

# CHARTER OF INCORPORATION

## I. NAME, SEAT, PURPOSE

### ARTICLE 1 – NAME

There is hereby incorporated an international association named « EUROPEAN FORUM FOR GOOD CLINICAL PRACTICE » (hereinafter referred to as « E.F.G.C.P. ») pursuant to the Belgian Law of October 25, 1919 as amended by the Law of December 6, 1954.

### ARTICLE 2 – SEAT, DURATION

2.1. E.F.G.C.P. shall have its seat at: Rue Washington 40 – 1050 Bruxelles (B)

It may be transferred to any other location in Belgium by decision of the Board of Directors, published in the Annexes of the Moniteur Belge (Official Gazette).

2.2. E.F.G.C.P. is incorporated in perpetuity. It may be dissolved at any time in accordance with the law and its charter.

### ARTICLE 3 – PURPOSE

3.1. Purpose.

The E.F.G.C.P. is a non-profit association facilitating discussion and dissemination of information on all matters related to Good Clinical Practice in Europe.

Its purpose is to promote Good Clinical Practice and encourage the development of common, high quality standards in all phases of clinical research throughout Europe.

This can only be achieved if, within the scope of the EC GCP Guidelines, all the parties having direct or indirect responsibilities work together to gain a common understanding of what these responsibilities are and how their various actions are interrelated. In general, any divergence at a national level is to be minimised.

The E.F.G.C.P. recognizes that formal lines of communication between the European Commission and the pharmaceutical industry are through EFPIA (European Federation of Pharmaceutical Industries Associations) and those from the WHO (World Health Organization) to the pharmaceutical industry are through the IFPMA (International Federation

of Pharmaceutical Manufacturers Associations). The E.F.G.C.P. does not intend to interfere with existing processes for the establishment of policy and legislation.

In particular, E.F.G.C.P.'s objectives are to:

- be a nucleus of European expertise and expert opinion on Good Clinical Practice.
- foster the development of methods and procedures of a high standard, which should be realistic and common.
- improve the effectiveness of clinical research, thereby facilitating ethical and scientific use of data.
- facilitate the international communication of clinical data.
- contribute to the international advancement of the recommendations of the Declaration of Helsinki, with regard to biomedical research including clinical research on medicinal products.

In all its activities, the E.F.G.C.P. will strive towards safeguarding the rights and welfare of human subjects, be they healthy volunteers or patients, who participate in clinical research.

Commercial issues are excluded from the objectives and pre-occupations of the E.F.G.C.P.

3.2. E.F.G.P.'s role can be described by the following activities designed to:

3.2.1. Provide Expert Opinions and Position Papers on Good Clinical Practice (GCP).

Using the expert resources of their multinational and multidisciplinary membership, the E.F.G.C.P. working groups will examine important issues related to clinical research in Europe.

They will also study other issues of international GCP-related interest, e.g., source document verification, quality assurance for computerized data handling, and ethical study design for difficult situations.

Position papers will be developed by the working groups and circulated among E.F.G.C.P. membership for comment. As appropriate, they will be published as monographs from the E.F.G.C.P. or in the literature relevant to the subject treated.

3.2.2. Collect and Disseminate GCP Information.

The E.F.G.C.P. will organize its communication lines through symposia and periodic newsletters to disseminate GCP-related information with multidisciplinary education as an objective. In association with experienced ethics review committees, the E.F.G.C.P. will promote the advancement of medical ethics in clinical studies through communication with health care providers, educators, and other groups with specific health care interests.

#### ARTICLE 4 – RELATIONSHIPS WITH OTHER ORGANISATIONS

E.F.G.C.P. will co-operate with other associations which have interests in maintaining the highest standards of Good Clinical Practice.

Trials on medicinal products are governed by the most advanced and thoroughly structured regulations that exist today in the field of biomedical research on human beings. E.F.G.C.P. offers its expertise to those in other fields of biomedical research who wish to implement the recommendations of the Declaration of Helsinki in a manner similar to GCP.

## II. MEMBERSHIP

#### ARTICLE 5 – MEMBERSHIP

##### 5.1. Applications for membership

Any individual located in Europe or any research-based pharmaceutical firm or company legally constituted in a country in Europe and any legally constituted organisation, association or professional society having a legitimate involvement in clinical research and/or in the promotion of Good Clinical Practice, may apply in writing to the Board of Directors to become a Member of E.F.G.C.P. Dependant on the degree of involvement with E.F.G.C.P. requested, the applicant can ask for "Full" or "Associate" membership (see article 5.2. and 5.3.).

The Board of Directors shall fix the procedure for the admission of members and fees.

The Board of Directors shall examine prospective applicants on the basis of their membership applications, having regard to such conditions as may be prescribed by the Board, for "Full", "Associate" or "Honorary" members, hereinafter described collectively as "Members". The Board of Directors shall decide on which fee category (industry/non-industry) is appropriate for each applicant.

5.2. **“Full” membership**

Where the Board approves the application, the applicant shall become a “Full” Member upon receipt by E.F.G.C.P. of the applicable membership fee or initial contribution.

“Full” Members shall be eligible to vote at all General Assemblies, receive all materials intended for Members, participate in E.F.G.C.P. working parties and have access to all appropriate information at the seat of E.F.G.C.P.

5.3. **“Associate” membership**

According to the degree of interest in active participation in the E.F.G.C.P., expressed by the applicant, the Board can approve the application for “Associate” membership upon receipt by E.F.G.C.P. of the applicable membership fee.

“Associate” Members are invited by right to attend all General Assemblies. They do not have the right to vote but may express opinions, for advisory purposes only. They will receive all materials intended for Members, but will not be eligible to participate in E.F.G.C.P. Working Parties.

5.4. **“Honorary” membership**

Where the Board does not approve the application, it can nevertheless confer to the applicant the quality of “Honorary” Member. “Honorary” Members are invited to all General Meetings of E.F.G.C.P. They are not to pay any subscription fee and do not have the right to vote but may express opinions, for advisory purposes only. “Honorary” Members may be invited to participate in E.F.G.C.P. Working Parties and have access to all appropriate information by agreement of the Board.

5.5. **Loss of membership**

Membership shall terminate:

1. When any Member ceases to meet the conditions for membership or fails to comply with the duty and obligations incumbent on Members; in such a case, his membership shall be terminated by the General Assembly by a two thirds' majority decision of the “Full” Members and the “Honorary” Members having the right to vote who are present at the General Assembly or voting by proxy.
2. By voluntary resignation addressed in writing to the Secretary General with a one-year notice.

5.6. **Re-application**

Any Member which has been excluded under the terms of Article 5.5.1. may reapply for membership. In such a case the application described in Article 5.1. must also be approved by the General Assembly on the basis of a two thirds' majority decision.

III. **GENERAL ASSEMBLY**

**ARTICLE 6 – GENERAL ASSEMBLIES**

6.1. **Ordinary and Extraordinary General Assemblies**

An Ordinary General Assembly shall be held annually in the first quarter of the year.

Extraordinary meetings of the General Assembly, for whatsoever purpose and unless provided otherwise in the Charter or By-laws, may be convened by:

1. The Chairman of the Board, with the support of another Board Member.
2. The Chairman of the Board or the Secretary upon the written request of at least one fifth of the Members of the E.F.G.C.P. having the right to vote. Such requests shall state the purpose or purposes of the proposed General Assembly.

6.2. **Notice of Assemblies**

Written notice of Ordinary and Extraordinary General Assemblies stating the place, date and time of the meeting, together with the business to be transacted thereat, shall be sent by the Secretary including all documents to each Member not less than fifteen but no more than fifty days before the date of the meeting.

Extraordinary General Assemblies shall be competent to transact only the business stated in the notice convening the meeting.

6.3. **Participation**

General Assemblies comprise the individual Members and the delegated representatives of each Member-legal representative. Each Member shall appoint in writing a representative or proxy, who shall have full authority to

represent such Member in all matters coming before E.F.G.C.P. Assembly.

With the exception of individuals holding membership in their own right, the term of a Member's representative shall automatically terminate if and when such individual ceases to be employed by or associated with the Member, his connection with the Member is otherwise severed, or the Member of which he is the representative ceases to be a Member of E.F.G.C.P.

**6.4. Quorum and Majority**

Two thirds of the "Full" members, present in person or voting by proxy, represent a quorum. All decisions shall be taken by simple majority vote of those persons having the right to vote who are present at the meeting or voting by proxy.

**6.5. Powers**

The General Assembly shall have the power to perform all acts necessary or useful for the accomplishment of the E.F.G.C.P. including without limitation to:

- A. Elect or dismiss the Chairman, Vice-Chairman and the other members of the Board of Directors;
- B. Appoint the auditors of the E.F.G.C.P.;
- C. Establish the main policies that will guide the activities of the E.F.G.C.P.;
- D. Consider and decide upon all such matters it may deem necessary as well as those that may be brought before it by the Board of Directors whatsoever for consideration or action by the General Assembly;
- E. Approve the programmes proposed by the Board of Directors;
- F. Recommend to the Board of Directors regarding the establishment of Committees as appropriate;
- G. Approve the budgets and the accounts;
- H. Modify the By-laws as provided herein;
- I. Dissolve the Association.

**6.6. Minutes**

The deliberations of the General Assembly shall be recorded in the Minutes prepared and signed by Secretary and approved by the General Assembly.

All members shall receive copies of the Minutes. The Board of Directors will decide where the master set of minutes should be located.

6.7. **Annual Report**

At the ordinary General Assembly, the Board of Directors will present a report of work completed during the preceding year and projects, activities and services for the year to come, for adoption by the General Assembly.

IV. **ADMINISTRATION**

**ARTICLE 7**

*Note: No discrimination between males or females is intended in the wording of this Article.*

7.1 **Board of Directors**

7.1.1 **Composition**

The Members of the Board of Directors shall be elected by the General Assembly from among the "Full" Members.

The number of Directors shall be not less than five nor more than fifteen. One Director, at least, should represent the interests of Ethics Committees. Also one Director, at least, shall be of Belgian nationality.

Members of the Board of Directors shall be appointed for a term of three years. One third shall retire each year, but shall be eligible for re-election for an unlimited number of terms.

7.1.2 **Powers**

The managing body of E.F.G.C.P. shall be the Board of Directors, which shall have the power to:

A. Direct and control the daily business of E.F.G.C.P.;

- B. Execute the decisions of the General Assembly and take all necessary steps to comply with the established objectives;
- C. Advise on the Membership of Working Parties so as to ensure that the appropriate multi-disciplinary/multi-sectoral balance is maintained;
- D. Advise on programme guidelines for the Working Parties;
- E. Control expenditure;
- F. Prepare budgets and annual accounts to be submitted to the General Assembly.

The Board may adopt such rules and regulations for the conduct of its business as it sees fit and may, within the scope of the powers conferred on it, delegate certain of its powers and responsibilities to the Executive Committee or to individuals.

## 7.2 Meetings, Quorum and Majority

The annual meeting of the Board of Directors shall be held immediately preceding or following the General Assembly. Regular meetings of the Board, whether held in Brussels or elsewhere, shall be held as determined by the Board.

Special meetings shall be held when convened by the Chairman by seven day's notice to each Board Member. Special meetings shall be called by the Chairman in like manner and on like notice upon the written request of two Directors.

A quorum shall consist of at least one-third of the Board, which must include both the Chairman of the Board and the Secretary.

Resolutions shall be passed by a majority of Directors present or represented. In case of an equality of votes, the Chairman shall have a casting vote.

The annual meeting of the Board of Directors shall be held at the call of the Chairman on not less than fifteen days, but not more than fifty days, written notice before the date of the meeting.

### 7.2.1 Representation

The E.F.G.C.P. shall be represented by the Chairman of the Board or by any two directors acting jointly. It may also be represented by any other person acting within the limits of authority delegated by or in accordance with a resolution of the General Assembly or the Board.

The Chairman – and, in case of absence, the Vice-Chairman – is the designated representative of E.F.G.C.P. to appear in Court on behalf of E.F.G.C.P.

## 7.3 Officers

### 7.3.1 Chairman

The Chairman of the Board shall chair all meetings of E.F.G.C.P., the Board of Directors and General Assemblies. He shall be responsible for the general management of E.F.G.C.P. and supervise the execution of all orders and resolutions of the General Assemblies and Board of Directors.

### 7.3.2 Vice-Chairman

The Vice-Chairman shall perform all duties of the Chairman in the event of his absence, disability or resignation.

The Vice-Chairman shall have such duties as may be assigned to him by the Board of Directors and shall assist the Chairman as he shall deem fit.

### 7.3.3 Treasurer

The Treasurer shall collect and (unless otherwise so ordered by the Board) be responsible for the funds of E.F.G.C.P. and shall deposit the same at a bank or other form of safe custody, or invest them, subject to approval by the Board; he shall make such disbursements as the Board may order. He shall render account of all transactions in his capacity as Treasurer, and shall report on the financial condition of E.F.G.C.P. to the Chairman and Board of Directors at its ordinary meetings or whenever so required by the Board.

He shall notify the Board of all Members more than sixty days in arrears of payment of membership fees or other sums owing.

#### 7.3.4 Secretary

The Secretary shall be responsible for all official correspondence of E.F.G.C.P. and shall have custody of all such official documents and records of E.F.G.C.P. as are not kept by the Treasurer or other officers. He shall send out the notices convening meetings of the General Assembly and Board of Directors, and prepare and sign the minutes of these meetings.

The Secretary may, with the prior agreement of the Board of Directors, employ administrative or technical personnel or other specialists to work for E.F.G.C.P. as necessary or appropriate.

#### 7.3.5 Membership Officer

The Membership Officer shall be responsible for the administration of Membership applications and shall organize the communications between all bodies of E.F.G.C.P. and its membership.

#### 7.3.6 Public Relations Officer

The Public Relations Officer shall be responsible for the publication of all E.F.G.C.P. activities as well as the generation of a regular Newsletter for all members.

#### 7.3.7 Ethics Officer

The Ethics Officer shall ensure that in all its activities, the E.F.G.C.P. will strive towards safeguarding the rights and welfare of human subjects as described in article 3.1. He shall be the link between E.F.G.C.P. and Ethics Review Committees.

#### 7.3.8 Ex-officio Officers

The Chairmen of the various Working Parties shall be ex-officio officers so as to facilitate communication between the Board of Directors and the Working Parties.

### 7.4 Expenses

Each member of the Board of Directors will be responsible for any costs resulting from the performance of this function. Members of the Board of Directors do not benefit from any emolument.

## 7.5 Communications

### 7.5.1 Position papers, publications

No document claiming to represent the opinion of E.F.G.C.P. will be published under the heading or in the name of E.F.G.C.P. without the prior approval of the Board of Directors.

The Members will be kept informed of the work of E.F.G.C.P.

### 7.5.2 Rights to ownership of and royalties from work produced

All rights to ownership of and royalties from work produced in part or in full by The Board of Directors or a third party having accepted to complete a task for the E.F.G.C.P., belong to the E.F.G.C.P. and can only be used in conformity with the decisions taken, or rules set, by the Board of Directors.

## 7.6 Working Parties

Each Working Party shall have a core membership of one representative from each of the relevant sectors.

## V. BUDGET AND ACCOUNTS

### ARTICLE 8 - FINANCES

#### 8.1 Annual Accounts

The fiscal year shall end on December 31st of each year.

E.F.G.C.P.'s annual financial statements shall be audited and attested at the end of each fiscal year by a body appointed by the Board of Directors.

The Board of Directors shall submit for approval to the General Assembly the annual financial statements for the past year together with the budget for the forthcoming year.

#### 8.2 Membership contributions

The Board of Directors shall propose the amount and manner of payment of membership contributions and other charges which shall be approved by the General Assembly. No change in the amount of membership

contributions or other charges shall take effect until thirty days after the Members have been notified in writing of such change.

Where any Member remains in arrears with his financial obligations for more than sixty days after the sending of formal notice by registered mail, his voting and all other rights attaching to his membership shall be held in abeyance until such time as the Treasurer shall receive payment of said liabilities.

## **ARTICLE 9 – ASSETS AND LIABILITIES**

### **9.1 Member's interes in the assets of E.F.G.C.P.**

A Member shall forfeit all interests in the funds, capital and assets of E.F.G.C.P. immediately upon termination of its membership for whatsoever cause.

In the event of such termination of membership, neither the Member concerned nor its representatives shall be entitled to institute whatsoever proceedings connected with such assets either against E.F.G.C.P., any other Member or its or their representatives.

### **9.2 Appropriation of the assets of E.F.G.C.P. on dissolution**

Upon the dissolution of E.F.G.C.P., the Board of Directors shall, after having paid or raised provision for the payment of all the liabilities of E.F.G.C.P. apply the remaining assets solely to purposes compatible with the purpose of E.F.G.C.P., or shall grant such remaining assets to one or more associations organised and administered exclusively for purposes similar to the purposes of E.F.G.C.P.

The Courts and Tribunals of Brussels, Belgium shall have jurisdiction over all assets not distributed as aforesaid.

## **VI. ALTERATION TO CHARTER - DISSOLUTION**

### **ARTICLE 10**

Without prejudice to Article 5 of the Public Act of October 25, 1919, proposals for alterations to the Charter or for the dissolution of E.F.G.C.P. shall be made only by the General Assembly.

The General Assembly shall be lawfully quorate when at least two thirds of the "Full" members are present or represented by proxy.

Resolutions shall be passed by a majority of two thirds of the votes of those Members having the right to vote which are present or represented.

Alterations to the Charter shall take effect only following their approval by Royal Decree and after the requirements of publication prescribed by article 3 of the Public Act of October 25, 1919, have been complied with.

The General Assembly shall fix the detailed procedures for dissolution of E.F.G.C.P.

## VII. GENERAL POINTS

### ARTICLE 11

Everything which is not foreseen in the above Charter of Incorporation, more specifically the publication in the attachments of the Moniteur Belge, will be treated according to Belgian Laws and Regulations.