**Purpose**

* This checklist is a tool to assist in the development of an effective and efficient CQMP.
* This checklist will assist the site personnel in the development of a CQMP that is a complete and accurate representation of the respective site’s quality management operations.

**How to use this checklist**

* Complete the checklist sections and fields as the CQMP is developed.
* If criteria are met, mark an X in the Yes column.
* If criteria are not met, mark an X in the No column.
* If an item is not applicable, mark an X in the NA column.
* Add clarification comment as needed for context.

**Submission**

* Submit the completed Checklist to DMID with the corresponding initial draft of the CQMP.

**Header:**

|  |  |
| --- | --- |
| **Checklist date** |  |
| **Site name** |  |
| **DMID Protocol number, version #, version date** | <mark NA if not protocol-specific> |
| **CQMP version #, version date** |  |
| **Reviewed by**  |  |
| **Review date** |  |
| **Date submitted to DMID (e.g., Clinical Project Manager; DMID CROMS CQMP team)** |  |

**Checklist items:**

| ***#*** | ***Section and brief description*** | ***Yes*** | ***No***  | ***NA*** | ***Comment*** |
| --- | --- | --- | --- | --- | --- |
| **1** | **FORMAT** |  |  |  |  |
|  | Is format consistent with prescribed template? * DMID-CROMS CQMP template
* Site template
 |  |  |  |  |
|  |  |  |
|  |  |  |
|  | Does information in the document footer and header match? |  |  |  |  |
| **2** | **PROTOCOL IDENTIFICATION** |  |  |  |  |
|  | Does the CQMP contain the correct protocol version #/date, site(s), site addresses?  |  |  |  |  |
|  | Does the CQMP version # and/or date correspond with the associated tools? |  |  |  |  |
| **3** | **SCOPE** |  |  |  |  |
|  | To whom does this plan apply (sites, subcontracted sites)?  |  |  |  |  |
|  | Is the relationship between primary and subcontractor sites defined? |  |  |  |  |
| **4** | **CQMP ROLES & RESPONSIBILITIES** |  |  |  |  |
|  | Is responsibility for the CQMP defined? (Investigator, designees); e.g., Is the name of the person(s) responsible for the development, implementation, and evaluation of the CQMP listed? |  |  |  |  |
|  | Does the CQMP detail the role(s) responsible for conducting the review of study product. Refer to protocol.(i.e., blinding status / limitations of delegated staff; blinded study product administrators do not perform subject assessments post administration.) |  |  |  |  |
| **5** | **CLINICAL QUALITY MANAGEMENT PROCESS** |  |  |  |  |
|  | Is a summary of Clinical Quality Management provided? |  |  |  |  |
| **6** | **QUALITY CONTROL ACTIVITIES** |  |  |  |  |
|  | Are Quality Control processes defined?(i.e., specific to QC, real-time) |  |  |  |  |
| **7** | **QUALITY CONTROL ROLES/RESPONSIBILITIES** |  |  |  |  |
|  | Are roles specific to QC defined? |  |  |  |  |
| **8** | **QUALITY CONTROL RECORD SELECTION / FREQUENCY** |  |  |  |  |
|  | Are study records selected for review defined?(i.e., Source documents, accountability log. Reference protocol and MOP for specific records) |  |  |  |  |
|  | Are Quality Control sample size (record selection) and quality review frequency defined?(i.e., 100%; in real time prior to data entry) |  |  |  |  |
| **9** | **QUALITY CONTROL TOOLS** |  |  |  |  |
|  | Are internal and external sources for quality tools used for documenting QC activities listed and included (submitted with the CQMP)? |  |  |  |  |
| **10** | **QUALITY ASSURANCE ACTIVITIES** |  |  |  |  |
|  | Are Quality Assurance processes defined?(i.e., specific to QA, retrospective)  |  |  |  |  |
| **11** | **QUALITY ASSURANCE ROLES / RESPONSIBILITIES** |  |  |  |  |
|  | Are roles specific to QA defined? |  |  |  |  |
| **12** | **QUALITY ASSURANCE RECORD SELECTION / FREQUENCY** |  |  |  |  |
|  | Are Quality Assurance sample size (record selection) and quality review frequency defined?(i.e., 10% / 20% / 50% / 100%, range; quarterly / biannually / annually) |  |  |  |  |
|  | Is study record sample size and review frequency timely and of sufficient size to represent study conduct? (i.e., 10% monthly. Ensure sample size is sufficient to represent data reliability, and review frequency supports timely notification of subject safety events) |  |  |  |  |
|  | Are study records selected for review defined?(i.e., Source documents, accountability log. Reference Protocol and MOP for specific records) |  |  |  |  |
| **13** | **QUALITY ASSURANCE TOOLS** |  |  |  |  |
|  | Are internal and external sources for quality tools used for documenting QA activities listed and included (submitted with the CQMP)? |  |  |  |  |
|  | Do the study records selected for review include the following, at a minimum? * Initial screening, enrollment and study visit records informing eligibility
* Study Product Accountability (receipt, inventory, dispensed, quarantined)
 |  |  |  |  |
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|  |  |  |
| **14** | **PROTOCOL-SPECIFIC CQMP** |  |  |  |  |
|  | Is the use of protocol-specific CQMPs defined? (If applicable) |  |  |  |  |
| **15** | **OVERSIGHT OF SUBCONTRACTOR** |  |  |  |  |
|  | Is oversight of subcontractor sites and workflow defined? (If applicable) |  |  |  |  |
| **16** | **KEY QUALITY INDICATORS** |  |  |  |  |
|  | Informed Consent Form and Process |  |  |  |  |
|  | Eligibility Criteria |  |  |  |  |
|  | Randomization Code List and Decoding Procedures |  |  |  |  |
|  | Study Product Management and Processes including receipt, handling, storage, preparation, administration, accountability, disposition (i.e., Study Product shipping records; Review and Comparison of the Study Product Accountability Logs, Shipping Records and Inventory; Study Product Storage, Handling, and Labeling Procedures) |  |  |  |  |
|  | AE/SAE Identification and Reporting |  |  |  |  |
|  | Protocol Visits (missed visits, out of window) |  |  |  |  |
|  | Protocol-specific procedures |  |  |  |  |
|  | Intervention/Study Discontinuation |  |  |  |  |
|  | Reactogenicity (If applicable) |  |  |  |  |
|  | Specimens (processing, storage, future use, transportation, shipping and documentation/declaration) |  |  |  |  |
|  | Other Protocol-Specific Indicators (as determined by site staff) |  |  |  |  |
| **17** | **REGULATORY FILE REVIEW** |  |  |  |  |
|  | Is the Review frequency for Regulatory Files defined? (i.e., prior to enrollment during the clinical phase of the protocol, close out) |  |  |  |  |
| **18** | **REGULATORY FILE REVIEW TOOLS** |  |  |  |  |
|  | Are tools and checklists used to document quality review listed/ referenced? |  |  |  |  |
| **19** | **QUALITY TOOLS AND CHECKLISTS** |  |  |  |  |
|  | Does the CQMP describe internal and external sources? |  |  |  |  |
| **20** | **STAFF TRAINING/QUALIFICATIONS** |  |  |  |  |
|  | Describe the quality review for determining training and licensure/certification requirements are met and current. Are all applicable trainings specified? Consider contractual requirements/obligations. |  |  |  |  |
| **21** | **CLINICAL QUALITY MANAGEMENT REPORTING** |  |  |  |  |
|  | Does the CQMP describe how quality review findings are summarized, analyzed, and communicated to the staff? |  |  |  |  |
|  | Are the tools used to document/summarize quality review summaries listed and included with the CQMP? |  |  |  |  |
|  | Are summary reporting elements addressed, including:* Identification of problem areas
* Trend Analysis
* Corrective action plan(s) e.g., Corrective and Preventive Action(s) (CAPA)
* Revision to the CQMP
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| **22** | **SITE EVALUATION OF THE CQMP** |  |  |  |  |
|  | Are details of the frequency of Site Evaluation of the CQMP included?(i.e., Evaluating the effectiveness of the CQMP annually, at a minimum) |  |  |  |  |
| **23** | **CQMP SIGNATURES/DATES** |  |  |  |  |
|  | Are applicable signatures and dates provided (site Investigator and Quality Management designee)? |  |  |  |  |