***COMPANY LOGO/LETTERHEAD/OFFICIAL STATIONERY/COMPANY DOCUMENT***

# Section 1 - Organizational Overview of the Certification Body (CB)

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| Company Name(s) |

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| --- |
| Address(es) |

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| --- |
| Key Contact(s)   * Name(s) and Title(s) * Email Contact(s) |

|  |
| --- |
| Corporate ownership |

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| --- |
| Company Details |

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| --- |
| General Information |

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| Certification program scope |

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| --- |
| List of relevant procedures |

# Section 2 - Scheme Overview and Oversight

Overview of program/description of scheme:

**Accreditation**

Organization Name:

Organization Number:

Accreditation Expiration Date:

**Oversight approach by internal and external audit bodies:**

External

Internal

Evidence of accreditation to ISO 17021-01 and/or ISO 17065

# Section 3 – Certification Scheme Program Details:

The table at the end of this document provides a cross-reference to clauses in ISO 17021-1 and ISO 17065.

## Legal responsibility

Identify the legal entity that is responsible for conducting audit / certification activity.

## Certification or service agreement

Describe how the CB communicates to the auditee the auditing scheme as well as the rights and duties of the auditee

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| Confirm there is a written agreement between the CB and Scheme Owner or accreditation body.  Agreement should include, at a minimum:   * auditee’s obligation to communicate substantive changes to the CB * CB’s responsibility to maintain confidentiality * authorized use by auditee of the certification mark (e.g. agreement) |

## Licenses, certificates and marks of conformity

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| Confirm that the auditing / certification agreement includes provisions which describe the appropriate and / or inappropriate use of certificates, marks, and statements of GMP and/or GDP conformance. |

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| Establish how the CB defines the scope and duration (in auditor-days) of the audit and how it is communicated to the auditees.  Confirm that the certification clearly identifies what is in-scope or out-of-scope. |

## Management of impartiality

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| Describe how the CB manages impartiality to ensure no commercial, financial or other pressures compromise the audit or certification decisions and how this is assured.  Confirm that there is an acknowledgement from the auditor that they are able to comply with the requirements for impartiality  For example, auditors should not be allowed to participate in audits:   * of organisations they previously worked in within the last X\* years * where they have a significant financial interest in the organisation * where they have provided consultancy to the organisation within the last X\* years.   \* ISO 170121-01 states 2 years; however, Users should define the period of time based on their business and regulatory needs |

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| Confirm that consulting service is not part of the services rendered by the auditing / certification legal entity. |

## Non-discriminatory conditions

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| Describe how the CB ensures its services are offered in a non–discriminatory manner and without the requirement for auditee affiliation to any industry, trade or other group. |

## Confidentiality

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| Describe how the CB ensures confidentiality. |

## Publicly available information

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| Provide “publicly” available CB details.  The CB should provide:   * Description of the auditing process, audit standard, and certification scheme * Information on how complaints from excipient users questioning the audit report or certification decision are handled * List of active certificates * Means by which excipient users can acquire information on suspended and withdrawn certificates * Details on how the excipient user can request an audit report or verify the authenticity and accuracy of an audit report received from an excipient supplier. * Where applicable, accreditation status of the CB |

## Organizational structure

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| Describe the organizational structure of the CB, noting who makes decisions on certification approval or certificate withdrawal. Where available, include a high-level diagram providing evidence of a separate legal structure. |

## Resource requirements and personnel competence

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| Describe and justify the resources and their adequacy to manage the audit scheme and ensure ongoing compliance with procedures, and as applicable, accreditation requirements. |

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| Confirm that independent contractor agreements (ICAs) are in place with the auditors, as applicable.  Confirm whether the ICA include provisions for confidentiality and impartiality. |

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| Describe how the auditing / CB ensures adequate auditor resources and that auditors are competent in their respective roles / assignments.  Describe how auditor competencies are reviewed and maintained. |

## Certification decision

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| Identify the party responsible for certification decisions. |

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| Describe how audit findings are classified.  Identify the criteria on which a certification decision is made. |

## Changes affecting certification scheme

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| Describe how the CB manages and communicates changes to the scheme requirements, audit standard(s) and/or certification criteria. |

## Complaints and appeals

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| Describe how the CB handles complaints and appeals.  Confirm that the persons engaged in addressing appeals (when an auditee disagrees with an audit finding or decision on certification) is different from those carrying out the audits or making certification decisions. |

# Section 4 - Roles and Responsibilities of the Scheme Owner or Accrediting Body

The roles and responsibilities for establishing the requirements that CB must meet should be either listed here or set forth in an accompanying document or weblink. For example, auditor training and qualification is the responsibility of the Scheme Owner or Accreditation Body to delineate. Training may be the responsibility of the Scheme Owner, as is the case for EXCiPACT® or may be provided by an independent organization such as IPEC.

# Section 5 - Revision history

The Scheme Owner completes those sections and items for which they have responsibility or provides relevant documentation such as a weblink and the CB completes the remainder.

The CB has responsibility for updating this document whenever a change to any item has been made.

* Date completed and approved by Scheme Owner and CB

**Cross-reference for sections of IPEC Guide and clauses in ISO 17021-1 and ISO 17065**

| **IPEC Guide1** | **ISO 17021-12** | **ISO 170653** |
| --- | --- | --- |
| 2.2.3.1 Legal responsibility | 5.1 Legal and contractual matters | 4.1 Legal and contractual matters |
| 2.2.3.2 Certification or service agreement | 5.1 Legal and contractual matters | 4.1 Legal and contractual matters |
| 2.2.3.3 License, certificates and marks of conformity | 8.3 Reference to certification and use of marks |  |
| 2.2.3.4 Management of impartiality | 5.2 Management of impartiality | 4.2 Management of impartiality |
| 2.2.3.5 Non-discriminatory conditions |  | 4.4 Non-discriminatory conditions |
| 2.2.3.6 Confidentiality | 8.4 Confidentiality | 4.5 Confidentiality |
| 2.2.3.7 Publicly available information | 8.1 Public information | 4.6 Public information |
| 2.2.3.8 Organizational structure | 6. Structural requirements | 5. Structural requirements |
| 2.2.3.9 Resource requirements and personnel competence | 7. Resource requirements | 6. Resource requirements |
| 2.2.3.10 Certification Decision | 9.5 Certification decision |  |
| 2.2.3.11 Changes affecting certification scheme | 8.5 Information exchange between a CB and its clients |  |
| 2.2.3.12 Complaints and appeals | 9.7 Appeals |  |

1 IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients, Version 1, 2020

2 ISO 17021-01 - Conformity assessment-requirements for bodies providing certification of excipient management systems, 2015

3 ISO 17065 - Conformity assessment-requirements for bodies certifying products, processes and services, 2012