formal change requests shall be sent to CONTRACT GIVER. Minor changes not requiring approval by CONTRACT GIVER will be listed in Annex C. A change not defined in the Annex must be notified in writing prior to implementation to the Contract Giver. The parties shall agree on the categorization of the respective change (minor or major).

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7. SUBCONTRACTING

CONTRACT LABORATORY agrees not to pass any of the work entrusted to them under this Quality Agreement to any third party without CONTRACT GIVER's prior written approval of the arrangement.

8. TEST SAMPLES, STORAGE

CONTRACT GIVER will ensure that the samples to be tested are prepared and unambiguously labelled (including the batch number) and that the necessary information (laboratory order per sample or cluster of samples, storage conditions, safety handling requirement/MSDS) is provided.

If not otherwise agreed in Annex D, the adequate transfer of test samples to CONTRACT LABORATORY is in the responsibility of CONTRACT GIVER.

CONTRACT LABORATORY is responsible to store samples received at ambient temperature or as specified differently in the analytical order accompanying the sample.

9. INSTRUMENT CALIBRATION AND VALIDATION

Quality controls must be carried out in compliance with the GMP Regulations, using qualified, calibrated equipment and machines as well as validated testing methods. Product specific validation of testing methods is in the responsibility of CONTRACT GIVER and will be ordered by CONTRACT GIVER. GMP relevant computerized systems shall be validated.

10. REAGENTS, MATERIALS

CONTRACT LABORATORY is liable for the regular quality of the reagents/materials used. For reagents/materials supplied by CONTRACT GIVER the requisite quality and suitability is considered as confirmed by CONTRACT GIVER. CONTRACT LABORATORY does not undertake any additional quality check on its own unless on advise in writing by CONTRACT GIVER to carry out distinct quality tests, or in case these turn out to be indispensable in the course of examination.

11. PERSONNEL

During the period of this Quality Agreement CONTRACT LABORATORY ensures that suitable rooms, equipment and qualified personnel can be substantiated to carry out the corresponding activities hereunder.

CONTRACT LABORATORY shall inform CONTRACT GIVER without delay if essential changes happen in the management of CONTRACT LABORATORY.

12. TESTING OF PRODUCT

Tests to be carried out are specified in Annex D. On CONTRACT GIVER's demand (confirmed in writing) additional tests and deviant testing instructions may be used for individual analytical orders. The deviant testing instructions will either be provided by CONTRACT GIVER or by CONTRACT LABORATORY after mutual consent.

If not otherwise agreed CONTRACT LABORATORY shall run testing to the extent specified in the analytical order and according to the test methods referenced in Annex D using the test equipment described there. The extent of method transfer and validation is in the responsibility of CONTRACT GIVER and is only performed on CONTRACT GIVER's written demand.

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13. REVIEW AND STORAGE OF RAW DATA AND REPORTS

All raw data acquired by CONTRACT LABORATORY for CONTRACT GIVER and the subsequent calculations of results shall be reviewed, dated and initialled by a second analyst. Each individual result shall be assessed for conformity. The summary reports shall be signed off by - an authorized Person.

CONTRACT LABORATORY shall keep the documentation (including but not limited to raw data, calculations, testing instructions and final reports) for at least XX years after issue of the final report.

In addition, all raw data related to analytical development, including but not limited to any raw data from method validation, shall be archived by CONTRACT LABORATORY over the life cycle of the concerned Product.

CONTRACT LABORATORY shall ask in writing for CONTRACT GIVER's authorisation prior to the disposal of any raw data related to CONTRACT GIVER's orders and Product, whereby it remains in CONTRACT GIVER's sole discretion if such raw data shall be disposed of by CONTRACT LABORATORY or have to be transferred to CONTRACT GIVER. In the case of closure of the business by CONTRACT LABORATORY or expiry of its authority approval the documentation has to be transferred to CONTRACT GIVER.

14. DEVIATIONS FROM TESTING INSTRUCTIONS AND OOS/OOE RESULTS

If not otherwise agreed in the Annex C, D or E, Out Of Specification (OOS) and Out of Trend results and/or unplanned deviations shall be handled according to the CONTRACT LABORATORY SOP and shall be reported to CONTRACT GIVER without delay (within X days). Prior to effecting any planned deviations from the agreed testing instructions CONTRACT GIVER shall be contacted. Subsequently CONTRACT LABORATORY shall draw up a deviation report including an explanation of the reasons for the deviation. This report shall be transferred to CONTRACT GIVER together with the final report for affected sample or Product batch.

15. REFERENCE STANDARDS

The reference standards needed for analysis at CONTRACT LABORATORY will be supplied by CONTRACT GIVER. CONTRACT LABORATORY shall be responsible for ensuring the security of the supply of reference standards by timely ordering from CONTRACT GIVER. Lead time for delivery of reference standards is XX days. CONTRACT GIVER must ensure the supply of reference standards within the mutual agreed time line.

16. FORMAT OF THE FINAL REPORTS

For each Product batch tested, CONTRACT LABORATORY routinely provides CONTRACT GIVER with a Certificate of Analysis (CoA) or Analytical Report. The minimal content of the CoAs or Analytical Reports is defined in Annex C. In addition, CONTRACT LABORATORY will provide Certificates of Compliance (CoC) with regard to GMP and registration compliance for certain Product batches tested, if specifically requested by CONTRACT GIVER.

Additional information (including raw data) may be required by CONTRACT GIVER and shall be provided by CONTRACT LABORATORY on request for certain Product batches, especially for investigations in case of complaints and/or recall.

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17. RESULT TRANSFER

CONTRACT LABORATORY shall complete the agreed tests without delay (within X business days), and transfer the final report (CoA or Analytical Report) by fax, e-mail and/or letter. CONTRACT GIVER's due dates for receipt of the final report (CoA or Analytical Report) are indicated at the analytical orders and shall be confirmed by CONTRACT LABORATORY in the reception of the samples. In case of delay CONTRACT LABORATORY immediately shall inform CONTRACT GIVER about reasons and time line. If no due date is expressly specified at the analytical order, time limits established in Annex F shall be accomplished.

18. FINAL PROVISIONS

This Quality Agreement shall become effective and binding upon the date of the final signature and shall remain in effect until 2 years after the last delivery of Product by CONTRACT GIVER to CONTRACT LABORATORY unless the Parties specifically agree in writing an extension of the Quality Agreement. Either Party may terminate this Quality Agreement by giving 6 months written notice to the other Party.

If individual provisions of this Quality Agreement are rendered void or unenforceable, they shall be replaced by the legally permissible interpretation that most closely approaches the original intent and they shall not be construed to render any other provision of this Quality Agreement either void or unenforceable.

Neither Party to this Quality Agreement shall be liable for failure or delay in the performance of its obligations where such failure or delay is attributable to force majeure. Such force majeure shall include acts of God, storm, fire, flood war, riot, civil disturbance, strikes, explosions or any unforeseen circumstances whether similar or dissimilar to those above enumerated beyond the control of the Party whose performance is affected.

Additionally to the provisions defined in this Quality Agreement the legal regulations shall be effective if not otherwise defined in the Quality Agreement.

19. ANNEX

- **Index of Annexes** Identifies the Annexes to this Quality Agreement
- **Annex A** List of responsible Contact Persons
- **Annex B** Table of Contract Product(s) / Testing Activities
- **Annex C** Delimitation of Responsibilities under GMP
- **Annex D** Product related Documents
(Identifies the documents directly related to QA of each Product, as specifications, storage and transport conditions, and directives, if any)
- **Annex E** General Procedures and Directives
- **Annex F** Organisational aspects and timelines

The actual versions of the Annexes are essential parts of this Quality Agreement. New versions of the Annexes become valid only after CONTRACT GIVER approval and mutual signature. They are added to this Quality Agreement without need for update for the Quality Agreement itself. Changes however must undergo formal change control as described above.

Approved CONTRACT LABORATORY (Dat/Vis)	Approved CONTRACT GIVER (Dat/Vis)

Signed for and on behalf of:

CONTRACT LABORATORY

Signature:

Date:

Name:

Position:

Signature:

Date:

Name:

Position:

CONTRACT GIVER

Signature:

Date:

Name:

Position:

Signature:

Date:

Name: abc

Position: Head of QA

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Index of Annexes

Code	Type of Annex	Effective date	Comments
A	List of responsible Contact Persons	DD.MM.YEAR	
B	Table of Contract Products / Testing Activities	DD.MM.YEAR	
C	Delimitation of Responsibilities under GMP	DD.MM.YEAR	
D	Product related Documents	DD.MM. YEAR	
E	General Procedures and Directives	DD.MM. YEAR	
F	Commercial Articles	DD.MM. YEAR	

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Annex A

List of responsible Contact Persons

CONTRACT GIVER

Function	Name	Telephone / Fax / E-mail
First Contact	Xx	Phone: + Fax: + E-mail:
Head Quality Assurance	Xxx	Phone: + Fax: + E-mail:
Head Quality Control	Xxx	Phone: + Fax: + E-mail:
Project Management	XXXX	Phone: + Fax: + E-mail:

CONTRACT LABORATORY

Function	Name	Telephone / Fax / E-mail
First Contact		Phone: Fax: E-mail:
Head Quality Assurance		Phone: Fax: E-mail:
Head Quality Control		Phone: Fax: E-mail:
XXXX		Phone: Fax: E-mail:

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Annex B

Table of Contract Products (product groups) / Testing Activities

Product	Pharmaceutical form (product group)	Testing activities to be performed by CONTRACT LABORATORY (if applicable)
XXXX		
XXXX		

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Annex C

Delimitation of Responsibilities under GMP

Contract Acceptor	: CONTRACT LABORATORY	(CA)
Contract Giver	: CONTRACT GIVER	(CG)
Product(s) / Activities	: As defined in Annex B	
Testing site of CA	: CONTRACT LABORATORY, XXXX	

The Parties hereto (CA and CG) wish to define their individual responsibilities as to the GMP and quality aspects of testing and release of Product to ensure regulatory compliance consistent Product testing.

In order to do so, this Annex includes a detailed listing of the activities associated with sampling, testing and release of Product and the related documentation. Responsibility for each activity (designated with 'X') is assigned to either CA or CG, or is assigned to both CA and CG.

Responsibility Matrix

ITEM	GMP-ACTIVITY	CA	CG	ADDITIONAL COMMENTS
1	General GMP-requirements			
1.1	Maintaining all necessary authorizations from the competent authorities covering the duties for the activities under this Quality Agreement	X	X	
1.2	Inform the other Party without delay of any restriction to the authorization for any activities or Product covered by this Quality Agreement	X	X	
1.3	Valid GMP-certificate (or equivalent authorization) available for CA issued by the competent Authority, for the type of activities covered by this Quality Agreement	X	0	Make copies available to CG (on request) Or: CA shall provide copies to CG at any renewal of its GMP-certificate
1.4	Provide any declarations and statements as required for regulatory purpose by CG or third parties of CG	X	0	
1.5	Maintain the facility, equipment and support systems used to test Product in compliance with the GMP Regulations, including qualification of equipment and critical utilities	X	0	

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ITEM	GMP-ACTIVITY	CA	CG	ADDITIONAL COMMENTS
1.6	Quality control testing of Product in compliance with the GMP Regulations and according to the methods defined in the specific orders from CG	X	0	
1.7	Refrain from subcontracting of any activities under this Quality Agreement without prior written consent from CG	X	0	
2	Audits and Inspections			
2.1	Internal audits (self-inspections) of premises and facilities used for testing of Product, in order to ensure compliance to the GMP Regulations	X	0	To be performed regularly by CA, with a frequency according to CA's SOP
2.2	Accept audits by CG and/or third parties of CG, of premises and facilities where CA analyses Product, and of any documentation pertaining to the activities under this Quality Agreement	X	0	
2.3	Audit report	0 X	X 0	Issue a report after any audit of CA; make report available to CA within 4 weeks Respond in writing to any observations made by CG within 4 weeks of receipt of report.
2.4	Upon prior written approval by CA, which approval shall not unreasonably be withhold, CG shall obtain the right of disclosure of audit reports to customer(s) of CG or any competent authority, such disclosure by CG to be considered outside of the scope of any confidentiality agreement between CA and CG.	0	X	For compliance with EU requirements based on Directive 2004/27/EC
2.5	Accept inspections in connection with the activities under this Quality Agreement, by any competent authority, including any sampling and analysis of materials as required by such authorities	X	0	For compliance with EU requirements based on Directive 2004/27/EC
2.6	Inform CG immediately of announcement of inspection by any regulatory authority, if directly related to Product of CG	X	0	
2.7	Inform CG without delay of the outcome of Inspection by any authority, if areas of concern affect CA's activities hereunder and/or Product	X	0	
3	Product Samples for Testing / Disposal			
3.1	Sampling of Product	0	X	For storage of retention samples see Item 4.13

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ITEM	GMP-ACTIVITY	CA	CG	ADDITIONAL COMMENTS
3.2	Delivery of Product samples to CA	0 or X	X	Options: As further defined in Annex XX (ordering process) Samples may be provided directly from third party of CG
3.3	Storage of Product samples at CA, upon receipt/until testing	X	0	
3.4	Disposal of redundant samples, in a way to preclude any misuse, environmentally compatible and in accordance with governmental requirements	X	0	CA may destroy any excessive samples not earlier than XX days after delivery of the complete testing report to CG, unless otherwise agreed by CG. Those samples which have led to OOS results will however be kept by CA until response and instruction from CG is available.
4	Quality Control & Quality Assurance			
4.1	Product Specifications, as relevant for testing by CA	0 X	X 0	Instruction (according to Annex XX or as defined in the analytical order) Implementation. For change control / approval of changes see Item 5
4.2	Analytical methods for testing of Product	0 X	X 0	Instruction (according to Annex XX or as defined in the analytical order) Implementation. For change control / approval of changes see Item 5 For all general procedures, CA directives shall be used. CA shall maintain and update its own SOPs to ensure that testing of Product can be done in full compliance with the GMP Regulations
4.3	Validation of analytical methods: <ul style="list-style-type: none"> (Verification of) Pharmacopoeial methods and standard methods routinely applied at CA Specific methods for certain Product, developed by CG and/or transferred to CA New methods requested by CG on basis of individual offers, after approval of the validation plan by CG 	X 0 X	0 X 0	Or: To be mutually agreed for new methods required by CG

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ITEM	GMP-ACTIVITY	CA	CG	ADDITIONAL COMMENTS
4.4	Analytical method transfer from CG to CA, if applicable	X	X	To be defined in a separate transfer protocol
4.5	Preparation and maintenance (including characterization/qualification) of a collection of reference standards needed for analysis of Product	0	X	CG will provide reasonable amounts of not commercially available reference standards, including Certificate of Analysis, to CA (on request, to be ordered by CA from CG, lead time XX days)
4.6	Analysis of Product	X	0	
4.7	Review of analytical documentation	X	0	
4.8	Certificate of Analysis (CoA) or Analytical Reports for each Product batch, including at least the following information: - Name of Product - Name of testing site - Batch/Lot number - Date of analysis - Reference to testing instruction actually used - Analytical results, alongside all limits shown in the Product Specification - Reference to deviation and OOS reports (if any: report shall be attached) - Signature and date of authorised person in Q-Unit responsible for testing and results	X	0	As further defined in Annex XX
4.9	Where required, provide a Certificate of Compliance (CoC) for tested batches, certifying that testing records were reviewed and testing has been performed in full compliance with the GMP Regulations and the agreed specifications and testing methods	X	0	On request by CG, if required by customer of CG
4.10	Release of Product	0	X (or: 0)	May be the responsibility of customer of CG (as applicable)
4.11	Retention of complete analytical testing records for each batch of Product	X	0	Retention time at least 10 years after testing of the said batch
4.12	Provide copies of any testing data (including raw data) as required and requested by CG	X	0	
4.13	Storage of retention samples of each Product batch	0	X	CA may store additional samples if required for fulfilment of their internal SOP
5	Change Control			

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ITEM	GMP-ACTIVITY	CA	CG	ADDITIONAL COMMENTS
5.1	Maintaining of a formal change control system to evaluate all changes that could affect the activities performed under this Quality Agreement (including but not limited to testing of Product)	X	0	
5.2	Notification to CG of any intended changes that might affect any activities performed under this Quality Agreement, prior to implementation	X	0	
5.3	Provide CG with any documentation for changes pursuant to 5.2, as needed for variations of registrations, in order to maintain the registrations valid	X	0	In addition CA shall provide CG with copies of any new version of the testing instructions used for Product
5.4	Approval by CG of changes affecting any registration documentation and of changes which could affect the testing of Product, prior to implementation at CA	0	X	
5.5	Listing of changes (minor and major)	X	X	Responsibilities should be specified in details
6	Deviations / OOS / Investigations			
6.1	Documentation of any deviation from approved (valid) testing instructions or OOS result, and investigation of major and critical deviations, including OOS results, in accordance with site specific SOPs	X	0	Major/critical deviations are deviations in testing with potential to affect/affecting analytical results. OOS-investigations in accordance with further provisions in Annex XX
6.2	Notification of CG, immediately (within 1 business day...3 days) and in writing, of any confirmed major or critical deviation in testing, any not identified laboratory error and any confirmed OOS, related to testing of Product	X	0	CG has the right to inspect all reports and records related to investigations of deviations or OOS related to testing of Product
6.3	Approval of major and critical deviations or confirmed OOS, before issuing the CoA or Analytical Report by CA for any affected Product batch	0	X	
7	Complaints / Recall			
7.1	Recording of all complaints on the Product (complaint file)	0	X	
7.2	Investigation of quality related complaints on Product, as far as testing at CA is concerned. Written response to CG, within 15 calendar days of receipt of complaint	X	0	

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CONTRACT GIVER / CONTRACT LABORATORY
Quality Agreement for Contract Laboratory
Annex C

Annex C C
Version : DD.MM. Year
Replaces: new
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ITEM	GMP-ACTIVITY	CA	CG	ADDITIONAL COMMENTS
7.3	Response to third parties of CG	0	X	
7.4	Decision on, and coordination of recall	0	X	As applicable, in agreement with any involved customer(s) of CG

Approved CONTRACT LABORATORY (Dat/Vis)	Approved CONTRACT GIVER (Dat/Vis)

Signed for and on behalf of:

CONTRACT LABORATORY

Signature:

Date:

Name:

Position:

Signature:

Date:

Name:

Position:

CONTRACT GIVER

Signature:

Date:

Name:

Position:

Signature:

Date:

Name: xxx

Position: Head of QA

Annex D

Product related documents

Document	to Product	Code	Effective date	Comment
Specification	XXXX			
Analytical methods	XXXX			
Protocol of cross-validation	XXXX			

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Annex E

General procedures & directives

Not applicable

Deviations must be documented with a remark in the testing report.

[Optional:] Definition of further procedures (company specific; provided below just as an example)

1 Ordering Process

(Referring to Item 3.2 in Annex C)

Required Information and Documentation as Part of the Ordering Process

- Order number of CONTRACT GIVER.....
- Product identification (material number and material name)
- Sample identification (e.g. batch number)
- Identification of applicable test methods or testing instructions (SOP's, monographs, etc.)
- Tests to be performed
- Specification sheet (if applicable and not included in test methods)
- Requested quality standard (GMP, GLP, ISO 9001)
- Declaration of data archiving (data to be archived at CONTRACT LABORATORY or data to be transferred to requestor)
- Declaration of the provided sample amount
- Special handling instructions for sample (if necessary)
- Safety data sheet or equivalent information (mandatory for toxic, highly active or hazardous components)
- Storage temperature (default is ambient temperature)
- Reference substances (if necessary) with certificate of analysis
- Due date
- Requestor (name, company, address, phone, e-mail)

CONTRACT LABORATORY's order forms see (as example):
[www.\[CONTRACT LABORATORY\].com](http://www.[CONTRACT LABORATORY].com)

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Annex F

Organisational aspects and timelines

Each calendar quarter CONTRACT GIVER shall furnish CONTRACT LABORATORY with a 12 month forecast concerning CONTRACT GIVER's requirements of number of analysis of batches of Product. CONTRACT GIVER shall send firm orders **8 weeks in advance of the week of shipment of samples together with the samples** to CONTRACT LABORATORY. CONTRACT LABORATORY will send the acknowledgment of receipt of the samples to CONTRACT GIVER by return. CONTRACT LABORATORY will perform the ordered analysis within **X working days** after receipt of the samples.

CONTRACT LABORATORY has the capacity to perform **XX** analysis of batches of Product per month.

Further commercial issues are arranged by offers of CONTRACT LABORATORY and its acceptance by CONTRACT GIVER; or another contract.

CONTRACT LABORATORY

Signature:
.....
Name:
Position:
Date:
.....

Signature:

Name:
Position:
Date:

CONTRACT GIVER

Signature:
.....
Name:
Position:
Date:
.....

Signature:

Name:
Position:
Date: