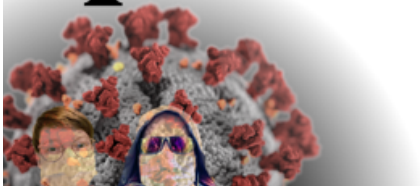


open.PAPR



Execution & Quality Plan

01 Authorization

| Role | Name | Date | Version | Signature |
|----------|--------------------------|----------|---------|-----------|
| Author | Ralph Lawrence Wunderlin | 20200415 | 01 | |
| Reviewer | Simon Bremer | 20200415 | 01 | |

02 Change Log

| Version | Author | Date | Reason |
|---------|--------------------------|----------|------------------------|
| 01 | Ralph Lawrence Wunderlin | 20200415 | First Revision 🐻❤️🌟 |
| | | | |

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03 Scope of this document

This document contains the procedures that are to be followed to execute the open.PAPR project in a transparent and traceable manner.

It also is the milestone for the start of the design and execution phases. The project will be closed out with a Execution & Quality Report. The report will state what has been achieved, and any changes and deviations that may have occurred.

04 Roadmap

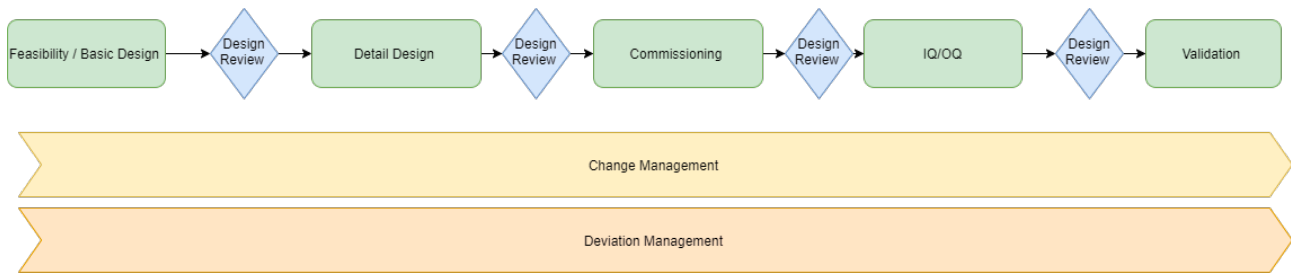


Diagram 01: Project Roadmap with milestones and CM/DM

04.1 Initiation and Closure

The project is initiated with the approval of this document and closed with a Project Execution & Quality Report.

04.2 Design Review

Design review is a must between every project phase.

This step ensures that the approved requirements have been checked against specifications. To speed this up, one shall reference approved requirements in it:

| open.PAPR Requirements-V01 | | |
|----------------------------|-------------|---|
| No | Category | Requirement |
| R-example1 | Business | The Filter and Fan Unit must contain at least one fan or blower |
| open.PAPR Instrument list | | |
| Position | Name | Description / Note |
| M01 | Main Blower | This blower transports air through the unit (R-V01-example1) |

Table-01: Design Review Example

This step may generate Change Requests or Deviation Reports.

There should be no Deviation Reports unresolved before releasing to the next phase.

Release to the next phase is done with the open.PAPR-Traceability Matrix.

This document is updated and its version incremented at every design review step.

All documents and their versions must be listed in the document list, only the final version of a specification, drawing, etc. is used to check against the requirements and listed in the traceability matrix.

Checking the requirements must be done in .pdf format with annotations, these are to be attached to the signed traceability matrix.

04.3 Feasibility / Basic Design

Feasibility is given as there are commercial products available.

Minimum deliverables for closure of BD:

| Document | Status | Comment |
|------------------------------------|---------------------|---|
| open.PAPR-Execution & Quality Plan | Reviewed & Approved | |
| open.PAPR-Requirements | Reviewed & Approved | |
| open.PAPR-Document List | Reviewed & Approved | All BD documents listed |
| open.PAPR-Org Chart | Updated | Including responsibility |
| open.PAPR-Media Flow Diagram | Draft | |
| open.PAPR-Risk Analysis | Reviewed & Approved | Status BD |
| open.PAPR-Traceability Matrix | Reviewed & Approved | All listed requirements checked: open.PAPR-Execution & Quality Plan; open.PAPR-Requirements Any CR's/DR's and their status |

04.4 Detail Design

| Document | Status | Comment |
|------------------------------|---------------------|---------|
| open.PAPR-Media Flow Diagram | Reviewed & Approved | |
| open.PAPR-P&ID | Reviewed & Approved | |
| open.PAPR-Instrument List | Reviewed & Approved | |
| open.PAPR-Bill of Materials | Finalized | |

| Document | Status | Comment |
|--|----------------------------------|---|
| open.PAPR-Functional Specification | Reviewed & Approved | Maybe SDS/SMDS spawn from this |
| open.PAPR-Source Code | Finalized | |
| open.PAPR-Wiring Diagram | Reviewed & Approved | |
| open.PAPR-CAD Hood | Reviewed & Approved & 3D-Printed | |
| open.PAPR-CAD Filter Fan Unit | Reviewed & Approved & 3D-Printed | May include battery compartment. If not: Separate CAD for battery compartment(s), same status |
| open.PAPR-Risk Analysis | Reviewed & Approved | Status DD To b executed as soon as the P&ID and CAD/3D-Prints are ready |
| open.PAPR-Document List | Reviewed & Approved | All DD documents listed |
| open.PAPR-Org Chart | Checked | |
| open.PAPR-Operating Manual | Reviewed & Approved | All relevant information contained, aim for CE |
| open.PAPR-Factory Acceptance Test Protocol | Reviewed & Approved | |
| open.PAPR-Traceability Matrix | Reviewed & Approved | Updated with DD-Information |

05 Review and Approval

All documents must be signed and approved by the author and at least one reviewer. From an approved version of a document to a new revision there must be a reason given. Valid reasons: Termination, a change or a deviation.

06 Change Management

Changes to the project scope must be initiated with an approved Change Request. The feature used in this project will be the Github incident reporting system with a custom template.

07 Deviation Management

Deviations must be avoided, but if there is a deviation it always must have a reason, a proposed solution and approval. The feature used in this project will be the Github incident reporting system with a custom template.

During testing a separate deviation management form will be provided. The feature used in this project will be the Github incident reporting system with a custom template.

08 CSV (Computer System Validation)

Any part of the system that has a parameter set or a unique software must be validated. The classification of each device with such functionality must be defined in the functional specification and judged under GAMP 4 or 5. Established languages (C, C++, µP, etc.) must be source-code reviewed, standard libraries are exempted.

09 Project Closeout

10 Code of Conduct

10.1 Our Pledge

In the interest of fostering an open and welcoming environment, we as contributors and maintainers pledge to making participation in our project and our community a harassment-free experience for everyone, regardless of age, body size, disability, ethnicity, sex characteristics, gender identity and expression, level of experience, education, socio-economic status, nationality, personal appearance, race, religion, or sexual identity and orientation.

We shall all work in a concentrated, transparent and honest way to ensure a quick and successful delivery.

10.2 Our Standards

Examples of behavior that contributes to creating a positive environment include:

- Following the principles „What does good look like?
- Using welcoming and inclusive language
- Being respectful of differing viewpoints and experiences
- Gracefully accepting constructive criticism
- Focusing on what is best for the community
- Showing empathy towards other community members
- Following the guideline defined in the project plan
- Democratic decisions on details, if tied the lead decides - or flips a coin

Examples of unacceptable behavior by participants include:

- The use of sexualized language or imagery and unwelcome sexual attention or advances
- Trolling, insulting/derogatory comments, and personal or political attacks
- Public or private harassment
- Publishing others' private information, such as a physical or electronic address, without explicit permission
- Other conduct which could reasonably be considered inappropriate in a professional setting
- Not following the guidelines laid out in the project execution and quality plan, especially those concerning good documentation practice and deviation management

10.3 Scope

This Code of Conduct applies both within project spaces and in public spaces when an individual is representing the project or its community. Examples of representing a project or community include using an official project e-mail address, posting via an official social media account, or acting as an appointed representative at an online or offline event. Representation of a project may be further defined and clarified by project maintainers.

10.4 Enforcement

Instances of abusive, harassing, or otherwise unacceptable behavior may be reported by contacting the project team at mondkind@mondkind.ch. All complaints will be reviewed and investigated and will result in a response that is deemed necessary and appropriate to the circumstances.

The project team is obligated to maintain confidentiality with regard to the reporter of an incident. Further details of specific enforcement policies may be posted separately.

Project maintainers who do not follow or enforce the Code of Conduct in good faith may face temporary or permanent repercussions as determined by other members of the project's leadership.

10.5 Attribution

This Code of Conduct is adapted from the [Contributor Covenant](https://www.contributor-covenant.org/version/1/4/code-of-conduct.html), version 1.4, available at <https://www.contributor-covenant.org/version/1/4/code-of-conduct.html>

For answers to common questions about this code of conduct, see <https://www.contributor-covenant.org/faq>

11 Conventions

11.1 File management

11.1-1 GENERAL GOOD DOCUMENTATION PRACTICE RULES

All documents must have a reference to the source requirement.

All documents must be listed in the overall document list.

All documents have a defined integer version.

All documents must be numbered in the format Page x of n

All tables, figures and pictures in documents must have a footnote.

Abbreviations can be listed in documents, but this is not a must if the abbreviation is common knowledge (i.e. ISO).

Duplicate information must be avoided with great care.

11.1-2 LOCATION

The primary location of finalized documents is the GitHub repository.

Drafts *should* be saved daily in the repository as well (use the folder drafts in the active project phase).

Documents are separated according to the phase the project is in. Further description of the phases will be provided as a separate chapter in this document.

11.1-3 TEMPLATE

For text documents and coversheets for other files (drawings, etc.) the current pages template shall be used. It shall reside on in repository in the folder „_template“.

Coversheets must contain a reference to the document that is attached to them. A template for this shall be available in the drafts folder of the repository.

11.1-4 FILE NAMES

Final version: open.PAPR-Document-Revision

Draft version: JJJJMMDD_open.PAPR-Document-Future revision

11.1-5 TIME AND DATES (ISO-8601)

Dates are to be noted in the format JJJJMMDD.

Example: 20200413

Alternative: DD, MMM JJJJ.

Example: 13. APR. 2020

11.1-6 TIME (ISO-8601)

UTC format shall be used. An exception can be made if there is a reference to UTC for every field, where one must a point in time.

The project must be finalised with a report that refereces the chapters defined in this plan and declares all actions taken to reach the state, where the project can be closed.
The project can be closed due to: Completion of the objectives (all deviations must be resolved) or a project change to terminate the project. Closure is possible at any milestone.

12 Copyright

Solely CERN-OHL-P is the license used for this project.

12.1 Copyright notice applicable to this document

See front page and CERN-OHL-P Documents supplied with this package.

The file „CHANGES.TXT“ mentioned in the CERN-OHL-P how-to is replaced by the Change Log as defined in Chapter 5.