1. Table of Contents 目录

Contents 内容

1. Table of Contents 目录 1
2. Purpose 目的 2
3. Scope 范围 3
4. General Requirements 一般要求 4
   4.1 Classification of Activities 活动分类 4
   4.2 Process Requirements 流程要求 5
      4.2.1 General Review and Approval Requirements 一般审查批准要求 5
      4.2.2 Specific Approval Requirements 特殊批准要求 6
      4.2.3 Initiators and Reviewers 发起人和审查者 7
      4.2.4 Other Process Requirements 其他流程要求 8
   4.3 Process 流程 9
      4.3.1 Event Plan 活动计划 9
      4.3.2 Event Application 活动申请 10
      4.3.3 Review and Approval 审查与批准 10
      4.3.4 Pre-execution Controls 执行前控制 12
      4.3.5 Execution 执行 14
      4.3.6 Post-Execution Controls 执行后控制 14
      4.3.7 Event Close 活动关闭 17
5. Roles and Responsibilities 角色和职责 18
6. Terms and Definitions 术语和定义 18
7. Appendices 附录 20
8. References 参考 20
9. Document History 文件历史 21

2. Purpose 目的

This SOP establishes an integrated process covering the conception, the approval, the preparation, the execution, and the post-execution of Ipsen activities with external stakeholders that are recorded in Ipsen China Activity Planning Management System (COPAM). It is intended to be a business instrument and to address risks of non-compliance with laws, regulations, and codes such as:
本标准操作流程（SOP）构建了集益普生活动的设计、审查批准、编制、执行与执行后于一体的综合流程，该活动的外部利益相关者记录于益普生中国活动管理系统（COPAM）中。本操作规程旨在成为一种业务守则，以管理不合规于法律、法规和规范的风险，包括：

- The Ipsen Code of Conduct
  益普生行为准则
- The Global Policy on Interactions with External Stakeholders GLB-POL-002
  与外部利益相关者互动交流全球政策 GLB-POL-002
- The Global Anticorruption Policy GLB-POL-004
  全球反腐败政策 GLB-POL-004
- Ipsen Global FMV Tiering Determination SOP
  益普生全球公允市场价值和分级 SOP
- Local Directive: Interaction with HCPs and HCOs CN-DIR-001
  合规指南：与医疗卫生专业人士/医疗卫生专业机构的互动交流 CN-DIR-001
- The EU Directive 2001/83/EC
  欧盟指南 2001/83/EC
- The IFPMA, the EFPIA and the PhRMA Codes
  国际药品制造商协会联合会、欧洲制药工业协会联合会及美国医药研究与制造商协会规范
- The FCPA, the UK Anti-Bribery Act, country specific anti-corruption laws and regulations
  反海外腐败法、英国反贿赂反腐败法案，国内相关反腐败法律法规
- Anti-Unfair Competition Law of China
  中国反不正当竞争法
- The RDPAC Code
  外商投资企业协会药品研制和开发行业委员会规范以及
- Other applicable country laws, regulations, and codes.
  其他适用法律、法规、规章及规范

3. Scope 范围

This SOP relates to the activities covered by
本 SOP 涉及以下文件所包含的活动

- CN-DIR-001 Local Directive: Interactions with HCPs and HCOs
  与医疗卫生专业人士及医疗卫生专业机构的互动交流
- IPSEN China Standard Operational Procedure of Promotional Materials Review & Approval.
  益普生中国推广资料审查批准标准操作流程
- China Local Non-Promotional Material Review SOP
  非推广材料中国本地审批流程
- CN-SOP-001 HCP Speakers and Consultants Management SOP
  HCP 讲者和咨询顾问管理规程

Any other Ipsen procedural documents that refer to this SOP such as Procurement SOP
供本 SOP 参考的任何其他益普生流程文件如采购 SOP 等

It covers related activities, physical or virtual, regardless of whether costs are involved or not,
本操作流程适用于以下相关实体或虚拟活动，无论是否涉及费用的发生：

- initiated by any business unit in China, or
  由中国任何事业部发起，或
- occurring in China, or
  发生在中国，或
- Involving stakeholders (e.g., HCPs, Government Officials, Patient Organizations, Media professionals, etc.) practicing in China regardless of where the event takes place.
  涉及中国利益相关者（例如，医疗卫生专业人士、政府官员、患者组织、媒体人等），无论活动在何处举行。

This SOP is applicable to all Ipsen employees engaged in related activities by Ipsen China. It also applies to Ipsen contractors that work on behalf of Ipsen.
本 SOP 适用于所有从事益普生中国相关活动的益普生员工，也适用于代表益普生工作的第三方派遣员工。

This SOP does not apply to:
本操作流程不适用于：

- One-to-one contacts and visits (e.g., Daily visits), unless part of a specific program, in which case the overall program must be approved.

一对一联系和拜访（例如，日常拜访），除非该类联系和拜访是一个项目中的一部分，对于这种情况，该项目的总体方案须得到批准。

- Ordinary One-to-One interactions and Group Calls/meetings, physical or virtual if all the following requirements are met:
  普通的一对一互动交流和集体拜访/会议，无论是面对面或者虚拟的，只要满足以下所有要求:
  - Sales Representatives are the only speakers and
    销售代表是唯一的讲者，及
  - Meeting takes place at the ordinary workplace of the HCPs (e.g., hospital, university, private practice) and
    会议地点在医疗卫生专业人士的普通工作场所（例如，医院、大学、私人诊所），及
  - no contract is required for the activity (e.g., no contract for logistics) and
    活动无需合同（例如，无物流合同），及
  - no local regulation declaration/hospital authorization is needed
    无需当地法规声明/医院授权
  - only ordinarily pre-approved materials are used; and
    仅使用常规的事先已经批准的资料；及
  - only meal costs occurred
    仅发生餐饮费用

- Internal meetings whereas no HCPs or Government Officials are invited, such as Ipsen internal trainings.
  内部会议，如益普生内部培训，无医疗卫生专业人士、政府官员的参与。
- Consultancy services not related to an activity/event/interaction as described above (e.g., services related to review or writing of scientific materials).
  与上述活动/事项/互动交流无关的咨询服务（例如，与审查或撰写科学材料有关的服务）。
- Sponsorships/partnerships/Grants and donations where there is no external event related to it (e.g., sponsorship of a website).
  没有与之相关的外部活动的赞助/伙伴关系/赠款或捐款（例如，网站赞助）。

Activities out of scope of the SOP do not require prior approval under this SOP.
超出本 SOP 范围的活动不需依本 SOP 获得事先批准。

4. General Requirements 一般要求

4.1 Classification of Activities 活动分类

Examples of activities subject to approval under this SOP can be found in Appendix 1.

需依本 SOP 批准的活动实例见附录 1。

4.2 Process Requirements 流程要求

4.2.1 General Review and Approval Requirements 一般审查批准要求

All activities in scope must be approved per this SOP before they are performed.
范围内的所有活动在执行前必须依照本 SOP 获得批准。

The process is based on the approval of an Event File in COPAM and its supporting documents. However, Activity Plan prepared per Ipsen strategy is not included in the COPAM review and approve process. BU activity plan is finalized as the reference of BU yearly operation plan and in corresponding with finance Internal Order approved.
该流程以COPAM中的项目文件及其支持文件的批准为基础。然而，根据益普生战略制定的活动计划不包含在COPAM审查批准流程中。各个事业部要根据年度运营计划和已被财务批准内部订单制定本部门的活动计划。

All required documentation must be mandatorily collected to support the approval and closure of the Event File. This documentation is necessary to prove that all engagements, services, and other interactions with stakeholders or other third parties, for which Ipsen Will make payments, are legitimate and commensurate to the value received and adequate to satisfy the related original and approved Ipsen need.
必须收集所有必备文件，以支持项目文件的批准和关闭。该类文件须证明与利益相关者或其他第三方的协议、服务和其他互动交流（由益普生进行付款）是合法的、与所获得的价值相称的，并足以满足相关原始的和批准的益普生需求。

Activity must be approved in COPAM in accordance with matrix of authority before any activity can take place or any final invitation can be sent, or any engagement can be made. All activities must be cancelled if the activity is not approved in COPAM.
进行任何活动之前或发出任何最终邀请函之前或做出任何聘任之前，活动必须依照授权矩阵在COPAM中获得批准。如果活动在COPAM中未获得批准，则该活动必须取消。

Closing of the Event File and all relevant documentation must take place as soon as possible after the event and once all the required documentation is collected and final controls are executed to enable payment.
活动之后，一旦收集完所有必备文件且为完成付款而进行的最终控制措施已经执行，须尽快对项目文件和所有相关文件关闭。

The initiator must check that the final program is aligned with Ipsen rules and external requirements, and should this not be confirmed, the activity must be cancelled.
发起人必须检查最终方案是否符合益普生规则和外部要求，如不能确定，则必须取消该活动。

If the company identifies any inconsistency between event execution and event application in COPAM system, the company has the right to evaluate the inconsistency to determine whether disciplinary sanctions to related personnel are required based on Employee Handbook and other procedural documents.
如果公司在监督检查过程中发现会议的执行与会议在COPAM系统中的申请不一致，则公司有权对该不一致进行评估，并决定是否有必要根据员工手册及其他内部流程文件对相关责任人员进行处分。

4.2.2 Specific Approval Requirements 特殊批准要求

If the information provided in the Event File has significant changes occurred between approval and execution, a new application must be sought. Significant changes include but are not limited to:
如果项目文件中提供的信息在批准和执行之间发生重大变更，则须重新审批。重大变更包括但不限于:

- Change in the rationale for the event (e.g., change of activity type, change in objective, change in disease area, etc.)
  活动的基本理由变更（例如，活动类型变更、目的变更、疾病领域变更等）。
- changes in venue, location
  会场、地点变更
- changes of speaker or chairman (this does not include the case where the speaker or consultant are not able to attend before the event takes place)
  讲者或主持变更（不包括讲者或主席临时未参会的情况）
- material budget increase (i.e., + 30%) in total
  总体预算显著增加（即，+30%）
- Any change in fee for service arrangements with stakeholders
- 对利益相关者服务费的变更
- Budget increase resulting in a change of Authority Approval; etc.
  预算增加导致授权审批的变更；等

Significant changes and any other changes must be duly reflected and documented in the Event File for re-approval. If any unexpected changes happen during the event, the initiator must report through email to his/her manager and upload the communication email to COPAM system after the meeting.
会议前的重大变更和任何其他变更必须在项目文件中适当反映和记录，以便重新审批。在会议执行过程中如遇到无法预料的突发情形，会议发起人应立即向其直线经理邮件报备，并在会后将沟通邮件在系统中上传。

If non-significant changes occur this need to be routinely recorded within the attached documentation with an explanation (e.g.,25% of participants have declined before the event).

如果发生非重大变更，则需要在所附文件中进行常规记录，并附有说明（例如，25%的参与者在活动开始前已拒绝）。

4.2.3 Initiators and Reviewers 发起人和审查者

Every head of function, business unit or team is accountable to ensure the processes in this SOP are appropriately complied with and matters are dealt with timely within their own area of responsibility.
各职能部门、事业部或团队负责人应负责确保本 SOP 中的流程得到适当遵守，并及时处理自己责任范围内的各项事宜。

Initiators are fully accountable for applying the process correctly and for the preparation, completeness, authenticity, accuracy, approval, finalization, and archiving of the Event File. They are fully accountable for the execution of the event in accordance with the approved Event Application or standardized relevant forms and all applicable laws, regulations, codes and Ipsen policies and procedures. They can delegate tasks to any necessary support roles (e.g. Assistants) but they remain accountable for the overall activity.
发起人对正确应用该流程以及项目文件的准备、完整性、真实性、准确性、批准、定稿和归档负全责。并对依照批准的活动申请或标准的相关表格和所有适用的法律、法规、规范和益普生政策和规程的活动的执行负全责。他们可以将任务委派给任何必要的支持角色（例如助理），但他们仍然对整体活动负责。

The Initiator must not be same as any approver.
发起人不能同时为审批人。

Initiators must attend the meetings by person. If in some urgent cases the initiator cannot attend the meeting by person, another person from the team must be assigned as on-site coordinator in advance to execute the meeting. Such cases must be pre-approved by ESR and department head / Business Unit Head and must be archived in the system prior to the meeting. The on-site coordinator and the initiator have the same level of accountability for the execution of the event.
发起人必须亲自参加其发起的会议，在紧急情况下，如果发起人不能到场参加活动，则在获得道德与社会责任部门以及发起人部门负责人的批准的前提下，可以由另一位同团队的员工在现场负责会议的执行，该批准邮件必须在会前上传至 COPAM 系统。现场执行员工与会议发起人对会议的执行承担同等程度的责任。

Each decision maker has the duty to review/approve all activities based on their functional competence, the applicable Ipsen strategy, and all applicable laws, regulations, codes and Ipsen policies, procedures, and ethical standards, while considering the activity in its entirety and complexity and considering the impact it can

have on Ipsen's reputation and image. Decision Makers must have the appropriate approval authority.
每个决策者都有义务根据其职能、适用的益普生战略以及所有的适用法律、法规、规范和益普生政策、流程和道德标准来审查/批准所有活动，在考虑活动整体性和复杂性的同时，还需考虑其对益普生声誉和形象的影响。决策者必须具有适当的核准权。

4.2.4 Other Process Requirements 其他流程要求

A unique sequential Event ID is assigned to the Event File by COPAM system. Should a project be canceled, the number should not be reused, the generation or disable of event ID is automatic in COPAM system.
通过COPAM系统将唯一的顺序活动代码分配给项目文件。如果一个项目被取消，则不得重复使用该代码。活动代码的生成和禁用在COPAM系统中是自动的。

Elements approved under other processes (e.g., materials, contracts) must be referenced through the specific ID number of the applicable process (e.g., CoMando, SAP, EMOS).
必须参考依照其他流程（例如材料、合同）批准的要素，但适用流程的 ID 号码是特定的（例如 CoMando，SAP, EMOS 等）。

4.3 Process 流程

4.3.1 Event Plan 活动计划

Initiator **发起人**	1. On a quarterly basis, initiator within function or Business Unit must prepare activity plan and have it approved by Head of Function or Business Unit Head. Each plan should be in corresponding with finance Internal Order approved. Internal Order apply, and approval process is followed by the related finance procedures. 每个季度，职能部门或事业部发起人必须准备活动计划，并使其获得职能或事业部负责人的批准。每项活动计划必须有对应的、已被财务批准的内部订单。内部订单的申请和批准流程遵守财务相关流程。 2. The approved Activity Plan must be uploaded into COPAM as a mandatory reference for the following Event File. 已批准的活动计划必须上传到 COPAM 系统，以作为随后项目文件的强制参照。 3. Activity Plan must include the following elements: Internal Order, event name/description, event type, number of events, initiator, department., region, city, product, whether it is international meeting or not, event status, estimated cost, etc. 活动计划必须包括以下要素：内部订单，活动名称/描述，活动类型，场次，负责人，部门，地区，城市，产品，是否为国际会议，活动状态，活动预算等。

4.3.2 Event Application 活动申请

Initiator **发起人**	4. Completes Event Application with all the relevant information and collects documentation as required by the Event Application and starts the approval process at least 15 days before the event planned date. 在活动申请中填入所有相关信息，按照活动申请的要求收集文件，并在计划的活动日期前至少 15 天展开申请流程。 5. If participants (e.g., delegates) or service providers (e.g., advisors or speakers) from another country are required for the planned activity, consults *CN-SOP-001 HCP Speaker/Consultant Management SOP* to verify what hospitality, contractual or additional local Ipsen or external approval requirements apply to those individuals and inserts information into Event File. 如果计划的活动需要来自另一个国家的参与者（例如代表）或服务提供者（例如咨询顾问或讲者），请查阅《CN-SOP-001 HCP 讲者和咨询顾问管理流程》，以核实适用于这些个体的招待方式、合同或其他当地益普生或外部批准要求，并将这些信息增加到项目文件中。 6. Submits Event Application to certify the accuracy and completeness of the details reported and compliance with the applicable Laws, Regulation and Codes as well as Ipsen Procedural Documents, that all hospitality elements are in line with *CN-DIR-001: Interactions with HCPs and HCOs*. 提交活动申请，以证明所报告的细节的准确性和完整性，以及对适用法律、法规和规范以及益普生流程文件的合规性，特别是所有招待要素要符合《CN-DIR-001 合规指南：与医疗卫生专业人士和医疗卫生专业机构的互动交流》。

4.3.3 Review and Approval 审查与批准

Decision Maker **决策者**	7. Reviews and approves entire Event Application based on their functional competence and Approval Authority, the applicable Ipsen strategy (e.g., Brand Plan for Marketing, Medical Plan for Medical, etc.), and all applicable laws, regulations, codes and Ipsen policies, procedures, and ethical standards, while considering the activity in its entirety and complexity and taking into account the impact it can have on Ipsen reputation and image in 4 days. 根据其职能和核准权、适用的益普生战略（例如，市场部品牌计划、医学部计划等），以及所有的适用法律、法规、规范和益普生政策、规程和道德标准，对整个活动申请进行审查和批准；在考虑活动整体性和复杂性的同时，还要考虑其对益普生声誉和形象的影响；审批过程在 4 天内完成。 In case of rejection or return, routes back Event Application to Initiator, with comments for the Initiator to rectify the Event Application and re-submit, if appropriate. 如果拒绝或退回申请，则将活动申请返回给发起人，并向发起人提供意见，以纠正活动申请并重新提交（如适用）。

Initiator **发起人**	8. In case of rejection, with comments, rectifies the Event Application, and re-submits by new request, if appropriate. 如果被拒，根据意见纠正并重新提交新的申请（如适用）。 In case of return with comments, the event application could be revised and re-submit, if appropriate. 如果被退回，可以根据意见修改原申请、重新提交（如适用）。 9. Checks all the reviews and approvals have been duly obtained, processed, and documented including Approval Authority. 检查所有已正式获取的、处理的和记录的审查和批准，包括核准权。 10. If participants (e.g., delegates) or service providers (e.g., advisors or speakers) from another country are required for the planned activity, contact Local Contact in those countries to facilitate the additional local approval, when this is required by relative SOP. In the countries where hospitality, contractual or additional local Ipsen or external review and approval requirements apply, an individual in the corresponding business unit in those countries will act as a Local Contact and will provide all the necessary information and support. 如果计划的活动需要来自另一个国家的参与者（例如代表）或服务提供者（例如咨询顾问或讲者），请与这些国家/地区的当地联系人联系，以便获得额外的当地批准，如果相关流程作出了要求。在适用招待、合同或额外的当地益普生或外部审查批准要求的国家，这些国家相应事业部的个人将担任当地联系人，并提供所有必要的信息和支持。 11. Per the approved Event Application and Event ID, initiates Procurement Request in SAP system. 根据经批准的活动申请及项目号，在 SAP 系统中发起采购申请。
Procurement **采购部**	12. Initiates Procurement order based on the approved Procurement Request or perform bidding as required by Ipsen internal Procurement SOP and select vendor for the event. 根据经审批的采购申请，发起采购订单。或者根据益普生内部采购 SOP 规定，进行三方比价，选择供应商举办活动。

4.3.4 Pre-execution Controls 执行前控制

Initiator **发起人**	13. Ahead of execution, ensures the external local requirements are satisfied and performed per applicable procedural documents. From 5 days before until 1 day before the event, the initiator must upload final version of all documents including but not limited to agenda, speaker, attendee, venue, and logistics. 在执行前，确保满足外部当地要求，并根据适用的流程文件执行活动。在会议日期前 5 天至会议前 1 天，发起人应上传所有最终版本的文件，包括日程、讲者和参会人名单、会议地点、行程安排等。 14. Ahead of the execution ensures all other relevant approvals are obtained per relevant processes e.g., contracts, materials, PO, etc. 在执行之前，确保根据相关流程（例如合同、材料、采购订单）获得所有其他相关批准。 15. Ahead of execution, ensures completeness and accuracy of the Event File, including documents to be obtained after the approval of the Event Application as required by the Checklist of the Event Application. 在执行之前，确保项目文件的完整性和准确性，包括活动申请核实清单所要求的活动申请获得批准后获得的文件。 16. Ensures activity does not take place if approval of the Event Application has not been obtained. 确保如果活动申请未获得批准，则该活动不会发生。 17. Ensures that individual HCPs or other stakeholders do not attend unless all necessary requirements/approvals have been fulfilled (e.g., Conflict of Interest assessment, final and signed contracts are in place etc.) directly or through country confirmation if organized with the help of other countries and approvals under local SOPs have been obtained as per *CN-SOP-001 HCP Speaker Management SOP*. 确保医疗卫生专业人士或其他利益相关者在所有必要的要求/批准（例如，利益冲突评估、最终和签署的合同均到位等）已直接完成或通过国家确认完成（如果是在其他国家的帮助下组织，并根据《CN-SOP-001 HCP 讲者管理流程》，获得了依照当地 SOP 的批准。）的前提下出席会议。

Initiator **发起人**	18. Verifies that all the tasks above (e.g., contracts, materials, POs) have been completed per related procedures and activity can take place. 核实根据相关流程已完成所有上述任务（例如合同、材料、采购订单），且活动可以进行。 19. If verification does not take place, the event must be cancelled. 如未进行核实，则必须取消该活动。 20. The cancellation of an event must be done in the system at least 1 day prior to the event. Any changes to the planned event must be communicated with line manager and Business Ethics Monitoring via email at least 1 day before the meeting and supporting documents must be uploaded after the event to the system. Any change upon receiving the notice of the spot check or having on-site monitors arrive without pre-notice via email will be violation to procedural requirements. 会议的取消必须在会前至少 1 天内完成。在会议开始前 1 天，如有可预见的会议相关的变更，应当提前邮件通知直线经理及商业道德部门合规监察团队进行备案，并在会后在系统中上传实际执行相关文件。如无会前提前邮件报备，在收到飞检通知后或者飞检人员到场后的任何时间、地点、讲者、参会人员的变化将被视为违规。

4.3.5 Execution 执行

Initiator **发起人**	21. Ahead of execution, ensures the external local requirements are satisfied and performed per applicable procedural documents. Notice any unpredictable changes via email as soon as possible. 在执行前，确保满足外部当地要求，并根据适用的流程文件执行活动。对任何无法预知的情况进行及时邮件报备。 22. Executes all elements of the activity in line with the Event Application, Ipsen strategy, this SOP, all applicable Ipsen policies, procedures and ethical standards and all applicable laws, regulations, and codes. 根据活动申请、益普生战略、本 SOP、所有的适用益普生政策、规程和道德标准以及所有的适用法律、法规和规范执行活动的所有要素。 23. Following execution, payments for all services genuinely received can processed per applicable finance/Procurement processes. 执行后，对真实收到的所有服务的付款可以根据适用的财务/采购程序进行处理。

4.3.6 Post-Execution Controls 执行后控制

Initiator **发起人**	24. When recording expenses in SAP or Concur, must cross-reference the related Event ID.

	在 SAP 或 Concur 中记录费用时，必须交叉引用相关项目编号。 25. Ensures document completion and filing by obtaining all relevant supporting information and documentation (e.g., minutes, sign-in sheets, records, etc.) and adding to the Event File based on the Checklist of the Event File. 通过获取所有相关的支持信息和文档（例如会议记录、签到表、记录等）并根据项目文件的核实清单添加到项目文件中，确保文件的完善和归档。 26. Verifies that executed activities are in line with what was approved in the Event Application as detailed in this task by verifying as a minimum the following: 通过核实以下至少一项，来核实执行的活动是否符合本活动申请中所批准的内容（如本任务所详述的）： 26.1 All services billed were received and are as per contractual terms and as per approved Event Application. 已实际收到所有服务账单，且账单符合合同条款和已批准的活动申请。 a) All invoices received (and relevant PO closed as required), all payments done as per Event File and consistent with relevant contracts and PO. Nothing outstanding. 收到的所有发票（以及所要求的已结束的相关采购订单），所有的款项都是根据项目文件支付的，并与相关合同和采购订单一致。没有例外项目。 b) Proof of Evidence obtained and attached for all services detailed in the Event File and in the contracts (see definition) 获得的和所附的项目文件和合同中详细说明的所有服务的证明文件（ 见定义） c) Ensures actual execution is in line with applicable limits of T&E procedures and CN-DIR-001for meals, honoraria, travel. 确保实际执行的餐费、报酬、差旅等费用符合 T&E 规程和合规指南的中相关的限制。 26.2 Ensures supporting documentation is appropriate/valid and consistent with Event File and contracts: 确保支持文件是适当/有效的，与项目文件和合同一致： a) Sign- in sheet contains the signature of all the participants and speakers.

	签到表包含所有参与者和讲者的签字。 b) Original meeting photos clearly shows the meeting attendances. Including clear photo of speakers and chairmen during presentation, and all attendees. Photo of other elements, such as the topic, photo of Ipsen sponsored elements, must also be provided in the system. 清晰显示会议举办情况的会议照片原件。包括清晰的讲者和主持人的演示照片以及展示全部参会人的照片。其他与会议相关的元素的照片亦必须在系统中上传，例如会议主题，赞助元素等。 c) The final agenda timelines should match the number of hours of services delivered at the event (excluding preparation time), as described in the contract and in the Event File. 最终的议程时间表应与活动中提供的服务小时数（不包括准备时间）相符合，如合同和项目文件中所述。 d) Ensure all the costs have gone to the appropriate project / have been accounted for appropriately as per the Event Application information. 确保所有费用已根据活动申请信息分配给适当的项目/已适当入账。 e) Sufficient supporting documents for Out-of-pocket expense incurred by external party (e.g., HCPs) as agreed are collected and documented properly, and are delivered to Event Management Agency for reimbursement. 收到并妥善记录外部各方（如医疗卫生专业人士）所产生的自付费用的充分支持文件，并交付给会务公司进行报销。 f) Ensure that Event Management Agency has provided Settlement File Package. Examine and confirm all invoices and detailed payment supporting documents aligns with actual service provided. An invoice is not a proof of service. 确保已收到会务公司结算清单、发票及明细付款文件，并检查和确认结算清单和附件是按照实际服务情况提供的。发票并不能作为服务提供的证明。 26.3 Verifies that all the pre-execution checks are visible in the supporting information & documentation: 核实所有的执行前检查在支持信息和文件中可见: a) All necessary contracts approved and signed appropriately prior to the event. 活动开始之前，所有必要合同已恰当地获批和签署。

	b) Materials reviewed and approved appropriately prior to the event. 在活动开始之前，所有资料已经恰当审查和批准。 c) Local requirements fulfilled and obtained appropriately prior to the event e.g., co-payment, employer's approval, approvals from regulatory authorities, notifications to regulatory authorities within given deadlines 在活动发生之前，当地要求得到了适当的满足，例如，得到了共同支付、雇主批准、监管部门的批准、在给定期限内向监管机构提供的通知。 d) Local requirements fulfilled and obtained appropriately after the event within given deadlines e.g., reporting to regulatory authorities etc. 当活动在给定期限内发生后，当地要求得到了适当的满足，例如向监管部门报告等。 e) Event Application have been completed and approved appropriately prior to the event and any significant change has been approved. 活动申请在活动发生前已经完成并得到适当批准，任何重大变更均已获得批准。 27. Escalate and report any potential issues as appropriate, depending on the nature of the issue and the related process (e.g., to Business Ethics). 根据问题的性质和相关流程（例如，向商业道德部门），适当地向上汇报任何潜在问题。
Initiator **发起人**	28. Confirms in the Event File that all the tasks above (in the Post-execution of the event) have been completed and activity can be closed and proceed to archiving 在项目文件中确认所有上述任务（活动执行后）已经完成，并确认活动可以结束并进行归档。

4.3.7 Event Close 活动关闭

Initiator **发起人**	29. Confirms Event File is dully completed in accordance with the Event File requirements and archiving has been completed. Event must be closed within 60 days after the event. 确认项目文件是根据项目文件要求正式完成，并已归档完成。活动关闭必须在活动结束之后 60 天内完成。
Decision Maker **决策人**	30. Ensures all related fields have been fulfilled and event has been executed per the Event Application and approves event closing in COPAM. 确保所有相关领域已经完成，活动已根据活动申请执行，并批准 COPAM 中的活动关闭。

5. Roles and Responsibilities 角色和职责

Roles 角色	Responsibilities 职责
Initiator **发起人**	Initiators are fully accountable for applying the process correctly and for the preparation, completeness, accuracy, approval, finalization and archiving of the Event Application and the Event Application. They are fully accountable for the execution of the event in accordance with the approved Event File or standardized relevant forms and all applicable laws, regulations, codes and IPSEN policies and procedures. They can delegate tasks to necessary personnel (i.e., Creators in COPAM) but they remain accountable for the overall activity. 发起人对正确应用该流程以及活动申请的准备、完整性、准确性、批准、定稿和归档负全责。并对依照批准的活动申请或标准的相关表格和所有的适用法律、法规、规范和益普生政策和规程（包括活动的真实性和合规性）的执行负全责。他们可以将任务委派给任何必要的人员（例如 COPAM 中的创建者），但他们仍然对整体活动的执行负责。
Decision Maker **决策者**	Reviews and approves entire Event File based on their functional competence, the applicable Ipsen strategy and all applicable laws, regulations, codes and Ipsen policies, procedures, and ethical standards, while considering the activity in its entirety and complexity and considering the impact it can have on Ipsen's reputation and image. 根据其职能、适用的益普生战略以及所有的适用法律、法规、规范和益普生政策、规程和道德标准来审查、批准所有项目文件，在考虑活动整体性和复杂性的同时，还要考虑其对益普生声誉和形象的影响。
Procedural Document Owner **流程文件所有者**	Ensures proper communication, training, and implementation and functioning of this SOP, assess its efficiency and proposes improvements as necessary. 确保对本 SOP 的适当沟通、培训、实施和运作，评估其效率，并在必要时提出改进建议。 Ensures update of the SOP at whenever a change is required 在需要变更时，确保更新本 SOP。

6. Terms and Definitions 术语和定义

Term 术语	Definition 定义
Healthcare professionals (HCP) **医疗卫生专业人士**	Healthcare professional means any member of the medical, dental, pharmacy or nursing professions or any other person who during his or her professional activities may prescribe,

	recommend, purchase, supply, or administer a pharmaceutical product. 医疗卫生专业人士是指所有医疗、牙科、药剂或护理专业人员，或者所有其他在其职业活动过程中可能开出处方、推荐、采购、供应或管理某一药品的人员。
Healthcare Organizations (HCO) **医疗卫生专业机构**	HCO means any legal entity that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university, or other teaching institution or learning society. 医疗卫生专业机构是指所有医疗保健、医学或科学协会或组织等法人实体（无论其法律或组织形式），例如医院、诊所、基金会、大学或其他教育机构或学习社团。
External Meetings **外部会议**	Meetings targeted at a non-Ipsen audience. Conversely, internal meetings are meetings targeted at an Ipsen audience (e.g., sales force training), even if some external persons attend as service providers (e.g., an external HCP speaking at an internal training session). 针对非益普生受众的会议。相反，内部会议是针对益普生受众的会议（例如，销售人员培训），即使一些外部人员作为服务提供者与会（例如，外部医疗卫生专业人士在内部培训会议上发言）。
COPAM	Ipsen China activity management system 益普生中国活动管理系统
Event Management Agency Settlement Document **会务公司结算文件**	Documents collected from the event management agency after the event has been executed and services has been provided. This includes but not limited to: 是指从会务公司所获取的，为了执行会议所获取的费用相关支持文件，以证明服务的发生。该类文件包括但不限于: • A settlement spreadsheet with all expenses summarized 包含所有费用明细的结算表 • Photocopies of payment supporting documents, including: 支付文件的复印件，包括: o Transportation: including but not limited to train tickets, flight itinerary, car rental details (including date, starting point and destination, name of passengers, etc.) and car rental tax invoice (if applicable) 交通费用：包括但不限于火车票、机票行程单、租车费明细（含日期、起始地点、乘车人姓名等）和租车费税务发票（如适用）

	○ Accommodation: Hotel reservation record, hotel bill with guest name and dates, tax invoice 住宿费用：酒店预订单、包含住客姓名和入住期间明细的酒店结算水单、税务发票 ○ Meeting room: meeting room rental detail and tax invoice. 会议室：酒店场租明细和税务发票 ○ Meal: including meal itemization, POS slip or bank transfer record, tax invoice 餐饮：包括点菜小票、刷卡单或者转账记录、税务发票 ○ Meeting registration: registration detail and tax invoice 会议注册费：注册明细、税务发票 ○ OPE summary (if applicable) and bank transfer records 现付费用汇总表（如有）以及转账记录明细

7. Appendices 附录

Appendix **附录**	**Title** **名称**
Appendix A 附录 A	Supporting Document Checklist 支持文件清单

8. References 参考

- CN-DIR-001 Local Directive: Interactions with HCPs and HCOs
  合规指南：与医疗卫生专业人士及医疗卫生专业机构的互动交流
- CN-SOP-001 HCP Speaker Management SOP
  HCP 讲者管理规程
- Ipsen China Standard Operational Procedure of Promotional Materials Review & Approval.
  益普生中国推广资料审查批准标准操作流程
- China Local Non-Promotional Material Review SOP
  非推广材料中国本地审批流程

9. Document History 文件历史

Effective Date 生效日期	Version Number 版本号	Description 说明
01/05/2017	1	Activities initiated from the effective date of this SOP will be processed under this SOP. Any activity which was in course of approval or already reviewed and approved under the pre-existing process at the effective date of this SOP will not need to be re-approved under this process. 自本 SOP 生效之日开始启动的活动将根据本 SOP 执行。 任何在本 SOP 生效日期前正在进行或已通过已存在的流程的批准的活动，不需要根据本流程重新获得批准。
01/04/2019	2	Updated in accordance with recent update of internal procedural documents as well as the organization re-structuring. 根据内部其他流程文件的更新以及组织架构的调整对本流程文件进行了更新。
01/03/2022	3	Updated in accordance with recent update of internal procedural documents, systems as well as the organization re-structuring. 根据内部其他流程文件、系统和组织架构对本流程文件进行了更新

APPENDIX A – Supporting Document List 附录 A – 支持文件清单

Ipsen Organized Event 由益普生组织的会议

Stage **阶段**	**文件要求** **Document requirement**
Event Application 活动申请	• Meeting Agenda draft 会议日程草稿 **系统填写会议基本信息，包括但不限于:** • Speaker / Chairman number name list or numbers 讲者/主席名单 • Estimated number of Attendee 预计参会人数 • Travel arrangements (if any) 会议差旅安排（如有）
Pre-Execution 预执行	• Invitation Letter 邀请函 • Meeting Agenda 会议日程 • Attendee / Speaker and Chairman List 参会者/讲者及主席名单 • Final logistics details 最终差旅安排 • Vendor Contract or PO (If applicable) 供应商合同或采购订单（如适用） • Conflict of Interest Evaluation (If applicable) 利益冲突评估（如适用） • Clinical trial agreement or confidentiality disclosure agreement for current or pending clinical trials (Investigator meeting) 用于当前或待定临床试验的临床试验协议或保密披露协议（研究者会议） • Explanation of future speaking service arrangements (Speaker Training) 对今后讲课服务安排的具体说明（适用于讲者培训） • Approval email for exceptional cases (If applicable) 例外事项的审批邮件（如适用）
Post-Execution 执行后	• Final Meeting agenda 会议日程最终版 • Attendee/Speaker and Chairman list and sign in sheet 参会者/讲者和主席名单及签到表

	• Speaker/Consultant Agreement 讲者/顾问服务协议 • Photo of the meeting (including photos of each speaker during presentation and at least one photo that clearly shows all attendees) 会议照片（包括每一名讲者讲课照片以及至少一张清晰展示全部参会人员的照片） • Internal and External Presentations 内部及外部展示材料 • Meeting Minutes （If applicable） 会议纪要（如适用） • Report of the meeting results usage (Advisory Board) 对会议结论的使用证明（顾问委员会） • Communication/Approval email for exceptional cases 例外事项的沟通/审批邮件（如适用） • Event Management Agency Settlement Document or other settlement documents from systems such as EMOS or COPAM 会务公司结算文件或其他平台结算文件，如 EMOS, COPAM

Third party event sponsorship and Sponsorship to individuals to third party events
第三方活动赞助及赞助个人参加第三方活动

Stage 阶段	文件要求 Document requirement
Event Application **活动申请**	**From the third party:** **来自第三方:** • Official Invitation to Sponsorship or Meeting Notice 会议通知或大会**正式**邀请函 • Drafted event agenda 会议日程草稿 **For meeting arrangements:** **针对会议安排** • Travel arrangements Draft (if applicable) 会议差旅安排草稿（如适用） • Sponsored individual list draft 赞助个人名单草稿（如适用）
Pre-Execution **预执行**	• Meeting agenda 会议日程 • Travel arrangements 会议差旅安排 • Sponsored individual list (if applicable) 赞助个人名单（如适用） • Vendor Contract or PO 供应商合同或采购订单 • Sponsorship Contract 赞助协议 • Conflict of Interest Evaluation (If applicable) 利益冲突评估（如适用） • Approval email for exceptional cases (If applicable) 例外事项的审批邮件（如适用）
Post-Execution **执行后**	• Final Meeting agenda 会议日程最终版 • Attendee/Speaker and Chairman list and sign in sheet) (for Satellite Meetings and sponsoring HCPs to attend events) 参会者/讲者和主席名单及签到表（适用于卫星会、赞助 HCP 参会） • Internal and External Presentations (If applicable) 内部及外部展示材料（如适用）

	• Photo of sponsorship elements including but not limited to booth / advertisement/Ipsen logo/official medial publication 赞助元素的证明照片，包括但不限于展台、广告、益普生标志、大会官方宣传文件等 • Event Management Agency Settlement Document or other settlement documents from systems such as EMOS or COPAM 会务公司结算文件或其他平台结算文件，如 EMOS, COPAM

Note 注:

- Other supporting documents may be required as per internal procedural documents. The document checklist is subject to the requirements described in applicable Ipsen procedural documents.
  根据内部流程文件的规定，可能需上传其他支持文件。该文件清单需要遵守适用的益普生内部流程文件的规定。
- If there is no change between Pre-execution stage and Post-execution stage in one document, the document uploaded on pre-execution stage will be considered as the final document.
  如果某些文件在预执行阶段和执行后阶段无变化，执行前阶段上传的文件将被视作最终版本文件。
- Speaker/consultant agreement can be uploaded after the event, but any contract/agreement must be signed before the meeting takes place.
  讲者/顾问的服务协议可以在会后上传，但是任何合同/服务协议必须在会议开始前签订。
- Meeting photo must clearly show: 1) each speaker or chairman during presentation (for Ipsen organized events or Ipsen sponsored satellite meetings in third party events; 2) meeting theme or other important elements such as the booth, etc.
  会议照片必须明确显示：1) 每一位讲者和主席的现场演讲（适用于益普生主办的会议和第三方会议中益普生赞助的卫星会）；2）其他重要的会议元素，如会议主题、展台等。