



# Intercompany Protocol for the joint of 3<sup>rd</sup> Party Audits to Suppliers



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## DOCUMENT HISTORY

### **Version 1 (28/JUN/2004)**

The first version of this document was created, reviewed and ratified by a group of 16 pharmaceutical manufacturing companies. Due to their interest in conducting audits to suppliers, a framework agreement called Intercompany Protocol was developed to perform audits to suppliers in a collaborative manner as well as to put in common information related to suppliers.

The development and co-ordination of the document and meetings leading to the Intercompany Protocol issuance were done by the company TDV, S.L.

### **Version 2 (16/DEC/2005)**

On December 9<sup>th</sup>, 2005, the *Asociación Forum Auditorías* was registered as a Civil Association of Pharmaceutical Companies to conduct supplier audits in a collaborative manner.

In order to update and adapt it to the new framework, a second version of the Intercompany Protocol was developed.

### **Version 3.00 (05/MAR/2007)**

The current version of the document includes the requirements published by the EMEA (*Questions & Answers on audits of active substances manufacturers*), reviews the validity periods of the reports and establishes the new confidentiality criteria between involved parties during audits.

### **Version 3.01 addition (14/NOV/2007)**

Auditor Qualification program in chapter 3.2.

### **Version 3.02 addition (25/NOV/2008)**

Audit follow-up implementation in chapter 4.5.



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## 1. INTRODUCTION

### 1.1 Purpose

This protocol constitutes the *Asociación Forum Auditorías* regulations to develop joint programmes for the validation of suppliers, which is one of the key activities to guarantee the quality of pharmaceutical products and therefore of Good Manufacturing Practices compliance.

The final objectives of these joint programs are:

- ▶ The compliance of regulatory requirements related to the qualification and homologation of suppliers, taking into account that the level of demand in the application of these requirements by the Health Authorities has increased recently
- ▶ The optimization of costs and resources of Quality areas dedicated to evaluate and qualify suppliers.
- ▶ The achievement of both previous objectives maintaining the technical rigour at the highest level.

The aim of the present document is to establish an adequate framework for the definition of joint Plans for supplier audits.

### 1.2 Background

Suppliers' validation processes represent a key activity for the compliance of Good Manufacturing Practices (GMP). Establishing this activity as a regulatory requirement is a need, among others, in the following regulations:

- **Materials. EU GMP. Part I** chapter 2 (point 2.7), chapter 4 (point 4.11), chapter 5 (points 5.25, 5.26), chapter 7 (point 7.3), Annex 5 (points 34, 36), Annex 8 (point 3), Annex 11 (see further on) and **Part II** points 7.11, 7.22, 7.30, 7.31), **US cGMP. US 21 CFR Part 211** (point 211.84). **Guideline 2001/83/CE** modified by the **2004/27/CE** epigraph 33 that modifies letter f of article 46. **EMA GMP: Questions and Answers on audits of active substances manufacturers.**

Regarding suppliers, and not only those of raw materials, the need of conducting audits of contract manufacturing, information systems suppliers is established. The following regulations should be highlighted:

- **Information Systems.** *EU GMP. Annex 11 point 5.*
- **Analysis Laboratory and Contract Manufacturing.** *EU GMP. Chapter 7 point 7.3*

Recently, pharmaceutical companies have developed supplier validation programs in order to comply with what is established in the applicable regulations while seeking the optimization of resources regarding the activities to control the product or service supplied.



The consolidation of an audits program presents some challenges since it is an activity requiring a high level of qualification, with high costs associated and, to a certain extent, without a regulated framework. These challenges have been the main motivation for creating the Association.

## 2. COLLABORATION AGREEMENT SCOPE

The collaboration agreement among the companies regarding the audits to suppliers could have an increasing scope. The current Protocol establishes the initial basis in order to be able to share the audits performed to suppliers in any of the following scopes:

- Active Pharmaceutical Ingredients (API) Manufacturing
- Excipients Manufacturing
- Packaging Materials Manufacturing
- Intermediate or Finish Products Contract Manufacturing
- Information System Design and Development
- Chemical or Microbiological Analysis Contract Laboratories
- Warehouses and distribution

## 3. REGULATION BASIS

Shared audits can be conducted either by contracting a third party or carried out by one of the associated members. In both cases following the methodology and working criteria established in this protocol.

### 3.1 Confidentiality

Confidentiality constitutes one of the key agreements that should be established for the correct application of the current protocol.

Preserving the confidentiality of the information provided by its associates and obeying the confidentiality agreements with the audited companies is among the missions of the Board of Directors of the *Asociación Forum Auditorías*.

Confidential Disclosure Agreements (CDA) among the four parties involved in the audits should be established:

- Audited companies (with the auditors, the *Asociación Forum Auditorías* and its associates)
- Auditors (with the auditees and the *Asociación Forum Auditorías*)
- *Asociación Forum Auditorías* (with the auditees and the associated members)
- Associates (with the auditees)



The following documents are established to execute the confidential disclosure agreements (CDAs):

- **Confidentiality agreement for each associated member.** A confidentiality agreement covering the information received through the audit reports shall be signed by each member of the *Asociación Forum Auditorías*. The use of this information shall be restricted to the process of suppliers' validation and as supporting evidence in front of the Health Authorities or potential clients. In case of a corporation and, unless otherwise indicated in the corresponding CDA with the audited company, the report could be used by the other affiliates for the same purpose. The *Asociación Forum Auditorías* represented by its Board of Directors is committed not to disclose the information received from the associated members on what the active substances, related products, observations, complaints or related projects refers to. The *Asociación Forum Auditorías* shall establish the necessary mechanisms to comply with this requirement. This information will be solely used for conducting the audit.
- **Confidentiality agreement for the auditors.** The *Asociación Forum Auditorías* contracted auditors shall sign a confidentiality agreement covering the information received during the preparation and development of the audit:
  - Information received from each associated members involved in the audit.
  - Information collected during the audit, which shall be entirely delivered to the *Asociación Forum Auditorías*.
  - The Audit report, which once issued, is property of the *Asociación Forum Auditorías*.
- **Confidentiality agreement with the audited companies.** Confidentiality agreement of the *Asociación Forum Auditorías* in relation to the audited companies regarding the audit reports

The *Asociación Forum Auditorías* protects the confidentiality of the information received from its associated members by means of the structure of the audit reports. If necessary, reports are divided in a common part related to general GMP aspects, such as organization, documentation, facilities, laboratories, warehouses, etc; and an specific part associated to a product or products, for each company, including typically contractual aspects, specifications, process validations, complaints, analytical methods, DMF, etc. The results of the audit will be documented in separated reports for each company where both parts are included:

- **Open part.** Shared by the members of the *Asociación Forum Auditorías*.
- **Closed part.** For the exclusive use of each one of the companies.

The *Asociación Forum Auditorías* will act as depositary of the audit reports and the related documentation that will remain available in a repository to Associated Members as per the conditions stated on section 3.7.

It is worth mentioning that in case of API manufacturers it is especially important to respect the confidentiality of the sponsors or applicants.



## 3.2 AUDITORS

### 3.2.1 Auditor's Profile

The auditors should have the following profile:

#### Basic Education:

- BSc Honours Degree in Pharmacy, Chemicals, Engineering or similar.
- Good knowledge of GxP as well as the community regulations that apply to the Research & Development, Manufacturing and Distribution of Pharmaceutical products.
- Knowledge of the procedures needed for the marketing authorisation of Pharmaceutical products.

#### Experience:

- A minimum of 2 years experience working in an organization regulated by the GxP principles, holding an upper management position.
- A minimum of 5 audits previously done within the same field of the audit to be performed.
- Experience in the processes of pharmaceutical manufacturing and control, chemical synthesis and the validation of these processes or methods.
- Experience in the design or qualification of facilities for GxP purposes.
- Experience in Quality Control organization and technology.
- Experience in the computer systems commonly used in the pharmaceutical and chemical environment and its validation.

#### Personal skills:

- Ability to maintain the objectivity and uniformity criteria during the audits.
- Communication skills and ability for creating an open atmosphere to ease the exchange of information.
- Analytical mind and tenacity.
- Maturity and open-minded.
- Personal integrity
- Ability for conveying ideas in a clear and concise manner.

### 3.2.2 AFA's Auditor Qualification Program

AFA has an internal qualification program that consists in:

- Successful attendant to training course in audit techniques and auditor skills development.
- Participation as Co-auditor in several audits until Senior Lead Auditors consider necessary.
- The Auditor's *Curriculum Vitae* and Qualification process will be approved by the *Asociación Forum Auditorías* Board.



### 3.3 Conflict of interests

The auditors or the companies contracted by the *Asociación Forum Auditorías* shall declare the absence of conflict of interests in the following terms:

- Absence of commercial relation with the audited company.
- In case the auditor has been part of the staff of the audited company, more than three years should have been elapsed since he/she left his/her position and no financial interest should exist between the auditor and the company.

The Declaration shall be done in a written form and must be signed by the auditor.

### 3.4 Criteria for sharing the audits

The audits can be shared whenever the supplier and the centre where the product being object of the audit is produced, developed, etc. matches. This implies that it is possible that the product (excipients, API, material, etc.) does not match but, as it is established in point 3.1, the audit will have an open part common to all participants and a closed part, specific for each participant, where the relevant aspects for each product and quality objectives will be specified.

### 3.5 Planning

Planning will be established starting from the preferences of the associates and will be structured in the following way:

- **Periodic Audit Plans.** Audit plans of general interest, subject to a special fee that allows free access to all subscribers to the audit reports, always obeying the confidentiality agreements with the auditees.
- **Audits excluded from Plans.** These audits, typically of limited interest, will be performed upon request by the associated members. All the Associates will be informed of the conduction of this type of audit and the incorporation of the audit report in the repository.

Every associate is responsible for his/her own audit plans and for answering the Health Authorities on the audit prioritization based on risk criteria.

### 3.6 Audits organization

Those associates who request audits to the *Asociación Forum Auditorías* will sign an agreement/contract where the conditions under which the audit shall be performed will be specified. In case of the Annual Plan, a global contract/agreement will be issued for the whole audits of interest for each associate.

The *Asociación Forum Auditorías* will contract the auditor team that will perform the audits following the selection criteria established in point 3.2 of this document. The auditor's Curriculum Vitae will be enclosed to the audit report.



The auditor could carry out the audit while being accompanied by representative members if interested. However, for practical reasons, the maximum number of companion is limited to two. Companions will act as observers without taking part in the auditor's team decisions-making process.

### 3.7 Access to the AFA's audits Repository

All the associates have the right to acquire audit reports from the repository, always obeying the confidentiality agreements with the auditees. These reports will be customized whenever they are required by all those interested. In addition, the audit report information will be completed as appropriate considering the needs of the associates, while taking advantage from the contact between the auditor and the auditee.

It is worth distinguishing between the following options:

- **Periodic Audit Plan**

Those audits performed within the scope of a Periodic Plan, and therefore subject to a special fee, will be available for each one of the subscribers always obeying the confidentiality agreements with the auditees. Should an associated member, who is not subscribed to the Plan, require one of the audit reports included on it, he/she shall pay for it, according to the corresponding fee which will be updated periodically depending on the report validity date.

- **Audits excluded from Plans and Campaigns**

Those audits excluded from Plans, which are performed upon request of some of the associates will be included in the Repository and will be available for all the associated members. The fee for these audits is established depending on the validity date of the report (expiry date). Half of the price of the audit will be distributed among all the promoters. The promoters corresponding part will be stated as a down-payment for services.

- **Audits conducted by associated members**

The condition under which the audits conducted by the associated members could be shared through the AFA is that they have been performed while obeying the working and methodology criteria established on the current Protocol. The inclusion of the audit in the Repository will require establishing both technical and economical conditions in writing.

### 3.8 Validity period of the reports

The validity of the reports will be established by each laboratory once the manufacturer or service supplier validation process is concluded.

In case of the audits to active substances manufacturers, the audit to the manufacturer shall be renewed at least every three years.

In general, the following validity period criteria to be applied when the audit is finished are established:



### **5 years**

Audits without critical observations and/or opened major observations and when having a Quality Agreement signed by the manufacturer with each one of the interested associates, which guarantees the control of significant changes. In case of packaging materials manufacturers, a validity of 5 years will be applied as long as no critical observations are identified.

### **3 years**

Audits without opened critical observations and when having a Quality Agreement signed by the manufacturer with each one of the interested associates, which guarantees the control of significant changes.

### **Less than 3 years**

For those audits with opened critical observations or provided that there is not enough confidence that the changes will be notified, a period of less than three years will be established in order to review the committed action plan.

The expiry date derived from the application of these overall criteria will be established for each case when the audit report is reviewed and a chapter justifying the assigned expiry date will be included.

Each one of the associates shall establish the final expiry date based on its overall supplier validation process.



## 4. AUDITS METHODOLOGY

### 4.1 Acceptance criteria

The acceptance criteria applied to audits will be established for each audit or group of audits of the same type, taking into account the following:

- a) The supply criticality as per the risk criteria described on point 4.2.
- b) The specific requirements of each company and what it is established in the laws, regulations, guides, standards or recognized practices for each type of supply.

Following are listed the guides and regulations taken into account within the scope of the supply. It is worth mentioning that it is not a closed list and that those references considered as the most adequate and agreed by the associates will be taken depending on each case.

<i>Type of audit</i>	<i>Acceptance Criteria References</i>
<b>Active Substances Manufacturing (APIs)</b>	<ul style="list-style-type: none"> <li>▶ Directive 2003/94/CE. EUGMP Part II (ICH Q7A)</li> <li>▶ LAW 29/2006, dated July 26th, on the guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July, 2006).</li> <li>▶ CPMP, EMEA, ICH, FDA Guides</li> </ul>
<b>Excipients Manufacturing</b>	<ul style="list-style-type: none"> <li>▶ Directive 2003/94/CE. EUGMP Part II</li> <li>▶ LAW 29/2006, dated July 26th, on guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July 2006).</li> <li>▶ GMP for bulk pharmaceuticals excipients, IPEC</li> <li>▶ Royal Pharmaceutical Society of Great Britain. "PS9100:2002 Pharmaceutical excipients"(2002)</li> <li>▶ WHO "Scheme for Certification of Pharmaceutical Starting Materials"</li> <li>▶ CPMP, EMEA, ICH, FDA Guides</li> </ul>



<i>Type of audit</i>	<i>Acceptance Criteria References</i>
<b>Packaging material manufacturing</b>	<ul style="list-style-type: none"> <li>▶ LAW 29/2006, dated July 26th, about guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July 2006).</li> <li>▶ ISO 9001 2000.</li> <li>▶ ISO 15378. Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP).</li> <li>▶ Code of Pharmaceutical Supplier Practices. The Institute of Quality Assurance. Pharmaceutical Quality Group.</li> <li>▶ Quality Assurance of Pharmaceutical and Packaging Materials. Cantor Verlag Aulendorf Edition (ECV)</li> </ul>
<b>Finished and intermediate products manufacturing</b>	<ul style="list-style-type: none"> <li>▶ Directive 2003/94/CE. EUGMP Part I</li> <li>▶ LAW 29/2006, dated July 26th, about guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July 2006).</li> <li>▶ PIC'S Guides</li> <li>▶ PIC/S, CPMP, EMEA, ICH, FDA Guides</li> </ul>
<b>Computer System Design and Development</b>	<ul style="list-style-type: none"> <li>▶ Directive 2003/94/CE. EUGMP Part I, Anexo 11</li> <li>▶ LAW 29/2006, dated July 26th, about guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July 2006).</li> <li>▶ PIC/S Guides, GAMP Forum</li> </ul>
<b>Chemical and microbiological analysis</b>	<ul style="list-style-type: none"> <li>▶ Directive 2003/94/CE. EUGMP</li> <li>▶ LAW 29/2006, dated July 26th, about guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July 2006).</li> <li>▶ CPMP, EMEA, ICH, FDA Guides</li> </ul>



Type of audit	Acceptance Criteria References
Logistics and warehouses	<ul style="list-style-type: none"> <li>▶ Guia de Bones Pràctiques en el Transport de Medicaments. versió 1. Set-05. Generalitat de Catalunya. Departament de Salut. Direcció General de Recursos Sanitaris.</li> <li>▶ Directive 2003/94/CE. EUGMP</li> <li>▶ LAW 29/2006, dated July 26th, about guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July 2006).</li> <li>▶ Royal Decree 2259/1994</li> <li>▶ CPMP, EMEA, ICH, FDA, WHO Guides</li> </ul>

## 4.2 Criticality based on indentified risks

The criticality of the supply will be always based on the ethic principle to guarantee the absence of risk to the patient. In order to ensure that the audit will follow this principle, the following aspects will be taken into account for each supply:

- Type of supply (excipient, active substance, contracted laboratory, etc.).
- Function of the supply regarding the related GxP processes.
- Pharmaceutical Form and administration route related to the supply.
- Activity/toxicity level or risks to the final product security or efficacy.

The result of taking into consideration all these factors will determine the requirements required to the supplier during the audit and the rigour to be applied when classifying any potential observations.

## 4.3 Classification of observations

The observations coming from the audit will be described in the report. One observation will be registered for each one of the aspects when considering that total or partial non compliance of acceptance criteria exists. The observations will be classified as Critical, Major, Minor and Recommendations based on the following definitions:

- **Critical:** *Non-compliance of a GxP principle, which implies a direct risk for the patient health, the security or efficacy of the final product. It requires immediate action from the audited organisation*
- **Major:** *Non-compliance of a GxP principle, or a significant combination of minor observations within the same area or system, which do not involve a direct risk since a controlled environment exists allowing the identification of any observation entailing any risk. It requires that an action plan is established and executed within a reasonable period of time.*



- **Minor:** Interpreted as a non-compliance of a GxP principle, however involving a low risk. A corrective action in order to eliminate any unnecessary risk is required.
- **Recommendation:** A recommendation does not represent a GxP non-compliance but, should not be taken into account, it could lead to observations in the future, or its consideration would improve the overall quality system of the related area or system.

#### 4.4 Execution of the audit

The execution of the audit entails the following steps:

1. **Establishment of the objectives and acceptance criteria** of the audit, taking into account the requirements of the associates.
2. **Preparation of the agenda and contact with the supplier.** The agenda is issued by the auditor taking into account the audit goals. The auditor sends it to the supplier with enough time in advance so the auditee can prepare it accordingly.
3. **Development of the audit.** The audit is divided in the following sequence of sections:
  - a) Presentation Meeting. Exchange of information.
  - b) Objectives and agenda agreement
  - c) Review and inspection of related documentation, facilities and processes.
  - d) Wrap-up meeting. Summary of the performed audit, overall impressions, and observations overview. Follow-up actions and expectations from the companies represented by the auditor.
4. **Audit Report Preparation.** In case that a “Closed Part” is necessary, individual reports or individual annexes to the Main Report will be issued. The report will be distributed in electronic format for review. The only valid report is the one issued in paper, duly signed and stamped by the *Asociación Forum Auditorías*.
5. **Presentation Meeting.** Once the audit report is issued it will be sent to the *Asociación Forum Auditorías* who will review it and will check that it meets the audit requirements and that the observations have been clearly stated. A first reviewed of the report is done by the *Asociación Forum Auditorías* responsible. Once completed, the report is sent to the interested associates. A meeting is scheduled among the interested associates and the auditor, if needed, so he/she can present audit results and answer any question the qualified members may have.
6. Issuing and sending a single **Audit Report Letter** to the supplier including the associates’ expectations for both the Open and the Closed parts of the audit report.



## 4.5 Audit Follow-up

Audits could identify observations related to compliance that the auditee should pay attention to, establishing an Action Plan for its resolution.

AFA's follow-up activities are described below:

- Action Plan request after Audit Report Letter sending.
- Evaluation of suitability of Action Plan.
- Distribution of Action Plan to the audit sponsors.
- Semi-annual follow-up of the progress of Action Plan.
- Updated Action Plan distribution to the sponsors.
- Follow-up audit when the audit validity expires, if the interest remains.

## 5. AUDIT REPORT

The audit report is the documentary support of the audit and consists of the following parts:

### 5.1.1 SUMMARY

It will summarize in a maximum of two pages the activities performed during the audit, the observations and impressions concerning the ability of the audited organization to meet the expectations or acquired compromises with the customer and the identification of the detected observations of each one of the types described in section 4.3.

### 5.1.2 AUDIT TEAM

It will identify the names and positions of all the persons involved in a relevant way on the audit development, concerning both the audited organization and the auditor team.

### 5.1.3 COMPANY INFORMATION

The company information will highlight the aspects describing the audited company, the scope of its activity and the certification level they have.

Typical aspects of this section are: Name and address of the company, foundation year, number of employees, turnover, product portfolio, main markets, quality certifications, previous audit experience, etc.



#### **5.1.4 METHODOLOGY**

The methodology followed in the audit will be described, always according to what is established in this Protocol and the audit objectives.

#### **5.1.5 REQUIREMENTS & DESCRIPTION OF THE AUDIT RESULTS**

In this section the applied acceptance criteria for each audited system as well as the observations of the audit will be detailed.

#### **5.1.6 OBSERVATIONS**

The observations that could be considered deviations of the acceptance criteria identified on each system will be detailed and classified by applying the criteria described in section 4.3. Corrective actions to eliminate any associated risks will be established for each identified observation. In addition, a due date will be set for each of them.

#### **5.1.7 CONCLUSIONS**

In this section an answer to each one of the objectives and conclusions that the sponsors of the audit have regarding the supplier and its quality system will be done. Besides, the validity period of the report will be established.

#### **5.1.8 COMPLEMENTARY DOCUMENTS AND APPENDIX**

The original copies of the documentation collected during the audit are enclosed as well as the auditors' professional history and any additional outstanding information.

### **6. FINAL EVALUATION OF THE SUPPLIER**

The audit is part of the suppliers' validation process and therefore, it is an additional element to be considered when the final evaluation of the supplier suitability is performed.

The audit and the report, by themselves and in isolation, are not conclusive. However, they constitute an integral part of the suppliers' validation process.

The final evaluation of the supplier is a complex process requiring the integration of several laboratory-specific aspects that should be known and assessed.

Each company will decide in a private way about the supplier and supply suitability, taking into account its own policy of suppliers' approval / validation and the risk criteria associated to its own products.

